COLORADO
Prescription Drug Affordability Board
Division of Insurance

2023 Affordability Review Summary Report: Enbrel

February 23, 2024

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Executive Summary

Affordability Review Summary Report Findings

Enbrel (etanercept), first approved by the United States Food and Drug Administration in 1998, is a tumor necrosis factor (TNF) inhibitor and is used to treat rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis, psoriatic arthritis, juvenile psoriatic arthritis, and polyarticular juvenile idiopathic arthritis. The FDA granted orphan drug designation in 1998 for polyarticular-course juvenile rheumatoid arthritis, now referred to as polyarticular juvenile idiopathic arthritis. The relevant professional medical guidelines identify the following in-class therapeutic alternatives for Enbrel: Humira, Cimzia, Simponi/Simponi Aria, and Remicade. Patients and caregivers, as well as individuals with scientific and medical training, provided input that patients need many treatment options to identify the medications that work for them.

When compared to a placebo, Enbrel has shown improvements in symptoms for each indication. For some indications, there is evidence that Enbrel and its in-class therapeutic alternatives are associated with beneficial treatment effects when compared to other prescription drug treatments not in class. Of the few studies evaluating Enbrel compared to in-class therapeutic alternatives for rheumatoid arthritis, most found no difference in treatment, though one study found Enbrel to be inferior to Humira for remission, while another study found Enbrel to be superior to Remicade for different measure of remission.

In passing Senate Bill 21-175, the legislature recognized the importance of evaluating both the effectiveness of a drug, as well as its cost to consumers and the larger health care system. Enbrel's wholesale acquisition cost has increased 1,582.24%, from [redacted] per unit at its launch in November 1998 to [redacted] per unit in January 2024, which is significantly greater than the increase in inflation for the same time period. Over half of insurance carriers who submitted information to the Colorado All Payer Claims Database (APCD) reported that Enbrel was one of the top 15 prescription drugs that raised premiums for all covered lives. Enbrel has also appeared in other states' assessments of the costliest drugs, including contributing to increases in insurance plan spending.

In Colorado in 2022, Enbrel was the second most utilized drug (3,406 patients) compared to its in-class therapeutic alternatives, Humira (7,526), Remicade (698), Simponi (579), and Cimzia (475), and saw relatively steady utilization from 2018 to 2022. According to 2022 APCD data, Enbrel cost $46,772 per patient and over $159,305,653 in total. In that year, the average annual out-of-pocket cost for patients with commercial insurance was $3,980 annually. Though there was evidence in both APCD data and patient and caregiver survey responses that monthly out-of-pocket costs were quite varied, 27 of 38 (71.1%) of Colorado patients and caregivers reported the cost of Enbrel has made it difficult to access the drug. The majority of patients and caregivers surveyed (33 of 38) stated they used some form of assistance program to access Enbrel, with over a quarter of patients (10 of 38) reporting they still had trouble affording Enbrel.

In 2023, it is estimated that [redacted] of Amgen Inc.'s national gross sales for Enbrel was spent on rebates, 340B discounts, manufacturer financial assistance programs, and other price concessions. International net revenue for Enbrel decreased from $4.465 billion in 2021 to $4.177 billion in 2022, which may be partly explained by [redacted].

The following report and its appendices provide detailed evidence necessary for the Board's consideration of whether Enbrel is unaffordable to Coloradans.

Board Deliberation and Vote Summary

After receiving and reviewing evidence in support of the affordability review components set forth in statute and rule, on February 16, 2024, the Colorado Prescription Drug Affordability Board (the Board)

acknowledged there was sufficient evidence to proceed with deliberations for the Enbrel affordability review. The Board then deliberated whether the use of Enbrel was unaffordable for Colorado consumers.

During deliberations, Board members noted that the data concerning out-of-pocket costs and patient and caregiver experience purchasing the drug provided evidence that the drug is unaffordable to patients in Colorado. Deliberation also included discussion of:

- Enbrel is clearly an effective drug that is comparable to therapeutic alternatives;
- Utilization of therapeutic alternatives and availability of biosimilars;
- Average out-of-pocket cost is relatively higher than some therapeutic alternatives;
- Concerns that Colorado patients may be paying higher out-of-pocket costs or have more affordability concerns than survey results from patients outside of Colorado;
- Health equity and patients in rural counties may be going undiagnosed or be unable to access medications; and
- High changes in wholesale acquisition cost (WAC).

After deliberations and hearing public comment from six individuals, the Board voted 4-0 that the use of Enbrel consistent with the labeling approved by the FDA or with standard medical practice is unaffordable for Colorado consumers. Dr. Sami Diab recused himself from the deliberation and vote due to a conflict of interest.

To view the meeting recording in full, see:
https://us06web.zoom.us/rec/share/Qok1gyXB8g_7SJI2Bt4UJSXdHre7F3jgFAdCJnaaxNplnTyuLgc3Vzt4RbyC5xpb.7RBSR3AvYJkCKjjw

Introduction

The Colorado Prescription Drug Affordability Board (the Board) was established in 2021 through the passage of Senate Bill 21-175. Governor Polis appointed five members to the Board in September 2021. Since then, the Board has appointed members to the 15-person Prescription Drug Affordability Advisory Council (the Advisory Council) and hosted a five-part learning series in spring 2022 to provide Board members, Advisory Council members, and interested stakeholders foundational knowledge necessary to implement a successful new prescription drug affordability program. The Board has also promulgated five rules to implement statutory requirements and developed five policies to guide the program.

One of the Board's duties is to perform affordability reviews of prescription drugs as described in section 10-16-1406, C.R.S. This section outlines the Board's four steps in conducting affordability reviews:(1) identification of eligible drugs, (2) selection of drugs for affordability reviews, (3) conducting affordability reviews on selected drugs, and (4) determining if use of the selected drugs are unaffordable for Colorado consumers.

The first step - identification of prescription drugs eligible for affordability reviews - was completed when the Board approved the final list of prescription drugs eligible for affordability reviews on June 9, 2023. The second step - selection of prescription drugs for affordability reviews - was completed when the Board selected five drugs for affordability reviews on August 4, 2023. This report has been prepared by Board staff to assist the Board in completing the third and fourth steps of the affordability review process for the prescription drug, Enbrel.

This report of the affordability review for Enbrel was conducted in accordance with 3 CCR 702-9, Part 3.1.E.6. Additionally, this report contains appendices with detailed information for each of the fifteen criteria the Board shall and may consider as a part of its affordability review, to the extent practicable.

Report Structure

About This Report

The main body of the Affordability Review Summary Report is divided into three profiles: a therapeutic and utilization profile; a cost and price profile; and an access to care profile. The profiles contain information from the fifteen statutory and regulatory components the Board considers as a part of an affordability review. The profiles were identified by Board members and Board staff as a way to present affordability review evidence in a commonsense manner. While these profiles incorporate all fifteen components the Board considers during affordability reviews, additional information is provided for each of the fifteen components in the appendices, with each component having an individual appendix. More information on the structure of each profile and the appendices is provided in the sections below.

While several components lend themselves to inclusion in only one profile, three components inform all profiles contained in the Summary Report. Those components, and information regarding the type and volume of feedback Board staff received, are summarized below:

- Input from patients and caregivers - Board staff gathered input from three patients and caregivers at one public meeting on September 19, 2023. Additionally, 287 patients and caregivers completed surveys regarding the health and financial effects of Enbrel, and many of these patients and caregivers also attended the public meetings.
- Input from individuals with scientific and medical training - Board staff gathered input from two individuals with scientific or medical training at one public meeting on September 19, 2023 as well as five individuals at small-group meetings. Additionally, three individuals with scientific & medical training completed surveys regarding the health and financial effects of Enbrel.
- Voluntarily submitted information - two patients, caregivers, and other entities submitted voluntary information. Amgen Inc., the manufacturer of Enbrel, also voluntarily submitted public and confidential information. Note: no assessment was conducted of accuracy of voluntarily submitted information or the extent to which the information applies to Coloradans.

The Summary Report and Appendices may contain proprietary, confidential, and trade-secret information. Such information is redacted in public reports.

Therapeutic and Utilization Profile

The Therapeutic and Utilization Profile includes information about Enbrel's clinical efficacy and the people who use it. This section provides information regarding Enbrel's indication, utilizer profile, health equity impact, and therapeutic alternatives. Affordability review components present in this profile include information from Appendices B, G, H, I, J, and L.

Price and Cost Profile

The Price and Cost Profile includes information on what different entities on the prescription drug supply chain charge for Enbrel, as well as what different entities pay for Enbrel. This profile also contains information on Enbrel's financial effects on health, medical, and social service costs. Affordability review components present in this profile include information from Appendices A, B, D, E, H, I, J, K, and O.

Access to Care Profile

The Access to Care Profile examines potential access to care concerns related to Enbrel and whether there is evidence that the causes of access to care concerns may be related to Enbrel's price or cost. This profile

includes an examination of potential relationships of changes between utilization, price, and costs as well as information on safety net providers, utilization management requirements, and health benefit plan design. Affordability review components present in this profile include information from Appendices A, B, C, E, F, H, I, J, K, M, and N.

Appendices

This report contains an appendix for each of the fifteen components the Board is to consider as a part of affordability reviews, as well as a last appendix, Appendix P - Data Sources and Limitations. Descriptions of the appendices related to the fifteen affordability review components are outlined below. Some appendices contain data and information specific to one or more of Enbrel's six FDA-approved indications. Those appendices are noted below with an asterisk (*). All other appendices contain data for Enbrel irrespective of indication.

Table 1
Appendices and Relevant Statutory, Rule, and Policy Guidance for Affordability Review Components

Component Name	Component Details
***Appendix A:** Current WAC & Change in WAC	The Board shall consider the wholesale acquisition cost of the drug. C.R.S. § 10-16-1406(4)(a).
***Appendix B:** Therapeutic Alternatives	The Board shall consider the cost and availability of therapeutic alternatives to the prescription drug in the state. C.R.S. § 10-16-1406(4)(b).
Appendix C: Price Effect on Access	The Board shall consider the effect of the price on Colorado consumers' access to the prescription drug. C.R.S. § 10-16-1406(4)(c).
***Appendix D:** Relative Financial Effects	The Board shall consider the relative financial effects on health, medical, or social services costs, as the effects can be quantified and compared to baseline effects of existing therapeutic alternatives to the prescription drug. C.R.S. § 10-16-1406(4)(d).
Appendix E: Patient Copayment & Other Cost Sharing	The Board shall consider the patient copayment or other cost sharing of the drug. C.R.S. § 10-16-1406(4)(e).
Appendix F: Safety Net Providers	The Board shall consider the impact on safety net providers if the prescription drug is available through section 340B of the federal "Public Health Service Act", Pub.L. 78-410. C.R.S. § 10-16-1406(4)(f).
***Appendix G:** Orphan Drug Status	The Board shall consider orphan drug status. C.R.S. § 10-16-1406(4)(g).
***Appendix H:** Patients & Caregivers	The Board shall consider input from patients and caregivers affected by the condition or disease that is treated by the prescription drug that is under review by the Board. C.R.S. § 10-16-1406(4)(h)(I).
***Appendix I:** Individuals with Scientific & Medical Training	The Board shall consider input from individuals who possess scientific or medical training with respect to a condition or disease treated by the prescription drug that is under review by the Board. C.R.S. § 10-16-1406(4)(h)(II).
Appendix J: Voluntarily Submitted Information	The Board shall consider any other information that a manufacturer, carrier, pharmacy benefit management firm, or other entity chooses to provide. C.R.S. § 10-16-1406(4)(i).

Component Name	Component Details
Appendix K: Rebates, Discounts, and Price Concessions	The Board may consider estimated manufacturer net-sales or net-cost amounts (including rebates, discounts, and price concessions) for the prescription drug and therapeutic alternatives; and The Board may consider manufacturer financial assistance the manufacturer provides to pharmacies, providers, consumers, and other entities. C.R.S. § 10-16-1406(4)(j); 3 CCR 702-9, Part 3.1.E.2.j.i.
***Appendix L:** Health Equity	The Board will consider whether the pricing of the prescription drug results in or has contributed to health inequities in priority populations. C.R.S. § 10-16-1406(4)(j); 3 CCR 702-9, Part 3.1.E.2.j.ii.
***Appendix M:** Information from HCPF	The Board shall consider information from the Department of Health Care Policy and Financing, including additional analyses HCPF conducts relevant to the prescription drug or therapeutic alternative under review; and/or information regarding safety net providers participating in the 340B, including information to assist with gathering input to assess the impact to safety net providers for a prescription drug under review that is available through Section 340B of the Federal "Public Health Service Act", Pub. L. 78-410. C.R.S. § 10-16-1406(4)(j); 3 CCR 702-9, Part 3.1.E.2.j.iii.
Appendix N: Non-Adherence & Utilization Management	The Board may use information regarding non-adherence to the prescription drug, as well as information related to utilization management restrictions placed on the prescription drug. C.R.S. § 10-16-1406(4)(j); 3 CCR 702-9, 3.1.E.2.j.iv.
Appendix O: Pricing Information	The Board may consider any documents and information relating to the manufacturer's selection of the introductory price or price increase of the prescription drug, including documents and information relating to: (a) Life-cycle management; (b) The average cost of the prescription drug in the state; (c) Market competition and context; (d) Projected revenue; (e) The estimated cost-effectiveness of the prescription drug; and (f) Off-label usage of the prescription drug. C.R.S. § 10-16-1406(6). The Board may access pricing information for prescription drugs by: (I) accessing publicly available pricing information from a state to which manufacturers report pricing information; (II) accessing available pricing information from the all-payer health claims database and from state entities; and (III) accessing information that is available from other countries. C.R.S. § 10-16-1406(7)(a).

*Appendix contains information specific to one or more of the six indications Enbrel treats.

Enbrel Therapeutic and Utilization Profile

The Therapeutic and Utilization Profile includes information about Enbrel's clinical efficacy and the people who use it. This section provides information regarding Enbrel's indication, utilizer profile, health equity impact, and therapeutic alternatives.

Indications

Enbrel has six FDA-approved indications:

- Rheumatoid arthritis (RA) - reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active RA (FDA approval in 1998).
- Ankylosing spondylitis (AS) - reducing signs and symptoms in patients with active AS (FDA approval in 2003).
- Plaque psoriasis (PsO) - treatment of patients 4 years or older with chronic moderate to severe PsO who are candidates for systemic therapy or phototherapy (FDA approval in 2004).

- Psoriatic arthritis (PsA) - reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with PsA (FDA approval in 2002).
- Juvenile psoriatic arthritis (JPsA) - treatment of active JPsA in pediatric patients 2 years of age and older (FDA approval in Oct. 2023).
- Polyarticular juvenile idiopathic arthritis (pJIA) - reducing signs and symptoms of moderately to severely active pJIA in patients ages 2 and older (FDA approval in 2016).

For context, all of the FDA-approved indications listed above are autoimmune diseases[1]. RA, AS, PsA, JPsA, and pJIA are forms of arthritis and rheumatic diseases[2], with AS sometimes also called axial spondylitis, and RA being the most common type of rheumatic diseases.[3] Juvenile idiopathic arthritis (JIA) is an umbrella term for chronic arthritis in children,[4] and JPsA, sometimes called psoriasis-related JIA[5], and pJIA are two different types of JIA.[6] Plaque psoriasis is the most common form of the chronic skin condition, psoriasis[7]. Psoriasis is also associated with PsA; the majority of patients who develop PsA already have some form of psoriasis (PsO or another psoriasis)[8], and juvenile patients with JPsA also have some form of psoriasis (PsO or another type of psoriasis).[9]

Enbrel is classified by the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification system as a tumor necrosis factor alpha (TNF-α or TNF) inhibitor.[10] Additional information is provided below for each FDA-approved indication.

Rheumatoid Arthritis (RA)

Rheumatoid arthritis (RA) is a chronic, symmetrical, inflammatory autoimmune disease that initially affects small joints, progressing to larger joints, and eventually the skin, eyes, heart, kidneys, and lungs. Often, the bone and cartilage of joints are destroyed, and tendons and ligaments weaken. Damage to joints can cause deformities and bone erosion, which can be painful. Common symptoms of RA include morning stiffness of the affected joints, fatigue, fever, weight loss, joints that are tender, swollen and warm, and rheumatoid nodules under the skin. The onset of this disease is usually from the age of 35 to 60 years, with remission and exacerbation.[11]

Around 1.3 million people in the US have rheumatoid arthritis.[12] The goals of treatment for RA are to reduce joint inflammation and pain, maximize joint function, and prevent joint destruction and deformity. Treatment regimens consist of combinations of pharmaceuticals, weight-bearing exercise, educating patients about the disease, and rest. Treatment regimens take into account factors such as disease progression, the joints involved, age, overall health, occupation, compliance, and education about the disease.[13]

[1] https://autoimmune.org/disease-information/
[2] https://www.niams.nih.gov/health-topics/arthritis-and-rheumatic-diseases
[3] https://www.ncbi.nlm.nih.gov/books/NBK532288/
[4] https://pubmed.ncbi.nlm.nih.gov/31779842/
[5] https://rarediseases.info.nih.gov/diseases/10970/psoriasis-related-juvenile-idiopathic-arthritis
[6] https://www.niams.nih.gov/health-topics/juvenile-arthritis
[7] https://www.niams.nih.gov/health-topics/psoriasis
[8] https://www.niams.nih.gov/health-topics/psoriatic-arthritis
[9] Id.
[10] https://www.whocc.no/atc_ddd_index/?code=L04AB&showdescription=no
[11] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6422329/
[12] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8348893/
[13] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6422329/

The Mayo Clinic states that, "RA can be difficult to diagnose in its early stages because the early signs and symptoms mimic those of many other diseases".[14] Individuals with scientific and medical training noted that patients taking Enbrel have moderate to severe RA and may have already tried other prescription drugs and that a patient's medications may depend on how long someone has had RA and the severity of their symptoms. Disease-modifying antirheumatic drugs (DMARDs) are often prescribed for RA, with conventional DMARDs more commonly recommended for DMARD-naive patients with moderate to high disease activity and biologic DMARDs (including TNF inhibitors like Enbrel) are recommended to be added to conventional DMARDs for patients taking maximally tolerated doses of conventional DMARDs.[15]

Ankylosing Spondylitis

Ankylosing spondylitis (AS), a subset of axial spondyloarthritis,[16] is an inflammatory disease that causes inflammation in the joints and ligaments of the spine. Axial spondyloarthritis has two types. When the condition is found on X-ray, it is called ankylosing spondylitis. When the condition can't be seen on X-ray but is found based on symptoms, blood tests and other imaging tests, it is called non-radiographic axial spondyloarthritis.[17]

Ankylosing spondylitis (AS) is a chronic, inflammatory disease primarily affecting the axial spine that can manifest with a range of clinical signs and symptoms. Symptoms typically begin in early adulthood. The hallmark features of AS include chronic back pain and progressive spinal stiffness, though it may also affect peripheral joints and digits.[18] AS often leads to impaired spinal mobility and can result in a hunched posture. In addition to skeletal involvement, AS can affect other body organs, manifesting in inflammatory bowel disease, acute anterior uveitis, and psoriasis. AS is also linked to an increased risk of cardiovascular disease and pulmonary complication.[19]

The exact cause of AS is unknown, but researchers believe that genetics play a role. The HLA-B27 gene is found in most white patients who have AS, but is only found in 50% of Black patients who have AS.[20] There is no cure for ankylosing spondylitis, but treatments can lessen symptoms and possibly slow progression of the disease. The goal of treatment is to ease pain and stiffness, prevent deformities, and maintain as normal a lifestyle as possible.[21]

Plaque Psoriasis

Plaque psoriasis (PsO) is the most common type of psoriasis, accounting for more than 80% of cases. Psoriasis affects both men and women, with earlier onset in women and those with a family history. An estimated 60 million people have psoriasis worldwide, and the condition is more common in high income areas and those with older populations.[22]

The National Psoriasis Foundation describes the appearance of psoriasis plaques as raised, inflamed, and scaly patches of skin that may also be itchy and painful. On white skin, plaques typically appear as raised, red patches covered with a silvery white buildup of dead skin cells or scale. On skin of color, the plaques may appear darker and thicker and more of a purple or grayish color or darker brown. Plaques can appear anywhere on the body, although they most often appear on the scalp, knees, elbows, and torso. Plaques

[14] https://www.mayoclinic.org/diseases-conditions/rheumatoid-arthritis/diagnosis-treatment/drc-20353653
[15] https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/acr.24596
[16] https://www.arthritis.org/diseases/ankylosing-spondylitis
[17] https://www.mayoclinic.org/diseases-conditions/ankylosing-spondylitis/symptoms-causes/syc-20354808
[18] https://www.ncbi.nlm.nih.gov/books/NBK470173/
[19] https://www.ncbi.nlm.nih.gov/books/NBK470173/
[20] https://www.hopkinsmedicine.org/health/conditions-and-diseases/ankylosing-spondylitis
[21] https://www.hopkinsmedicine.org/health/conditions-and-diseases/ankylosing-spondylitis
[22] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8140694/

generally appear symmetrically on the body, affecting the same areas of the body on the right and left sides.[23] Patients with psoriasis may also present with other chronic conditions such as Crohn's disease, psoriatic arthritis, psychological disorders, and uveitis.[24]

Treatment options for plaque psoriasis include topicals, phototherapy, oral treatments, and biologics. Recognition and management of comorbidities (such as psoriatic arthritis, psychological, cardiovascular and hepatic diseases) is an essential part of holistic care for individuals with psoriasis.[25]

Plaque psoriasis is also the most common clinical form of psoriasis in children.[26] One article reported that approximately 70% of children with psoriasis present with chronic plaque psoriasis.[27] Nearly 40% of adult patients with psoriasis have reported having the condition in childhood, with at least one-third of the patients showing symptoms of psoriasis before the age of 16 years. [28]

One study states that pediatric patients with psoriasis are also likely to have various comorbidities such as hyperlipidemia, hypertension, diabetes mellitus, rheumatoid arthritis, and Chrohn's disease. The long-term comorbidities associated with psoriasis can place a great burden on the physical and mental wellbeing of children with psoriasis beyond the symptoms of psoriasis itself, therefore it is encouraged to screen patients periodically and receive treatment not only for their skin lesions but also for comorbidities.[29]

Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic, inflammatory disease of the joints and entheses, where tendons and ligaments connect to bone.[30] It is a type of arthritis linked with psoriasis, a chronic skin disease. PsA affects men and women almost equally with a peak age at onset of 40 and 50 years[31], though it may also affect children. For many people, it starts about 10 years after psoriasis develops, but some develop PsA first or without ever developing or noticing psoriasis.[32]

PsA affects multiple organ systems including peripheral and axial joints, skin, and nails, and is associated with comorbidities such as osteoporosis, uveitis, subclinical bowel inflammation, and cardiovascular disease.[33] Joint pain, stiffness, and swelling are the main symptoms of PsA, and disease flares can alternate with periods of remission.[34] PsA is similar to RA in symptoms and inflammation but it tends to affect fewer joints than RA.[35]

Diagnosing psoriatic arthritis begins with a physical exam to look for swollen or painful joints, and nail and skin changes. X-rays or scans like ultrasound, MRI or CT can show joint damage. Blood tests may help rule out other diseases, and a skin biopsy can confirm psoriasis.[36] Though there is no cure, a growing range of

[23] https://www.psoriasis.org/plaque/
[24] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4323693/#:~:text=Comorbidities%20classically%20associated%20with%20psoriasis,have%20been%20associated%20with%20psoriasis.&text=Gelfand%20et%20al.
[25] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8140694/
[26] https://www.uptodate.com/contents/psoriasis-in-children-epidemiology-clinical-manifestations-and-diagnosis?topicRef=112983&source=see_link
[27] https://onlinelibrary.wiley.com/doi/full/10.1111/1346-8138.17049#:~:text=International%20studies%20have%20shown%20that,significantly%20higher%20incidence%20in%20men.
[28] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3132900/
[29] https://onlinelibrary.wiley.com/doi/full/10.1111/1346-8138.17049#:~:text=International%20studies%20have%20shown%20that,significantly%20higher%20incidence%20in%20men.
[30] https://www.psoriasis.org/about-psoriatic-arthritis/
[31] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6758836/
[32] https://www.psoriasis.org/about-psoriatic-arthritis/
[33] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6758836/
[34] https://www.mayoclinic.org/diseases-conditions/psoriatic-arthritis/symptoms-causes/syc-20354076
[35] https://www.hopkinsmedicine.org/health/conditions-and-diseases/arthritis/psoriatic-arthritis
[36] https://rheumatology.org/patients/psoriatic-arthritis

treatments are available to help stop the disease progression, lessen pain, protect joints, and preserve range of motion. Early recognition, diagnosis, and treatment of PsA can prevent or limit the extensive joint damage that can occur in later stages of the disease.[37]

Juvenile Psoriatic Arthritis

Juvenile idiopathic arthritis (JIA) is an umbrella-term describing a group of conditions characterized by chronic arthritis beginning before the age of 16 years, persisting for at least 6 weeks, and having no other identifiable cause.[38] Juvenile psoriatic arthritis (JPsA) is a relatively rare condition in childhood as it represents approximately 5% of the entire JIA population.[39] JPsA most often appears between the ages of 11 and 12. Girls are more likely to develop it when they are younger and boys when they are older.[40]

Symptoms can vary considerably but may include stiffness, pain, and swelling in one or more joints, pitted nails, stiffness and limited range of motion, fatigue, swelling, redness and pain in the eyes, and a red itchy rash on the joints, scalp, face, and trunk.[41] Early diagnosis improves the chances of successful treatment and the prevention of joint damage and other complications. Treatment for JPsA aims to relieve pain, reduce swelling, and prevent further damage to the joints.[42]

The literature is inconsistent regarding the features of JPsA, and there is debate among rheumatologists whether it is a distinct entity within JIA.[43] The few studies that have compared the clinical characteristics and genetic determinants of JPsA with those of the other JIA categories have obtained competing findings. The debate on the categorization of JPsA as a distinct entity within JIA classification is still ongoing and has prompted the revision of its current classification.[44] Due to the relatively sparse research and very recent FDA approval of Enbrel for treatment of JPsA, some sections of this summary report and the appendices may have less information for this indication.

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

Polyarticular juvenile idiopathic arthritis (pJIA) also falls beneath the umbrella of JIA. JIA can affect not only joints, but extra-articular structures, including eyes, skin, and internal organs, leading to disability and even associated fatality.[45] Within this cluster of conditions, the polyarticular form of JIA (involving more than four joints within the first 6 months) is further divided based on the presence of rheumatoid factor. Blood tests for rheumatoid factor (RF) will show if this type is RF-positive or RF-negative.[46] Both RF-positive and negative variants have characteristic clinical features: for RF-negative pJIA, inflammation can be asymmetrical, but for RF-positive pJIA symmetric involvement of the large and small joints of hands and feet is the most prevalent.[47]

Children with pJIA pose unique diagnostic and therapeutic challenges compared to children with involvement of fewer joints. Polyarticular JIA patients tend to be at increased risk for joint damage, resulting in poorer functional outcomes and decreased quality of life.[48] Chronic inflammation leads to cartilage and bone erosions and resulting joint damage. This presents clinically as a painful, red, swollen

[37] https://www.psoriasis.org/about-psoriatic-arthritis/
[38] https://ped-rheum.biomedcentral.com/articles/10.1186/s12969-021-00629-8
[39] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9199423/
[40] https://www.medicalnewstoday.com/articles/322612#causes-and-risk-factors
[41] https://www.medicalnewstoday.com/articles/322612#symptoms
[42] https://www.medicalnewstoday.com/articles/322612#treatment
[43] https://www.jrheum.org/content/94/11
[44] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9821505/
[45] https://ped-rheum.biomedcentral.com/articles/10.1186/s12969-021-00629-8
[46] https://www.tandfonline.com/doi/full/10.2147/CLEP.S53168
[47] https://ped-rheum.biomedcentral.com/articles/10.1186/s12969-021-00629-8
[48] https://www.tandfonline.com/doi/full/10.2147/CLEP.S53168

joint(s) with limited range of movement and, if the arthritis is prolonged, potential for joint deformities and growth disturbances.[49]

The progressive nature of JIA and potential for long-term damage emphasizes the critical need for a prompt and accurate diagnosis. The clinical presentation of JIA may vary depending on JIA sub-type. Children with systemic or polyarticular disease may present with more varied symptoms of fatigue, fever, weight loss or growth failure.[50]

Once diagnosed, the early treatment of JIA is critical to increase the potential for disease remission and to avoid further joint damage.[51] The damage caused by JIA can affect patients into adulthood and cause chronic disability. Up to half of young adults will continue to have active disease, and up to one third will have chronic disability into adulthood. Additionally, RF-positive polyarticular JIA is the least likely to achieve remission[52]

Utilizer Profile

Enbrel's utilization has increased since the FDA approved the drug in 1998. According to Colorado's All Payer Claims Database (APCD), 3,406 individuals utilized Enbrel in 2022. Additionally, data from the APCD indicates that patients who utilize Enbrel are most commonly insured through commercial insurance, followed by nearly equal utilization for patients insured by Medicaid and Medicare Advantage plans.[53] APCD utilization estimates can be viewed as low estimates, since data for some self-insured commercial insurance plans (ERISA) and Medicare FFS enrollees, as well as uninsured individuals, is not included. See Appendix P for more information.

Table 2
Utilization of Enbrel

Drug Name	2018	2019	2020	2021	2022
Enbrel	3,890	3,653	3,440	3,692	3,406

Table 2 shows the number of utilizers of Enbrel by year from 2018 - 2022.

[49] https://www.mdpi.com/2227-9032/9/12/1683
[50] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(07)60363-8/fulltext
[51] https://www.mdpi.com/2227-9032/9/12/1683
[52] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(07)60363-8/fulltext
[53]Utilization information in this section is from the Colorado All Payer Claims Database (APCD). APCD data limitations are outlined in Appendix P.

Figure 1
Enbrel Utilization by Payer Type

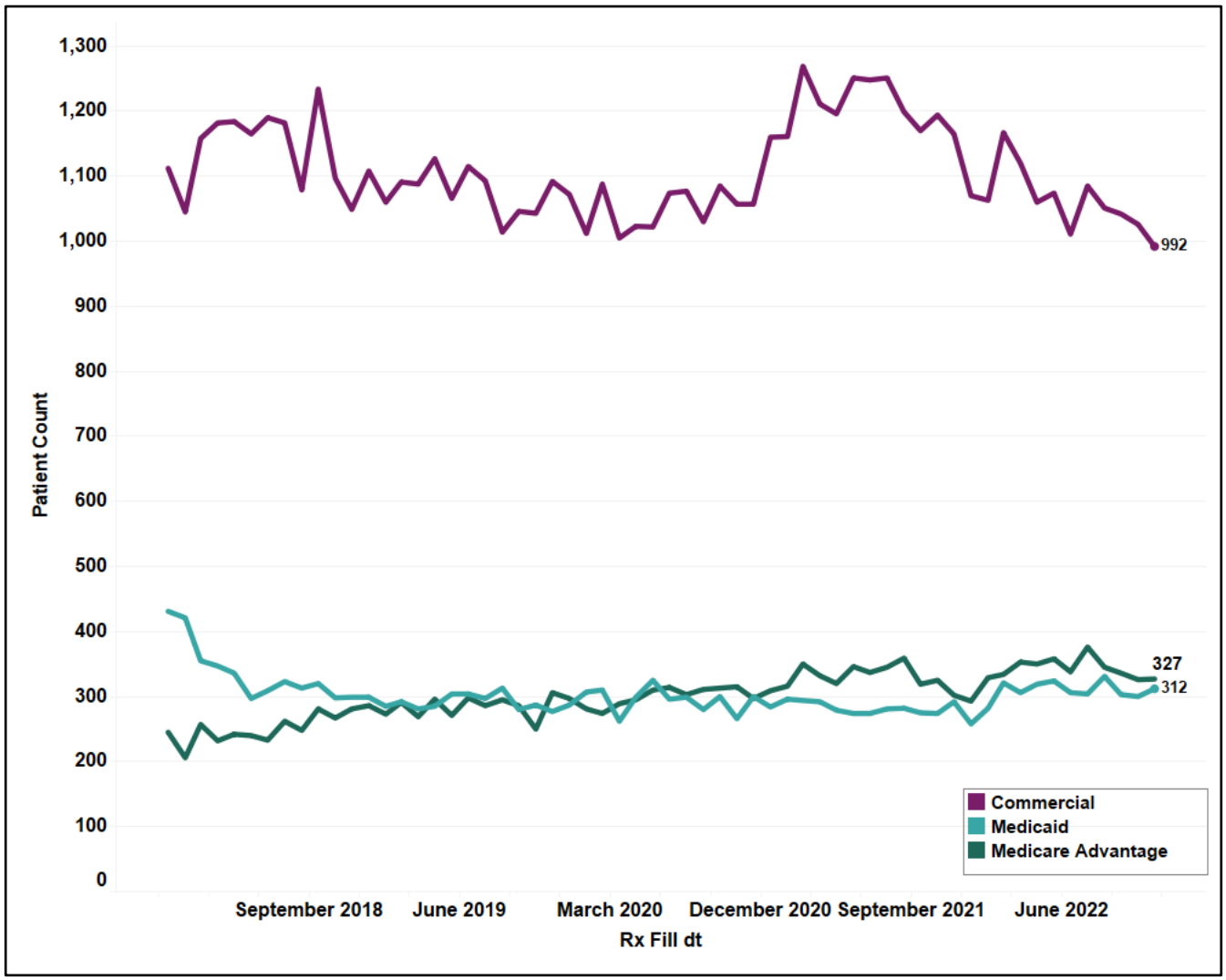


Figure 1 shows the monthly number of patients who filled a prescription for Enbrel each month between January 2018 and December 2022, where the purple line represents the number of commercially insured patients, the teal line shows the number of Medicaid patients, and the green line shows the number of Medicare Advantage patients.

Figure 2
Insurance Information

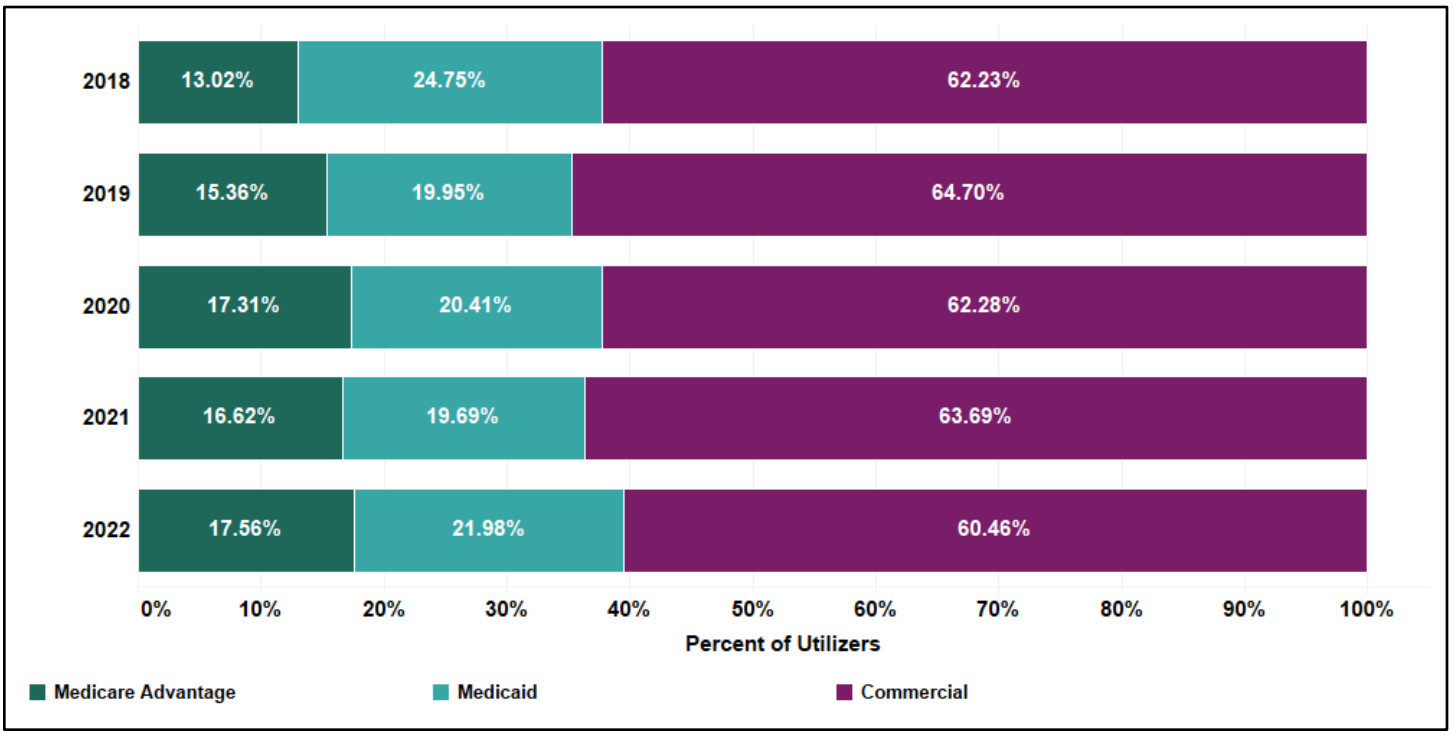


Figure 2 shows Enbrel payer mix percentages from 2018-2022. This figure shows the percent of patients by payer type and year where green represents patients with Medicare Advantage, teal represents patients with Medicaid, and purple represents patients with commercial insurance. From 2018-2022, between 60.46% and 64.70% of Enbrel utilizers were commercially insured.

Health Equity Impact

Obtaining prescription drug-specific information regarding health equity can be a complex task. There is evidence that priority populations[54] experience health inequity associated with their use of medications, which causes an increased risk of adverse outcomes including mortality, morbidity burden, quality of life deficit, and patient safety issues.[55] Further, there may be condition- or disease-specific studies that investigate health inequities, but there are not always studies that investigate the impacts of a specific prescription drug. While there was not significant data regarding Enbrel specifically, there was data regarding indications Enbrel treats. Health equity literature reviews were conducted for five of Enbrel's FDA-approved indications and are summarized in the table below. See Appendix L for more information.

[54] The Board's adopted definition of priority populations is: people experiencing homelessness; people involved with the criminal justice system; black people, indigenous people, and people of color; American Indians and Alaska natives; veterans; people who are lesbian, gay, bisexual, transgender, queer, or questioning; people of disproportionately affected sexual orientations, gender identities, or sex assigned at birth; people who have AIDS or HIV; older adults; children and families; and people with disabilities, including people who are deaf and hard of hearing, people who are blind and deafblind, people with brain injuries, people with intellectual and developmental disabilities, people with other co-occurring disabilities; and other populations as deemed appropriate by the Prescription Drug Affordability Board. 3 CCR 702-9, 1.1.C.
[55] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10037618/#:~:text=In%20comparison%20to%20the%20general,16%2C17%2C18%5D.

Table 3
Enbrel Health Equity Literature Review Highlights by Indication

Indication	Health Equity Literature Review Highlights
RA	• Non-Hispanic African Americans and people with low family income had a significantly higher RA risk, while people with high education levels had a significantly lower RA risk. • Geographic distance from a rheumatologist can increase negative health outcomes by delaying diagnosis and making it difficult for patients to receive the frequent reassessments needed to monitor disease activity. One study found that patients with the longest driving distances to rheumatology providers had approximately 30% decreased odds of receiving an RA diagnosis compared with those located nearest to rheumatology care.
AS	• Ankylosing spondylitis (AS), a subset of axial spondyloarthritis, is historically considered a disease predominantly impacting men and it is often under-recognized or misdiagnosed in women. • Multiple researchers have raised concerns about detection bias with regard to diagnosing AS among people of color. Despite being diagnosed at lower rates than white and Hispanic patients, Black patients reported greater discomfort and impairment, had higher levels of inflammation, and showed more joint damage and deterioration on X-rays and MRIs.
PsO	• Hispanic and Black patients with psoriasis experienced more provider-related bias, stereotyping, misdiagnosis, and delayed diagnosis compared with white patients. Additionally, people with skin of color are underrepresented in clinical trials of psoriasis therapies. • Children with psoriasis are at approximately 20% to –30% higher risk of developing psychiatric disorders, such as depression and anxiety, than children without any psoriasis diagnosis.
PsA	• One study found that white patients were five times more likely to be diagnosed with psoriatic arthritis compared with Black patients. The disparity in prevalence could potentially be due to underdiagnosis in historically marginalized racial/ethnic groups. • One study reported a significantly higher degree of disease severity and lower use of biologics among Black patients compared with white patients. One study found Black patients were 70% less likely to receive biologics than white patients.
pJIA	• One US study showed that Black children with pJIA were nearly twice as likely to have joint damage than their white counterparts. • Lower socioeconomic status was associated with persistent functional disability, race/ethnicity was associated with higher disease activity, and use of public insurance and a guardian's education level of high school or lesser were associated with both functional disability and persistent moderate to severe disease activity across the first year of treatment.

During the selection of eligible prescription drugs for affordability reviews, the Board reviewed a Social Vulnerability Index Score (SVI) for all eligible prescription drugs. The SVI score represents the percent of individuals who use Enbrel who live in a county with a score above the Colorado average score. Individuals residing in counties with SVI scores higher than the statewide average may be more vulnerable to adverse outcomes due to social conditions in their county. The SVI score measurement is not meant to be a comprehensive assessment of Enbrel and health equity. Rather, it is meant to be a contextual snapshot to better understand if the typical patient who uses Enbrel lives in a county that has a higher vulnerability to adverse outcomes due to social conditions than the average Colorado county.

In 2022, 48.65% of patients taking Enbrel lived in a county with a higher SVI score than the statewide average. This means that patients taking Enbrel have a slightly lower likelihood of living in a county with higher vulnerability to adverse outcomes due to social conditions than the average Coloradan. See Appendix L for more information.

Figure 3
Map of Colorado by 2022 SVI Score for Utilizers of Enbrel

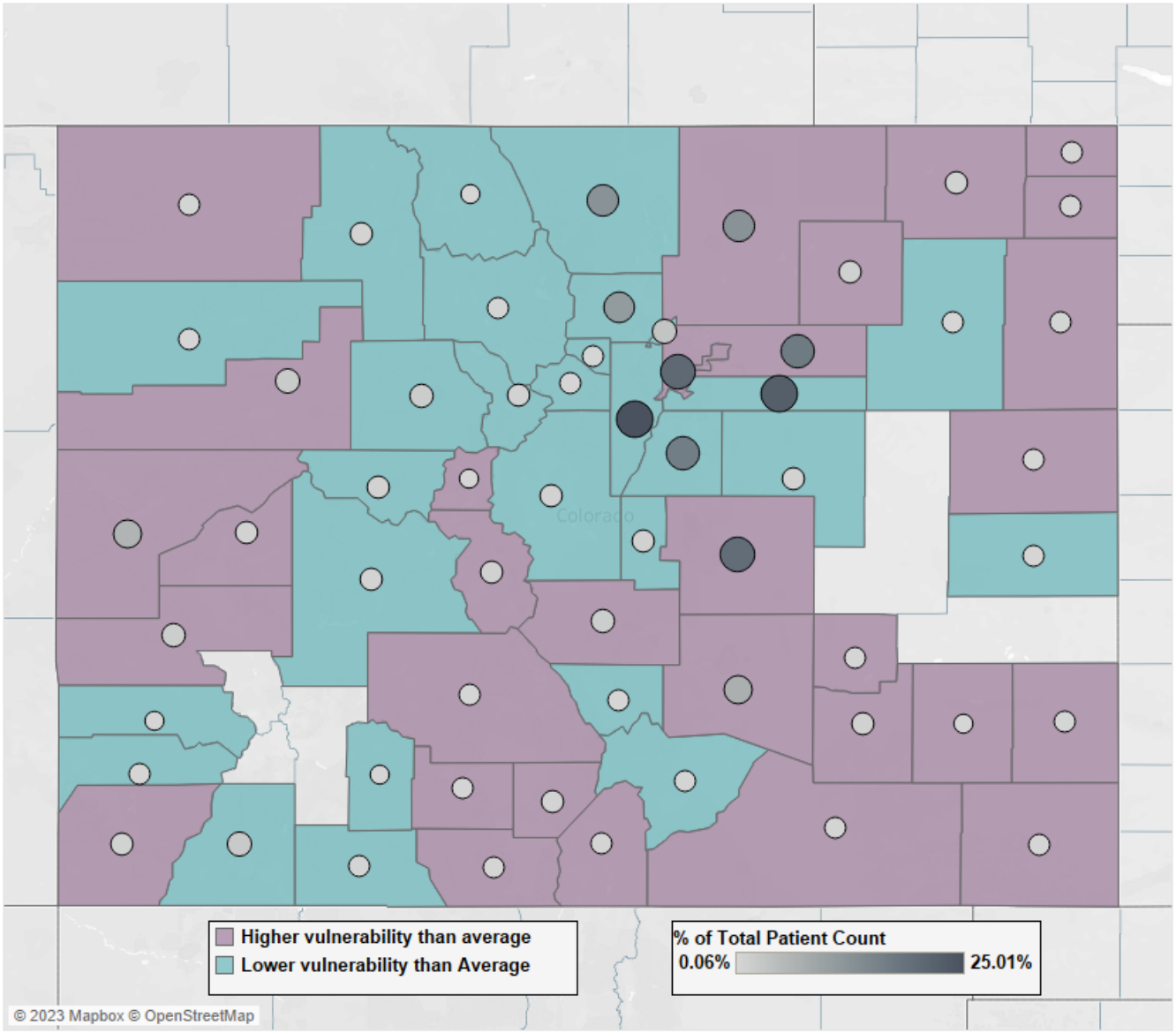


Figure 3 shows a map of Colorado by county, where purple counties indicate higher than average SVI scores and teal counties indicate a lower than SVI score, and counties without color did not have any patients who used Enbrel in 2022 residing in them. The dots on each county show the percent of patients who used Enbrel in 2022 by county where a larger, darker dot represents a higher portion of utilizers and smaller, lighter dots represent a smaller portion of the population.

Board staff received robust patient and caregiver input through an online survey aimed at gathering information regarding the health and financial effects of Enbrel. Survey participants could voluntarily provide information regarding whether they were a member of a priority population. Of the 38 Colorado respondents, eight were children and family members, 15 were older adults, 18 were people with a disability, one was disproportionately affected by sexual orientation, gender, identity, or sex assigned at birth, and six were people who are lesbian, gay, bisexual, queer, or questioning.

Therapeutic Alternatives

The Board adopted a definition of therapeutic alternatives as prescription drugs in the same pharmacological or therapeutic class that have been shown through peer-reviewed studies to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose or prescription drugs recommended as consistent with standard medical practice by medical professional association guidelines (3 CCR 702-9, Part 1.1.C). For the purposes of this affordability review, therapeutic alternatives were identified through the review of medical professional association guidelines. The resulting in-class therapeutic alternatives are summarized in Table 4 below. Information related to Enbrel's therapeutic alternatives is contained throughout this summary report and appendices. Humira and Remicade have FDA-approved biosimilar products. The following biosimilar products are approved for Humira (US market entrance date): Abrilada (11/29/2023), Amjevita (1/31/2023), Cyltezo (7/1/2023), Hadlima (7/6/2023), Hulio (7/6/2023), Hyrimoz (7/6/2023), Idacio (7/1/2023), Yuflyma (7/5/2023), Yusimry (7/6/2023). The following biosimilar products are approved for Remicade (FDA approval date): Avsola (7/6/2020), Inflectra (11/21/2016), Reflexis (8/1/2017).[56]

Table 4
Enbrel Therapeutic Alternatives Details

Non-proprietary name	Brand Name	Mechanism of Action	Approved Indication(s) (FDA Approval Date)
adalimumab	Humira	TNF inhibitor	RA (2002), AS (2006), PsO (2008), PsA (2005), pJIA (2008)
certolizumab pegol	Cimzia	TNF inhibitor	RA (2009), AS (2013), PsO (2018), PsA (2013)
golimumab	Simponi / Simponi Aria	TNF inhibitor	RA (2009), AS (2009), PsA (2009), pJIA (2020)
infliximab	Remicade	TNF inhibitor	RA (1999), AS (2004), PsO (2006), PsA (2005)

Table 4 shows details of Enbrel's therapeutic alternatives and FDA approval dates.

Utilization information for Enbrel and therapeutic alternatives is outlined below.

Table 5
Utilization of Enbrel and identified Therapeutic Alternatives

Brand Name	2018	2019	2020	2021	2022
Enbrel	3,890	3,653	3,440	3,692	3,406
Cimzia	350	337	368	453	475
Humira	4,920	5,557	5,960	7,339	7,526
Remicade	1,172	1,271	1,161	1,087	698
Simponi	337	375	400	501	579

Table 5 shows the number of utilizers of Enbrel and therapeutic alternatives by year from 2018 - 2022.

[56] Analytics were not conducted on biosimilar products due their relatively new introduction and low utilization in 2018-2022 APCD data.

Figure 4

Insurance information for Therapeutic Alternatives

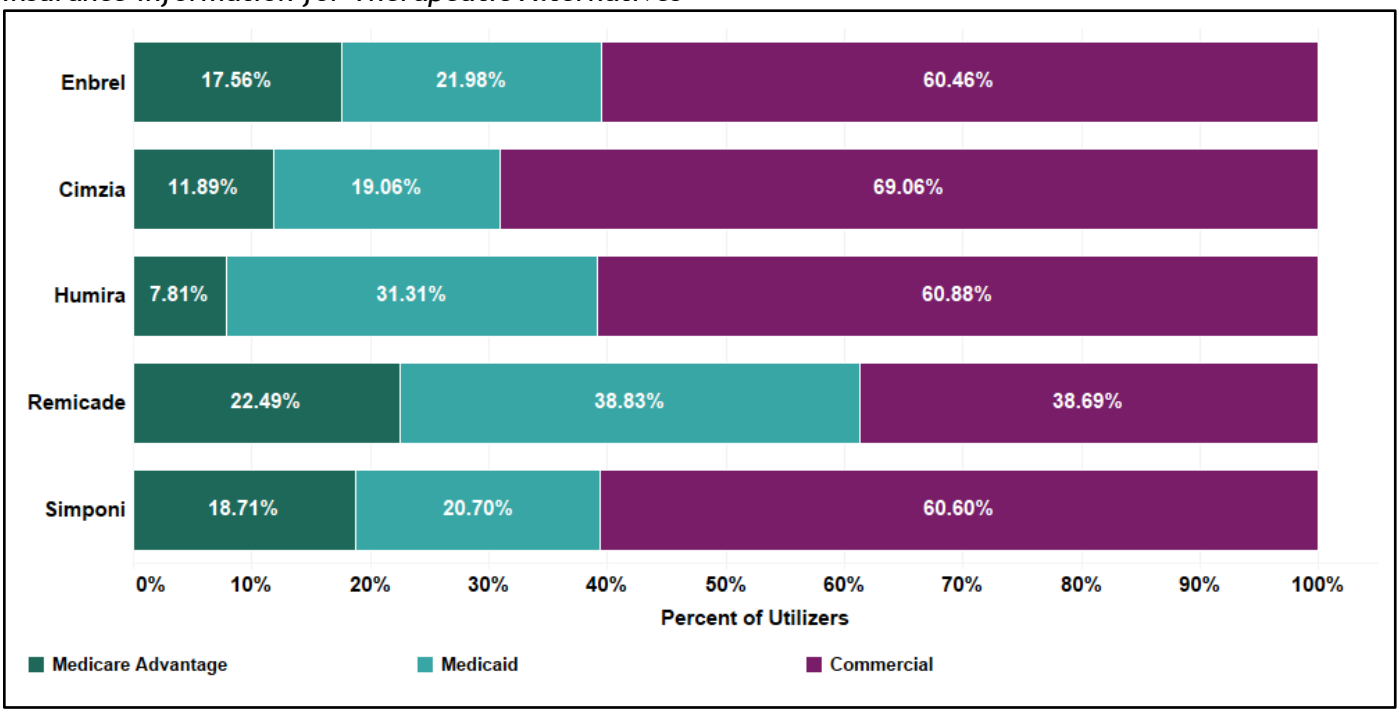


Figure 4 shows the 2022 payer mix for Enbrel and its identified therapeutic alternatives. This figure shows the percent of patients by payer type and year where green represents patients with Medicare Advantage, Teal represents patients with Medicaid, and purple represents patients with commercial insurance. Enbrel, Humira, and Simponi had around 60% of patients with commercial insurance while Cimzia had higher commercial coverage (69.06%) and Remicade had lower commercial coverage (38.69%).

Enbrel Price and Cost Profile

The Price and Cost Profile includes information on what different entities on the prescription drug supply chain charge for Enbrel, as well as what different entities pay for Enbrel. This profile also contains information on Enbrel's financial effects on health, medical, and social service costs.

Table 6

Enbrel's 2022 Price & Cost per Person Statistics

Price & Cost Per Person Statistics	Amount
Average WAC per Course of Treatment per Person[57]	[redacted]
Average Paid per Person	$46,772
APPY - Plan Paid	$41,769

[57] Course of treatment is calculated based on utilization not FDA labeling recommended doses. For course of treatment methodology please see June 9th, 2023 PDAB Board staff memo: https://drive.google.com/file/d/16BFOEB-LMiulmYzhKhxeGjvbFoh88cTs/view?usp=sharing

APPY - Out-of-Pocket[58]	$2,295

Table 7
Enbrel's 2022 Statewide Price & Cost Statistics

Statewide Price and Cost Statistics	Amount
Total Paid Amount	$159,305,653
Total Plan Paid[59]	$142,264,673
Total Medicaid Paid	$24,456,550
Total Patient Paid	$9,860,820
Gross-to-net Estimates	[redacted]

The current WAC for Enbrel is [redacted] per unit, with the most recent update to the WAC in January 2024. The initial WAC was [redacted] in November 1998. This is a 1,582.24% increase from November 1998 to January 2024, a 40.27% increase in the past five years, and a 5% increase from 2023. The average course of treatment is [redacted] units per patient per year, making the current WAC per course of treatment [redacted].[60] See Appendix A for more information.

Pursuant to section 10-16-1405, C.R.S., carriers and pharmacy benefit managers submit data about the highest cost prescription drugs to the APCD, including the fifteen prescription drugs that caused the greatest increase to the carrier's premiums. Ten of the nineteen carriers who submitted data reported Enbrel in the top fifteen drugs that caused the greatest increase to premiums, seven of these submitters reported Enbrel in the top five drugs that caused the greatest increase to premiums. Additionally, prescription drug transparency data from other states indicates Enbrel is among the costliest drugs in the state (Maine, Oregon) and has price increases above certain thresholds (Minnesota). See Appendix O for more information. The SEC requires all public companies to file a Form 10-K each year, and a Form 10-Q each quarter.[61] These forms provide a financial snapshot of the company's revenues, assets, and liabilities for the previous year. Amgen Inc.'s 2022 10-K details that Enbrel's international Product Revenue decreased from approximately $4.465 billion in 2021 to $4.117 billion in 2022 (p.F-17). See Appendix O for more information.

Out-of-Pocket Estimates

Patient copayment and other cost sharing depends on many factors, including: a patient's insurance coverage, how much has already been contributed to out-of-pocket maximum amounts in a benefit year, and whether the patient receives other assistance to pay for their portion of prescription drug. The APCD

[58] Medicaid copayments are $0-$3 for each prescription fill, as a result, Medicaid out of pocket paid amounts are removed from all averages in the data presented below, however, it is included in the statewide totals when reviewing the total amount patients paid. Medicaid copay information: https://www.healthfirstcolorado.com/copay/
[59] Total Plan Paid represents the amount paid by a patient's primary insurance coverage, even though secondary coverage may have paid an amount. Secondary insurance coverage paid amounts are generally captured in Total Paid Amounts.
[60] Course of Treatment methodology outlined in Board Staff Memo from June 6, 2023: https://drive.google.com/file/d/16BFOEB-LMiulmYzhKhxeGjvbFoh88cTs/view?usp=sharing.
[61] United States Securities and Exchange Commission, Form 10-K, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, Transition Report Pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934, Amgen Inc., : https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/data/318154/000031815423000017/amgn-20221231.htm.

provides data on the patient portion of the claim paid for the drug, but does not contain any information on assistance programs. Patients, caregivers, and individuals with scientific or medical training provided input regarding their experiences with assistance programs through public meetings, surveys, and voluntarily submitted information. See Appendices H, I, and J for more information.

The average annual out-of-pocket cost per person per year for individuals with commercial insurance is $3,980. There was wide variation in monthly average out-of-pocket costs, where 57.3% of individuals paid a total amount between $0-$50, though some individuals paid as much as $9,850-9,990.[62] Figure 5 outlines the annual out-of-pocket amounts for commercially insured individuals by type of out-of-pocket expense. See Appendix E for more details.

Figure 5

Average Commercial Out-of-Pocket Cost Comparison

[62] For the vast majority of patients covered by Medicaid, patient prescription drug copayments are between $0-$3 for each prescription drug fill and most individuals with Medicaid coverage do not have deductibles or coinsurance. See Appendix E for more information.

Figure 5 shows each out-of-pocket cost type for commercially insured individuals with Enbrel in dark purple and its therapeutic alternatives by year. There is a light gray line that shows the average of the therapeutic alternatives as a comparison to determine if Enbrel is more or less expensive than the average of its therapeutic alternatives. For example, the bottom right corner shows the average total out-of-pocket cost in 2022, Enbrel was $3,980, which is higher than the average of the four identified therapeutic alternatives, but lower than one of the therapeutic alternatives.

Another snapshot of out-of-pocket costs for individuals with commercial insurance is summarized below for both Enbrel and identified therapeutic alternatives.

Table 8
Average Monthly Commercial Out-of-Pocket Cost Information in 2022

	Enbrel	Cimzia	Humira	Remicade	Simponi
Average Total OOP Cost	**$373**	$305	$356	$303	$263
Average Coinsurance Amount	**$151**	$103	$171	$124	$105
Average Copay Amount	**$78**	$53	$56	$21	$48
Average Deductible Amount	**$132**	$146	$129	$125	$98
Average Days Supply	**34.3**	31.5	32.4	45.5	35.6

Table 8 shows average monthly out of pocket expenditures for individuals who are commercially insured.

In 2022, in an average month, an individual with commercial insurance paid a total of $373, $132 went towards a patient's deductible, $151 was paid towards coinsurance, and $78 was paid via copayment. Similar information is provided for therapeutic alternatives. These averages are calculated based on claims from the APCD, which does not include information about assistance programs that individuals might use when filling their prescriptions.

Figure 6
Changes in Copay amounts by Year and Drug 2018-2022

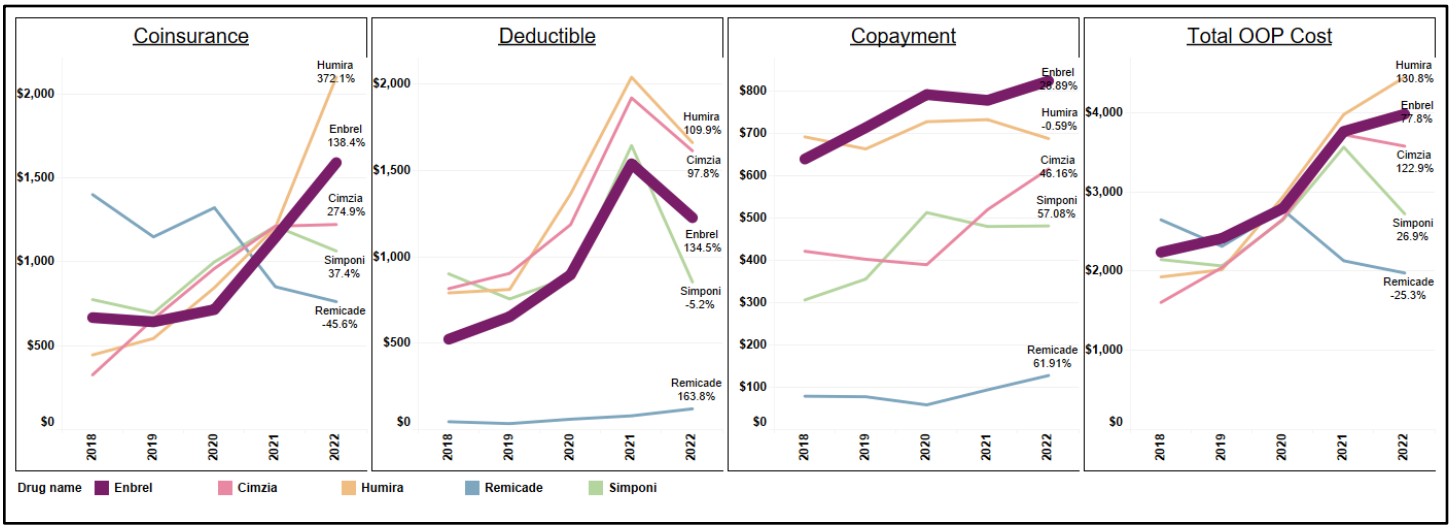


Figure 6 shows the annual change in the annual average oop amounts comparing Enbrel (dark purple) to its therapeutic alternatives. Each line is labeled with the name of the therapeutic alternative and the percent change from January 2018 - December 2022. Enbrel had the third highest increase in total out-of-pocket costs with a 77.8% increase. See Appendix E for more information.

Amgen Inc. provided information on the Enbrel Co-Pay Card program and Amgen Safety Net Foundation, which is available to eligible patients who need additional help and provides free or reduced medicine to patients who do not have insurance and meet certain eligibility criteria. See Appendices J and K for more information. Board staff received information in surveys that as many as 87% (33 of 38) of patients utilize some form of patient assistance program (could be manufacturer or another entity), though 30% (10 of 33) still had trouble affording Enbrel. See Appendices H, I, J, and K for more information.

Rebates, Discounts, and Price Concessions Estimates

The gross-to-net sales estimate is a proprietary estimate where SSR Health estimates all price concessions the manufacturer gives, including rebates, 340B discounts, assistance programs, and other price concessions provided by manufacturers compared to gross sales to get a percentage estimate of all discounts.[63] The gross-to-net sales estimate was [redacted] in the third quarter of 2008 (the earliest SSR Health estimates available), which increased to [redacted] in the third quarter of 2023. Additionally, In 2021, 14 of 25 carriers reported to the APCD that Enbrel was in the top 15 drugs for which the carrier received the largest rebate. See Appendix K for more information.

[63] All gross-to-net estimates are provided on a four quarter moving average.

Figure 7
Estimated Total Gross-to-Net Sales

Figure 7 shows the total gross-to-net sales estimate for Enbrel and identified therapeutic alternatives. The gross-to-net sales estimate for Enbrel has increased to [redacted] in the third quarter of 2023, [redacted]

Enbrel's Health and Financial Effects

One component of affordability reviews is an assessment of the relative financial effects on health, medical, or social service costs, as the effects can be quantified and compared to baseline effects of existing therapeutic alternatives to the prescription drug. Information regarding Enbrel's relative financial effects on health, medical, or social service costs is summarized here from literature reviews (Appendix D), input from patients and caregivers (Appendix H), input from individuals with scientific and medical training (Appendix I), and voluntarily submitted information (Appendix J). These summaries are structured to focus first on Enbrel's health effects, followed by financial effects.

Enbrel's Health Effects

The FDA label provides information on Enbrel's impact on the health effects on the indications it is approved to treat. See Appendix D for more information. Patients, caregivers, and individuals with scientific and

medical training reported in meetings and surveys regarding health effects. Examples of feedback, including two quotes that summarize common themes, are provided below; see Appendix H and Appendix I for more information.

- *"This drug has given me my life back. My flares are farther apart and Enbrel has allowed me to live my own life with few modifications and compromises"* Survey respondent with rheumatoid arthritis.
- *"We cycle through these drugs because sometimes they lose effectiveness or we just build up an immunity to them. That happened with Enbrel, but it was a glorious remission when I had it."* Public input session attendee.
- Enbrel has reduced pain and symptoms in the majority of patients of all indications, though some rheumatoid arthritis and psoriatic arthritis patients reported no improvements. Other patients stated that Enbrel worked well until it lost its effectiveness and they had to cycle to a new medication. One patient at a public input session liked that Enbrel is self-injectable, which cut down on trips to the doctor to get infusions.
- The most common side effect reported for all indications was pain and bruising at the injection site. Less common symptoms were chills, nausea, lowered immune system, depression, and dry mouth leading to dental issues. One patient reported not caring for the delivery method of self-injection.

Additionally, patients and caregivers provided input regarding therapeutic alternatives. Select answers are summarized below; see Appendix H for more information.

- **Humira:** Many patients reported it to be ineffective, and others reported that it worked well for a time to reduce inflammation and pain before it lost efficacy. One patient stated that it works better than Enbrel for them. Patients reported similar side effects as Enbrel.
- **Remicade**: Patients reported that this worked well but then plateaued and stopped working. One patient stated it gave them no relief.
- **Cimzia**: Effective and pregnancy safe option. One said getting sick too often.
- **Methotrexate:** Some patients said it did not work, others said it reduced inflammation but caused extreme severe side effects leading them to stop taking it. Reported side effects include nausea, blurry vision, severe fatigue and nausea, brain fog, hair loss, sores in mouth, and liver damage.

In addition to gathering information from patients, caregivers, and individuals with scientific and medical training, Board staff conducted literature reviews to compile evidence of the clinical effectiveness of Enbrel. To do this, Board staff examined studies conducted by Health Technology Assessment (HTAs) organizations. HTA organizations, often found within or supporting governmental agencies in other countries, can provide consistent and thorough assessments of a prescription drug's clinical and cost effectiveness. See Appendix D for information compiled from six HTA organizations for Enbrel's FDA-approved indications.

Enbrel's Financial Effects

Understanding a prescription drug's financial effects on health, medical, and social service costs as compared to therapeutic alternatives can be a complex task. HTA organizations conduct evaluations of the effects and impacts of a prescription drug, which may address the direct, intended consequences as well as their indirect, unintended consequences. Though nearly all HTA organizations take into account patient, caregiver, and provider perspectives when determining a prescription drug's cost effectiveness, Board staff were able to gather direct input from those groups on Enbrel's financial effects on health, medical, and social service costs.

Patients, caregivers, and individuals with scientific and medical training were asked in public meetings and in surveys to share any additional information about how Enbrel affects them financially. Participants and

respondents shared experiences related to out-of-pocket costs, assistance programs, and utilization management requirements. Select answers are highlighted below; see Appendix H for more information.

Table 9
National and Colorado Patient Responses: How does Enbrel impact each patient or their family?[64]

Survey Prompt	National Responses	Colorado Responses
This medication reduces the amount of time and money going to the doctor.	110 of 267	14 of 38
This medication reduces the amount of time and money spent going to the hospital or needing surgery.	63 of 267	9 of 38
This medication allows me to work and support my family.	110 of 267	15 of 38
Due to the cost of this medication, I have had to cut costs in other areas of my life.	74 of 267	20 of 38
Out-of-pocket costs have caused me to accrue medical debt.	36 of 267	8 of 38

Additionally, of the 33 of 38 Colorado patients who use assistance programs, 10 patients still had trouble affording Enbrel despite assistance. See Appendix H (input from patients and caregivers), Appendix I (input from individuals with scientific and medical training), and Appendix J (voluntarily submitted information) for more detail.

Board staff conducted literature reviews to compile evidence of the cost effectiveness of Enbrel. A summary of these organizations, the country where they are found, and their conclusions regarding the clinical effectiveness of Enbrel are outlined in Appendix D.

Enbrel Access to Care Profile

The Access to Care Profile examines potential access to care concerns related to Enbrel and whether there is evidence that the causes of access to care concerns may be related to Enbrel's price or cost. This profile includes an examination of potential relationships of changes between utilization, price, and costs as well as information on safety net providers, utilization management requirements, and health benefit plan design.

Price Effect on Access

Enbrel's WAC has increased 36 times since it was approved by the FDA in 1998, increasing a total of 1,582.24% since introduction, an increase that is significantly more than inflation (Figure 8 below). See Appendix A for more information. From 2018 to 2022, APCD data shows fluctuations in Enbrel's average annual patient out-of-pocket costs and total patient paid amounts, but with general increases across the five years and a 35.9% increase in average annual out-of-pocket costs (Table 10 below). See Appendix E for more information. Meanwhile, APCD data shows monthly fluctuations in average utilization of Enbrel, which

[64] 45 out of 267 national survey participants did not answer regarding the impact Enbrel has on the patient or their family. 3 out of 38 Colorado survey participants did not answer regarding the impact Enbrel has on the patient or their family.

appear relatively steady, though there was a decrease in utilization from 2018 to 2022 (See Figure 9 and Table 10 below).

Two of Enbrel's therapeutic alternatives, Humira and Remicade, have recent FDA-approved biosimilar products. While this affordability review does not contain information or analyses related to biosimilar products, there is evidence that biosimilar entry for TNF inhibitors resulted in increased utilization and price reduction in European markets.[65] Currently, Enbrel has patent protection and is protected from biosimilar competition and patents that prevent the introduction of biosimilar products are set to expire in 2029.[66] See Appendix C for more information.

Patient and caregiver survey results provide further insight that patients report the cost of Enbrel has impacted their ability to access the prescription drug (see Table 11 below). While this impact varies by the self-reported out-of-pocket cost per month, over half (10 of 19) of Colorado patients paying between $0-50 per month for Enbrel still reported that cost has at some point impacted their ability to access Enbrel. See Appendices E and H for more information.

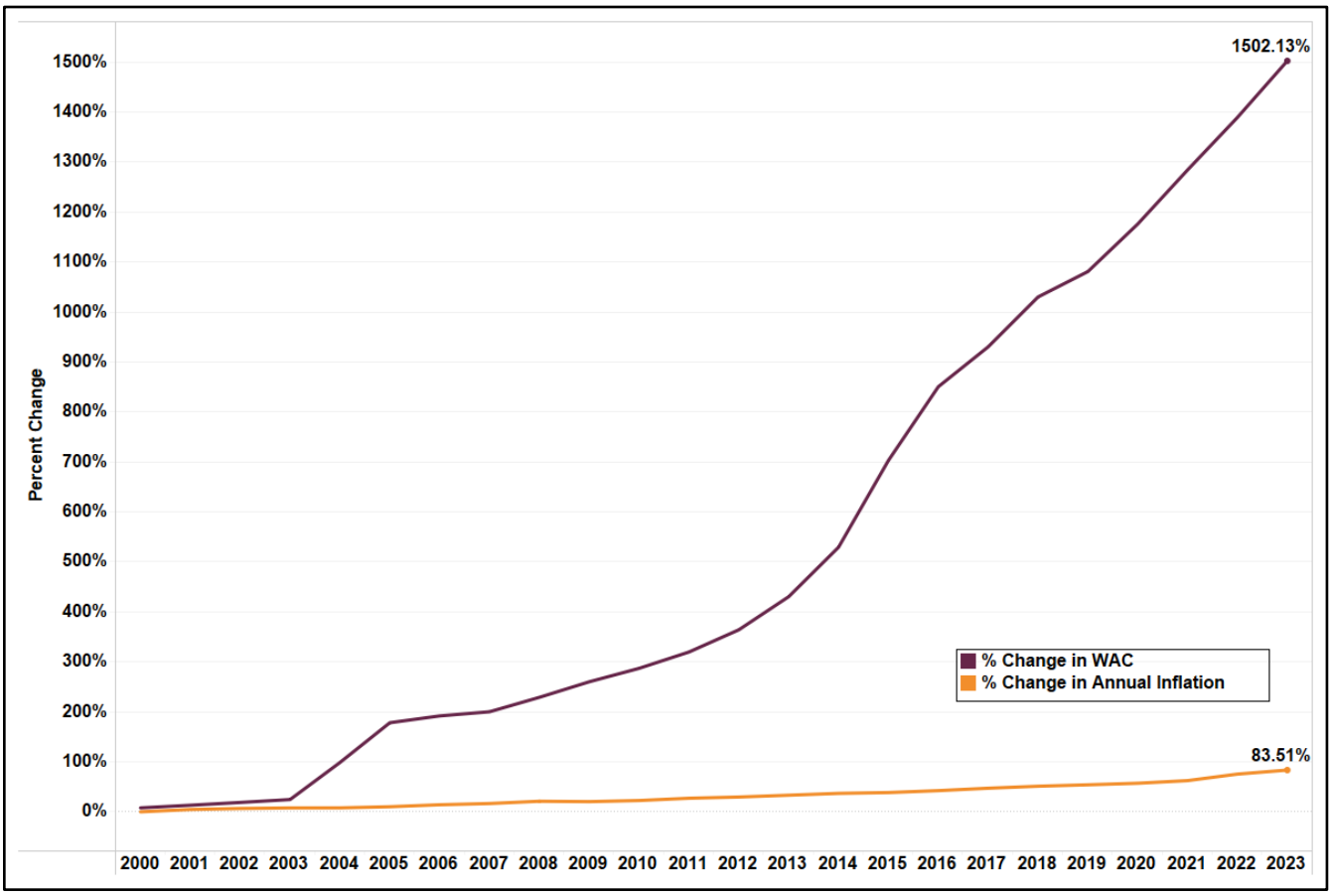
Table 10
Annual Utilization and Expenditures

	2018	2019	2020	2021	2022
Patient Count	3,890	3,653	3,440	3,692	3,406
Total Paid	$129,421,272	$127,959,896	$134,815,241	$161,483,771	$159,305,653
Average Paid Per Person	$33,270	$35,029	$39,190	$43,739	$46,772
Total Patient Paid	$6,720,180	$7,399,691	$7,700,602	$10,524,066	$9,860,820
Average OOP	$1,688	$1,866	$2,189	$2,526	$2,295
WAC Per Unit	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table 10 shows the year-over-year increases in the number of patients using Enbrel, the total amount paid for Enbrel, the average paid per person, the total amount that patients paid, and the average amount that each patient paid.

[65] https://www.frontiersin.org/journals/pharmacology/articles/10.3389/fphar.2023.1151764/full
[66] https://www.centerforbiosimilars.com/view/nj-court-decision-means-3-decades-of-product-exclusivity-for-enbrel

Figure 8
Percentage Change in WAC (Enbrel) Compared to Annual Inflation



For additional context, Figure 8 shows the same change in WAC as a percent change (purple) and annual inflation (orange) over the same time frame.[67]

[67] Figure 8 shows a comparison with inflation, which was not calculated for the complete year of 2023 at the time of this report, so the most recent WAC price is not included in this graphic and the percent change in WAC noted here is from 2018 through 2022.

Figure 9
Monthly Utilizers for Enbrel and Therapeutic Alternatives

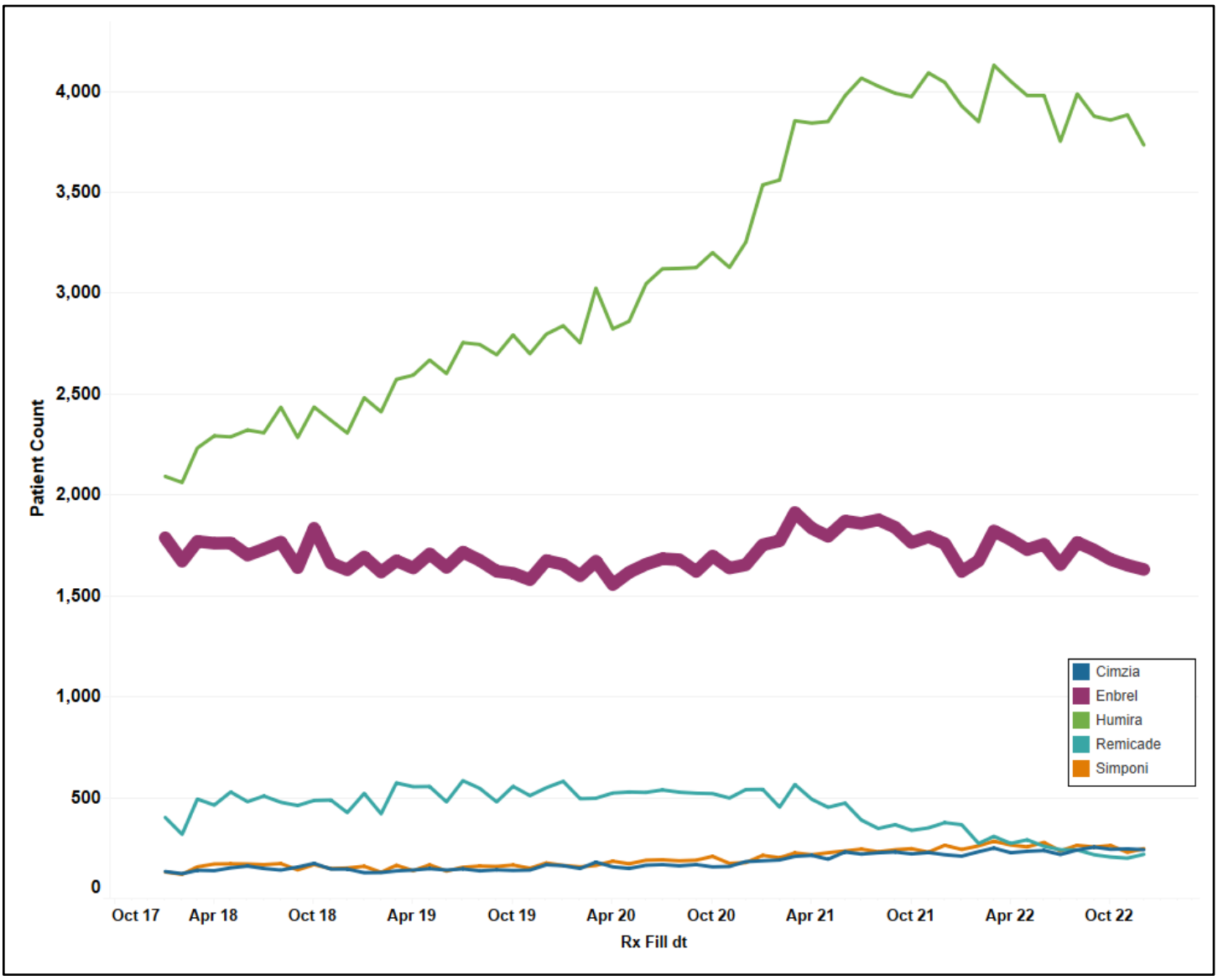


Figure 9 shows the monthly number of utilizers for Enbrel and therapeutic alternatives. Utilization of Enbrel has stayed consistent from January 2018 to December 2022, it is the second highest utilized drug after Humira which has increased significantly in the same timeframe.

Figure 10
Monthly Total Paid and Average Total Paid

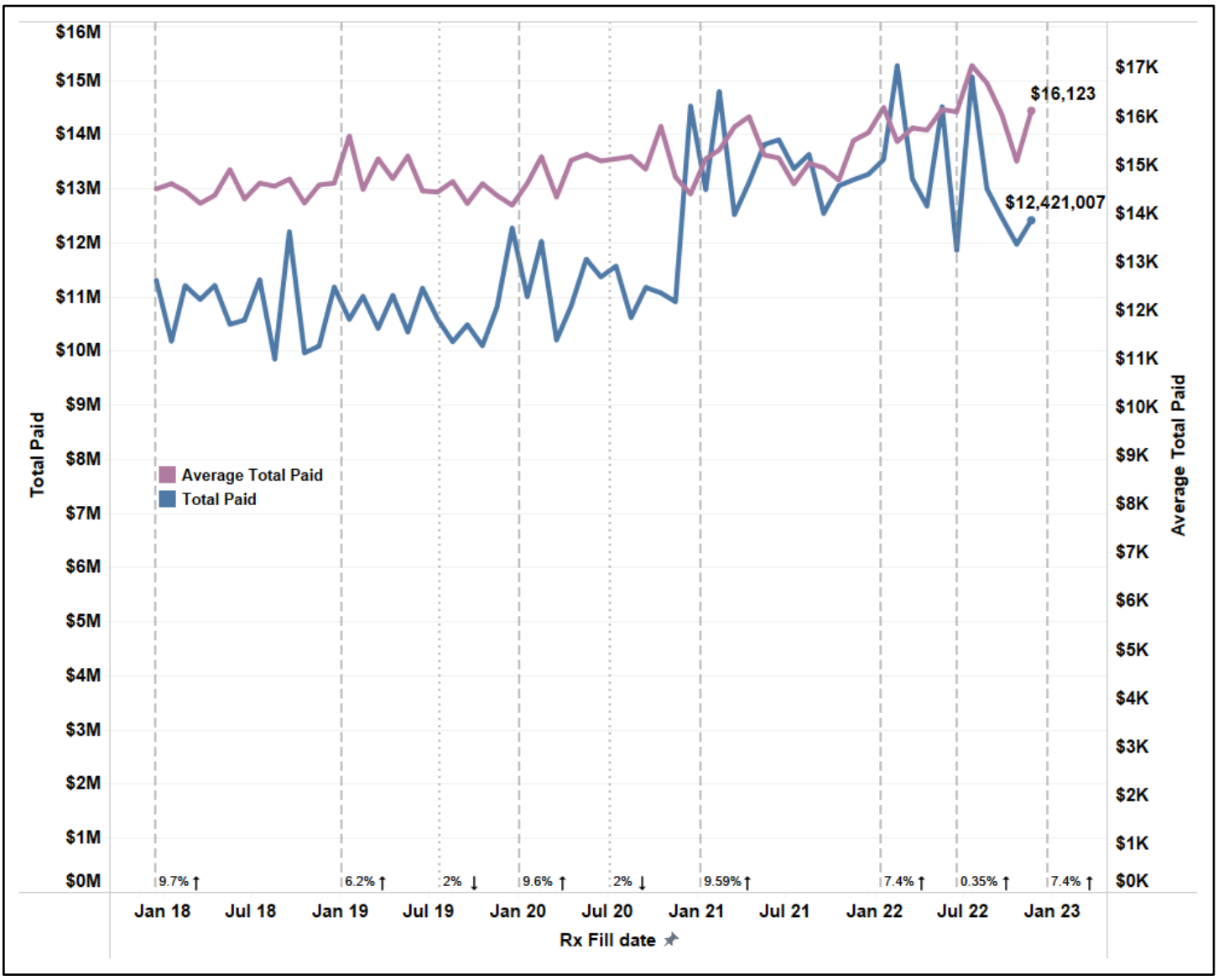


Figure 10 shows the monthly total paid with the blue line (left axis) and the monthly average paid per person with the purple line (right axis) with vertical lines representing changes in WAC with the magnitude of the change written to the right of the line with an arrow up or down indicating an increase or decrease in the WAC. There is no visible correlation between the WAC change and the corresponding change in the APCD paid amounts. During this time frame, the number of patients using Enbrel increased from 3,890 in 2018 to 3,406 in 2022.

Table 11
Colorado Patients' Self-Reported Out-of-Pocket Cost and Access Due to Cost

Out-of-Pocket Cost per Month	Colorado Response	Cost Affects Access
$0 - $50	19 of 38	10 of 19 said cost does affect access.

$50 - 100	4 of 38	2 of 4 said cost does affect access.
$100 - $150	1 of 38	1 of 1 said cost does affect access.
$150 - $250	2 of 38	2 of 2 said cost does affect access.
$250 - $500	1 of 38	1 of 1 said cost does affect access.
$500 - $1000	6 of 38	6 of 6 said cost does affect access.
More than $1000 per month	5 of 38	5 of 5 said cost does affect access.

Safety Net Providers, Utilization Management Requirements, and Health Benefit Plan Design

Individuals with scientific and medical training provided input that safety net providers participate as covered entities in the federal 340B Drug Pricing Program administered by the U.S. Health Resources & Services Administration (HRSA) and dispense Enbrel. See Appendix H for more information. No safety net providers volunteered information regarding Enbrel's utilization in a safety net setting, nor the nature of the 340B discount for Enbrel. See Appendices F, I, and M for more information.

It is difficult to precisely know how many uninsured patients in Colorado have an indication treated by Enbrel. Patients and caregivers who responded to the survey provided some insight. See Appendix H for more information.

Patients and caregivers who completed surveys provided the following information regarding utilization management:

Table 12
Survey response: Utilization management.

Survey Prompt	National Responses	Colorado Responses
I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	23 of 267 (9%)	6 of 38 (16%)
My insurance plan has dropped or switched my drug coverage after the plan year started.	25 of 267 (9%)	2 of 38 (5%)
My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor.	73 of 267 (27%)	14 of 38 (37%)
My insurance plan requires prior approval to fill the prescription.	183 of 267 (69%)	24 of 38 (63%)
My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	97 of 267 (36%)	18 of 38 (47%)

I worry that the cost of my prescription will raise my insurance premium.	56 of 267 (21%)	8 of 38 (21%)

Table 12 shows both national and Colorado patient responses to a survey question asking if they had experienced any of the listed utilization management practices. See Appendix H for more information.

Utilization management requirements, along with prescription drug formularies, are meant to encourage the use of medically appropriate and cost-effective drug-related products that meet the needs of patient populations.[68] To better understand health benefit plan design coverage and formulary structure, data was accessed by Colorado Division of Insurance (DOI) staff for the affordability review. Data pulled was for carriers in the individual and small group markets for which DOI receives annual rate filings. As such, this data does not describe the entire insurance market in Colorado, but can shed valuable information on benefit plan design and out-of-pocket costs.

Of the ten carriers that submitted filings, eight carriers cover four or more dosage forms of Enbrel. All carriers that cover Enbrel require prior authorization. In total, 576 plans provide coverage for Enbrel and the majority of carriers place Enbrel on the highest two formulary tears, meaning a higher portion of the drug is paid by patients than prescription drugs on lower tiers (until the maximum out-of-pocket amount under the plan is paid by the patient). See Appendix E for more information.

68 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10398227/#:~:text=The%20intent%20of%20a%20formulary,the%20needs%20of%20patient%20populations.

Appendix A

Enbrel: Wholesale Acquisition Cost

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider the wholesale acquisition cost of the drug. (C.R.S. § 10-16-1406(4)(a)).

Rule: The Board will consider both the current wholesale acquisition cost of the prescription drug and changes in the prescription drug's wholesale acquisition cost over time. (3 CCR 702-9, Part 3.1.E.2.a).

Policy: Information regarding the initial WAC, the current WAC, and changes to WAC over time. (PDAB Policy 04, p. 6).

Underlying Methodology: Board staff compiled wholesale acquisition cost (WAC) data for Enbrel for the Board's consideration in the following manner:

1. Using AnalySource, staff pulled all effective WAC per unit amounts and dates associated with the drug.
2. Staff calculated the percent change in WAC since launch and in past five years by using the following calculation: (Current WAC - Initial WAC) / Initial WAC
3. Staff calculated annual inflation amounts by identifying the Bureau of Labor Statistics' (BLS) Annual Inflation Numbers using the Denver-Aurora-Lakewood area to compare WAC changes over time to inflation.[1]

Data Source(s):

- AnalySource's WAC amount, representing the manufacturer's published catalog or list price for a drug product to wholesalers as reported to First Databank by the manufacturer.
- U.S. Bureau of Labor Statistics for Denver-Aurora-Lakewood for annual inflation numbers.

Considerations and Data Limitations:

- Precise WAC amounts are confidential and may only be shared with the Board, Board staff, and Board contractors.
- The WAC does not consider rebates, discounts, or actual paid amounts.

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[1] https://www.bls.gov/regions/mountain-plains/news-release/ConsumerPriceIndex_Denver.htm. Annual inflation numbers were for all items, not seasonally adjusted, with the current base (1982-40 = 100), and inflation change was calculated on an annual basis.

Enbrel: Wholesale Acquisition Cost Evidence

The current WAC for Enbrel is [redacted] per unit, with the most recent update to the WAC in January 2024. The initial WAC was [redacted] in November 1998. This is a 1,582.24% increase from November 1998 to January 2024, a 40.27% increase in the past five years, and a 5% increase from 2023. The average course of treatment is [redacted] units per patient per year, making the current WAC per course of treatment [redacted].[2]

Table A-1

WAC per unit: Date, Price, and Percent Increase (Enbrel)

Enbrel WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	2.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	104.08%
[redacted]	[redacted]	4.31%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	-3.92%

[2] For course of treatment methodology please see June 6, 2023 PDAB Board staff memo: https://drive.google.com/file/d/16BFOEB-LMiulmYzhKhxeGjvbFoh88cTs/view?usp=sharing

[redacted]	[redacted]	9.18%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	5.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	7.90%
[redacted]	[redacted]	9.90%
[redacted]	[redacted]	7.90%
[redacted]	[redacted]	7.90%
[redacted]	[redacted]	9.90%
[redacted]	[redacted]	8.40%

[redacted]	[redacted]	9.68%
[redacted]	[redacted]	6.20%
[redacted]	[redacted]	-2.00%
[redacted]	[redacted]	9.59%
[redacted]	[redacted]	-2.00%
[redacted]	[redacted]	9.59%
[redacted]	[redacted]	7.40%
[redacted]	[redacted]	0.35%
[redacted]	[redacted]	7.40%
[redacted]	[redacted]	4.99%

Table A-1 shows all historical WAC per unit amounts and the percent difference of each change.

Figure A-1
Change in WAC per Unit Price (Enbrel)

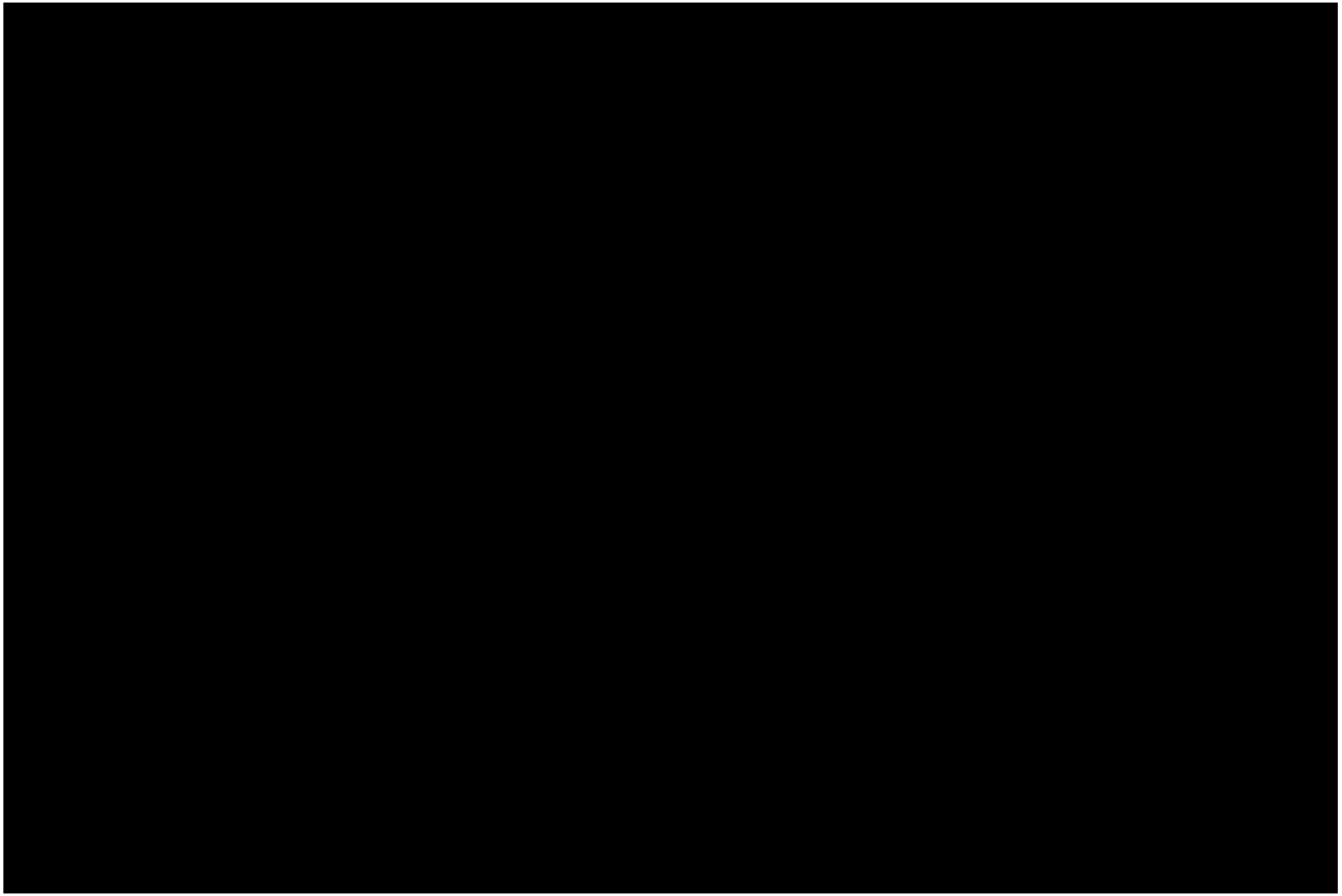
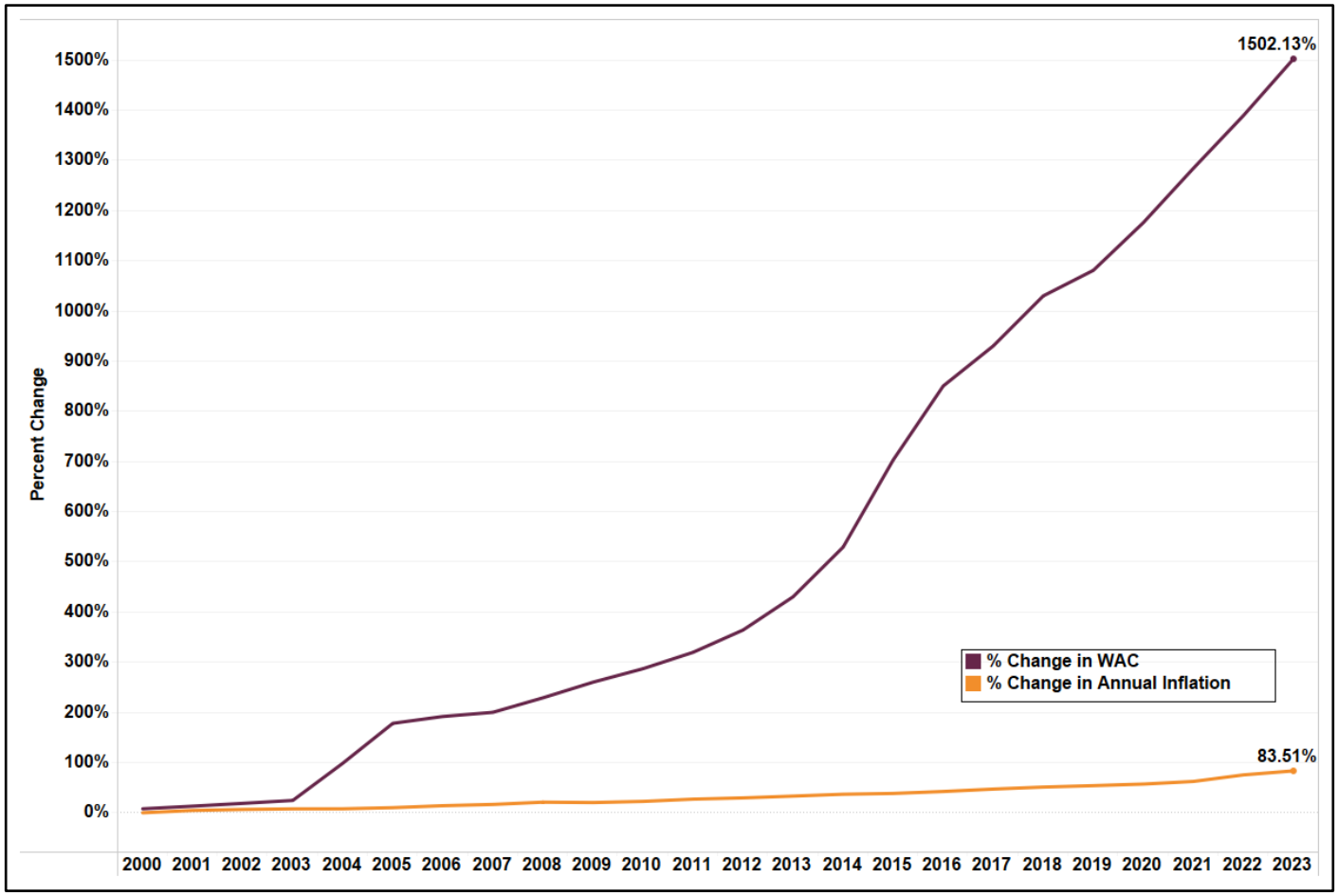


Figure A-1 shows the change in WAC per unit price since its initial WAC price in November 1998.

Figure A-2
Percentage Change in WAC (Enbrel)



For additional context, Figure A-2 shows the same change in WAC as a percent change (purple) and annual inflation (orange) over the same time frame.[3]

[3] Figure A-2 shows a comparison with inflation, which was not calculated for the complete year of 2023 at the time of this report, so the most recent WAC price is not included in this graphic and the percent change in WAC noted here is from 2018 through 2022.

Figure A-3
WAC per Course of Treatment for Enbrel and Therapeutic Alternatives

Figure A-3 shows the changes in WAC per course of treatment for Enbrel and identified therapeutic alternatives.[4] This graphic highlights the changes in WAC for each drug, as listed in table A-2 below, as well as the WAC per course of treatment of each drug as determined by average

[4] The course of treatment calculation used in selecting drugs, calculated from 2021 APCD claims experience was used across all time frames to highlight the changes in WAC relative to each drug. For course of treatment methodology please see June 6, 2023 PDAB Board staff memo: https://drive.google.com/file/d/16BFOEB-LMiulmYzhKhxeGjvbFoh88cTs/view?usp=sharing

utilization in Colorado. If a line does not continue to the end of the figure, it is because the WAC has not changed from the last year displayed. Enbrel has the third highest current WAC per course of treatment after Humira and Simponi.

Table A-2

WAC Changes from Initial and within the Last 5 Years for Therapeutic Alternatives to Enbrel

Cimzia WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	228.90%
[redacted]	[redacted]	7.00%
[redacted]	[redacted]	4.00%
[redacted]	[redacted]	5.90%
[redacted]	[redacted]	5.90%
[redacted]	[redacted]	5.90%

Humira WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	395.00%
[redacted]	[redacted]	7.40%
[redacted]	[redacted]	7.40%
[redacted]	[redacted]	7.40%

[redacted]	[redacted]	8.00%

Remicade WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	136.74%
[redacted]	[redacted]	4.90%

Simponi WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	205.33%
[redacted]	[redacted]	4.50%
[redacted]	[redacted]	4.80%
[redacted]	[redacted]	5.80%
[redacted]	[redacted]	5.30%
[redacted]	[redacted]	4.00%

Table A-2 shows the initial WAC and any changes in WAC in the last five years for identified therapeutic alternatives.[5]

[5] The first percent increase may cover up to 16 years, which is why some of the initial increases appear to be larger. Where there are multiple WACs per unit for a drug, only one strength and dosage form is included to display the increases in identified therapeutic alternatives.

Analysis of differences in WAC for Enbrel and identified therapeutic alternatives is complex due to the different indications a prescription drug may be used to treat. More information regarding Enbrel and identified therapeutic alternatives' indications and FDA-recommended dosages is provided below for context.

Table A-3
FDA Recommended Dosage by Drug & Indication

Drug Name	Indication	FDA Recommended Dosage
Enbrel[6]	Rheumatoid Arthritis (RA)	50 mg once weekly
	Polyarticular Juvenile Idiopathic Arthritis (JIA)	0.8 mg/kg weekly with a max of 50 mg per week
	Psoriatic Arthritis (PsA)	50 mg once weekly
	Ankylosing Spondylitis (AS)	50 mg once weekly
	Plaque Psoriasis (PsO)	50 mg twice weekly for 3 months, followed by 50 mg once weekly
Therapeutic Alternative	**Indication**	**FDA Recommended Dosage**
Cimzia[7]	Rheumatoid Arthritis (RA)	400 mg initially and at weeks 2 and 4, followed by 200 mg every other week. For maintenance dosing, 400 mg every 4 weeks can be considered
	Psoriatic Arthritis (PsA)	400 mg initially and at weeks 2 and 4, followed by 200 mg every other week. For maintenance dosing, 400 mg every 4 weeks can be considered
	Ankylosing Spondylitis (AS)	400 mg is given as 2 subcutaneous injections of 200 mg each (initially) and at weeks 2 and 4, followed by 200 mg every other week or 400 mg every 4 weeks
	Rheumatoid Arthritis (RA)	40 mg every other week.

[6] https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/103795s5591lbl.pdf
[7] https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125160s270lbl.pdf

Humira[8]	Juvenile Idiopathic Arthritis (JIA)	• 10 kg (22 lbs) to <15 kg (33 lbs):10 mg every other week • 15 kg (33 lbs) to < 30 kg (66 lbs):20 mg every other week • ≥ 30 kg (66 lbs):40 mg every other week
	Psoriatic Arthritis (PsA)	40 mg every other week.
	Ankylosing Spondylitis (AS)	40 mg every other week.
	Plaque Psoriasis (Ps)	80 mg initial dose, followed by 40 mg every other week starting one week after the initial dose.
Remicade[9]	Rheumatoid Arthritis (RA)	In conjunction with methotrexate, 3 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some patients may benefit from increasing the dose up to 10 mg/kg or treating as often as every 4 weeks.
	Psoriatic Arthritis (PsA)	5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.
	Ankylosing Spondylitis (AS)	5 mg/kg at 0, 2, and 6 weeks, then every 6 weeks.
	Plaque Psoriasis (Ps)	5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks.
Simponi[10]	Rheumatoid Arthritis (RA)	50 mg administered by subcutaneous injection once a month.
	Psoriatic Arthritis (PsA)	50 mg administered by subcutaneous injection once a month.
	Ankylosing Spondylitis (AS)	50 mg administered by subcutaneous injection once a month.

Table A-3 shows the FDA label's suggested dosing for each indication of Enbrel and identified therapeutic alternatives.

[8] https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125057s410lbl.pdf
[9] https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/103772s5359lbl.pdf
[10] https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/125289s0064lbl.pdf

Appendix B

Enbrel: Therapeutic Alternatives

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider the cost and availability of therapeutic alternatives to the prescription drug in the state. (C.R.S. § 10-16-1406(4)(b)).

Rule: The Board will consider the cost and availability of therapeutic alternatives to the prescription drug in the state. The Board may review any relevant data regarding costs and expenditures related to the prescription drug and its therapeutic alternatives, as well as any relevant data regarding availability and utilization related to the prescription drug and its therapeutic alternatives. (3 CCR 702-9, Part 3.1.E.2.b).

Therapeutic alternative is defined as a drug product that contains a different therapeutic agent than the drug in question, but is the same pharmacological or therapeutic class and has been shown through peer-reviewed studies to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose or has been recommended as consistent with standard medical practice by medical professional association guidelines. (3 CCR 702-9, Part 1.1.C)

Policy: Information containing a list of therapeutic alternatives for the Board's consideration through review and consultation of sources such as the Orange Book, the Purple Book, World Health Organization's anatomical therapeutic classification code system, and peer-reviewed research. Information prepared for the Board's consideration includes:

- The cost of the therapeutic alternative in the state by examining APCD expenditure data or other data sources relevant to cost of the therapeutic alternatives in the state;
- The availability of the therapeutic alternative in the state by examining APCD utilization data or other data sources relevant to the therapeutic alternatives in the state; and
- Rebate data for the therapeutic alternative(s) by examining external databases. (PDAB Policy 04, p. 6).

Underlying Methodology: Board staff and members of the Program on Regulation, Therapeutics, and Law (PORTAL) have compiled data for Enbrel and identified therapeutic alternatives for the Board's consideration in the following manner:

1. Identified therapeutic alternatives for Enbrel.
2. Presented utilization data from 2018-2022, including both units utilized and the number of patients who utilized the prescription drug.[1]
3. Presented expenditure data from 2018-2022, including total paid amount, total plan paid amount, total patient paid amount, average paid per person per year, and average patient out-of-pocket cost per person per year.[2]
4. Examined rebate estimates, when available, for selected prescription drugs and identified therapeutic alternatives.

Data Source(s): Members of PORTAL assisted Board staff in compiling information on identified therapeutic alternatives of Enbrel. Data sources used to identify therapeutic alternatives include:

- FDA website, which contains information on current FDA labeling for each drug and FDA-approved indication.
- Websites of medical professional organizations for specific disease areas to identify medical association guidelines.

[1] Utilization data for Enbrel's four identified therapeutic alternatives can be found in Appendices C and E.

[2] Expenditure data for Enbrel's four identified therapeutic alternatives can be found in Appendix C and E.

- UpToDate, an online, evidence-based clinical decision support database, to identify therapeutic alternatives that may have been approved since the most recent medical association guidelines.

Considerations and Data Limitations:

- Medical professional association guidelines used in this affordability review component are often unique to a particular indication and authored by different professional associations. As such, these guidelines are not consistently organized or structured.
- Medical professional guidelines may be published every several years. As such, there may be instances where the selected drug or identified therapeutic alternatives are not in the most recent medical professional association guidelines. If this is the case, it will be noted.

Enbrel: Therapeutic Alternatives Evidence

Therapeutic Alternatives Identification

Members of PORTAL identified therapeutic alternatives in the following manner:

1. Identified the Enbrel's therapeutic class as defined under the WHO Anatomical Therapeutic Chemical[3] (WHO-ATC) classification system. Only drugs listed in the same therapeutic class as Enbrel under this system were evaluated as therapeutic alternatives.
2. Reviewed the current FDA labeling for Enbrel and identified each FDA-approved indication. Pediatric and adult indications were reviewed separately if separate medical professional guidelines were available for the respective populations.
3. Identified U.S. medical professional association guideline(s), which rely upon peer-reviewed research, relevant to each FDA-approved indication done via internet search and reviewing the websites of medical professional organizations. If both U.S. and international guidelines were available, use the US guidelines exclusively. If guidelines were available from multiple U.S. organizations, both were included.
4. Located Enbrel in the guidelines to determine how the drug is recommended for use. For example, was the drug recommended as first-line treatment or subsequent line after failure of another treatment? Was it recommended for all patients or specific sub-populations? This was compared to the drug's FDA label, documenting any discrepancies and off-label uses.
5. Summarized the guideline recommendations and how the selected drug fits into those recommendations. This included information about how the treatment of different subpopulations may deviate from the standard pathway.
6. Within the guidelines, identified other drugs in the same WHO-ATC drug class that were recommended to be used similarly to the selected drug. For each in-class therapeutic alternative, identified the drug's non-proprietary name and brand name.
7. To identify in-class alternatives approved after guideline publication, reviewed treatment options for each indication via UpToDate[4], an online evidence-based clinical decision support database. If recently approved in-class drugs were identified that were not included in the guidelines, these drugs' labeling were reviewed and included as alternatives if the drug had an FDA-approved indication that matched that of the selected drug.
8. Used the FDA approval history database via Drugs.com to identify the estimated indication approval date for each therapeutic alternative. This date was verified using the Drugs@FDA database[5]. If drugs

[3] https://www.whocc.no/atc_ddd_index/

[4] https://www.wolterskluwer.com/en/solutions/uptodate

[5] https://www.fda.gov/drugs/development-approval-process-drugs/drug-approvals-and-databases

were recommended in the guidelines but were not FDA-approved for the indication, these will be marked as off-label alternatives.

Board Consideration of Therapeutic Alternatives to Enbrel

During the Board's September 15, 2023 meeting, the Board directed Board staff to narrow data analyses of APCD, WAC, and rebate data for purposes of this component to identify therapeutic alternatives that are in the same class as Enbrel.

Relevant Medical Professional Guidelines

Enbrel's therapeutic class as defined under the WHO-ATC classification system is Tumor necrosis factor alpha (TNF-α) inhibitors.[6] The following guidelines were used to identify in-class therapeutic alternatives for all FDA approved indications in Table B-X.

Table B-1
Enbrel Indications and Relevant Guidelines

[6] https://www.whocc.no/atc_ddd_index/?code=L04AB&showdescription=no

FDA Approved Indications (as of October 2023)[7]	Relevant Guidelines	Guideline Publication Date
Enbrel is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with **moderately to severely active rheumatoid arthritis (RA)**.	Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research [8]	6/8/2021
Enbrel is indicated for reducing signs and symptoms in patients with **active ankylosing spondylitis (AS)**.	Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol.[9]	8/22/2019
Enbrel is indicated for the treatment of **patients 4 years or older with chronic moderate to severe plaque psoriasis (PsO)** who are candidates for systemic therapy or phototherapy.	Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. Journal of the American Academy of Dermatology.[10] Menter A, Cordoro KM, Davis DMR, et al. Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis in pediatric patients. Journal of the American Academy of Dermatology. [11]	4/2019
Enbrel is indicated for reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in **adult patients with psoriatic arthritis (PsA)**.	Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol.[12]	11/30/2018
Enbrel is indicated for the treatment of **active juvenile psoriatic arthritis (JPsA) in pediatric patients 2 years of age and older**.	Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Care Res.[13]	4/25/2019
Enbrel is indicated for reducing signs and symptoms of moderately to severely active **polyarticular juvenile idiopathic arthritis (pJIA)** in patients 2 years of age and older.	Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Care Res.[14]	4/25/2019

[7] www.accessdata.fda.gov/drugsatfda_docs/label/2023/103795s5595lbl.pdf
[8] https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/acr.24596
[9] https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/art.41042
[10] https://pubmed.ncbi.nlm.nih.gov/30772098/
[11] https://pubmed.ncbi.nlm.nih.gov/31703821/
[12] https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/art.40726
[13] https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/acr.23870

Table B-1 shows the FDA approved indications for Enbrel and relevant guidelines and guideline publication date.

In-Class Therapeutic Alternatives

The relevant guidelines outlined above identify the following in-class therapeutic alternatives for Enbrel:

- Humira
- Cimzia
- Simponi / Simponi Aria
- Remicade

Humira

- **Non-Proprietary Name:** adalimumab
- **Brand Name:** Humira
- **Mechanism of Action:** TNF Inhibitor

Table B-2
Humira: In-Class Therapeutic Alternatives by Indication

Indication	In Guidelines	FDA Approval Date
Rheumatoid Arthritis (RA)	Yes	12/31/2002
Ankylosing spondylitis (AS)	Yes	7/28/2006
Plaque Psoriasis: Adult and Pediatric	Yes	1/18/2008
Psoriatic arthritis (PsA)	Yes	10/3/2005
Juvenile Psoriatic Arthritis (JPsA)	No	NA
Polyarticular Juvenile Idiopathic Arthritis (pJIA)	Yes	2/21/2008

Cimzia

- **Non-Proprietary Name:** certolizumab pegol
- **Brand Name:** Cimzia
- **Mechanism of Action:** TNF Inhibitor

Table B-3
Cimzia: In-Class Therapeutic Alternatives by Indication

Indication	In Guidelines	FDA Approval Date
Rheumatoid Arthritis (RA)	Yes	5/13/2009
Ankylosing spondylitis (AS)	Yes	10/17/2013
Plaque Psoriasis: Adult and Pediatric	Yes	5/24/2018
Psoriatic arthritis (PsA)	Yes	9/27/2013

[14] https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/acr.23870

Juvenile Psoriatic Arthritis (JPsA)	No	N/A
Polyarticular Juvenile Idiopathic Arthritis (pJIA)	No	N/A

Simponi / Simponi Aria

- **Non-Proprietary Name:** golimumab
- **Brand Name:** Simponi / Simponi Aria
- **Mechanism of Action:** TNF Inhibitor

Table B-4
Simponi / Simponi Aria: In-Class Therapeutic Alternatives by Indication

Indication	In Guidelines	FDA Approval Date
Rheumatoid Arthritis (RA)	Yes	4/24/2009
Ankylosing spondylitis (AS)	Yes	4/24/2009
Plaque Psoriasis: Adult and Pediatric	No	N/A
Psoriatic arthritis (PsA)	Yes	4/24/2009
Juvenile Psoriatic Arthritis (JPsA)	Yes	9/29/2020
Polyarticular Juvenile Idiopathic Arthritis (pJIA)	Yes	9/29/2020

Remicade

- **Non-Proprietary Name:** infliximab*
- **Brand Name:** Remicade
- **Mechanism of Action:** TNF Inhibitor

Table B-5
Remicade: In-Class Therapeutic Alternatives by Indication

Indication	In Guidelines	FDA Approval Date
Rheumatoid Arthritis (RA)	Yes	11/10/1999
Ankylosing spondylitis (AS)	Yes	12/17/2004
Plaque Psoriasis: Adult and Pediatric	Yes	9/26/2006
Psoriatic arthritis (PsA)	Yes	5/13/2005
Juvenile Psoriatic Arthritis (JPsA)	No	N/A

Polyarticular Juvenile Idiopathic Arthritis (pJIA)	No	N/A

Utilization and expenditure data for Enbrel and identified therapeutic alternatives is contained in Appendix C and Appendix E.

Appendix C

Enbrel: Price Effect on Consumer Access

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider the effect of the price on Colorado consumers' access to the prescription drug. (C.R.S. § 10-16-1406(4)(c)).

Rule: The Board will consider the effect of price on Colorado consumers' access to the prescription drug by reviewing changes in pricing, expenditure, and utilization over time. (3 CCR 702-9, Part 3.1.E.2.c).

Policy: Information regarding changes in pricing compared to changes in expenditure and utilization over the same time period to analyze potential correlation. Information will also be presented from APCD data and subject matter experts to better understand potential confounding variables, such as:

- When therapeutic alternative(s) were available;
- Changes to patents; and
- Changes in rebate amounts for the prescription drug or therapeutic alternative. (PDAB Policy 04, pp. 6-7).

Underlying Methodology: Board staff have compiled data on price effect on consumer access for the Board's consideration in the following manner:

1. From APCD pharmacy claims, Board staff pulled all claims for Enbrel from October 2018 - December 2022.
2. Board staff combined the claims data with WAC data from AnalySource by joining on the month and year of the claim with the effective WAC of the same month and year.
3. Board staff combined the claims and WAC data with the gross-to-net sales estimates from SSR Health by joining the month and year of the claim with the month and year of the quarter estimates in SSR Health.

Data Source(s): Board staff compiled information on price effect on access for the selected prescription drug from the following sources:

- APCD, which provides detail on utilization and expenditure,
- AnalySource for current and historical WAC,
- FDA and Centers for Medicare and Medicaid Services (CMS) for other pricing data,
- FDA website for changes to patents, and
- SSR Health for gross-to-net sales estimates.

Considerations and Data Limitations: Claims-based utilization data shows what health care services were accessed, but this data does not show what health care services were potentially under-accessed or not accessed at all. Qualitative data (such as surveys or anecdotes) may illuminate which health care services were under-accessed or not accessed at all, but there is no validated data source that provides this information.

Enbrel: Price Effect on Access Evidence

This appendix provides more detailed information regarding: utilization, price, out-of-pocket costs, and gross-to-net sales estimates, and patent information.

Table C-1

Changes in Enbrel Utilization, Expenditure, and Gross-to-Net Sales from 2018-2022

	2018	2022	Percent Change
Total OOP Costs	$1,688	$2,295	35.90%
Total Paid Amount	$129,421,272	$159,305,653	23.09%
Patient Count	3,890	3,406	-12.44%
Gross-to-Net Sales	[redacted]	[redacted]	[redacted]

Table C-1 shows the total OOP costs, the total paid amount, the total number of patients utilizing Enbrel, and the gross-to-net sales estimate in 2018 and 2022, with the percent change over that time period. There was a 12.44% decrease in the number of patients utilizing Enbrel, a 23.09% increase in the total paid amount, and a 35.90% increase in total Out-of-Pocket expenses. During this timeframe there was a [redacted] The decrease in the number of patients utilizing Enbrel could be from a number of situations like individuals moving or changing health insurance but it could also indicate that fewer patients are able to access the drug. In the patient and caregiver survey, 71% of Colorado respondents indicated that the cost of Enbrel impacted their adherence. Please see appendices A, E, H, and K for more detail.

Table C-2

Annual Utilization and Expenditures

	2018	2019	2020	2021	2022
Patient Count	3,890	3,653	3,440	3,692	3,406
Total Paid	$129,421,272	$127,959,896	$134,815,241	$161,483,771	$159,305,653
Average Paid Per Person	$33,270	$35,029	$39,190	$43,739	$46,772
Total Patient Paid	$6,720,180	$7,399,691	$7,700,602	$10,524,066	$9,860,820
Average OOP	$1,688	$1,866	$2,189	$2,526	$2,295
WAC Per Unit	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table C-2 shows the year-over-year increases in the number of patients using Enbrel, the total amount paid for Enbrel, the average paid per person, the total amount that patients paid, and the average amount that each patient paid.

Figure C-1

Monthly Total Paid and Average Total Paid

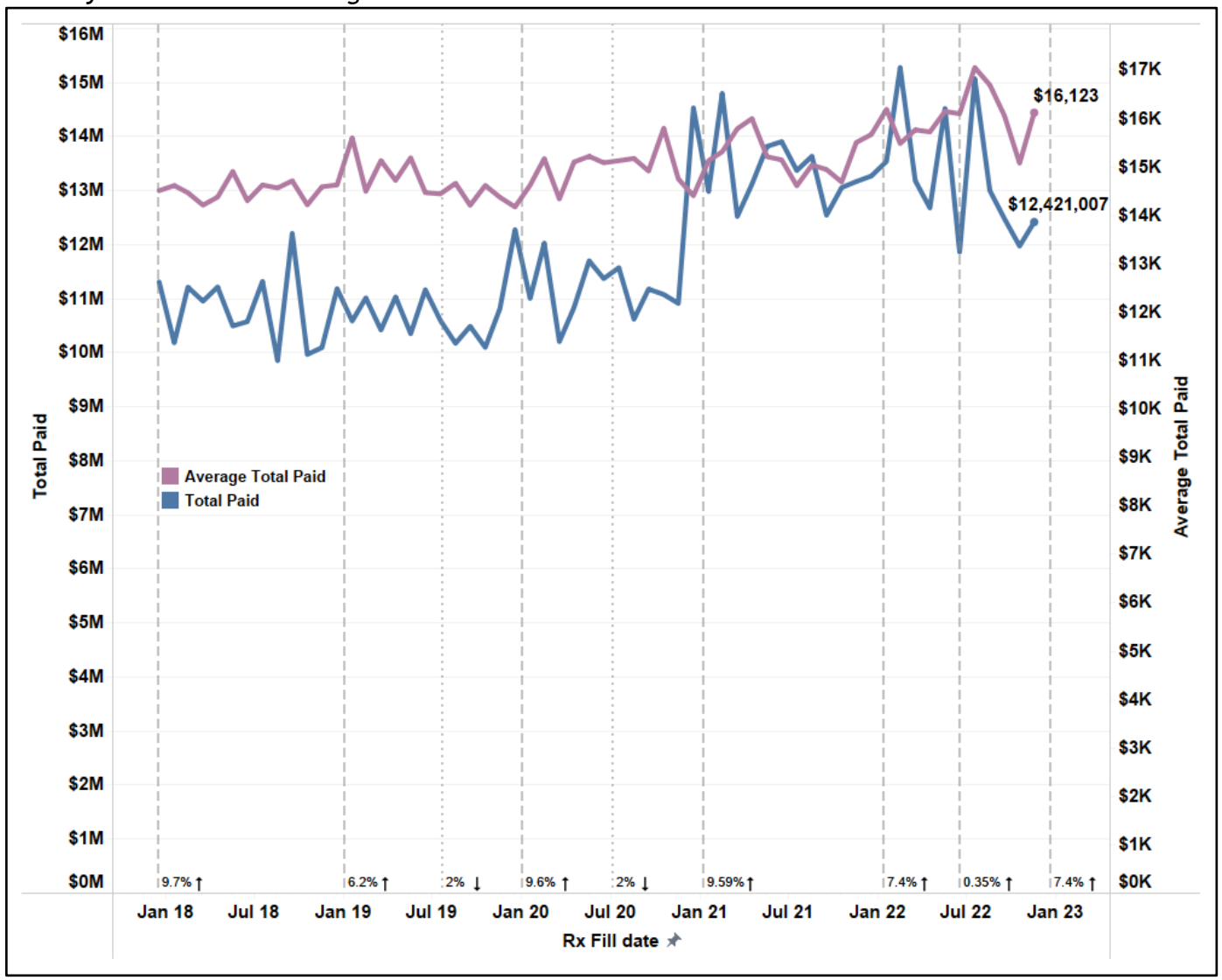


Figure C-1 shows the monthly total paid with the blue line (left axis) and the monthly average paid per person with the purple line (right axis) with vertical lines representing changes in WAC with the magnitude of the change written to the right of the line with an arrow up or down indicating an increase or decrease in the WAC. There is no visible correlation between the WAC change and the corresponding change in the APCD paid amounts. During this time frame, the number of patients using Enbrel decreased from 3,890 in 2018 to 3,406 in 2022.

Table C-3

APCD Utilization and Cost, WAC, and Gross-to-Net Sales Estimates

Month, Year of Rx Fill Date	Patient Count	WAC per unit	Gross-to-net-sales estimate	Total Paid	Average Paid	Average OOP Cost	Average Deductible Amount	Average Coinsurance Amount	Average Copay Amount	Average days supply
Jan-18	1,788	[redacted]	[redacted]	$11,311,524	$6,326	$1,579	$553	$589	$282	31
Feb-18	1,672	[redacted]		$10,185,625	$6,092	$1,240	$272	$651	$219	31
Mar-18	1,770	[redacted]		$11,215,634	$6,337	$808	$92	$534	$160	31
Apr-18	1,761	[redacted]	[redacted]	$10,956,773	$6,222	$483	$47	$259	$160	30
May-18	1,762	[redacted]		$11,218,793	$6,367	$563	$48	$373	$135	31
Jun-18	1,702	[redacted]		$10,498,285	$6,168	$456	$44	$277	$133	31
Jul-18	1,732	[redacted]	[redacted]	$10,578,024	$6,107	$649	$35	$478	$113	31
Aug-18	1,767	[redacted]		$11,322,686	$6,408	$521	$45	$292	$178	32
Sep-18	1,640	[redacted]		$9,855,871	$6,010	$555	$30	$388	$126	31
Oct-18	1,835	[redacted]	[redacted]	$12,210,087	$6,654	$472	$44	$304	$124	30
Nov-18	1,662	[redacted]		$9,970,968	$5,999	$430	$42	$289	$103	31

Month, Year of Rx Fill Date	Patient Count	WAC per unit	Gross-to-net-sales estimate	Total Paid	Average Paid	Average OOP Cost	Average Deductible Amount	Average Coinsurance Amount	Average Copay Amount	Average days supply
Dec-18	1,629	[redacted]		$10,097,002	$6,198	$383	$32	$230	$119	32
Jan-19	1,693	[redacted]	[redacted]	$11,188,372	$6,609	$1,562	$583	$570	$309	32
Feb-19	1,618	[redacted]		$10,589,531	$6,545	$1,162	$226	$528	$279	32
Mar-19	1,674	[redacted]		$11,017,082	$6,581	$719	$100	$361	$223	33
Apr-19	1,638	[redacted]	[redacted]	$10,423,010	$6,363	$807	$48	$526	$203	30
May-19	1,708	[redacted]		$11,035,221	$6,461	$616	$65	$361	$190	32
Jun-19	1,641	[redacted]		$10,354,192	$6,310	$669	$45	$465	$149	32
Jul-19	1,717	[redacted]	[redacted]	$11,166,931	$6,504	$570	$59	$363	$147	31
Aug-19	1,676	[redacted]		$10,598,839	$6,324	$559	$47	$373	$134	31
Sep-19	1,622	[redacted]		$10,176,518	$6,274	$502	$14	$368	$115	32
Oct-19	1,612	[redacted]	[redacted]	$10,491,164	$6,508	$571	$41	$432	$96	30
Nov-19	1,580	[redacted]		$10,101,495	$6,393	$432	$63	$289	$84	31

Month, Year of Rx Fill Date	Patient Count	WAC per unit	Gross-to-net-sales estimate	Total Paid	Average Paid	Average OOP Cost	Average Deductible Amount	Average Coinsurance Amount	Average Copay Amount	Average days supply
Dec-19	1,675	[redacted]		$10,817,543	$6,458	$551	$48	$409	$91	31
Jan-20	1,656	[redacted]	[redacted]	$12,278,737	$7,415	$1,296	$526	$394	$295	31
Feb-20	1,600	[redacted]		$11,007,438	$6,880	$1,007	$218	$470	$235	32
Mar-20	1,672	[redacted]		$12,031,233	$7,196	$798	$130	$436	$202	32
Apr-20	1,556	[redacted]	[redacted]	$10,208,684	$6,561	$641	$92	$348	$183	30
May-20	1,617	[redacted]		$10,838,427	$6,703	$663	$99	$397	$164	33
Jun-20	1,657	[redacted]		$11,703,383	$7,063	$537	$32	$329	$153	32
Jul-20	1,684	[redacted]	[redacted]	$11,373,742	$6,754	$613	$72	$387	$156	32
Aug-20	1,679	[redacted]		$11,575,497	$6,894	$527	$42	$351	$134	32
Sep-20	1,621	[redacted]		$10,622,000	$6,553	$632	$41	$447	$143	31
Oct-20	1,698	[redacted]	[redacted]	$11,179,835	$6,584	$472	$23	$315	$128	32
Nov-20	1,638	[redacted]		$11,080,689	$6,765	$617	$31	$457	$121	33

Month, Year of Rx Fill Date	Patient Count	WAC per unit	Gross-to-net-sales estimate	Total Paid	Average Paid	Average OOP Cost	Average Deductible Amount	Average Coinsurance Amount	Average Copay Amount	Average days supply
Dec-20	1,654	[redacted]		$10,915,575	$6,600	$464	$35	$313	$118	32
Jan-21	1,753	[redacted]	[redacted]	$14,532,693	$8,290	$1,262	$522	$471	$242	32
Feb-21	1,773	[redacted]		$12,987,023	$7,325	$928	$278	$428	$195	32
Mar-21	1,913	[redacted]		$14,800,942	$7,737	$931	$253	$481	$166	32
Apr-21	1,835	[redacted]	[redacted]	$12,525,328	$6,826	$729	$202	$385	$144	32
May-21	1,795	[redacted]		$13,120,766	$7,310	$666	$101	$429	$135	33
Jun-21	1,871	[redacted]		$13,821,073	$7,387	$569	$87	$356	$122	31
Jul-21	1,859	[redacted]	[redacted]	$13,908,320	$7,482	$643	$126	$389	$129	33
Aug-21	1,877	[redacted]		$13,374,249	$7,125	$581	$83	$397	$102	32
Sep-21	1,840	[redacted]		$13,638,254	$7,412	$496	$62	$326	$105	31
Oct-21	1,764	[redacted]	[redacted]	$12,546,370	$7,112	$456	$45	$296	$109	31
Nov-21	1,793	[redacted]		$13,058,533	$7,283	$469	$82	$292	$100	31

Month, Year of Rx Fill Date	Patient Count	WAC per unit	Gross-to-net-sales estimate	Total Paid	Average Paid	Average OOP Cost	Average Deductible Amount	Average Coinsurance Amount	Average Copay Amount	Average days supply
Dec-21	1,759	[redacted]		$13,170,220	$7,487	$630	$226	$335	$91	32
Jan-22	1,621	[redacted]	[redacted]	$13,272,308	$8,188	$1,390	$560	$540	$270	33
Feb-22	1,674	[redacted]		$13,542,932	$8,090	$1,068	$337	$474	$211	32
Mar-22	1,822	[redacted]		$15,279,699	$8,386	$741	$98	$462	$147	33
Apr-22	1,779	[redacted]	[redacted]	$13,185,263	$7,412	$726	$165	$424	$132	33
May-22	1,729	[redacted]		$12,682,429	$7,335	$578	$65	$376	$135	32
Jun-22	1,756	[redacted]		$14,521,016	$8,269	$662	$80	$452	$122	32
Jul-22	1,655	[redacted]	[redacted]	$11,867,545	$7,171	$617	$68	$412	$125	32
Aug-22	1,765	[redacted]		$15,073,167	$8,540	$619	$63	$451	$104	32
Sep-22	1,727	[redacted]		$13,002,216	$7,529	$516	$33	$371	$108	33
Oct-22	1,681	[redacted]	[redacted]	$12,481,838	$7,425	$615	$114	$405	$105	32
Nov-22	1,652	[redacted]		$11,976,233	$7,250	$412	$33	$296	$86	31

Month, Year of Rx Fill Date	Patient Count	WAC per unit	Gross-to-net-sales estimate	Total Paid	Average Paid	Average OOP Cost	Average Deductible Amount	Average Coinsurance Amount	Average Copay Amount	Average days supply
Dec-22	1,631	[redacted]		$12,421,007	$7,616	$461	$55	$326	$76	33

Table C-3 above shows the monthly amounts of APCD, WAC, and gross-to-net sales estimates for Enbrel. Columns in this table are defined below and all columns are from APCD data unless otherwise noted:

- Month, Year of Rx Fill Date: The month and year the prescription was filled. All data in this table is aggregated to the month and year.
- Patient count: The total number of patients who filled a prescription that month.[1]
- WAC per unit[2]: The per unit WAC amount that was effective that month.
- Gross-to-net sales estimate[3]: The gross-to-net sales estimate of that quarter. Estimates are on a rolling four quarter average, so each estimate covers the previous year. Estimates appear in the first month of each quarter.
- Total Paid: The total amount paid for Enbrel that month, inclusive of payer(s) and patient paid amounts.
- Average Paid: The average paid per person for that month.
- Out-of-pocket Cost: The average out-of-pocket cost (total of copayment, coinsurance, and deductible) per person that month.
- Average Deductible Amount: The average amount that individuals with commercial insurance and Medicare Advantage coverage paid towards their deductible that month. Note the generally higher amounts at the beginning of each year indicating patients contributing to their deductible with lower amounts later in the benefit plan year when the deductible has been met.
- Average Coinsurance Amount: The average amount that individuals with commercial insurance and Medicare Advantage coverage paid towards coinsurance that month. Potential to note that this is increasing.
- Average Copayment Amount: The average amount that individuals with commercial insurance and Medicare Advantage coverage paid in copayments that month.
- Average Days Supply: The average days supply that was filled with prescriptions that month.
- Per Unit Cost: The average per unit cost of the total amount paid per unit distributed. As Enbrel was approved in October 2019, earlier estimates show a ramp of utilization as patients began taking the drug and early estimates may not show an accurate representation of all eligible patients taking the drug.

[1] Patient count in Table C-3 may not add up to the total annual patient count in Table C-2 above it as some patients moved between insurance types throughout a given year

[2] First Databank, AnalySource

[3] SSR Health Estimates

Patents and Exclusivity

There are several ways for prescription drugs to gain exclusivity, which is a period of time when a brand-name drug is protected from generic competition. As of January 29, 2024, there were 75 approved patents for Enbrel with the latest expiration date of 12/31/2039.[4] Thirty-five of these patents expired between 2009 and 2021, while 40 will expire between 2024 and 2039. The Enbrel-related patents that prevent the introduction of biosimilar products are set to expire in 2029.[5] Evaluating patents and exclusivity can be helpful in understanding potential access concerns, because there is evidence that such intellectual property rights can be associated with increased drug prices, delayed availability, and increased costs to consumers and governments.[6]

[4] I-MAK's 'The Drug Patent Book' https://drugpatentbook.i-mak.org/.

[5] https://www.centerforbiosimilars.com/view/nj-court-decision-means-3-decades-of-product-exclusivity-for-enbrel

[6] https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-022-00826-4

Figure C-2

Enbrel Patents and Expiration dates

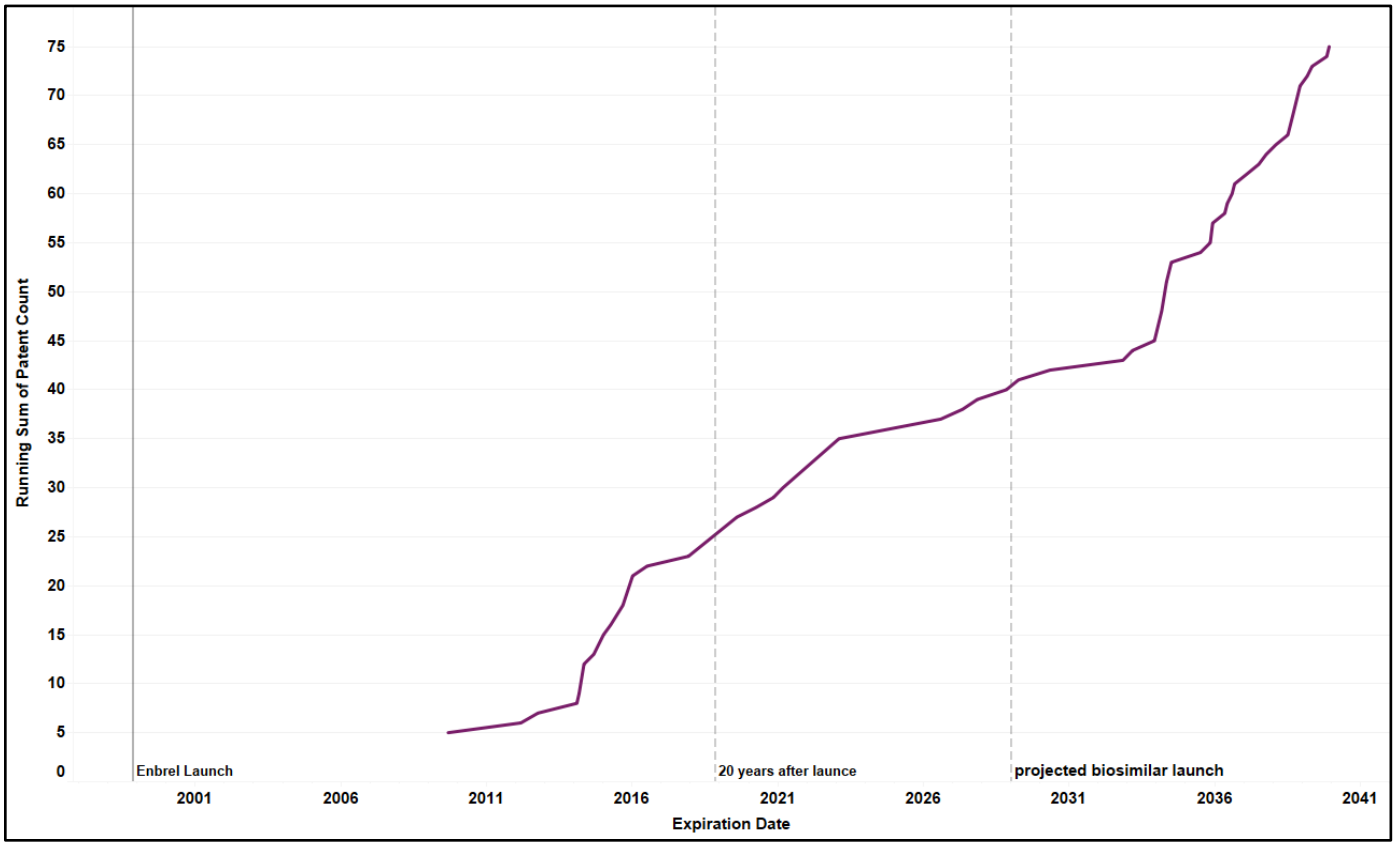


Figure C-2 shows the total number of approved patents for Enbrel based on their expiration date with reference lines highlighting 20 years after launch, the typical patent protection window, and the projected launch of approved biosimilars.

Information about patents for Enbrel contain important public information related to exclusivity of the drug due to litigation around these patents.

A patent for a recombinant protein encoding a receptor for tumor necrosis factor (TNF) was initially issued in 1997 with an expiration date in 2014 under US Patent #5610279.[7] This so-called '279 patent is one of several "core" patents that Amgen has used to ensure its U.S. market exclusivity of Enbrel.[8]

In 2011 and 2012, Amgen applied for two additional patents. The granting of these patents (US Patents #8063182 and 8163522) was somewhat unusual in that the '182 is a "composition of matter" patents for a larger version of the protein claimed in the '279 patent, and the '522 patent describes the method to isolate that larger protein version. These "core" patents--which are considered to be quite strong--are usually granted very early in drug development and make the creation of a non-infringing biosimilar drug nearly impossible. The '182 and '522 patents are due to expire in 2028 and 2029, respectively.[9]

Amgen has protected Enbrel through litigation of its patents in U.S. courts. In 2016, Novartis subsidiary Sandoz gained FDA approval for the first etanercept biosimilar, Erelzi. Amgen sued Sandoz later that year, claiming that Erelzi infringed on the '182 and '522 patents. In defense, Sandoz claimed that the 2 patents were invalid. The US District Court of New Jersey decided against Sandoz and found that both patents were valid. In 2019, drug manufacturer Samsung Bioepis gained approval for a second etanercept biosimilar, Eticovo. Amgen again sued claiming that Eticovo would infringe the same two patents and won in 2021. As a result, despite there being two approved biosimilars for Enbrel, both biosimilars are not allowed to enter the market until at least 2029.[10]

[7] https://www.biopharmadive.com/news/amgen-enbrel-patent-thicket-monopoly-biosimilar/609042/

[8] Estimates of the number of patents protecting Enbrel range from around 40 to 68, with at least 57 patent applications included in one analysis. ~40 patents, pg. 126 https://scholarship.kentlaw.iit.edu/cgi/viewcontent.cgi?article=1263&context=ckjip, ~68 patents, https://www.biopharmadive.com/news/amgen-enbrel-patent-thicket-monopoly-biosimilar/609042/, at least 57 patent applications https://www.i-mak.org/wp-content/uploads/2020/10/i-mak.enbrel.report-REVISED-2020-10-06.pdf).

[9] https://www.biopharmadive.com/news/amgen-enbrel-patent-thicket-monopoly-biosimilar/609042/

[10] https://www.biopharmadive.com/news/amgen-enbrel-patent-thicket-monopoly-biosimilar/609042/

Appendix D

Enbrel: Relative Financial Effects of the Prescription Drug on Health, Medical, or Social Service Costs

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider the relative financial effects on health, medical, or social services costs, as the effects can be quantified and compared to baseline effects of existing therapeutic alternatives to the prescription drug. (C.R.S. § 10-16-1406(4)(d)).

Rule: To the extent such information can be quantified, the Board may consider the relative financial effects of the prescription drug on broader health, medical, and/or social services costs, compared with therapeutic alternatives and/or no treatment. This may include considering results from external analyses and modeling studies.

- The Board may identify if the literature uses a quality-adjusted life-year analysis or a similar measure that discounts the value of a life because of an individual's disability or age. The Board may use information that uses a quality-adjusted life year analysis to evaluate relative financial effects, but will not use quality adjusted life year analysis to determine an upper payment limit or other appropriate costs of a prescription drug. If quality-adjusted life year analysis is used during affordability review, the Board will acknowledge any health equity impacts to priority populations. (3 CCR 702-9, Part 3.1.E.2.d).

Policy: Information providing an overview of the research regarding the relative financial effects of the prescription drug on health, medical, or social services costs. This will be done by reviewing research that is:

- Publicly available;
- To the extent the Board has funding, data accessible from the Drug Effectiveness Review Project; or
- Is voluntarily provided by manufacturers. (PDAB Policy 04, p. 7).

Underlying Methodology: Board staff compiled data for Enbrel for the Board's consideration in the following manner:

1. Staff reviewed the current FDA labeling for each selected drug and identified each FDA-approved indication.
2. Identified relevant medical professional guidelines and manufacturer's purported benefits by indication.
3. Found evidence supporting the purported benefits by indication and compared the clinical effectiveness of identified therapeutic alternatives to each drug under review.[1]
4. Assessed the financial effects of a drug compared to identified therapeutic alternatives. This was completed for this appendix by examining studies with cost effectiveness analyses. Staff will note when studies use a quality-adjusted-life-year (QALY) or similar measure. The Affordability Review Summary Report may incorporate additional information of a prescription drug's financial effects that

[1] Staff will note when studies evaluate the clinical effectiveness of a therapeutic alternative that is not being considered by the Board in Appendix B. Further, staff will note when studies compare the clinical effectiveness of each drug under review to a placebo (i.e., when there is not a comparison to a therapeutic alternative).

is not reported in this appendix, but was gathered from patients and caregivers, individuals with scientific and medical training, or provided in voluntarily submitted information.

Considerations and Data Limitations: Staff provided citations for any literature utilized to compile evidence for this component, but some studies may need a subscription for the public to access. Additionally, studies frequently outline limitations. Staff will note these limitations and also note any differences in the specific strengths and dosage forms utilized in studies.

Enbrel: Relative Financial Effects Evidence

Background

One component of affordability reviews is an assessment of the relative financial effects on health, medical, or social services costs, as the effects can be quantified and compared to baseline effects of existing therapeutic alternatives to the prescription drug. This sort of assessment is commonly referred to as a health technology assessment (HTA), which may be used by organizations or governments to systematically evaluate the effects and impacts of health care technology, or, relevant to this work, prescription drugs.[2] HTAs may address the direct, intended consequences of a prescription drug as well as a drug's indirect, unintended consequences. While some other countries (e.g., the United Kingdom, Canada) use governmental HTAs to guide prescription drug coverage and reimbursement policies, the United States does not have a government-run HTA body.

While the FDA is the primary federal regulator of prescription drugs in the United States, the agency does not take a significant role in regulating HTA activities. The focus of FDA approvals for new drugs and biological products is the result of Phase III human trials, which are aimed at determining the dose at which a drug is effective. In general, there is not typically a requirement for a manufacturer to demonstrate that a new drug is superior to existing treatments in order to be approved.

FDA Approved Indication

Enrbel has six FDA-approved indications:

- Rheumatoid Arthritis (RA)
- Ankylosing Spondylitis
- Plaque Psoriasis: Adult and Pediatric
- Psoriatic Arthritis
- Juvenile Psoriatic Arthritis
- Polyarticular Juvenile Idiopathic Arthritis (JIA)

Information below is provided by indication when appropriate.

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[2] https://www.nlm.nih.gov/nichsr/hta101/ta10103.html

Supporting Evidence, Clinical Effectiveness, and Cost Effectiveness

Supporting evidence, clinical effectiveness information, and cost effectiveness information was compiled from the sources below. These resources allowed for an efficient review of HTA reports, meta-analyses, and secondary resources developed by established domestic and international organizations. This approach allows for consistent review and leveraging established methodologic processes to assess quality and conclusion of evidence.

- **Cochrane Library**[3]: an organization that prepares systematic reviews and meta-analyses for a range of clinical areas, drug classes, and diseases/conditions. Literature in this appendix was pulled by searching Cochrane Reviews for "etanercept" and indication and reviewing "Cochrane Reviews" (i.e., not compiling information from Cochrane Protocols, Trials, Editorials, Special Collections, or Clinical Answers). "Etanercept" and indication.
- **Institute for Clinical and Economic Review** (ICER)[4]: a U.S.-based independent non-profit organization that seeks to place a value on medical care by providing comprehensive clinical and cost-effectiveness analyses of treatments, tests, and procedures. Literature in this appendix was pulled by searching ICER Research Assessments for "etanercept" and indication. ICER cost-effectiveness recommendations are non-binding for any U.S. federal, state, and local governments.
- **National Institute for Health and Care Excellence** (NICE)[5]: a United Kingdom-based governmental institute that provides national guidance and guidelines based on evaluations of efficacy, safety, and cost-effectiveness. Literature in this appendix was pulled by searching published NICE guidance for "etanercept" and indication.
- **Canadian Agency for Drugs and Technologies in Health** (CADTH)[6]: a Canada-based not-for-profit organization responsible for providing health care decision makers with objective evidence to help make informed decisions about the optimal use of health technologies, including providing advice, recommendations, and tools. Literature in this appendix was pulled by searching Health Technology Assessment and Reimbursement Reviews for "etanercept" and indication. CADTH's recommendations are non-binding for federal, provincial, and territorial public drug plans and provincial cancer agencies (with the exception of Quebec).[7]
- **Institute for Quality and Efficiency in Health Care** (IQWiG)[8]: a Germany-based governmental agency responsible for assessing the quality and efficiency of medical treatments, including drugs, non-drug interventions, diagnostic and screening methods, and treatment and disease management. Literature in this appendix was pulled by searching Drug Assessment Projects and Reports for "etanercept" and indication.
- **International Network of Agencies for Health Technology Assessment** (INAHTA)[9]: maintains an **international HTA database** that compiles assessments across jurisdictions. Studies and benefit assessments not already identified from ICER, NICE, CADTH, and IQWiG may be pulled for the Board's review. Only studies with robust English summaries will be summarized in this appendix.

[3] https://www.cochranelibrary.com/
[4] https://icer.org/
[5] https://www.nice.org.uk/
[6] https://www.cadth.ca/
[7] https://www.cadth.ca/cadth-reimbursement-reviews
[8] https://www.iqwig.de/en/
[9] https://database.inahta.org/

Literature that met the above criteria are displayed below and quoted directly, with page numbers for reference, to summarize clinical effectiveness conclusions and cost-effectiveness conclusions. Additional information beyond these conclusions can be found in the literature itself, which is cited.

Priority Populations and QALYs: The Board considered health equity impacts to priority populations of Enbrel. Please see Appendix H, Appendix J, and Appendix L for more information. Acknowledging that QALYs may discount the value of life because of an individual's disability or age, the Board has noted when studies utilize QALYs below.

Input from Patients and Caregivers, Input from Individuals with Scientific and Medical Training, and Voluntarily Submitted Information

The FDA released an updated Benefit-Risk Assessment for New Drug and Biological Products: Guidance for Industry on October 20, 2023.[10] This guidance states (pp.12-13):

"FDA recognizes the importance of enabling meaningful patient input to inform drug development and regulatory decision-making, including in the context of FDA's benefit-risk assessment. Patients are experts in the experience of their disease or condition, and they are the ultimate stakeholders in the outcomes of medical treatment. Different types of patient experience data can inform nearly every aspect of FDA's benefit-risk assessment…"

- This appendix provides a robust overview of the scientific studies of clinical and cost effectiveness of Enbrel, with many of the HTA organizations including patient perspectives in some manner. There is additional information contained in Appendix H: Input from Patients and Caregivers, Appendix I: Input from Individuals with Scientific and Medical Training, and Appendix J: Voluntarily Submitted information which may contain additional patient perspectives of the relative financial effects of Enbrel on health, medical, and social costs not captured in this appendix. The Board may want to weigh information from all four appendices when evaluating the relative financial effects of Enbrel.

Rheumatoid Arthritis

Relevant Medical Professional Guidelines and Manufacturer-Reported Benefits

Relevant Medical Professional Guidelines

2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis.[11]

[10] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/benefit-risk-assessment-new-drug-and-biological-products

[11] https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/acr.24596

Manufacturer-Reported Benefits

Information contained in Enbrel's FDA label, Section 14 Clinical Studies, reports on the following four studies and the resulting primary and key secondary efficacy analyses.[12]

Figure D-1

Study I, II, and III Summary (Table 6)

Table 6. ACR Responses in Placebo- and Active-Controlled Trials (Percent of Patients)

	Placebo-Controlled				Active-Controlled	
	Study I		Study II		Study III	
	Placebo	Enbrel*	MTX/Placebo	MTX/Enbrel*	MTX	Enbrel*
Response	**N = 80**	**N = 78**	**N = 30**	**N = 59**	**N = 217**	**N = 207**
ACR 20						
Month 3	23%	62%†	33%	66%†	56%	62%
Month 6	11%	59%†	27%	71%†	58%	65%
Month 12	NA	NA	NA	NA	65%	72%
ACR 50						
Month 3	8%	41%†	0%	42%†	24%	29%
Month 6	5%	40%†	3%	39%†	32%	40%
Month 12	NA	NA	NA	NA	43%	49%
ACR 70						
Month 3	4%	15%†	0%	15%†	7%	13%‡
Month 6	1%	15%†	0%	15%†	14%	21%‡
Month 12	NA	NA	NA	NA	22%	25%

* 25 mg Enbrel SC twice weekly.

† $p < 0.01$, Enbrel versus placebo.

‡ $p < 0.05$, Enbrel versus MTX.

Figure D-1 above outlines the percentage of RA patients who reached a 20% (ACR 20), 50% (ACR 50), and 70% (ACR 70) level of improvement in their American College of Rheumatology (ACR) response score after three, six, and 12 months in the clinical trials. The three studies compare patients using Enbrel to patients using a placebo (Study I), patients using Enbrel and methotrexate in combination to patients using methotrexate and a placebo (Study II), and patients using Enbrel to patients using methotrexate (Study III). Footnotes b and c indicate that differences in ACR between the Enbrel and control groups are statistically significant. Therefore, all ACR groups for participants using Enbrel in months three and six of Study I and months 3-12 of Study II are significantly higher than the control groups. In Study III (comparing Enbrel to methotrexate), differences in ACR scores are only statistically significant for participants at months 3 and 6 of the study, suggesting less certainty of differences in comparative value between Enbrel and methotrexate.

[12] https://www.accessdata.fda.gov/spl/data/29187b7c-d166-45e4-bc8c-4cbf71a67702/29187b7c-d166-45e4-bc8c-4cbf71a67702.xml#section-13

Figure D-2
Study IV Summary (Table 7)

Table 7. Study IV Clinical Efficacy Results: Comparison of MTX versus Enbrel versus Enbrel in Combination with MTX in Patients with Rheumatoid Arthritis of 6 Months to 20 Years Duration (Percent of Patients)

Endpoint	MTX (N = 228)	Enbrel (N = 223)	Enbrel/MTX (N = 231)
ACR N*, †			
Month 12	40%	47%	63%‡
ACR 20			
Month 12	59%	66%	75%‡
ACR 50			
Month 12	36%	43%	63%‡
ACR 70			
Month 12	17%	22%	40%‡
Major Clinical Response§	6%	10%	24%‡

* Values are medians.

† ACR N is the percent improvement based on the same core variables used in defining ACR 20, ACR 50, and ACR 70.

‡ $p < 0.05$ for comparisons of Enbrel/MTX versus Enbrel alone or MTX alone.

§ Major clinical response is achieving an ACR 70 response for a continuous 6-month period.

Figure D-2 depicts the major results of Study IV, which included patients with RA for 6 months-20 years who had failed use of a different disease modifying RA drug (a DMARD other than methotrexate) before the start of the trial. 43% of participants had used methotrexate before the trial without stopping use due to insufficiency. The ACR 20, 50, and 70 rows show the percentage of patients who reached these marks of improvement within 12 months of the study. The use of methotrexate in combination with Enbrel was statistically significant for all categories but this significance was for “Enbrel/MTX versus Enbrel alone or MTX alone.” The “Major Clinical Response” category (defined as patients who reached ACR70 for 6 months, continuously) also outlines a statistically significant difference between Enbrel in combination with methotrexate and one of the two comparator groups. Finally, “ACR N" outlines the median ACR score for each study group, demonstrating a statistically significant difference for the Enbrel/methotrexate group.

Voluntarily Submitted Manufacturer Information

- “The introduction of Enbrel® effectively redefined the clinical course of moderate to severe rheumatoid arthritis (RA). Many patients who previously would have endured progressive and painful deformities and immobility now live for years or decades with lower pain, less progression, and greater function.”
- “Enbrel® monotherapy in moderate to severe RA has shown greater efficacy than methotrexate monotherapy, the previous standard treatment, in achieving American College of Rheumatology (ACR) criteria, low disease activity (LDA) response, and reduced radiographic progression.”
- “In RA, Enbrel® patients experience fewer adverse reactions, including infections, compared to those on methotrexate (MTX).”

- “Finally, Enbrel® improves PROs and productivity in adults with moderate to severe RA, PsA, and PsO, boosting patient wellbeing and reducing costs for employers.”

Confidential Information

[redacted]

See Appendix J for more information, including Amgen Inc.'s citations for reported benefits.

Clinical Effectiveness and Cost Effectiveness

Table D-1

Rheumatoid Arthritis Clinical and Cost Effectiveness Conclusion Summaries

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
Cochrane Library	*Etanercept for the treatment of rheumatoid arthritis, published May 2013:*[13] Etanercept 25 mg administered subcutaneously twice weekly together with MTX was more efficacious than either etanercept or MTX monotherapy for ACR50 and it slowed joint radiographic progression after up to three years of treatment for all participants (responders or not). There was no evidence of a difference in the rates of infections between groups. *Biologics for rheumatoid arthritis: an overview of Cochrane reviews, published October 2009:*[14] Based upon indirect comparisons, anakinra seemed less efficacious than etanercept and adalimumab. Etanercept seemed to cause fewer withdrawals due to adverse events than adalimumab, anakinra and infliximab. Significant heterogeneity in characteristics of trial populations imply that these findings must be interpreted with caution. These findings can inform physicians and patients regarding their choice of biologic for treatment of RA.	Not applicable.
ICER - Rheumatoid Arthritis[15]	*Targeted Immune Modulators for Rheumatoid Arthritis: Effectiveness & Value - Evidence Report, published April 2017 (pp. 47-48):*[16] One head-to-head trial of etanercept and adalimumab (primarily in combination with concomitant conventional DMARDs) reported similar changes in disease activity and quality of life; observational data suggest no difference in remission or ACR response between etanercept and adalimumab. We identified one head-to-head trial that compared etanercept with	*Targeted Immune Modulators for Rheumatoid Arthritis: Effectiveness & Value - Evidence Report, published April 2017 (pp. 79-81):*[17] While TIMs have been highly effective in improving outcomes in comparison to conventional DMARDs, there is uncertainty around the comparative effectiveness of the different types of TIMs and the most effective sequence of TIM therapy. This review focuses on the comparative clinical effectiveness and value of TIMs currently used in RA treatment, as well as TIMs currently under review by the Food and

[13] https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD004525.pub2/full?highlightAbstract=etanercept

[14] https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD007848.pub2/full?highlightAbstract=arthriti%7Carthritis%7Cetanercept%7Crheumatoid

[15] https://icer.org/assessment/rheumatoid-arthritis-2017/#overview - QALY used in this literature.

[16] https://icerorg.wpengine.com/wp-content/uploads/2020/10/NE_CEPAC_RA_Evidence_Report_FINAL_040717.pdf - QALY used in this literature.

[17] https://icerorg.wpengine.com/wp-content/uploads/2020/10/NE_CEPAC_RA_Evidence_Report_FINAL_040717.pdf - QALY used in this literature.

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	adalimumab added to existing conventional DMARD therapy in TIM-naïve patients. In addition, we identified three observational studies that compared the three TNFα inhibitors adalimumab, infliximab and etanercept. Disease Activity and Remission: In the one trial that directly compared etanercept with adalimumab primarily in combination with existing conventional DMARDs in TIM-naive patients, the rates of clinical remission and low disease activity were not reported. The mean change from baseline in disease activity (based on DAS28CRP) showed a similar level of change between adalimumab and etanercept at week 24. In addition to the RCT, we reviewed three observational studies for disease activity. In the first observational study based on data from the CORRONA registry in the US, no statistically significant difference was found in rates of clinical remission among the three TNFα inhibitors evaluated (infliximab, adalimumab and etanercept). The second study, based on the Hellenic Registry of Biologic Therapies in Greece, found no statistically-significant difference in remission between the three agents using the DAS28-ESR definition, but found adalimumab to be superior to both infliximab and etanercept based on CDAI and SDAI defined remission (15% vs. 8% vs. 7%, p=0.022 using CDAI; and 17% vs. 8% vs. 8% using SDAI, p=0.009). The third study, based on the DANBIO registry in Denmark, did not find a significant difference between etanercept and adalimumab. ACR20/50/70: We identified head-to-head evidence of ACR response for etanercept in two observational studies. In one study from the CORRONA registry, significant differences were not demonstrated between adalimumab, etanercept, or infliximab for any level of response. Another observational study of the same TIMs used data from the Danish DANBIO registry and found no differences between adalimumab and etanercept in ACR70 response but found etanercept to be superior to infliximab (adjusted OR 1.78; 95% CI 1.28-2.50). Radiographic Progression: We did not identify any studies of etanercept in comparison to another TIM that reported on radiographic progression. HAQ-DI: We did not identify any head-to-head studies of etanercept that reported on HAQ-DI. Other Patient-Reported Outcomes: Comparable improvements in quality of life were observed among patients in the adalimumab and etanercept arms of the RED-SEA trial using the EuroQol-5 domain health state profile (EQ-5D).	Drug Administration (FDA). All 11 TIMs evaluated in combination with conventional DMARDs significantly improved outcomes in disease activity, remission, and ACR response compared to conventional DMARDs alone. Radiographic progression was also significantly reduced with most TIMs in comparison to conventional DMARDs, but differences in the progression measures used made comparisons across studies difficult. Improvements in function and disability as measured on the HAQ-DI were statistically superior for all TIMs compared to conventional DMARDs. Findings were much more limited for TIM monotherapy. We have high certainty that all FDA-approved TIMs provide a substantial net health benefit relative to conventional DMARD therapy alone. Although the long-term effectiveness and safety of the two investigational TIMs (baricitinib and sarilumab) is less clear, we have moderate certainty of an incremental or better net health benefit with these two agents compared to conventional DMARDs. Head-to-head comparisons of TIMs: • Among monotherapy regimens, there is moderate certainty of an incremental or better net health benefit for sarilumab and intravenous tocilizumab compared to adalimumab. • Combination (i.e., with conventional DMARDs) regimens involving tofacitinib, subcutaneous abatacept, certolizumab pegol, and etanercept have been compared to adalimumab + methotrexate in single trials. Comparisons yielded comparable net health benefits. In a single trial, combination therapy with baricitinib provided statistically-significant but modest benefits over adalimumab, yielding a “comparable or better” rating. For TIMs that have never been compared head to head in a randomized setting, we judge there to be insufficient evidence to differentiate among therapies, including intra-class comparisons of the remaining TNFα inhibitors, IL-6 inhibitors, and JAK inhibitors.

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
NICE	*Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed, published January 2016:*[18] Three of the trials reported that ACR response rates were similar for both of the biological DMARDs included in the trial: adalimumab and subcutaneous abatacept (AMPLE), etanercept and infliximab (De Filippis) and intravenous abatacept and infliximab (ATTEST). However, in the ADACTA study, ACR response rates were statistically significantly higher with tocilizumab monotherapy than with adalimumab monotherapy. Three trials provided EULAR response data for the population who had had methotrexate before. Two of the trials reported that EULAR response rates were similar for both of the biological DMARDs included in the trial: adalimumab and etanercept (RED-SEA) and abatacept and infliximab (ATTEST). The results showed that all interventions except for adalimumab monotherapy were associated with beneficial treatment effects compared with conventional DMARDs. The credible intervals for all the interventions, both biological and non-biological, tended to overlap with each other. There was a trend for higher estimated probability of achieving ACR20, 50 or 70 response for the biological DMARD combination therapy than for biological monotherapy. *Adalimumab, etanercept, infliximab, rituximab and abatacept for the treatment of rheumatoid arthritis after the failure of a TNF inhibitor, published August 2010:*[19] For etanercept, the Assessment Group identified seven uncontrolled studies with durations of follow-up ranging from 3 months to over 9 months. Sample sizes ranged from 25 to 201. The results were not pooled because of substantial clinical and statistical heterogeneity between studies. Four studies reported ACR 20, 50 and 70 response rates ranging from 38% to 72%,	*Adalimumab, etanercept, infliximab and abatacept for treating moderate rheumatoid arthritis after conventional DMARDs have failed, published July 2021:*[20] Therefore, the committee recommended adalimumab and infliximab as first-line biological treatments for moderate active rheumatoid arthritis that has had an inadequate response to intensive therapy with 2 or more conventional DMARDs. Although the assessment group's ICER for etanercept was higher than those for adalimumab and infliximab, it was below £30,000 per QALY gained. In response to consultation, it was highlighted that there are some people for whom etanercept would be a particularly useful treatment option. For example, etanercept has a much lower risk of reactivating latent tuberculosis, which has a higher prevalence in people with a South Asian family background. In addition, compared with some of the other biologicals, etanercept does not need to be stopped as far in advance by people wishing to conceive. The committee recognised that these groups would likely only represent a small number of people with moderate rheumatoid arthritis. The committee noted that the recommendations state that if more than 1 biological is an appropriate treatment option, treatment should start with the least expensive. So it also recommended etanercept as an option. *Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed, published January 2016:*[21] Most studies were of etanercept, infliximab and adalimumab, with no studies found for certolizumab pegol or golimumab. The studies had a wide range of model methods, time horizons, price years, currencies and discount rates. The Assessment Group stated that a detailed analysis of the parameters used in each study was not feasible, and that drawing strong conclusions on the cost effectiveness of individual

[18] https://www.nice.org.uk/guidance/ta375/resources/adalimumab-etanercept-infliximab-certolizumab-pegol-golimumab-tocilizumab-and-abatacept-for-rheumatoid-arthritis-not-previously-treated-with-dmards-or-after-conventional-dmards-only-have-failed-pdf-82602790920133

[19] https://www.nice.org.uk/guidance/ta195/resources/adalimumab-etanercept-infliximab-rituximab-and-abatacept-for-the-treatment-of-rheumatoid-arthritis-after-the-failure-of-a-tnf-inhibitor-pdf-82598558287813

[20] https://www.nice.org.uk/guidance/ta715/resources/adalimumab-etanercept-infliximab-and-abatacept-for-treating-moderate-rheumatoid-arthritis-after-conventional-dmards-have-failed-pdf-82611135252421 - QALY used in this literature.

[21] https://www.nice.org.uk/guidance/ta375/resources/adalimumab-etanercept-infliximab-certolizumab-pegol-golimumab-tocilizumab-and-abatacept-for-rheumatoid-arthritis-not-previously-treated-with-dmards-or-after-conventional-dmards-only-have-failed-pdf-82602790920133 - QALY used in this literature.

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	18% to 21% and 8% to 20% respectively. Four studies reported mean improvements in DAS28 score ranging from 0.47 to 1.80 when compared with pre-treatment values. Three studies reported mean improvements in HAQ score ranging from zero to 0.45 when compared with pre-treatment values. None of the studies assessed joint damage or quality of life.	therapies was not possible. The results of the Assessment Group's systematic review indicated that, in people who had previously had DMARD therapy, many biological DMARDs had incremental cost-effectiveness ratios (ICERs) close to £30,000 per quality-adjusted life year (QALY) gained in both directions, and that the ICERs were often higher for those people not previously treated with DMARDs. No individual biological DMARD was seen to be consistently more cost effective than any other biological DMARD.
CADTH	*Drugs for the Management of Rheumatoid Arthritis (March/April 2018)*[22] The analysis came to the following conclusions: In general, in the patient population included in the review (i.e., those with an inadequate response to MTX), most treatments appear to be more effective than MTX alone. Compared with double-csDMARD therapy, triple-csDMARD therapy appears to be more effective regarding disease response and equally effective for improved function. Compared with biologics in combination with MTX, triple-csDMARD therapy appears to be comparable regarding disease response. Combining MTX with a biologic, a biosimilar, or a tsDMARD appears to be more effective than biologic or tsDMARD monotherapy. The review could not indicate if any one treatment has greater benefits than the others because not all treatments had data available for each of the outcomes and there were often no important differences in the head-to-head comparison results of these treatments.	Not applicable.
IQWiG	*Benefit assessment of biotechnologically produced drugs for the treatment of rheumatoid arthritis (September 17, 2019)*[23] In the combination therapy with MTX without MTX pretreatment, the following biologics were compared with each other in the present benefit assessment: abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, and tocilizumab. A direct comparative study was not available for any comparison of biologics.	Not applicable.

[22] https://www.cadth.ca/drugs-management-rheumatoid-arthritis

[23] https://www.iqwig.de/en/projects/a16-70.html

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	For the combination therapy with MTX without MTX pretreatment, the evidence base is as follows. there is no hint of greater or lesser benefit of any biologic versus another biologic for clinical remission (which particularly in this subquestion is the primary treatment goal to be achieved); there is a hint of greater benefit of adalimumab and etanercept versus certolizumab pegol and tocilizumab for low disease activity; there is no hint of greater or lesser benefit of any further biologic versus another biologic for low disease activity; there is no hint of greater or lesser benefit or harm of any biologic versus another biologic for further patient-relevant outcomes. For the combination therapy with MTX after MTX failure, the evidence base is as follows: there is a hint of greater benefit of adalimumab, certolizumab pegol and golimumab versus anakinra for the primary treatment goal of clinical remission; there is a hint of greater benefit of abatacept, adalimumab, infliximab, and tocilizumab versus anakinra for low disease activity; there is hint of greater benefit of abatacept and tocilizumab versus anakinra for pain; there is a hint of greater benefit of golimumab versus anakinra for health-related quality of life (physical component summary score of the Short Form 36 - Health Survey); there is a hint of greater harm of certolizumab pegol versus all other biologics for 1 or more of the following 3 outcomes: serious adverse events, infections, serious infections. In addition, there is a hint of greater harm of golimumab and tocilizumab versus infliximab for serious infections; there is a hint of greater harm of anakinra versus abatacept, adalimumab, etanercept and infliximab as well as of tocilizumab versus abatacept for discontinuations due to adverse events For monotherapy after MTX intolerance, the evidence base is as follows: there is no hint of greater or lesser benefit or harm of any biologic versus another biologic for the primary treatment goal of clinical remission or other outcomes. For the combination therapy with MTX after biologic failure, the evidence base is as follows: there is no hint of greater or lesser benefit or harm of any biologic versus another biologic for the primary treatment goal of clinical remission or other outcomes. *Biologic medications as second-line therapy for rheumatoid arthritis, published August 2013:*[24]	

[24] https://www.iqwig.de/download/a10-01_biologics-second-line-therapy-for-rheumatoid-arthritis_executive-summary.pdf

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	Etanercept + MTX - At study level both studies showed a low risk of bias. The risk of bias of the results at outcome level was generally high, except for the results for the outcome “remission” in Study 0881A1-308-EU/AU (TEMPO). One of the reasons that applied in most cases and to both studies was that under placebo + MTX substantially more patients discontinued the studies prematurely due to lack of efficacy. Although statistical replacement procedures were used for the patients who discontinued, relevant bias could still occur. If possible, in these cases sensitivity analyses were conducted for the present benefit assessment to investigate the impact of bias. A statistically significant effect with a low risk of bias was shown for the outcome “remission” in the larger of the two studies. The result of the smaller study with a high risk of bias was not statistically significant, but the effect was in the same direction. There is therefore an indication of a benefit of etanercept + MTX for the outcome “remission”. Etanercept versus sulfasalazine - Results were available from one study with a low risk of bias at study level. However at outcome level, the risk of bias was consistently assessed as high. With the exception of remission, this was because of the lack of information as to how many patients from the treatment groups discontinued the study because of lack of efficacy and whether or how these patients were taken into account in the analysis. Accordingly, no sensitivity analyses could be conducted either. For the outcome “remission” it was unclear whether the outcome assessors were blinded. Statistically significant results were shown or an irrelevant effect could be excluded for the outcomes “painful joints”, “swollen joints”, “pain”, “global assessment of disease activity by the patient”, “general health”, “morning stiffness” and “status of physical functioning”. For each of these outcomes there was a hint of an added benefit of etanercept compared with sulfasalazine in patients with intolerance of MTX. Etanercept versus MTX - Results of one study with a low risk of bias at study level were available. However at outcome level, the risk of bias was consistently assessed as high. With the exception of remission, the reason was the lack of information as to how many patients from the treatment groups discontinued the study because of lack of efficacy and whether or how these patients were taken into account in the analysis. For the outcome “remission” it was unclear whether the outcome assessors were blinded. Statistically significant results were shown or an irrelevant effect could be excluded for the outcomes “remission”, “painful joints”, “swollen joints”, “pain”, “global assessment of disease activity by the patient”, “general health” and “morning stiffness”. For each of these outcomes there was a hint of an added benefit of etanercept compared with MTX in	

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	patients with severe active and progressive RA.	
INAHTA	Not applicable.	*Adalimumab, etanercept, infliximab,certolizumab pegol, golimumab, tocilizumab and abatacept for the treatment of rheumatoid arthritis not previously treated with disease-modifying antirheumatic drugs and after the failure of conventional disease-modifying antirheumatic drugs only: systematic review and economic evaluation, published 2016:*[25] Conclusion: bDMARDs appear to have cost per QALY values greater than the thresholds stated by the National Institute for Health and Care Excellence for interventions to be cost-effective. Future research priorities include: the evaluation of the long-term HAQ trajectory while on cDMARDs; the relationship between HAQ direct medical costs; and whether or not bDMARDs could be stopped once a patient has achieved a stated target (e.g. remission).

Emerging Evidence, Clinical Effectiveness, and Cost Effectiveness

There may be ongoing or recently completed clinical trials that the Board may want to consider. To identify more recent clinical studies typically not captured in the studies above, information is provided below for completed Phase III or IV studies found on the National Institute of Health's Clinical Trials website. The results column only contains information if there is a published, peer-reviewed study or poster available. For Enbrel, there were no applicable results in the following studies found on ClinicalTrials.Gov:

- Study To Evaluate The Response To Enbrel And The Impact Of Rheumatoid Factor(RF) And Anti-Cyclic Citrullinated Peptide(Anti-CCP) In Rheumatoid Arthritis(RA) Patients[26]
- A Study Comparing LBEC0101 to Enbrel® in Subjects With Active Rheumatoid Arthritis Despite Methotrexate Therapy[27]
- Study of Enbrel in Rheumatoid Arthritis (RA) Subjects With Comorbid Disorders[28]
- Randomized Double-blind Parallel Trial to Evaluate Equivalence in Efficacy and Safety of HB203 and Enbrel in RA Patients[29]

[25] https://njl-admin.nihr.ac.uk/document/download/2003416 - QALY used in this literature.
[26] https://clinicaltrials.gov/study/NCT04428424?cond=Rheumatoid%20Arthritis&intr=Etanercept%20%5C(Enbrel%5C)&rank=2
[27] https://clinicaltrials.gov/study/NCT02357069?cond=Rheumatoid%20Arthritis&intr=Etanercept%20%5C(Enbrel%5C)&rank=3
[28] https://clinicaltrials.gov/study/NCT00132418?cond=Rheumatoid%20Arthritis&intr=Etanercept%20%5C(Enbrel%5C)&rank=6
[29] https://clinicaltrials.gov/study/NCT01270997?cond=Rheumatoid%20Arthritis&intr=Etanercept%20%5C(Enbrel%5C)&rank=8

Ankylosing Spondylitis

Relevant Medical Professional Guidelines and Manufacturer-Reported Benefits

Relevant Medical Professional Guidelines

2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Non Radiographic Axial Spondyloarthritis[30]

Manufacturer-Reported Benefits

Information contained in Enbrel's FDA label, Section 14 Clinical Studies, reports on studies in patients between 18 and 70 years of age with active ankylosing spondylitis. Compared with placebo, treatment with Enbrel resulted in improvements in measures of disease activity.[31]

Figure D-3
Study I (Table 12)

Table 12. Components of Ankylosing Spondylitis Disease Activity

	Placebo N = 139		Enbrel[a] N = 138	
Median values at time points	Baseline	6 Months	Baseline	6 Months
ASAS response criteria				
Patient global assessment [b]	63	56	63	36
Back pain [c]	62	56	60	34
BASFI [d]	56	55	52	36
Inflammation [e]	64	57	61	33
Acute phase reactants				
CRP (mg/dL) [f]	2.0	1.9	1.9	0.6
Spinal mobility (cm):				
Modified Schober's test	3.0	2.9	3.1	3.3
Chest expansion	3.2	3.0	3.3	3.9
Occiput-to-wall measurement	5.3	6.0	5.6	4.5

[a] $p < 0.0015$ for all comparisons between Enbrel and placebo at 6 months. P values for continuous endpoints were based on percent change from baseline.
[b] Measured on a Visual Analog Scale (VAS) with 0 = "none" and 100 = "severe".
[c] Average of total nocturnal and back pain scores, measured on a VAS with 0 = "no pain" and 100 = "most severe pain".
[d] Bath Ankylosing Spondylitis Functional Index (BASFI), average of 10 questions.
[e] Inflammation represented by the average of the last 2 questions on the 6-question Bath Ankylosing Spondylitis Disease Activity Index (BASDAI).
[f] C-reactive protein (CRP) normal range: 0-1.0 mg/dL.

[30] https://assets.contentstack.io/v3/assets/bltee37abb6b278ab2c/blt74558fbe6f37b611/6328a49019c64564c313f918/axial-spa-guideline-2019.pdf
[31] https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/103795s5595lbl.pdf

Figure D-3 above shows the clinical responses of patients with ankylosing spondylitis who received Enbrel versus placebo.

Voluntarily Submitted Manufacturer Information

Confidential Information

[redacted]

See Appendix J for more information, including Amgen Inc.'s citations for reported benefits.

Clinical Effectiveness and Cost Effectiveness

Table D-2
Ankylosing Spondylitis Clinical and Cost Effectiveness Conclusion Summaries

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
Cochrane Library	*TNF-alpha inhibitors for ankylosing spondylitis, 2015*[32] Compared with placebo, there was high quality evidence that patients on an anti-TNF agent were three to four times more likely to achieve an ASAS40 response (assessing spinal pain, function, and inflammation, as measured by the mean of intensity and duration of morning stiffness, and patient global assessment) by six months (adalimumab: risk ratio (RR) 3.53, 95% credible interval (CrI) 2.49 to 4.91; etanercept: RR 3.31, 95% CrI 2.38 to 4.53; golimumab: RR 2.90, 95% CrI 1.90 to 4.23; infliximab: RR 4.07, 95% CrI 2.80 to 5.74, with a 25% to 40% absolute difference between treatment and placebo groups. The number needed to treat (NNT) to achieve an ASAS 40 response ranged from 3 to 5. There was high quality evidence of improvement in physical function on a 0 to 10 scale (adalimumab: mean difference (MD) -1.6, 95% CrI -2.2 to -0.9; etanercept: MD -1.1, 95% CrI -1.6 to -0.6; golimumab: MD -1.5, 95% CrI -2.3 to -0.7; infliximab: MD -2.1, 95% CrI -2.7 to -1.4, with an 11% to 21% absolute difference between treatment and placebo groups. The NNT to achieve the minimally clinically important difference of 0.7 points ranged from 2 to 4. Compared with placebo, there was moderate quality evidence (downgraded for imprecision) that patients on an anti-TNF agent were more likely to achieve an ASAS partial remission by six months (adalimumab: RR 6.28, 95% CrI 3.13 to 12.78; etanercept: RR 4.24, 95% CrI 2.31 to 8.09; golimumab:	Not applicable.

[32] https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD005468.pub2/full?highlightAbstract=spondyl%7Cspondylitis%7Cankylos%7Cankylosing%7Cetanercept

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	RR 5.18, 95% CrI 1.90 to 14.79; infliximab: RR 15.41, 95% CrI 5.09 to 47.98 with a 10% to 44% absolute difference between treatment and placebo groups. The NNT to achieve an ASAS partial remission response ranged from 3 to 11.	
ICER	Not applicable.	Not applicable.
NICE	*TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis, 2016*[33] For BASDAI 50 the RRs of a response were 3.16 with adalimumab, 3.17 with etanercept, 3.57 with golimumab, 3.60 with certolizumab pegol, and 4.86 with infliximab. The additional reduction in BASDAI and BASFI scores achieved with adalimumab, certolizumab pegol, etanercept and infliximab compared with placebo were all statistically significant and clinically important. Additional reductions in BASDAI scores compared with placebo were 1.46 units with certolizumab pegol, 1.55 units with adalimumab, 1.75 units with etanercept and 2.28 units with infliximab. Additional BASFI reductions were 1.1 units with certolizumab pegol, 1.25 units with adalimumab, 1.43 units with etanercept, 1.45 units with golimumab and 2.16 units with infliximab. This conclusion was based on results from a trial by Giardina et al. that compared infliximab with etanercept. In the Giardina et al. trial, the BASDAI and BASFI outcomes at week 12 favoured treatment with infliximab, but by week 48 the results for infliximab and etanercept were almost identical.	*TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis, 2016*[34] For ankylosing spondylitis, the companies compared the 5 TNF-alpha inhibitors that have a marketing authorisation for this indication (adalimumab, certolizumab pegol, etanercept, golimumab and infliximab) with each other, and with conventional care. For non-radiographic axial spondyloarthritis, the companies compared the 3 TNF-alpha inhibitors that have a marketing authorisation in this indication (adalimumab, certolizumab pegol and etanercept) with each other and with conventional therapy (except for AbbVie, which did not include etanercept in its model). All evaluations adopted an NHS perspective. Costs and benefits in all cases were discounted at 3.5%. Based on recommendations in NICE's technology appraisal guidance on adalimumab, etanercept and infliximab for ankylosing spondylitis, all models included response criteria to decide whether TNF-alpha inhibitors were continued or stopped. The criteria were ASAS 20, ASAS 40 or BASDAI 50 at week 12, except for UCB Pharma which used response criteria at week 24, in its base-case model for the ankylosing spondylitis population.
CADTH	Not applicable.	Not applicable.
IQWiG	Not applicable.	Not applicable.
INAHTA	*[Adalimumab, etanercept, infliximab and golimumab for the treatment of*	*Adalimumab, etanercept and infliximab for the treatment of*

[33] https://www.nice.org.uk/guidance/ta383/resources/tnfalpha-inhibitors-for-ankylosing-spondylitis-and-nonradiographic-axial-spondyloarthritis-pdf-82602848027077 - QALY used in this literature.

[34] https://www.nice.org.uk/guidance/ta383/resources/tnfalpha-inhibitors-for-ankylosing-spondylitis-and-nonradiographic-axial-spondyloarthritis-pdf-82602848027077 - QALY used in this literature.

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	ankylosing spondylitis and reactive arthritis][35] Anti-TNF-alpha therapy has proved to better control ankylosing spondylitis inflammatory symptoms when compared to placebo or DMDs.	*ankylosing spondylitis: a systematic review and economic evaluation*[36] The review of clinical data related to the three drugs (including conventional treatment) compared with conventional treatment plus placebo indicates that in the short term (12;24 weeks) the three treatments demonstrate clinical and statistical effectiveness in relation to assessment of ASAS, BASDAI and BASFI. Indirect comparisons of treatments were limited and were not able to determine a significant difference in effectiveness between the three agents. The short-term economic assessment indicates that none of the three anti-TNF-a agents is likely to be considered cost-effective at current acceptability thresholds, with infliximab consistently the least favourable option. Analyses carried out by the assessment group over the longer term challenge the assumptions made in the company submissions that costs will decrease over time. Owing to these large and sustained costs, the impact on the NHS budget is likely to be considerable.

Plaque Psoriasis: Adult and Pediatric

Relevant Medical Professional Guidelines and Manufacturer-Reported Benefits

Relevant Medical Professional Guidelines

Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *Journal of the American Academy of Dermatology*[37].

Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis in pediatric patients. *Journal of the American Academy of Dermatology*.[38]

[35] https://database.inahta.org/article/14348
[36] https://database.inahta.org/article/6962
[37] https://pubmed.ncbi.nlm.nih.gov/30772098/
[38] https://pubmed.ncbi.nlm.nih.gov/31703821/

Manufacturer-Reported Benefits

Information contained in Enbrel's FDA label, Section 14 Clinical Studies, reports on the following two studies in adults with plaque psoriasis. The studies generally show that more subjects randomized to Enbrel than placebo achieved at least a 75% reduction from baseline Psoriasis Area and Severity Index (PASI) score.[39]

Figure D-4
Study I (Table 13)

Table 13. Study I Outcomes at 3 and 6 Months

	Placebo/Enbrel 25 mg BIW (N = 168)	Enbrel/Enbrel 25 mg QW (N = 169)	Enbrel/Enbrel 25 mg BIW (N = 167)	Enbrel/Enbrel 50 mg BIW (N = 168)
3 Months				
PASI 75 n (%)	6 (4%)	23 (14%)[a]	53 (32%)[b]	79 (47%)[b]
Difference (95% CI)		10% (4, 16)	28% (21, 36)	43% (35, 52)
sPGA, "clear" or "minimal" n (%)	8 (5%)	36 (21%)[b]	53 (32%)[b]	79 (47%)[b]
Difference (95% CI)		17% (10, 24)	27% (19, 35)	42% (34, 50)
PASI 50 n (%)	24 (14%)	62 (37%)[b]	90 (54%)[b]	119 (71%)[b]
Difference (95% CI)		22% (13, 31)	40% (30, 49)	57% (48, 65)
6 Months				
PASI 75 n (%)	55 (33%)	36 (21%)	68 (41%)	90 (54%)

[a] p = 0.001 compared with placebo.
[b] p < 0.0001 compared with placebo.

Figure D-4 shows the efficacy of Enbrel versus placebo in adult patients with plaque psoriasis.

[39] https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/103795s5595lbl.pdf

Figure D-5
Study II (Table 14)

Table 14. Study II Outcomes at 3 Months

	Placebo (N = 204)	Enbrel 25 mg BIW (N = 204)	Enbrel 50 mg BIW (N = 203)
PASI 75 n (%)	6 (3%)	66 (32%)[a]	94 (46%)[a]
Difference (95% CI)		29% (23, 36)	43% (36, 51)
sPGA, "clear" or "minimal" n (%)	7 (3%)	75 (37%)[a]	109 (54%)[a]
Difference (95% CI)		34% (26, 41)	50% (43, 58)
PASI 50 n (%)	18 (9%)	124 (61%)[a]	147 (72%)[a]
Difference (95% CI)		52% (44, 60)	64% (56, 71)

[a] $p < 0.0001$ compared with placebo.

Figure D-5 shows the efficacy of Enbrel versus placebo in adult patients with plaque psoriasis.

Information contained in Enbrel's FDA label, Section 14 Clinical Studies, reports on the following study in pediatric subjects 4 to 17 years of age with moderate to severe plaque psoriasis.[40]

Figure D-6
Study 1(Table 15)

Table 15. Pediatric Plaque Psoriasis Outcomes at 12 Weeks

	Placebo (N = 105)	Enbrel 0.8 mg/kg Once Weekly (N = 106)
PASI 75, n (%)	12 (11%)	60 (57%)
PASI 90, n (%)	7 (7%)	29 (27%)
sPGA "clear" or "almost clear" n (%)	14 (13%)	55 (52%)

Figure D-6 shows efficacy of Enbrel when compared to placebo in pediatric patients with plaque psoriasis.

[40] www.accessdata.fda.gov/drugsatfda_docs/label/2023/103795s5595lbl.pdf

Voluntarily Submitted Manufacturer Information

Public Information

- "Across moderate to severe RA, psoriatic arthritis (PsA), and plaque psoriasis (PsO), Enbrel® has demonstrated clinically meaningful improvements in outcomes, such as reductions in joint pain and damage, improved physical functioning, and reduction in skin-related Symptoms."
- "In PsO, where safety of systemic treatments is particularly important in the risk-benefit calculation, Enbrel® improves multiple measures of skin signs and symptoms, as well as a number of patient reported outcome (PRO) measures. Improvements in disease activity and PROs with Enbrel® were maintained long-term (up to 96 weeks).
- "Enbrel® improves PROs and productivity in adults with moderate to severe RA, PsA, and PsO, boosting patient wellbeing and reducing costs for employers."

Clinical Effectiveness and Cost Effectiveness

Table D-3

Adult and Pediatric Plaque Psoriasis Clinical and Cost Effectiveness Conclusion Summaries

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
Cochrane Library	*Systemic pharmacological treatments for chronic plaque psoriasis: a network meta-analysis. 2023*[41] For reaching PASI 90, the most effective drugs when compared to placebo were (SUCRA rank order, all high-certainty evidence): infliximab (risk ratio (RR) 49.16, 95% CI 20.49 to 117.95), bimekizumab (RR 27.86, 95% CI 23.56 to 32.94), ixekizumab (RR 27.35, 95% CI 23.15 to 32.29), risankizumab (RR 26.16, 95% CI 22.03 to 31.07). Clinical effectiveness of these drugs was similar when compared against each other. Bimekizumab and ixekizumab were significantly more likely to reach PASI 90 than secukinumab. Bimekizumab, ixekizumab, and risankizumab were significantly more likely to reach PASI 90 than brodalumab and guselkumab. Infliximab, anti-IL17 drugs (bimekizumab, ixekizumab, secukinumab, and brodalumab), and anti-IL23 drugs except tildrakizumab were significantly more likely to reach PASI 90 than ustekinumab, three anti-TNF alpha agents, and deucravacitinib. Ustekinumab was superior to certolizumab. Adalimumab, tildrakizumab, and ustekinumab were superior to etanercept. *Anti-TNF agents for paediatric psoriasis. 2015*[42]	Not applicable.

[41] https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD011535.pub6/full?highlightAbstract=plaque%7Cplaqu%7Cetanercept

[42] https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010017.pub2/full?highlightAbstract=plaque%7Cplaqu%7Cetanercept

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	We can conclude, based on this single included study, that etanercept seems to be efficacious and safe (at least in the short term) for the treatment of paediatric psoriasis.	
ICER	Not applicable.	*Targeted Immunomodulators for the Treatment of Moderate-to-Severe Plaque Psoriasis: Effectiveness and Value. 2016*[43] Third, the newer IL-17A targeted agents provide good economic value in relation to etanercept. The lower initial effectiveness of etanercept, high long-term discontinuation rates, and the need for more expensive second-line therapy decrease its overall value despite lower initial drug cost. In summary, our analyses suggest that if health care payers are able to achieve significant drug rebates, the most effective (and most expensive) targeted drugs provide the greatest benefit to psoriasis patients at a reasonable economic value.
NICE	Not applicable.	Not applicable.
CADTH	*Biologics in Plaque Psoriasis: A Summary. 2021*[44] Health Canada has approved 11 biologics for plaque psoriasis. Biologics for plaque psoriasis can be divided into 2 groups based on mechanisms of action and market authorization dates: Old-generation biologics (5): include anti-TNF drugs (etanercept, adalimumab, infliximab, and certolizumab pegol) and an anti-IL-12/IL-23 inhibitor (ustekinumab), which were approved in Canada before 2010 New-generation biologics (6): include anti-IL-17 inhibitors (secukinumab, ixekizumab, and brodalumab) and anti-IL-23 inhibitors (guselkumab, tildrakizumab, and risankizumab), which were approved in Canada in 2015 or later. *Adalimumab, etanercept and ustekinumab for treating plaque psoriasis in children and young people. 2017* Adalimumab (Humira), etanercept (Enbrel) and ustekinumab (Stelara) are all available on the NHS as possible treatments for plaque psoriasis. Adalimumab is for children and young people 4 years or older, etanercept for those 6 years or older and ustekinumab for those 12 years or older. They are only available if the psoriasis:is severe and has not improved with other treatments, for example, ciclosporin, methotrexate or phototherapy, or these can't be used.	Not applicable.

[43] https://icerorg.wpengine.com/wp-content/uploads/2020/10/NE_CEPAC_Psoriasis_Evidence_Report_FINAL_012317.pdf - QALY used in this literature.

[44] https://www.cadth.ca/biologics-plaque-psoriasis-summary

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	If the psoriasis doesn't improve enough, treatment with etanercept should be stopped after 12 weeks and with adalimulab and ustekinumab treatments after 16 weeks.	
IQWiG	Not applicable.	Not applicable.
INAHTA	Not applicable.	*Adalimumab, etanercept and ustekinumab for treating plaque psoriasis in children and young people: systematic review and economic evaluation. 2017* [45] The paucity of clinical and economic evidence to inform the cost-effectiveness of biological treatments in children and young people imposed a number of strong assumptions and uncertainties. Health-related quality-of-life (HRQoL) gains associated with treatment and the number of hospitalisations in children and young people are areas of considerable uncertainty. The findings suggest that biological treatments may not be cost-effective for the management of psoriasis in children and young people at a willingness-to-pay threshold of £30,000 per quality-adjusted life-year, unless a number of strong assumptions about HRQoL and the costs of BSC are combined. Registry data on biological treatments would help determine safety, patterns of treatment switching, impact on comorbidities and long-term withdrawal rates. Further research is also needed into the resource use and costs associated with BSC. Adequately powered randomised controlled trials (including comparisons against placebo) could substantially reduce the uncertainty surrounding the effectiveness of biological treatments in biologic-experienced populations of children and young people, particularly in younger children. Such trials should establish the impact of biological therapies on HRQoL in this population, ideally by collecting direct estimates of EuroQol-5 Dimensions for Youth (EQ-5D-Y) utilities.

Emerging Evidence, Clinical Effectiveness, and Cost Effectiveness

There may be ongoing or recently completed clinical trials that the Board may want to consider. To identify more recent clinical studies typically not captured in the studies above, information is provided below for completed Phase III or IV studies found on the National Institute of Health's Clinical Trials website. For Enbrel, there were no applicable results in the following studies found on ClinicalTrials.Gov:

[45] https://www.journalslibrary.nihr.ac.uk/hta/hta21640/#/abstract - QALY used in this literature.

- Study Evaluating Etanercept for the Treatment of Moderate to Severe Psoriasis (PRISTINE)[46]
- Study to Evaluate the Efficacy of Enbrel as a Biological Treatment in Moderate to Severe Plaque Psoriasis Patients[47]
- Pediatric Open-Label Extension Study of Etanercept in Patients With Plaque Psoriasis[48]
- Etanercept (Enbrel®) in Psoriasis - Pediatrics[49]
- Pediatric Study in Children and Adolescents With Severe Plaque Psoriasis[50]

Psoriatic Arthritis

Relevant Medical Professional Guidelines and Manufacturer-Reported Benefits

Relevant Medical Professional Guidelines

2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis[51]

Manufacturer-Reported Benefits

Information contained in Enbrel's FDA label, Section 14 Clinical Studies, reports on studies in patients between 18 and 70 years of age with active psoriatic arthritis. Compared to placebo, treatment with Enbrel resulted in significant improvements in measures of disease activity.[52]

46 https://clinicaltrials.gov/study/NCT00663052?cond=Plaque%20Psoriasis&term=etanercept&rank=4
47 https://clinicaltrials.gov/study/NCT04398732?cond=Plaque%20Psoriasis&term=etanercept&rank=8
48 https://clinicaltrials.gov/study/NCT00141921?cond=Pediatric%20Plaque%20Psoriasis&intr=Etanercept&rank=1
49 https://clinicaltrials.gov/study/NCT00078819?cond=Pediatric%20Plaque%20Psoriasis&intr=Etanercept&rank=2
50 https://clinicaltrials.gov/study/NCT02471144?cond=Pediatric%20Plaque%20Psoriasis&intr=Etanercept&rank=3
51 https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/art.40726
52 https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/103795s5595lbl.pdf

Figure D-7
Study I (Table 11)

Table 11. Components of Disease Activity in Psoriatic Arthritis

	Placebo N = 104		Enbrel[a] N = 101	
Parameter (median)	Baseline	6 Months	Baseline	6 Months
Number of tender joints[b]	17.0	13.0	18.0	5.0
Number of swollen joints[c]	12.5	9.5	13.0	5.0
Physician global assessment[d]	3.0	3.0	3.0	1.0
Patient global assessment[d]	3.0	3.0	3.0	1.0
Morning stiffness (minutes)	60	60	60	15
Pain[d]	3.0	3.0	3.0	1.0
Disability index[e]	1.0	0.9	1.1	0.3
CRP (mg/dL)[f]	1.1	1.1	1.6	0.2

Figure D-7 above shows… the clinical responses of patients with psoriatic arthritis who received Enbrel versus placebo.

Voluntarily Submitted Manufacturer Information

Public Information

- "Across moderate to severe RA, psoriatic arthritis (PsA), and plaque psoriasis (PsO), Enbrel® has demonstrated clinically meaningful improvements in outcomes, such as reductions in joint pain and damage, improved physical functioning, and reduction in skin-related symptoms."
- "Amgen has invested capital studying Enbrel® for additional indications and introduced new, more patient-friendly formulations and administration methods, such as the easy-to-use, self-injection device specifically designed to meet the needs of moderate-to-severe rheumatoid arthritis patients and psoriatic arthritis patients."
- "Finally, Enbrel® improves PROs and productivity in adults with moderate to severe RA, PsA, and PsO, boosting patient wellbeing and reducing costs for employers."

See Appendix J for more information, including Amgen Inc.'s citations for reported benefits.

Clinical Effectiveness and Cost Effectiveness

Table D-5

Psoriatic Arthritis Clinical and Cost Effectiveness Conclusion Summaries

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
Cochrane Library	Not applicable.	Not applicable.
ICER	Not applicable.	Not applicable.
NICE	*Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis, 2010*[53] At 24 weeks the treatment effect on psoriasis favoured etanercept with RRs for PASI 75 of 7.05 (95% CI 1.68 to 29.56), PASI 50 of 2.65 (95% CI 1.46 to 4.80) and PASI 90 of 1.88 (95% CI 0.36 to 9.90). At 1 year the mean annualised rate of progression on the Total Sharp Score for all people was −0.03 (standard deviation [SD] 0.87), indicating that on average there was no clinically significant progression of joint erosion based on uncontrolled follow-up data.	*Backsback et al., 2007*[54] The study by Bansback et al. (2007) compared etanercept with ciclosporin and leflunomide. The economic model focused on response according to PsARC and associated HAQ score, with changes in HAQ and further withdrawals modelled over 10 years. Mease 2004 was the source of evidence for response rates and HAQ. The base-case results showed an ICER of around £28,000 per QALY gained for etanercept compared with ciclosporin and £38,000 per QALY gained for etanercept compared with leflunomide. *Bravo Vergel, 2006*[55] The study by Bravo Vergel (2006) compared etanercept with infliximab and palliative care. The model included response according to PsARC and associated HAQ score. Changes in HAQ and further withdrawals were modelled over 40 and 10 years. Evidence from Mease 2000, Mease 2004 and IMPACT was used to model the PsARC response. The ICER for etanercept was between £26,361 and £30,628 per QALY gained compared with palliative care depending on the assumptions made about the deterioration in HAQ score at treatment withdrawal (rebound). Infliximab was the most effective strategy, and generated the highest number of QALYs. *NICE, 2004* A published cost-effectiveness model originally used to support a submission to NICE in 2004 was adapted to incorporate additional effectiveness evidence and new comparators. The adjusted model

[53] https://www.nice.org.uk/guidance/ta199/resources/etanercept-infliximab-and-adalimumab-for-the-treatment-of-psoriatic-arthritis-pdf-82598565006277 - QALY used in this literature.

[54] https://www.nice.org.uk/guidance/ta199/resources/etanercept-infliximab-and-adalimumab-for-the-treatment-of-psoriatic-arthritis-pdf-82598565006277 - QALY used in this literature.

[55] https://www.nice.org.uk/guidance/ta199/resources/etanercept-infliximab-and-adalimumab-for-the-treatment-of-psoriatic-arthritis-pdf-82598565006277 - QALY used in this literature.

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
		compared the costs and benefits associated with etanercept, infliximab, adalimumab and best supportive care over a lifetime horizon. Best supportive care was assumed to be ciclosporin because the population considered in the model were assumed to have already tried other DMARDs (leflunomide, sulfasalazine and methotrexate).[56]
CADTH	Not applicable.	Not applicable.
IQWiG	Not applicable.	Not applicable.
INAHTA	*Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis: a systematic review and economic evaluation, 2011*[57] Pooled estimates of effect demonstrated a significant improvement in patients with PsA for all joint disease and functional status outcomes at 12-14 weeks' follow-up. The biologic treatment significantly reduced joint symptoms assessed by PsARC for etanercept [relative risk (RR) 2.60, 95% confidence interval (CI) 1.96 to 3.45], infliximab (RR 3.44, 95% CI 2.53 to 4.69) and adalimumab (RR 2.24, 95% CI 1.74 to 2.88). This was consistent with the results from the pooled estimates of ACR 20. Furthermore, the statistically significant reduction in HAQ score also indicated a beneficial effect of these biologic therapies on patients' functional status. Significant heterogeneity was observed only in the outcome of PsARC in infliximab. The 24-week data for all three biologics demonstrated that the treatment effects are maintained. Trial data demonstrate a significant effect of all three biologics on skin disease in terms of PASI response, at 12 or 24 weeks. The results of evidence synthesis found that infliximab appears to be the most effective of the three biologics. Across all outcomes of joint and skin disease at 12 weeks, infliximab is associated with the highest probabilities of response. The response in joint disease (PsARC and ACR) is greater with etanercept than with adalimumab, whereas the response in skin disease (PASI) is greater with adalimumab than with etanercept, although these differences are not statistically significant. In those patients who achieve a PsARC response to treatment the highest mean reductions in the functional and psychological impact of the disease, measured by HAQ, are seen with	*Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis: a systematic review and economic evaluation, 2011*[58] The published models estimated that the incremental cost-effectiveness ratio (ICER) for etanercept versus palliative care was between £26,000 and £38,000 per QALY, but did not consider the impact of biologics on the skin component of PsA. The de novo York Assessment Group model evaluated the cost-effectiveness of the three biologic therapies and palliative care only. Under base-case assumptions, for patients with PsA and mild-to-moderate skin disease, the ICER etanercept versus palliative care is about £18,000 per QALY, and the ICER of infliximab versus etanercept is about £44,000 per QALY. Adalimumab is extendedly dominated. The probability that etanercept is cost-effective is 0.436 at a threshold of £20,000 per QALY and 0.475 at a threshold of £30,000 per QALY. The expected lifetime prescription costs of biologic therapies is considerably greater than offset cost savings elsewhere in the NHS. For patients with PsA and moderate-to-severe skin disease who continue on biologics after 3 months if they respond for skin or joints, the ICER of adalimumab versus palliative care is about £16,000 per QALY, the ICER of etanercept versus adalimumab is about £21,000 per QALY and the ICER for infliximab versus etanercept is about £26,000 per QALY. If the cost-effectiveness threshold were £20,000 per QALY then all biologics have a similar probability of being cost-effective.

[56] https://www.nice.org.uk/guidance/ta199/resources/etanercept-infliximab-and-adalimumab-for-the-treatment-of-psoriatic-arthritis-pdf-82598565006277 - QALY used in this literature.

[57] https://www.ncbi.nlm.nih.gov/books/NBK56827/

[58] https://www.ncbi.nlm.nih.gov/books/NBK56827/ - QALY used in this literature.

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	infliximab and etanercept (-0.657 for infliximab and -0.630 for etanercept). For all three biologics the changes in HAQ for those patients who did not respond to treatment were below the minimum clinically significant threshold (-0.3).	For patients with PsA with negligible skin involvement, the ICER of etanercept versus palliative care is about £18,000 per QALY, and the ICER of infliximab versus etanercept is about £65,000 per QALY. Adalimumab is extendedly dominated in this group.

Emerging Evidence, Clinical Effectiveness, and Cost Effectiveness

There may be ongoing or recently completed clinical trials that the Board may want to consider. To identify more recent clinical studies typically not captured in the studies above, information is provided below for completed Phase III or IV studies found on the National Institute of Health's Clinical Trials website. The results column only contains information if there is a published, peer-reviewed study or poster available. For Enbrel, there were no applicable results in the following studies found on ClinicalTrials.Gov:

- REPArE: Rating Evaluations in Psoriatic Arthritis (PsA) With Etanercept (Enbrel®)[59]
- Etanercept and Methotrexate in Combination or as Monotherapy in Psoriatic Arthritis[60]
- Study Evaluating Etanercept on Skin and Joint Disease in Psoriatic Arthritis[61]

Juvenile Psoriatic Arthritis

The FDA approved Enbrel for the treatment of active juvenile psoriatic arthritis in patients 2 years of age and older in October, 2023. Due to the relatively recent approval, some information may not be available.

Relevant Medical Professional Guidelines and Manufacturer-Reported Benefits

Relevant Medical Professional Guidelines

Manufacturer-Reported Benefits

Information contained in Enbrel's FDA label states that the safety and effectiveness of Enbrel have been established in pediatric patients 2 years to 17 years old with JPsA. Use of Enbrel in JPsA is supported by evidence from adequate and well controlled studies of Enbrel in adults with PsA; pharmacokinetic data from adult patients with psoriatic arthritis, rheumatoid arthritis, and psoriasis; and pharmacokinetic data from pediatric patients with active juvenile idiopathic arthritis and psoriasis.[62]

[59] https://clinicaltrials.gov/study/NCT00127842?cond=Psoriatic%20Arthritis&term=etanercept&rank=1
[60] https://clinicaltrials.gov/study/NCT02376790?cond=Psoriatic%20Arthritis&term=etanercept&rank=2
[61] https://clinicaltrials.gov/study/NCT00245960?cond=Psoriatic%20Arthritis&term=etanercept&rank=3
[62] www.accessdata.fda.gov/drugsatfda_docs/label/2023/103795s5595lbl.pdf

Voluntarily Submitted Manufacturer Information

No voluntary information was submitted by Amgen Inc. for JPsA. This may be due to the fact that Enbrel received FDA approval for treatment of JPsA after the voluntarily submitted information deadline.

Confidential Information

[redacted]

Clinical Effectiveness and Cost Effectiveness

Table D-7
Juvenile Psoriatic Arthritis Clinical and Cost Effectiveness Conclusion Summaries

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
Cochrane Library	*Two-year Efficacy and Safety of Etanercept in Pediatric Patients with Extended Oligoarthritis, Enthesitis-related Arthritis, or Psoriatic Arthritis*[63] The main objective was to determine the 2-year clinical benefit and safety of etanercept (ETN) in children with the juvenile idiopathic arthritis (JIA) categories of extended oligoarthritis (eoJIA), enthesitis-related arthritis (ERA), or psoriatic arthritis (PsA). Over 96 weeks of therapy, ETN demonstrated sustained efficacy at treating the clinical symptoms of all 3 JIA categories, with no major safety issues. *LONG-TERM SAFETY AND EFFICACY OF ETANERCEPT IN PAEDIATRIC SUBJECTS WITH EXTENDED OLIGOARTICULAR JUVENILE IDIOPATHIC ARTHRITIS, ENTHESITIS-RELATED ARTHRITIS, OR PSORIATIC ARTHRITIS*[64] Aim: To assess the long-term safety and clinical benefit of etanercept (ETN) in paediatric subjects with the extended oligoarticular (eo), enthesitis-related (ERA), and psoriatic (PsA) JIA subtypes. Conclusions: ETN treatment for 96 weeks was well-tolerated and effective in treating subjects with the JIA subtypes, eoJIA, ERA, or PsA, as expected from the previous data from polyarticular JIA.	Not applicable.
ICER	Not applicable.	Not applicable.
NICE	Not applicable.	Not applicable.

[63] https://www.jrheum.org/content/43/4/816
[64] https://onlinelibrary.wiley.com/doi/10.1111/imj.12426

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
CADTH	Not applicable.	Not applicable.
IQWiG	Not applicable.	Not applicable.
INAHTA	Not applicable.	Not applicable.

Emerging Evidence, Clinical Effectiveness, and Cost Effectiveness

There may be ongoing or recently completed clinical trials that the Board may want to consider. To identify more recent clinical studies typically not captured in the studies above, information is provided below for completed Phase III or IV studies found on the National Institute of Health's Clinical Trials website. The results column only contains information if there is a published, peer-reviewed study or poster available. For Enbrel, there were no applicable results in the following studies found on ClinicalTrials.Gov:

- Study Evaluating Etanercept in Patients With Rheumatoid Arthritis(RA), Juvenile Idiopathic Arthritis (JIA), or Psoriatic Arthritis (PsA) in Spain[65]
- Study Evaluating Etanercept in 3 Subtypes of Childhood Arthritis[66]

Polyarticular Juvenile Idiopathic Arthritis (JIA)

Relevant Medical Professional Guidelines and Manufacturer-Reported Benefits

Relevant Medical Professional Guidelines

2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis[67]

Manufacturer-Reported Benefits

Information contained in Enbrel's FDA label, Section 14 Clinical Studies, reports on the following two-part study in children with polyarticular JIA who had a variety of JIA onset types. In part 1, all patients received 0.4mg/kg Enbrel twice weekly. In part 2, patients with a clinical response at day 90 were randomized to remain on Enbrel or receive placebo for 4 months and assessed for disease flare. In part 1, 74% of

[65] https://clinicaltrials.gov/study/NCT00195377?cond=Juvenile%20Psoriatic%20Arthritis&term=etanercept&rank=2
[66] https://clinicaltrials.gov/study/NCT00962741?cond=Juvenile%20Psoriatic%20Arthritis&term=etanercept&rank=1
[67] https://assets.contentstack.io/v3/assets/bltee37abb6b278ab2c/bltea21f1baaea35cf3/63321ee13df1404a8501fc67/jia-guideline-2019.pdf

patients demonstrated a clinical response and entered part 2. In part 2, 24% of patients remaining on Enbrel experienced disease flare compared to 77% of patients receiving placebo. The median time to flare was 116 days for patients receiving Enbrel and 28 days for patients who received placebo. Of patients who entered part 2 of the study, some patients remaining on Enbrel continued to improve from month 3-7, while those who received placebo did not improve.[68]

Voluntarily Submitted Manufacturer Information

Confidential Information

[redacted]

Clinical Effectiveness and Cost Effectiveness

Table D-8

Juvenile Idiopathic Arthritis Clinical and Cost Effectiveness Conclusion Summaries

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
Cochrane Library	*Etanercept in Children with Polyarticular Juvenile Rheumatoid Arthritis. 2000*[69] At the end of the open-label study, 51 of the 69 patients (74 percent) had had responses to etanercept treatment. In the double-blind study, 21 of the 26 patients who received placebo (81 percent) withdrew because of disease flare, as compared with 7 of the 25 patients who received etanercept (28 percent) (P=0.003). The median time to disease flare with placebo was 28 days, as compared with more than 116 days with etanercept (P<0.001). In the double-blind study, there were no significant differences between the two treatment groups in the frequency of adverse events. Treatment with etanercept leads to significant improvement in patients with active polyarticular juvenile rheumatoid arthritis. Etanercept is well tolerated by pediatric patients. *Etanercept improves linear growth and bone mass acquisition in MTX-resistant polyarticular-course juvenile idiopathic arthritis. 2011*[70] Baseline patient and disease characteristics were similar in both groups. Clinical disease activity (Pediatric ACR30) was equally well controlled in both groups. Growth velocity increased significantly allowing catch-up	Not applicable.

68 https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/103795s5503lbl.pdf

69 https://www.nejm.org/doi/full/10.1056/NEJM200003163421103

70 https://academic.oup.com/rheumatology/article/49/8/1550/1790206?login=false

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	growth in the etanercept + MTX group only. BMD (lumbar spine Z-score) improved significantly in both groups. A significant increase of bone mineral content and lean : fat mass ratio was seen in the etanercept + MTX group, but not in the MTX group.	
ICER	Not applicable.	Not applicable.
NICE	Not applicable.	Not applicable.
CADTH	Not applicable.	Not applicable.
IQWiG	Not applicable.	Not applicable.
INAHTA	*The clinical effectiveness and cost-effectiveness of abatacept, adalimumab, etanercept and tocilizumab for treating juvenile idiopathic arthritis: a systematic review and economic evaluation. 2016*[71] Biologic DMARDs are superior to placebo (with methotrexate where permitted) in children with (predominantly) polyarticular course JIA who have had an insufficient response to previous treatment. Randomised comparisons of biologic DMARDs with long-term efficacy and safety follow-up are needed to establish comparative effectiveness. RCTs for JIA subtypes for which evidence is lacking are also required.	*The clinical effectiveness and cost-effectiveness of abatacept, adalimumab, etanercept and tocilizumab for treating juvenile idiopathic arthritis: a systematic review and economic evaluation. 2016*[72] Four economic evaluations of biologic DMARDs for patients with JIA were identified but all had limitations. Two quality-of-life studies were included, one of which informed the cost-utility model. The incremental cost-effectiveness ratios (ICERs) for adalimumab, etanercept and tocilizumab versus methotrexate were £38,127, £32,526 and £38,656 per quality-adjusted life year (QALY), respectively.

Emerging Evidence, Clinical Effectiveness, and Cost Effectiveness

There may be ongoing or recently completed clinical trials that the Board may want to consider. To identify more recent clinical studies typically not captured in the studies above, information is provided below for completed Phase III or IV studies found on the National Institute of Health's Clinical Trials website. The results column only contains information if there is a published, peer-reviewed study or poster available. For Enbrel, there were no applicable results in the following studies found on ClinicalTrials.Gov:

- Treatment Tapering in JIA With Inactive Disease (AJIBIOREM)[73]

[71] https://database.inahta.org/article/16252

[72] https://database.inahta.org/article/16252

[73] https://clinicaltrials.gov/study/NCT02840175?cond=Polyarticular%20Juvenile%20Rheumatoid%20Arthritis&term=etanercept&rank=2

- Etanercept Plus Methotrexate Alone in Children With Polyarticular Course Juvenile Rheumatoid Arthritis[74]

[74] https://clinicaltrials.gov/study/NCT03781375?cond=Polyarticular%20Juvenile%20Rheumatoid%20Arthritis&term=etanercept&rank=1

Appendix E

Enbrel: Patient Copayment and Other Cost Sharing

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider the patient copayment or other cost sharing that is associated with the prescription drug and typically required pursuant to health benefit plans issued by carriers in the state. (C.R.S. § 10-16-1406(4)(e)).

Rule: The Board will consider the copayment and other cost sharing data, across different health benefit plan designs, to the degree such information is available in the APCD, including copayment, coinsurance, deductible, and/or any other copayment and cost sharing data. (3 CCR 702-9, Part 3.1.E.2.e).

Policy: Information from ACPD data, in aggregate and by payer, for out-of-pocket costs; other data sources that approximate out-of-pocket costs not captured in APCD data; and out-of-pocket analyses will examine up to five years of data and will be consistent across all prescription drugs. (PDAB Policy 04, p. 7).

Underlying Methodology: Board staff have compiled data on patient copayment and other cost sharing for the Board's consideration in the following manner:

1. From APCD pharmacy claims, board staff pulled all claims for Enbrel and relevant insurance coverage information for the patients on those claims for five years from January 2018 - December 2022.
2. Using this claims data and insurance plan information, reviewed out-of-pocket amounts by deductible, copay, and coinsurance.
3. Using this claims data and insurance plan information, reviewed the out-of-pocket cost amounts by payer type (commercial, Medicare Advantage, or Medicaid) and plan type (high deductible plans or not)
4. Using information from the Colorado Division of Insurance (DOI), summarized DOI-regulated plans rate filings relevant to Enbrel.

Data Source(s): Board staff compiled information on patient copayment and other cost sharing for the selected prescription drug from the following sources:

- APCD for patient out-of-pocket cost amounts from January 2018 - December 2022,
- Publicly available information on manufacturer assistance programs, and
- Colorado Division of Insurance (DOI) rate filing information for Colorado health benefit plans, which aggregates data including from plans and benefits and prescription drug templates.

Considerations and Data Limitations: Variation in commercial out-of-pocket costs might reflect different plan designs more than differing costs of the drug, which could impact certain patient's affordable access to the selected drug. Additionally, publicly available manufacturing assistance program information is limited.

APCD data limitations include, in regards to out-of-pocket spending, claims data includes the amount the patient was charged, it does not include how the patient paid for their portion of the drug. Data sources do not contain information on patients' use of an assistance program.

Enbrel: Patient Copayment and Other Cost Sharing Evidence

Background

Patients typically pay for covered prescription drugs in three different ways, all of which are considered patient out-of-pocket (OOP) payment types:

- Copayment: a fixed amount paid for a covered health care service.
- Coinsurance: a percentage of costs paid for a covered health care service.
- Deductible: a total amount paid for covered health care services by a patient, after which insurance pays for the majority of remaining health care services in the remaining plan year.

Health benefit plan design can have a significant impact on both the amount a patient pays for prescription drugs and when in the plan year a patient may pay more for a prescription drug. For example, a patient's cost sharing for prescription drugs might be higher during the beginning of their plan year and then drop significantly after the patient has met their deductible amount.

Health benefit plan designs typically have the most flexibility, and therefore most variability, in the commercially insured market. While there is some variability in plan design for Medicare Advantage and Medicaid, there is very limited variability in patient copayment and cost sharing for patients covered by Medicaid. For the vast majority of patients covered by Health First Colorado (Colorado's Medicaid Program) administered by the Colorado Department of Health Care Policy and Financing, patient prescription drug copayments are between $0-$3 for each prescription drug fill and most individuals with Medicaid coverage do not have deductibles or coinsurance.[1] Since this patient out-of-pocket cost amount is very small relative to individuals with other types of insurance, it has the potential to skew the average Coloradan's out-of-pocket costs much lower than what a typical individual with commercial insurance might pay. As such, Medicaid patient out-of-pocket amounts are removed from estimates of the average out-of-pocket dollar amounts. Medicaid patient out-of-pocket amounts are included in total spend estimates, and Medicaid patients are included in utilization estimates.

Lastly, as previously mentioned, the APCD contains claims data regarding how much a patient was charged for a prescription drug; it does not include information on how the patient paid.If a patient utilized an assistance program that information would not be evident in the APCD. While there is no database that routinely and consistently collects information about patient assistance programs, patients, caregivers, and Enbrel's manufacturer provided some information. See Appendices H and J for more information.

[1] https://www.healthfirstcolorado.com/copay/

Average Patient Payments

Information regarding the average patient payment is provided below in a variety of ways to better understand the different types of patient payments (i.e., copayment vs deductible vs coinsurance) and different amounts over time.

Figure E-1

Changes in Patient Out-of-Pocket Amounts from January 2018 - December 2022

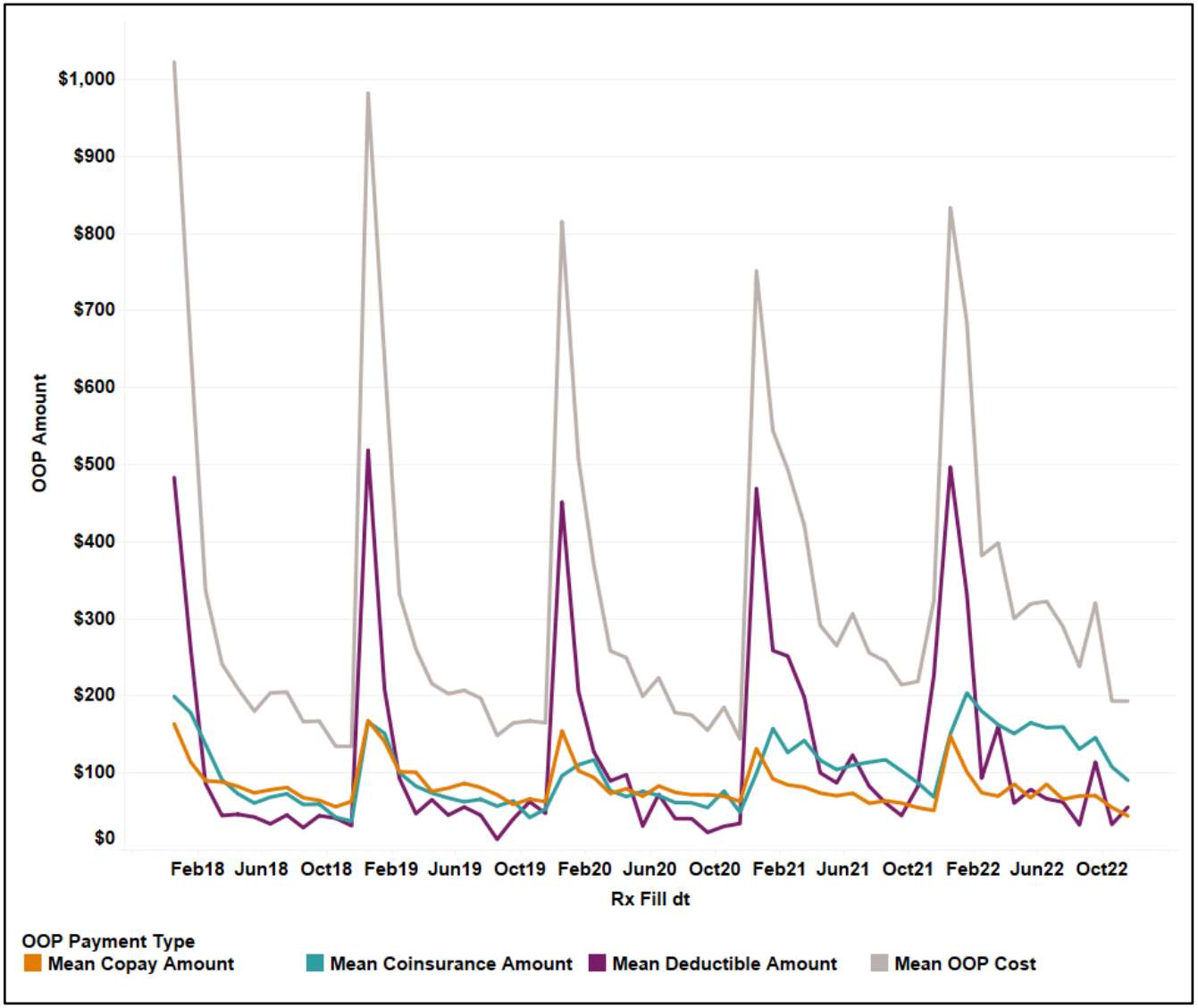


Figure E-1 shows the average out-of-pocket amount for commercially insured patients, where the orange line shows the monthly average copayment amount, the purple line shows the monthly average deductible amount, the teal line shows the monthly average coinsurance amount, and the gray line shows the monthly average total out-of-pocket amount. The deductible has a clear increase at the beginning of each plan year as patients pay more to hit their deductible.

Figure E-2

Average Commercial Out-of-Pocket Cost Comparison

Figure E-2 shows each out-of-pocket cost type for commercially insured individuals with Enbrel in dark purple and identified therapeutic alternatives by year. There is a light gray line that shows the average of identified therapeutic alternatives as a comparison to determine if Enbrel is more or less expensive than the average of identified therapeutic alternatives. For example, the bottom right corner shows the average total out-of-pocket cost in 2022, Enbrel was $3,980, which is higher than the average of the identified therapeutic alternatives, but lower than one of the identified therapeutic alternatives.

Table E-1

Average Annual Totals and Year-Over-Year Changes for Out-of-Pocket Amounts for Commercial Payers from 2018-2022

Drug name	Out of Pocket Cost Type	2018	2019	2020	2021	2022
Enbrel	**Avg Copay**	$639	$713	$791	$777	$823
	Percent Difference		*11.62%*	*10.94%*	*-1.72%*	*5.90%*
	Avg Coinsurance	$667	$642	$715	$1,145	$1,591
	Percent Difference		*-3.81%*	*11.39%*	*60.18%*	*38.89%*
	Avg Deductible	$523	$653	$896	$1,539	$1,226
	Percent Difference		*24.93%*	*37.14%*	*71.70%*	*-20.29%*
	Avg Total OOP Cost	$2,238	$2,413	$2,790	$3,763	$3,980
	Percent Difference		*7.79%*	*15.66%*	*34.87%*	*5.77%*
Cimzia	**Avg Copay**	$421	$402	$389	$519	$615
	Percent Difference		*-4.50%*	*-3.20%*	*33.46%*	*18.48%*
	Avg Coinsurance	$326	$659	$960	$1,212	$1,222
	Percent Difference		*102.32%*	*45.55%*	*26.27%*	*0.82%*
	Avg Deductible	$816	$904	$1,186	$1,920	$1,614
	Percent Difference		*10.84%*	*31.20%*	*61.86%*	*-15.96%*

Drug name	Out of Pocket Cost Type	2018	2019	2020	2021	2022
	Avg Total OOP Cost	$1,604	$2,045	$2,655	$3,721	$3,576
	Percent Difference		*27.44%*	*29.86%*	*40.14%*	*-3.89%*
Humira	**Avg Copay**	$691	$662	$727	$732	$687
	Percent Difference		*-4.12%*	*9.70%*	*0.67%*	*-6.12%*
	Avg Coinsurance	$445	$543	$846	$1,205	$2,100
	Percent Difference		*22.11%*	*55.78%*	*42.45%*	*74.22%*
	Avg Deductible	$791	$811	$1,364	$2,040	$1,661
	Percent Difference		*2.56%*	*68.13%*	*49.56%*	*-18.59%*
	Avg Total OOP Cost	$1,927	$2,017	$2,937	$3,977	$4,447
	Percent Difference		*4.68%*	*45.61%*	*35.41%*	*11.83%*
Remicade	**Avg Copay**	$79	$78	$58	$94	$128
	Percent Difference		*-1.62%*	*-24.76%*	*60.83%*	*36.00%*
	Avg Coinsurance	$1,400	$1,148	$1,322	$851	$762
	Percent Difference		*-17.99%*	*15.13%*	*-35.62%*	*-10.44%*
	Avg Deductible	$46	$35	$60	$80	$120
	Percent Difference		*-24.16%*	*73.68%*	*32.50%*	*51.15%*
	Avg Total OOP Cost	$2,647	$2,313	$2,775	$2,130	$1,976
	Percent Difference		*-12.62%*	*19.96%*	*-23.24%*	*-7.21%*

Drug name	Out of Pocket Cost Type	2018	2019	2020	2021	2022
Simponi	**Avg Copay**	$306	$355	$512	$479	$481
	Percent Difference		*16.12%*	*44.16%*	*-6.42%*	*0.27%*
	Avg Coinsurance	$774	$695	$999	$1,212	$1,064
	Percent Difference		*-10.31%*	*43.88%*	*21.22%*	*-12.18%*
	Avg Deductible	$902	$756	$884	$1,644	$854
	Percent Difference		*-16.15%*	*16.92%*	*86.03%*	*-48.05%*
	Avg Total OOP Cost	$2,146	$2,065	$2,644	$3,564	$2,722
	Percent Difference		*-3.73%*	*28.01%*	*34.80%*	*-23.63%*

Table E-1 shows the average annual coinsurance, copayment, deductible, and total out-of-pocket amounts for Enbrel and identified therapeutic alternatives, as well as the year-over-year percent change across all commercial payers from January 2018 though December 2022. Enbrel, Cimzia, and Humira had consistent increases in total OOP cost, while Remicade and Simponi had some decreases. This is further illustrated in Figure E-3 below.

Figure E-3
Changes in Copay Amounts by Year and Drug 2018-2022

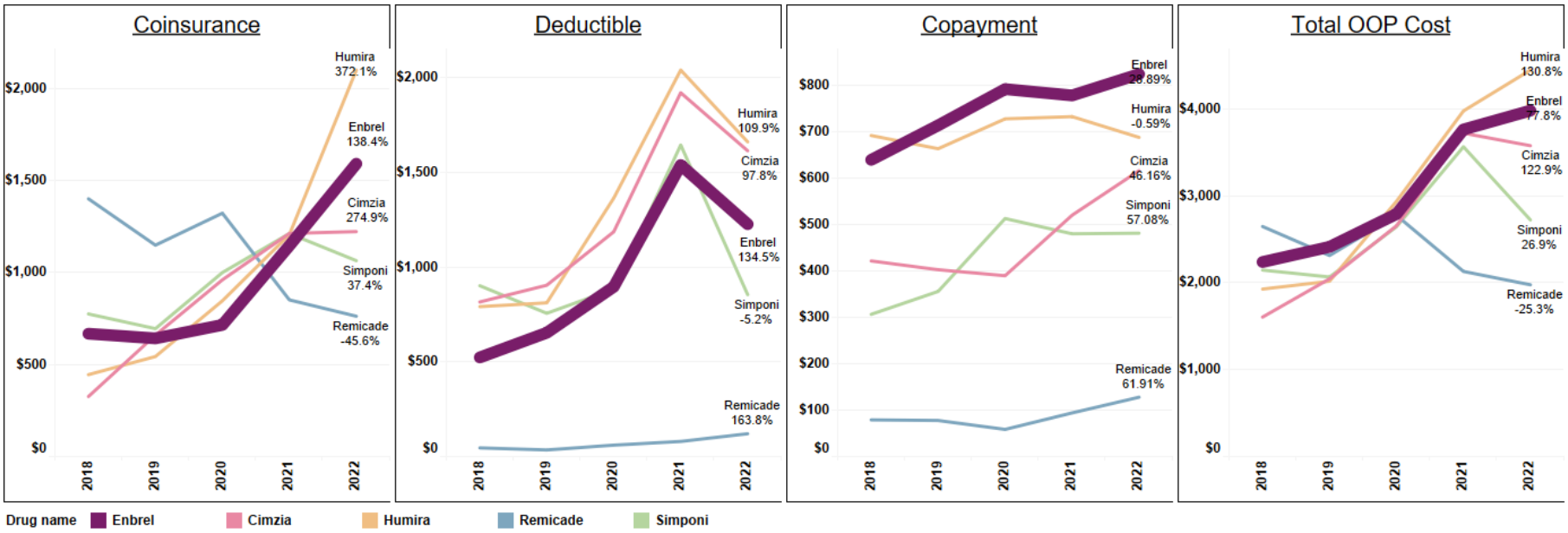


Figure E-3 shows the annual change in the annual average oop amounts comparing Enbrel (dark purple) to identified therapeutic alternatives. Each line is labeled with the name of the identified therapeutic alternative and the percent change from January 2018 to December 2022. Enbrel had the third highest increase in total out-of-pocket costs with a 77.8% increase.

Table E-2
Average Monthly Commercial Out-of-Pocket Cost Information in 2022

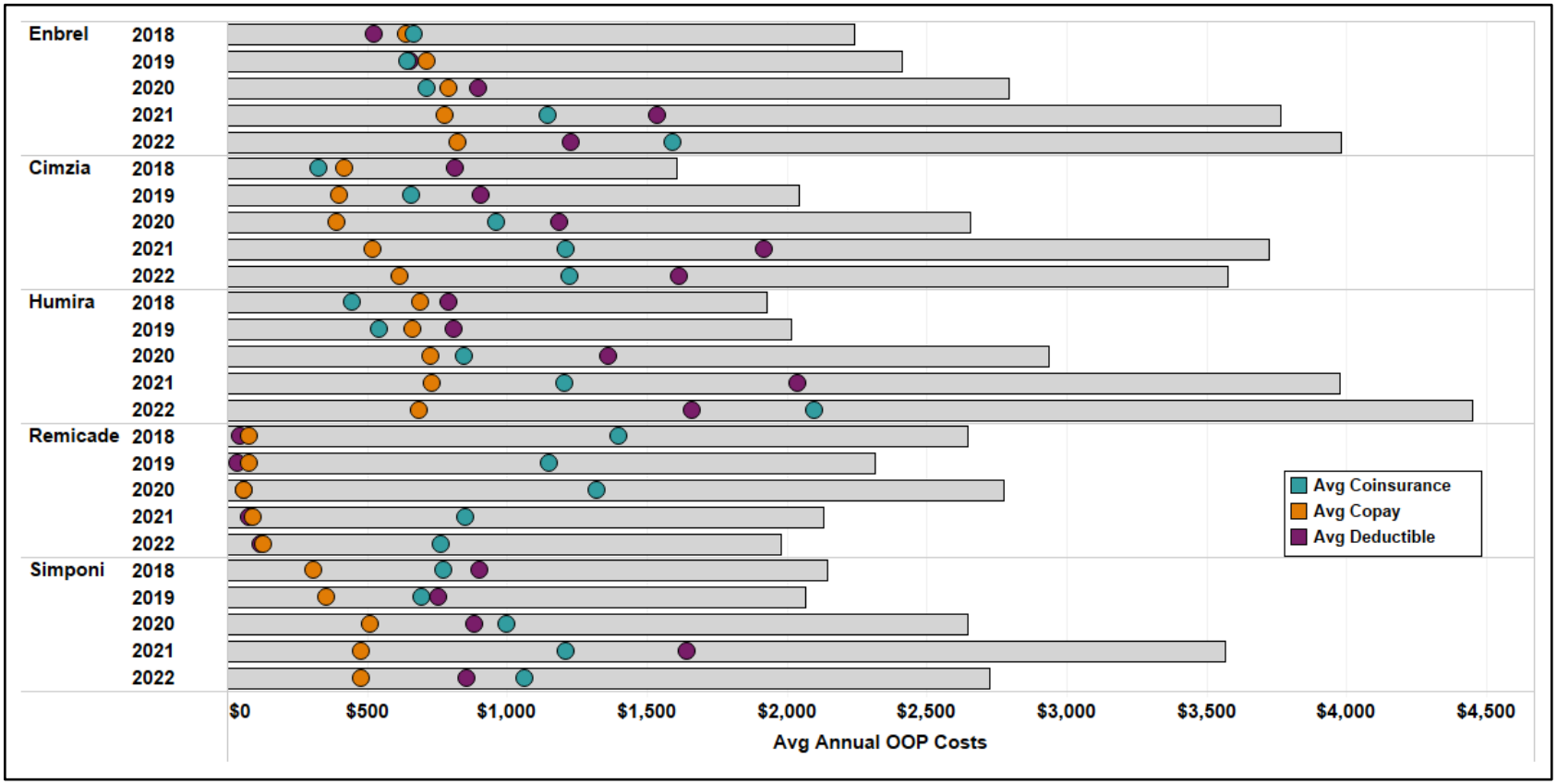
	Enbrel	Cimzia	Humira	Remicade	Simponi
Average Total OOP Cost	**$373**	$305	$356	$303	$263
Average Coinsurance Amount	**$151**	$103	$171	$124	$105
Average Copay Amount	**$78**	$53	$56	$21	$48

Average Deductible Amount	**$132**	$146	$129	$125	$98
Average Days Supply	**34.3**	31.5	32.4	45.5	35.6

Table E-2 shows that in 2022, in an average month an individual with commercial insurance paid a total of $373, $132 went towards a patient's deductible, $151 was paid towards coinsurance, and $78 was paid via copayment. These payments were for an average of 34.3 days. Enbrel is higher than Cimzia, Remicade, and Simponi in all out-of-pocket payments and is lower than Humira in all out-of-pocket payments except the average copay, where it is the highest of all drugs presented.

Figure E-4

Average Total Out-of-Pocket Cost and by Cost Sharing Type from 2018-2022



In Figure E-4, the gray bar displays the annual total out-of-pocket cost and out-of-pocket amounts are displayed as circles, with copayment in amounts in orange, coinsurance amounts as teal, and deductibles amounts as purple. This graphic shows an annual increase in total out of pocket costs for Enbrel with large increases in coinsurance and deductible amounts. These increases are similar to those seen with Cimzia and Humira though Remicade and Simponi show more variation from year to year.

Figure E-5

Patient Out-of-Pocket Payment as a Percentage of Plan Payment from 2018 - 2022

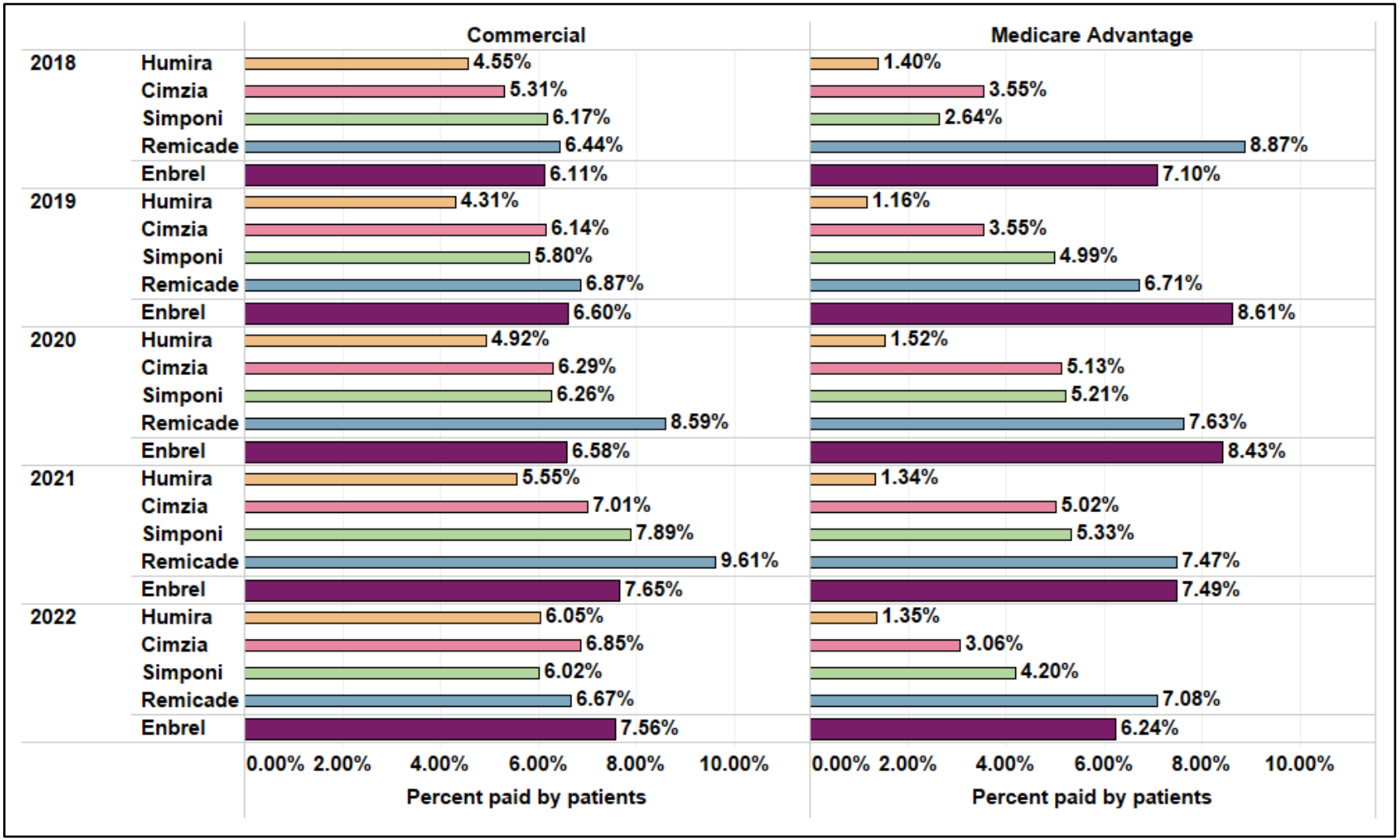


Figure E-5 provides context for what patients paid, as compared to their insurance plan, for Enbrel or its identified therapeutic alternatives from 2018 through 2022. In 2022, commercial patients paid for 7.56% of the total paid for Enbrel, a higher portion than any of identified

therapeutic alternatives. Whereas patients with Medicare Advantage coverage paid for 6.24% of the total paid amount for Enbrel, higher than three of the therapeutic alternatives, but lower than Remicade.

Figure E-6
Total Out-of-Pocket Cost Histogram for Enbrel and Therapeutic Alternatives for 2022

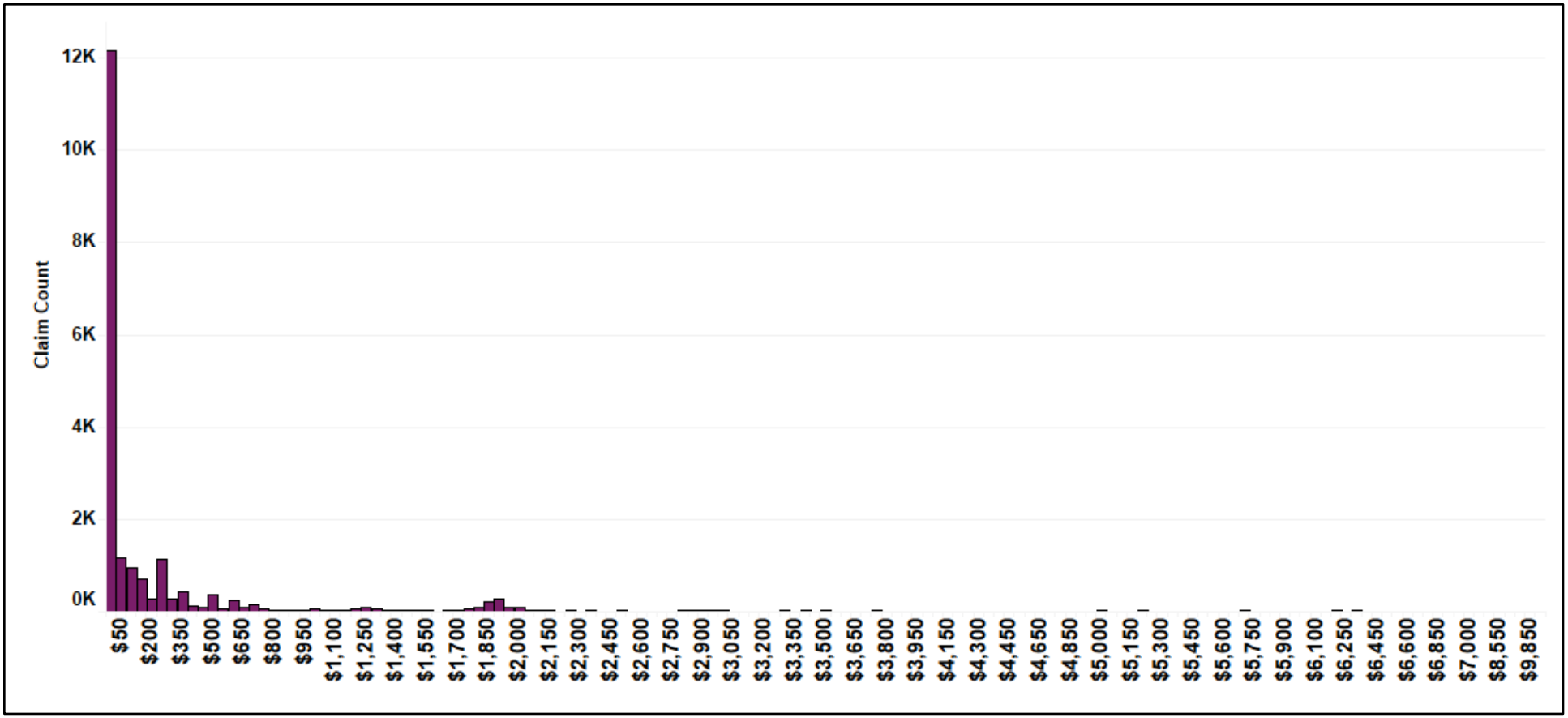


Figure E-6 shows a histogram of annual total out-of-pocket costs for individuals with commercial insurance in 2022 for utilizers of Enbrel. It shows the variation of the total out-of-pocket costs, where 57.3% of Enbrel utilizers paid between $0-$50, though some individuals paid as much as $9,850- $9,900.

Health Benefit Plan Design

A patient's insurance benefit design impacts how much of the health care service cost a patient is responsible for paying. In high deductible health plans (HDHP), a patient or family has a higher deductible that must be met before the insurance company will contribute to claims. When reviewing patient out-of-pocket costs on claims, differentiating between a high deductible benefit plan and a different benefit plan provide some indication of why a patient's out-of-pocket cost was different at different prescription fill points throughout the benefit year. For some individuals on a high deductible plan, they may share in more of the total costs of the drug due to the higher deductible. Below is a table

outlining what portion of the patients using Enbrel on commercial health plans were enrolled in high deductible health plans. In 2021 and 2022, fewer than 6% of patients using Enbrel were enrolled in a high deductible health plan, which means that the out-of-pocket costs presented in this report do incorporate deductibles, but are not necessarily skewed by a large portion of patients on HDHPs.

Table E-3

Percent of patients on HDHP 2018 - 2022

Drug name	2018	2019	2020	2021	2022
Enbrel	9.32%	9.26%	6.33%	4.86%	6.59%
Cimzia	8.37%	7.00%	5.80%	6.09%	7.42%
Humira	7.67%	7.11%	5.51%	4.79%	5.79%
Remicade	5.99%	7.22%	6.58%	7.60%	11.55%
Simponi	7.11%	7.01%	6.69%	5.23%	4.64%

Table E-3 shows the percent of patients on high deductible health plans in the APCD for Enbrel and identified therapeutic alternatives from 2018 to 2022.

Colorado Division of Insurance Regulated Plans Rate Filing Analysis

As part of its rate review processes and enforcement of Regulation 4-2-58, the Colorado Division of Insurance (DOI) receives filings from carriers in the individual and small group markets.[2] Rate filings are filed on an annual basis for compliance reviews by DOI. The following information was pulled by DOI staff for the affordability review and does not describe the entire market in Colorado, but can shed valuable information on benefit plan design and out-of-pocket costs.

Of the ten carriers that submitted filings, eight carriers cover four or more dosage formulas of Enbrel. All Carriers that cover Enbrel require Prior Authorization. In total, 576 Plans provide coverage for Enbrel. In general, the majority of carriers place Enbrel on the highest two tiers, meaning a higher portion of the drug is paid by patients than drugs on lower tiers until the maximum out-of-pocket amount under the plan is paid by the insured.

[2] Regulation 4-2-58: https://drive.google.com/file/d/1_1iwkGf_vI_jxMeUKOmuYVKfc79WtS-K/view

In order to summarize the cost sharing attributes of DOI-regulated plans, they are split into three parts:

- Percent Coinsurance after deductible: the amount of money that a consumer pays for each claim submitted
- Copayment after deductible: the copayment associated with each visit or prescription fill once the deductible is met, and
- Copayment only.

Some of the plans that apply the copayment may apply the deductible, whereas the coinsurance plans always apply the deductible.

Table E-4

DOI-Regulated plans Enbrel Out-of-Pocket Costs Overview

	Total Number of Plans	Minimum	Maximum	Average	Mode
% Coinsurance after Deductible	188	0.00%	50.00%	27.57%	50.00%
Copayment after Deductible	93	$0.00	$150.00	$121.13	$125.00
Copayment	295	$110.00	$775.00	$286.97	$125.00
Total Plans	**576**				

Table E-4 shows a summary of different types of cost sharing and their applicable ranges for DOI regulated plans for Enbrel. The data included in this summary was taken from the Master Review Tool.[3] This tool is distributed through CMS and gathers information from the plans data submitted to the Division through SERFF for the Plan Year 2024.[4]

Patients survey responses showed 27 of 38 Colorado patients reported that cost has affected their access. See Appendix H for more information.

Input from Patient and Caregivers

Table E-5

Colorado Patients' Self-Reported Out-of-Pocket Cost and Access Due to Cost

Out-of-Pocket Cost per Month	Colorado Response	Cost Affects Access
$0 - $50	19 of 38	10 of 19
$50 - 100	4 of 38	2 of 4
$100 - $150	1 of 38	1 of 1
$150 - $250	2 of 38	2 of 2

[3] https://www.qhpcertification.cms.gov/s/Review%20Tools

[4] The information was collected and organized through Excel to calculate the minimum, maximum, average, and mode. The minimum, maximum, average, and mode were calculated.

$250 - $500	1 of 38	1 of 1
$500 - $1000	6 of 38	6 of 6
More than $1000 per month	5 of 38	5 of 5

Appendix F

Enbrel: Impact on Safety Net Providers

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider the impact on safety net providers if the prescription drug is available through section 340B of the federal "Public Health Service Act", Pub.L. 78-410. (C.R.S. § 10-16-1406(4)(f)).

Rule: When the prescription drug is available through section 340B of the Federal "Public Health Service Act", Pub.L. 78-410, the Board will evaluate:

- The utilization of the prescription drug by the safety net provider's patients;
- Whether the safety net provider receives a 340B discount for the prescription drug;
- Where the safety net provider does not receive a discount, whether access to the prescription drug is impeded; and
- Any other topics identified by safety net provider stakeholders for discussion. (3 CCR 702-9, Part 3.1.E.2.f).

Policy: As part of the Board's obligation to consider the impact of an affordability review of the cost of a prescription drug on safety net providers, Staff will request all safety net providers to voluntarily provide information to the Board. To facilitate gathering the information from safety net providers, Staff may request a list of 340B approved safety net providers from HCPF. (PDAB Policy 04, p. 7).

Underlying Methodology: Board staff compiled data for the Board's consideration in the following manner:

1. Documented information provided during the stakeholder sessions to gather input from individuals with scientific or medical expertise, specifically the portion of those meetings dedicated to safety net providers. Staff attempted to compile information directly related to the information outlined in rule during stakeholder meetings, as well as a survey.
2. Compiled relevant information provided by entities who submitted information voluntarily.

Data Source(s): Board staff compiled information on safety net provider impact from the following sources:

- Input from safety net providers gathered during stakeholder meetings with individuals with scientific or medical expertise, and
- Relevant voluntarily submitted information.

Considerations and Data Limitations: Information provided to the Board by safety net providers may be confidential. Input provided both via stakeholder meetings and surveys is voluntary. Such qualitative data may not capture information from all safety net providers.

Enbrel: Impact on Safety Net Providers Evidence

Background

The 340B Drug Pricing Program is a means for certain hospitals and clinics to stretch scarce federal resources by buying outpatient prescription drugs at a discount (typically 25-50%), while receiving typical reimbursement from payers. This is intended to allow safety net providers to stretch their financial resources to reach more financially vulnerable patients and deliver comprehensive services.

Eligible health care organizations (called covered entities) are defined in statute and include HRSA-supported health centers and look-alikes, Ryan White clinics and State AIDS Drug Assistance programs, Medicare/Medicaid Disproportionate Share Hospitals, children's hospitals, and other safety net providers.[1]

Evidence

HRSA maintains a database of covered entities and contract pharmacies, including the number of unique covered entities and addresses by covered entity type.[2] In Colorado, there are 108 unique active covered entity names, with an associated 536 unique addresses. Additionally, there are approximately 2,974 approved and participating contract pharmacies. Table F-1 provides information on the number of unique address in Colorado designated by covered entity type:

Table F-1
340B Covered Entity Types and Number of Unique Addresses

340B Entity Type	Unique Addresses[3]
Critical Access Hospital (CAH)	68
HRSA-Funded Health Center (CH)	212
Disproportionate Share Hospital (DSH)	160
Family Planning - Title X (FP)	38
Tribal Contract/Compact with HIS (FQHC638)	1
Health Center Program Look-Alike (FQHCLA)	1
Comprehensive Hemophilia Treatment Center (HM)	1
Ryan White Part C (HV)	1
Children's Hospital (PED)	21
Rural Referral Center (RRC)	6
Ryan White Part A (RWI)	2
Ryan White Part B (RWII)	6

[1] https://www.hrsa.gov/opa
[2] https://340bopais.hrsa.gov/SearchLanding
[3] Table F-1 sums to more than 536 because several covered entities have the same unique name and address but are designated as multiple 340B covered entity types.

340B Entity Type	Unique Addresses[3]
Ryan White Part B ADAP Direct Purchase (RWIID)	1
Ryan White Part B ADAP Rebate Option (RWIIR)	1
Sole Community Hospital (SCH)	6
Sexually Transmitted Diseases (STD)	39
Tuberculosis (TB)	2
Urban Indian Health Center (UI)	1

Due to the differences in the form and manner in which information is submitted to HRSA and the Colorado All Payer Claims Database (APCD), Board staff did not analyze how many of these covered entities dispense Enbrel.

In accordance with HHS 340B Drug Pricing Program Ceiling Price, prescription drug manufacturers are only allowed to charge $0.01 for a prescription drug when its quarterly 340B ceiling price calculation results in an amount less than a penny. This "penny pricing" occurs when a manufacturer raises the price of a drug substantially more quickly than the rate of inflation.[4] While Figure 8 (also Figure A-2) does not display the rate of inflation, the fact that Enbrel's wholesale acquisition cost (WAC) has risen significantly higher than inflation since its launch, suggests that Enbrel may be, at times, subject to the 340B "penny pricing" policy.

Board staff and HCPF discussed that there was no readily available list or email listserv of 340B covered entities maintained by HCPF that could be used to facilitate Board staff outreach.

There is additional information contained in Appendix I and Appendix J which may contain additional information on impact to safety net providers not captured in this appendix. The Board may want to weigh information from all three appendices when evaluating the impact to safety net providers.

[4] https://www.govinfo.gov/content/pkg/FR-2017-01-05/pdf/2016-31935.pdf

Appendix G

Enbrel: Orphan Drug Status

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider orphan drug status. (C.R.S. § 10-16-1406(4)(g)).

Rule: The Board will identify whether the prescription drug is an orphan drug, as designated by the FDA pursuant to the Orphan Drug Act (Pub.L. 97-414).

The Board may further consider:

- The use of the prescription drug for indications with an orphan drug designation as compared to the use of the prescription drug for other indications; and/or
- The extent to which the drug addresses an unmet need or treats a rare or serious disease for which limited therapeutic alternatives are available. (3 CCR 702-9, Part 3.1.E.2.g).

Policy: The Board will compile evidence and information regarding the prescription drug's orphan drug status as designated by the FDA pursuant to the Orphan Drug Act (Pub.L. 97-414), including:

- Reviewing the Orphan Drug List for the quarter during which the affordability review begins.
- Designation date of the prescription drug on the orphan drug list.
- Treatment designation of the prescription drug on the orphan drug list as an indicator of the population the orphan drug serves.
- Reviews of literature and patient, caregiver, and clinical expertise to understand the extent to which the prescription drug addresses an unmet need or treats a rare or serious disease for which limited therapeutic alternatives are available (PDAB Policy 04, p. 7).

Underlying Methodology: Board staff compiled data regarding orphan drug status for the Board's consideration in the following manner:

- Analyzed listed indications for the selected drug, and using the FDA website, identified if any of the selected drugs treat active orphan drug indications.
- To identify if the drug meets an unmet need or treats a rare condition, Board staff reviewed information received from patient/caregiver and scientific medical training public input sessions and surveys.

Data Source(s): Board staff obtained information regarding the selected drug's orphan drug status from the following sources:

- FDA website, which contains information on current FDA labeling for each drug, FDA-approved indication, and orphan drug status,
- Results from public input sessions and surveys from patients and caregivers and individuals with scientific or medical training, and
- Relevant voluntarily submitted information.

Considerations and Data Limitations: Orphan drug designations are related to the condition or indication being treated. There may be prescription drugs that treat multiple indications, but not all of those indications may be a rare disease. Data limitations that apply broadly to APCD data may apply here.

Enbrel: Orphan Drug Status Evidence

Background

The Orphan Drug Act, passed by Congress in 1983, incentivizes the development of drugs to treat rare diseases. A rare disease is defined as a disease or condition that affects less than 200,000 people in the United States.[1] The FDA does not maintain an exhaustive list of rare diseases, but rather, prescription drug manufacturers submit disease prevalence estimates and other documentation to the FDA in a request for orphan drug designation, which the FDA then assesses.[2]

An orphan drug is defined in the United States as one used for the treatment of a disease or condition affecting fewer than 200,000 people. The FDA has authority to grant orphan drug designation to a drug or biological product to prevent, diagnose or treat a rare disease or condition. Companies and other drug developers can request orphan drug designation and FDA will grant such designation if the drug meets specific criteria. While an orphan drug can be designated prior to the FDA approving the drug, it is not a guarantee that the drug will be approved for orphan drug status. Orphan drug designation provides incentives such as tax credits, fee exemptions, and a potential seven years of market exclusivity after approval.[3]

Orphan Drug Status

Table G-1
Enbrel Orphan Drug and Rare Disease Status

Indication	Orphan Drug Status	Rare Disease
Reduction in signs and symptoms of moderately to severely active **polyarticular-course juvenile rheumatoid arthritis** in patients who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs.	Designated/Approved 10/27/1998	Yes

Table G-1 shows Enbrel's FDA approved orphan drug status[4] and rare disease status.

Polyarticular juvenile idiopathic arthritis (pJIA) was formerly called polyarticular-onset juvenile rheumatoid arthritis[5] and is a subset of juvenile idiopathic arthritis (JIA) and is included in the group termed "childhood polyarthritis.[6] Two subgroups of the disease can be distinguished, based on the presence or absence of rheumatoid factor.[7] Polyarticular juvenile idiopathic arthritis comprises 20 to 30 percent of the approximately 300,000 children and adolescents in the US that live with JIA.[8][9]

[1] https://www.fda.gov/patients/rare-diseases-fda
[2] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-316/subpart-C/section-316.21
[3] https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/designating-orphan-product-drugs-and-biological-products
[4] https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=116198
[5] https://www.uptodate.com/contents/polyarticular-juvenile-idiopathic-arthritis-treatment
[6] https://www.uptodate.com/contents/polyarticular-juvenile-idiopathic-arthritis-clinical-manifestations-diagnosis-and-complications
[7] https://www.orpha.net/consor/cgi-bin/OC_Exp.php?lng=EN&Expert=404580
[8] https://www.uptodate.com/contents/polyarticular-juvenile-idiopathic-arthritis-treatment/print#:~:text=In%20the%20revised%20nomenclature%2C%20this,of%20juvenile%20idiopathic%20arthritis%22
[9] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3970916/

Table G-2
Enbrel Orphan Drug Designations and Approvals

Generic Name	etanercept
Trade Name	Enbrel
Date Designated	10/27/1998
Orphan Designation	Reduction in signs and symptoms of moderately to severely active polyarticular-course juvenile rheumatoid arthritis in patients who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs.
Orphan Designation Status	Designated/Approved
First Marketing Approval Date	05/27/1999
Approved Labeled Indication	Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients ages 2 and older.

Table G-2 shows Enbrel's orphan drug designations and approvals.[4]

Utilization data was not pulled for Enbrel and identified therapeutic alternatives for the specific indication of polyarticular JIA because diagnoses are not listed on pharmacy claims (see Appendix P for more information). Board staff did hear from patients, caregivers, and individuals with scientific and medical training that Enbrel meets an unmet need for polyarticular JIA, though some stakeholders provided input that access to a variety of medications, including Enbrel and identified therapeutic alternatives is important. See Appendices H, I, and J for more information.

Appendix H

Enbrel: Input from Patients and Caregivers

Affordability Review Statute, Rule, and Policy

Statute: The Board shall consider input from patients and caregivers affected by the condition or disease that is treated by the prescription drug that is under review by the Board (C.R.S. § 10-16-1406(4)(h)(I)).

Rule: The Board will seek input from patients and caregivers affected by a condition or disease that is treated by the prescription drug by gathering information related to:

- The impact of the disease,
- Patient treatment preferences,
- Patient perspective on the benefits and disadvantages of using the prescription drug,
- Caregiver perspective on the benefits and disadvantages of using the prescription drug, and/or
- Available patient assistance in purchasing the prescription drug.

In seeking additional information, the Board will attempt to gather a diversity of experience among patients from different socioeconomic backgrounds (3 CCR 702-9, Part 3.1.E.2.h.i).

Policy: Staff will gather input from patients and caregivers through outreach and holding a public meeting(s).

- Patients and caregivers may continue to provide input via verbal public comment and written public comment.
- During the following Board meeting(s), staff will present input provided by patients and caregivers and will report such information in their final report (PDAB Policy 04, p. 8).

Underlying Methodology: Board staff compiled information from patients and caregivers for the Board's consideration in the following manner:

1. Documented information provided during public input sessions to gather input from patients and caregivers being treated with Enbrel. Staff attempted to compile information directly related to the information outlined in rule during stakeholder meetings and from a publically-available online survey.
2. After the survey deadline and public input sessions concluded, Board staff aggregated responses, identified high-level themes, and compiled findings for the Board.

Data Source(s): Board staff compiled input from patients and caregivers for selected prescription drugs from the following sources:

- Results from public input sessions and surveys completed by patients and caregivers.

Considerations and Data Limitations: Input provided both via stakeholder meetings and surveys is voluntary. Such qualitative data may not capture information from all patients and caregivers.

Enbrel: Input from Patients and Caregivers Evidence

Background

Board staff gathered input from patients and caregivers in two ways: meetings and surveys. Input was gathered from 3 patients and caregivers at public meetings on September 19, 2023. These meetings were structured to be a focus-group style meeting to gather information on the health and financial effects of

Enbrel, and largely followed the survey questions. In addition to input gathered through public meetings, 279 patients and caregivers completed surveys regarding the health and financial effects of Enbrel.

At the initial time of survey release, the Board received 12 responses from patients and caregivers, 11 of whom are Colorado residents. At the December 15th PDAB meeting, Board members requested more information from patients and voted to reopen the surveys until January 21, 2024. After reopening, the Board received a total of 267 responses from Enbrel patients from across the United States, 38 of whom are Colorado residents.

To qualify to participate in patient and caregiver stakeholder meetings or surveys, respondents had to have been prescribed the prescription drug under review or be caregiver for an individual prescribed the drug under review. Outreach was conducted via the public listserv and website, as well as communicating with patient advocacy organizations who reached out to their patient and caregiver populations. Board staff attempted to gather a diversity of patient experiences by holding meetings in the evenings and conducting outreach to multiple consumer organizations.

Input summaries are presented below in a manner similar to how meetings and the survey were conducted: patient information, health effects of Enbrel, and financial effects of Enbrel. Specifically, staff collected information in a manner that encompassed the categories required by Board rule, including the impact of the disease, patient treatment preferences, patient perspective on the benefits and disadvantages of using the prescription drug, caregiver perspective on the benefits and disadvantages of using the prescription drug, and/or available patient assistance in purchasing the prescription drug. This appendix also contains links to the two public meetings audio recordings, the survey, and survey results.

There is additional information contained in Appendix J which may contain additional input from patients and caregivers not captured in this appendix. The Board may want to weigh information from both appendices when evaluating input from patients and caregivers.

Patient Profile

The Board received a total of 267 responses from Enbrel patients from across the United States, 38 of whom are Colorado residents.[1] Three patients attended public input sessions for Enbrel, and one of the three patients also filled out a survey. Themes from survey responses and public input sessions are summarized below.

Oftentimes individuals with autoimmune disorders present with more than one diagnosis. Many survey respondents selected multiple conditions for which they were being treated by Enbrel.

- Of the 267 total respondents, 184 were being treated for rheumatoid arthritis, 56 were being treated for psoriatic arthritis, 19 were being treated for psoriasis, 8 were being treated for juvenile idiopathic arthritis, and 14 were being treated for ankylosing spondylitis.
- Of the 38 Colorado specific respondents, 25 were being treated for rheumatoid arthritis, 8 were being treated for psoriatic arthritis, 2 were being treated for psoriasis, 3 were being treated for juvenile idiopathic arthritis, and 1 was being treated for ankylosing spondylitis.
- Of the three patients who attended the public input session, two were being treated for rheumatoid arthritis, and one patient was being treated for ankylosing spondylitis.

Complete survey results are contained at the bottom of this appendix. This appendix highlights both national trends and Colorado-specific trends for the Board's consideration.

The 38 Colorado specific respondents were insured via:

- Individual/ACA Marketplace: 6

[1] The survey was also completed by a computer who submitted approximately 30,000 identical responses. These responses were identified by staff during the survey review and removed from the data in this report.

- Employer: 14
- Kaiser/Peracare: 1
- Medicaid/Health 1st: 3
- Medicare: 16

The 38 Colorado specific respondents identified as one or more of the following priority populations:

- Children and families: 8
- Older Adults: 15
- People with Disabilities: 18
- People of disproportionately affected sexual orientation, gender, identity, or sex assigned at birth: 1
- People who are lesbian, gay, bisexual, transgender, queer, or questioning: 6

Board staff reviewed survey results and meeting recording transcripts to identify common themes about patient and caregiver experience. The word cloud below was created as a visual representation of the shared experiences of many patients prescribed Enbrel. The greater the number of patients and caregivers who shared an experience is correlated with the size of the word or phrase in the following word cloud. Patients and caregivers with one or more of the following conditions (rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and juvenile idiopathic arthritis) stated that their conditions affect their daily lives in the following ways:

Figure H-1
Word Cloud: Patient Experience

Figure H-1 shows a word cloud of common patient experiences heard in public meetings and surveys. Patients being treated for psoriasis reported itchy inflamed skin, sores and plaques and skin cancer as a result of previous treatment.

Patients at public input sessions were able to provide more detail about their conditions. They stressed the physical and emotional toll that the unpredictability of their condition has on them, and the immense fatigue that accompanies the condition. Patients also discussed the difficulty of living with an invisible disease and how each condition presents uniquely in each individual patient. In addition to physical symptoms, patients all agreed that navigating the logistics of their condition, their care team, medications, and insurance felt like a full time job.

- *"My main health outcome is to slow the progression and to possibly have long periods of remission."* Survey respondent.
- *"I want to be able to have something that resembles a normal life." Public input session attendee.*

Patients and caregivers were also asked about the health outcomes that are most important to them when being treated for their conditions. Patients and caregivers with one or more of the following conditions (rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and juvenile idiopathic arthritis) stated that

the health outcomes that were most important to them are reduction in pain, discomfort, and inflammation, fewer flares, and management of chronic pain and fatigue to improve their quality of life. Patients being treated for psoriasis indicated that the health outcomes that were most important to them were reduced inflammation, scalp irritation, and reduction in plaques.

Health Effects of Enbrel

When it came to the health effects of Enbrel, patients and caregivers provided a significant amount of input. Some of the more common themes are outlined below. More detailed information regarding each of the themes is found in meeting recordings and survey results.

- *"This drug has given me my life back. My flares are farther apart and Enbrel has allowed me to live my own life with few modifications and compromises"* Survey respondent with rheumatoid arthritis.
- *"We cycle through these drugs because sometimes they lose effectiveness or we just build up an immunity to them. That happened with Enbrel, but it was a glorious remission when I had it."* Public input session attendee.

Common themes regarding the health effects of Enbrel included:

- Enbrel has reduced pain and symptoms in the majority of patients of all indications, though some rheumatoid arthritis and psoriatic arthritis patients reported no improvements. Other patients stated that Enbrel worked well until it lost its effectiveness and they had to cycle to a new medication. One patient at a public input session liked that Enbrel is self-injectable, which cut down on trips to the doctor to get infusions.
- The most common side effect reported for all indications was pain and bruising at the injection site. Less common symptoms were chills, nausea, lowered immune system, depression, and dry mouth leading to dental issues. One patient reported not caring for the delivery method of self-injection.

Therapeutic Alternatives

Of all 267 survey respondents, 176 reported that they cycled through another medication to get to Enbrel. Three of 267 respondents reported not trying another treatment, 27 had tried one other treatment, 42 had tried two other treatments, 35 had tried three other treatments, and 158 had tried three or more treatments.

The experiences of the 38 Colorado patients using other treatments for their conditions is summarized below.

- **Methotrexate:** Some patients said it did not work, others said it reduced inflammation but caused extreme severe side effects leading them to stop taking it. Reported side effects include nausea, blurry vision, severe fatigue and nausea, brain fog, hair loss, sores in mouth, and liver damage.
- **Humira:** Many patients reported it to be ineffective, and others reported that it worked well for a time to reduce inflammation and pain before it lost efficacy. One patient stated that it works better than Enbrel for them. Patients reported similar side effects as Enbrel.
- **Cosentyx:** Patients reported that this works well for them at the moment and report similar side effects to Enbrel.
- **Remicade**: Patients reported that this worked well but then plateaued and stopped working. One patient stated it gave them no relief.
- **Xeljanz**: One patient stated their symptoms worsened and they worried about heart issues linked to the medication. One patient reported side effects of nausea and rash.
- **Rituxan:** Effective but safety data for pregnancy was not available.
- **Cimzia**: Effective and pregnancy safe option. One said getting sick too often.
- **Hydroxychloroquine**: One said works best for them.
- **Taltz**: currently working the best to reduce pain and flares. One said gets sick too often.

- **Plaquenil**: Not strong enough.
- **Diclofenac**: Not safe for long term use.
- **Amitriptyline**: No benefit, lowered seizure threshold leading to my first seizure incident.
- **Gabapentin**: Some pain relief but caused sensory issues.
- **Light treatments for psoriasis:** Resulted in precancerous or cancerous skin.

Other prescriptions patients reported taking include Sulfasalazine, Orencia, Meloxicam, Sulindac, Cymbalta, Stelara, Simponi Aria, Naproxen, meloxicam, Indocin, and Mobic. Patients also reported taking topical and oral steroids, NSAIDs, and muscle relaxants.

- *"I've literally tried them all. I'm kind of old school."* Public input session attendee.

Financial Effects of Enbrel

Patients and caregivers were asked three types of questions related to the financial effects of Enbrel. Some survey questions and meeting discussions focused on better understanding patient out-of-pocket (OOP) costs for Enbrel, while other survey questions and meeting discussions focused on better understanding the relative financial effects of Enbrel on health, medical, or social services costs, and a third type of question aimed to better understand patient experience with utilization management requirements. Information from all types of questions are summarized below.

Patient Out-of-Pocket Cost, Access, and Adherence

There is additional information contained in Appendix E, Appendix J, and Appendix K related to patient costs not captured in this appendix. The Board may want to weigh information in all four appendices when evaluating patient costs.

Patients were asked about their monthly out-of-pocket cost for Enbrel and if the cost of Enbrel has ever affected their access. 122 of 267 national patients and 27 of 38 Colorado patients reported that cost has affected their access.

Table 1
National Patients' Self-Reported Out-of-Pocket Cost and Access Due to Cost

Out-of-Pocket Cost per Month	National Response[2]	Cost Affects Access
$0 - $50	174 of 267	51 of 174
$50 - 100	29 of 267	18 of 29
$100 - $150	8 of 267	5 of 8[3]
$150 - $250	9 of 267	8 of 9
$250 - $500	14 of 267	9 of 14
$500 - $1000	19 of 267	19 of 19
More than $1000 per month	12 of 267	12 of 12

Table 1 shows the number of national patients who self-reported their monthly out-of-pocket costs and the number of patients within each cost bracket who reported that cost affected their access.

[2] 2 out of 267 national survey participants did not answer regarding their out-of-pocket cost per month for Enbrel.

[3] 1 national survey participant whose out-of-pocket cost per month equaled $100-$150 did not respond regarding if cost affected their access to Enbrel.

Table 2
Colorado Patients' Self-Reported Out-of-Pocket Cost and Access Due to Cost

Out-of-Pocket Cost per Month	Colorado Response	Cost Affects Access
$0 - $50	19 of 38	10 of 19
$50 - 100	4 of 38	2 of 4
$100 - $150	1 of 38	1 of 1
$150 - $250	2 of 38	2 of 2
$250 - $500	1 of 38	1 of 1
$500 - $1000	6 of 38	6 of 6
More than $1000 per month	5 of 38	5 of 5

Table 2 shows the number of Colorado patients who self-reported their monthly out-of-pocket costs and the number of patients within each cost bracket who reported that cost affected their access.

Table 3
Survey Response: How does Enbrel impact each patient or their family?[4]

Survey Prompt	National Responses	Colorado Responses
This medication reduces the amount of time and money going to the doctor.	110 of 267	14 of 38
This medication reduces the amount of time and money spent going to the hospital or needing surgery.	63 of 267	9 of 38
This medication allows me to work and support my family.	110 of 267	15 of 38
Due to the cost of this medication, I have had to cut costs in other areas of my life.	74 of 267	20 of 38
Out-of-pocket costs have caused me to accrue medical debt.	36 of 267	8 of 38

Table 3 shows both national and Colorado patient responses to a survey question asking how Enbrel impacts each patient and their family.

[4] 45 out of 267 national survey participants did not answer regarding the impact Enbrel has on the patient or their family. 3 out of 38 Colorado survey participants did not answer regarding the impact Enbrel has on the patient or their family.

Table 4
Survey Responses: Has the cost of Enbrel ever affected your adherence to it?[5]

Survey Prompt	National Responses	Colorado Responses
I have skipped doses of the drug in order to save money	44 of 267	9 of 38
I have reduced the dose of the drug in order to save money.	9 of 267	0 of 38
I have stretched time between doses of the drug in order to save money.	52 of 267	9 of 38
I have changed prescription drugs to treat my condition due to cost.	53 of 267	10 of 38

Table 3 shows both national and Colorado patient responses to a survey question asking if the cost of Enbrel has ever affected adherence.

Assistance Programs

Patients were asked if they use copay assistance programs, discount cards, or savings provided by prescription drug manufacturers or non-profit organizations to help with out-of-pocket costs. Of 267 national patients, 49 did not use manufacturer assistance programs. 216 of 267 patients reporting using patient assistance, and 61 still had trouble affording Enbrel despite assistance.

Of the 38 Colorado respondents, four patients did not use assistance programs, and one did not answer. Of the 33 of 38 Colorado patients who use assistance programs, 10 patients still had trouble affording Enbrel despite assistance.

Patients at public input sessions stated that assistance programs were not difficult to find, but that it was nearly impossible to understand how insurance would be applied, particularly when copay accumulators were involved.

Utilization Management Requirements

Table 5
Survey response: Utilization management.[6]

Survey Prompt	National Responses	Colorado Responses
I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	23 of 267	6 of 38

[5] 89 out of 267 national survey participants did not answer regarding if the cost of Enbrel has affected their adherence to it. 10 out of 38 Colorado survey participants did not answer regarding if the cost of Enbrel has affected their adherence to it.

[6] 36 out of 267 national survey participants did not answer regarding utilization management of Enbrel. 1 out of 38 Colorado survey participants did not answer regarding utilization management of Enbrel.

My insurance plan has dropped or switched my drug coverage after the plan year started.	25 of 267	2 of 38
My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor.	73 of 267	14 of 38
My insurance plan requires prior approval to fill the prescription.	183 of 267	24 of 38
My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	97 of 267	18 of 38
I worry that the cost of my prescription will raise my insurance premium.	56 of 267	8 of 38

Table 5 shows both national and Colorado patient responses to a survey question asking if they had experienced any of the listed utilization management practices.

When talking about cycling through a drug and having to wait due to prior authorizations and step therapy, one patient at a public input session said "When you have to go through all of that, you deteriorate in the process. As a result of those things, I've lost an incredible amount of functioning."

Additional Financial Effects

Patients and caregivers were asked in public meetings and in surveys to share any additional information about how Enbrel affects them financially. The most common theme from patients was that their condition led to absence from work, inability to work, or loss of productivity due to mobility issues. Patients also reported transportation costs and time lost from having to travel hours to a rheumatologist or pick up medicines. Other patients stated that they will save money because they will no longer require surgeries.

Patients in surveys and in public input sessions reported that the administrative burden of their condition cost them time and money:

- *"Yes, I spend so much time on the phone. Mostly dealing with meds that aren't covered. It's exhausting being a full time patient. Insurance is usually the reason. I went Bankrupt thanks to my condition."*
- *"Another cost was the many, many hours I had to spend on the phone with insurance, specialty pharmacies, and copay assistance programs to figure out how to afford the medication I needed."*

Other patients said that they will struggle without copay assistance.

- *"The max annual costs covered through the Enbrel financial assistance program has decreased over the years……The Enbrel program only works if you have good health insurance and it is stable throughout the calendar year, which is sometimes not feasible."*
- *"The copay assistance runs out before end of year and then insurance does not cover so cost can be near $5000.00."*

- *"The entirety of our financial issue is from medical debt. Without access, my body shuts down and I slowly start to die. My RA is one of the most aggressive forms and I've had to stop medication several times because we can't afford it unless there is coverage assistance. During those times, I become unable to work, unable to walk, and unable to care for myself at all."*
- *"The copay assistance runs out before end of year and then insurance does not cover so cost can be near $5000.00."*

There is additional information contained in Appendix D and Appendix J related to the relative financial effects of Enbrel not captured in this appendix. The Board may want to weigh information in all three appendices when evaluating patient costs.

Audio from Public Patient and Caregiver Meetings

The audio from the September 19, 2023 public Zoom meeting is found via the following link: https://zoom.us/rec/play/yGLW2uq6iAHgGdal-qnkHGgvidk87SLmmHZoqw3Up3Fdc5PzOqGm_l-tPoskL_5rvCrGVSdU6y-ac27Q.ji5NBubFa-H1gZ6M?autoplay=true.

Patient and Caregiver Survey

The Patient and Caregiver Survey was initially live on the Prescription Drug Affordability Board website from September 12 to October 12, 2023. At the December 15th PDAB meeting, Board members requested more information from patients and voted to reopen the surveys until January 21, 2024. Though survey results are not a representative sample of the experience of all Coloradans taking Enbrel, the results can provide important input from patients and caregivers for the Board to consider.

Survey results are sometimes highlighted in the Summary Report and in appendices. A sample of the survey is below, and full survey results are contained in the next section of this appendix. To protect patient and caregiver privacy, all names and other identifying information are redacted.

Figure H-2
Patient and Caregiver Survey (begins on next page).

Name *

Your answer

Email address *

Your answer

Have you attended, or do you plan to attend, a public input session for patients and caregivers? *

- ◯ Yes
- ◯ No

After you complete this survey, Board staff may have follow up questions for you. Do you consent to staff reaching out to you via email after you complete this survey?

- ◯ Yes
- ◯ No

Zip code

Your answer

If you have health insurance, what type of health insurance do you have? *

- ○ I do not have health insurance
- ○ Insured through employer
- ○ Individual (private) insurance
- ○ Medicare
- ○ Medicaid/Health First Colorado
- ○ Unsure
- ○ Other:

I am responding to this survey as: *

- ☐ A patient living with a condition which is currently or formerly being treated by Enbrel, Genvoya, Cosentyx, Stelara, or Trikafta.
- ☐ A caregiver for someone living with a condition which is currently or formerly being treated by Enbrel, Genvoya, Cosentyx, Stelara, or Trikafta.

If you are a patient, please answer this survey based on your personal experience. If you are a caregiver, please answer the survey based on the experience of the person for whom you are caring.

Which prescription drug are (you/the person you are caring for) taking currently or previously? *

Choose ▾

Health Effects

What condition does this drug treat for you?

Your answer

How does the condition affect your daily life, or the life of person you are caring for? (Consider mobility, self care, usual activities like work, study, housework, family, leisure activities, pain/discomfort, any anxiety/depression).

Your answer

What health outcomes are most important to you when being treated for your condition?

Your answer

What beneficial health effects have you experienced from using this prescription drug, if any?

Your answer

What adverse health effects have you experienced from using this prescription drug, if any?

Your answer

What factors led you to the prescription drug you are currently taking? Select all that apply:

- [ ] It's the only one designated for my condition.
- [ ] I cycled through other medications that didn't work before finding this one.
- [ ] It's the drug my provider prescribed and it works for me.
- [ ] It was required by my insurance company.
- [ ] The method of delivery or injection works best for me.
- [ ] Other:

Have you tried taking other prescription drugs to treat your condition? If so, how many?

- ○ None
- ○ Yes, one other treatment.
- ○ Yes, two other treatments.
- ○ Yes, three other treatments.
- ○ Yes, more than three other treatments.
- ○ Unsure

If you have tried other prescription drugs to treat your condition, what were they? Were there any beneficial or adverse health effects of these other prescription drugs?

Your answer

Financial Effects

How much do you pay out-of-pocket each month for the prescription drug? By out-of-pocket, we mean after insurance or any patient assistance program used to cover the cost of the medication.

- ○ $0-$50 per month
- ○ $50 - $100 per month
- ○ $100 - $150 per month
- ○ $150 - $250 per month
- ○ $250 - $500 per month
- ○ $500- $1000 per month
- ○ More than $1000 per month

Has the cost of this drug ever made it difficult for you to access it?

- ○ Yes
- ○ No

Has the cost of this drug ever affected your adherence to it? Select all that apply.

- ☐ I have skipped doses of the drug in order to save money.
- ☐ I have reduced the dose of the drug in order to save money.
- ☐ I have stretched time between doses of the drug in order to save money.
- ☐ I have changed prescription drugs to treat my condition due to cost.
- ☐ Other:

How does this drug impact you and/or your family? Select all statements that are true for you.

- [ ] This medication reduces the amount of time and money spent going to the doctor.
- [ ] This medication reduces the amount of time and money spent going to the hospital or needing surgery.
- [ ] This medication allows me to work and help support my family.
- [ ] Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.
- [ ] Out-of-pocket costs have caused me to accrue medical debt.

The following questions are centered around any financial assistance you may have received to help purchase the prescription drug. Many patients requiring ongoing treatments for chronic diseases receive financial assistance from drug manufacturers and non-profit organizations in the form of copay assistance programs, discount cards, or savings cards. These help patients pay their out-of-pocket costs (such as deductibles, copays, etc.) for their prescription drugs.

Do you/the person you are caring for use, or have ever used, any copay assistance programs, discount cards, or savings that are provided by prescription drug manufacturers, or non-profit organizations to help with out-of-pocket costs (such as deductibles, copays, etc.) for this drug?

- ◯ Yes
- ◯ No

If you replied "yes" to the question above, how did you hear about the financial assistance?

- ○ Friend or family member
- ○ My provider
- ○ My pharmacist
- ○ My insurance company
- ○ Prescription drug manufacturer
- ○ Internet search
- ○ Other:

Do you have difficulty affording the drug despite using a patient assistance program?

- ○ Yes
- ○ No

If you are insured, please select any of the following statements that are true for you. Select all that apply.

- ☐ I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.
- ☐ My insurance plan has dropped or switched my drug coverage after the plan year started.
- ☐ My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor.
- ☐ My insurance plan requires prior approval to fill the prescription.
- ☐ My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.
- ☐ I worry that the cost of my prescription will raise my insurance premium.

Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?

Your answer

Patient and Caregiver Survey Results

Survey results are provided first for Personal Information, then Health Effects, followed by Financial Effects.

Table H-1

Patient and Caregiver Survey Results

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
1	Patient	Enbrel	Yes	80204	Medicare	People with disabilities	Psoriatic Arthritis	If I am not on a biological I am bedridden. Cannot go up/down stairs, walk, etc.	Can do daily life activities and exercise	Can live daily life and exercise
2	Patient	Enbrel	Yes	80130	Insured through employer		psoriatic arthritis	pain in joints, changes in ability to work	limited joint pain/stiffness, no development of further issues	limited joint pain/stiffness, no development of further issues
3	Patient	Enbrel	Yes	80503	Insured through employer	Children and families	juvenile idiopathic arthritis	for years it restricted my mobility and caused extreme pain and discomfort that was associated with inflammation.	pain relief and reduced inflammation	reduced inflammation and pain for years until Embrel stopped having a significant effect on my knees.
4	Caregiver	Enbrel	No	65689	Insured through employer	Children and families, People with disabilities	Juvenile Arthrits	Loss of mobility, unable to work sustainable hours. Interferes with learning.	Mobility	Full medicated remission. Was able to attend school, exercise and not use wheelchair.
5	Patient	Enbrel	Yes	80109	Medicare	Older adults, People with disabilities	Rheumatoid Arthritis	Mobility, housework pain anxiety quality of life	Mobility	My first medication for RA when it came out

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
										had great experience with it.
6	Patient	Enbrel	No	84057	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning	Rheumatoid Arthritis	Severely limits physical abilities	Less pain, become more able bodied	None
7	Patient	Enbrel	No		Medicare	People involved in the criminal justice system, Children and families, People with disabilities	Rheumatoid Arthritis	I am completely disabled at the age of 38. I am a mom of 4 small children and my RA has robbed them of so much either due to my physical symptoms or not being able to afford things because of the high costs of my treatment and medication. I am unable to cook or clean so that all falls on my husband to do on top of working a full time job.	Stopping the progression of the disease and preventing the pain	

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
8	Patient	Enbrel	No	75571	Insured through employer	Black people, indigenous people, and people of color	Psoriatic Arthritis	PsA takes a toll on my joints and skin. Untreated, I have pain in my knees and hips. I had degeneration of those joints while I was not yet being treated. Work and school were both affected by these condition. I was a poker dealer that couldn't deal poker because my thumbs were swollen. In school, I couldn't sit long enough to be in class. I couldn't get help because at the time I wasn't diagnosed with PsA. My skin drew looks and perpetual self consciousness that is still present.	I needed pain relief and joint damage to slow	My pain and swelling was greatly decreased. So much so that I was able to attend college. I was also able to resume dealing poker when I was on Enbrel
9	Patient	Enbrel	No	56007	Insured through employer	Older adults	RA	It makes it hard for me to accomplish all that needs to be done on a daily basis. It also makes my job difficult.	Pain relief, relief from fatigue	
10	Patient	Enbrel	No	26378	Medicaid/Health First Colorado	People with disabilities	Rheumatoid	Significantly	Treatment	Stopped working after 2 years

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
11	Patient	Enbrel	Yes	80122	Insured through employer	People with disabilities	Rheumatoid Arthritis	It can absolutely paralyze me and self care can seem impossible. I no longer work because of my condition. Pain can truly be unbearable at times and can lead to depression	Little to no pain	This drug has given me my life back. My flares are farther apart and Enbrel has allowed me to live my own life with few modifications and compromises
12	Patient	Enbrel	No	55337	Insured through employer	People with disabilities	RA	Pain, fatigue and lack of sleep make everything more difficult. It's hard not to miss work. You miss fun plans hopefully being able to go to work. Being stiff and in constant pain makes an unhappy person full of fear and anxiety.	Less inflammation side effects. Less pain . Getting better sleep. Relief is a great thing to survive.	I have been on many RX, Enbrel was the best working I've experienced in 14 years.
13	Patient	Enbrel	No	32712	Insured through employer	People with disabilities	Rheumatoid Arthritis	Hard to move around, and painful. Housework tends to fall by the wayside as I just can't do it some days. The pain definitely increases my anxiety and depression.	Less pain	none

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
14	Patient	Enbrel	No	15825	Insured through employer	Older adults, People with disabilities	Rheumatoid Arthritis	Ra makes everything harder to accomplish(pain, fatigue, stiffness, etc). RA has caused me to have multiple conditions or comorbidities. When Ra is controlled these comorbidities are likely to be as well. When Ra rages so do my comorbidities. Multiple specialists have said if I only could ra under control then _____would be in control	I want pain and stiffness to be lessened but in the last few years I've learned that I need my inflammation from ra to be controlled for overall health	My pain and stiffness is reduced. My inflammation control is better which has improved many of my comorbidities
15	Patient	Enbrel	No	19026	Insured through employer	People with disabilities	Rheumatoid arthritis	Hinders all Aspects of my life, financial, physical, Emotional, social	Pain and fatigue reduction	Decrease in pain

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
16	Patient	Enbrel	No	87121	Medicare	Black people, indigenous people, and people of color, American Indians and Alaska natives, People who are lesbian, gay, bisexual, transgender, queer, or questioning, People of disproportionately affected sexual orientations, gender identities, or sex assigned at birth, People with disabilities	Rheumatoid arthritis	I no longer am independent… I need help daily doing things most can do without assistance.. causing depression and anxiety to heighten.	Being more independent	It allowed better movement
17	Caregiver	Enbrel	Yes	80916	Medicaid/Health First Colorado	Children and families, People with disabilities	JIA	Limited her ability to walk	Less pain	Helped with my pain
18	Patient	Enbrel	Yes	81432	Individual (private) insurance		Rheumatoid arthritis	Some days I'm "normal", some days I am in so much that I can't do anything.	Reduce inflammation	Allowed me to live a normal life

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
19	Patient	Enbrel	No	28625	Insured through employer	Older adults	Rheumatoid arthritis	Constant stiffness especially in hands, currently affects simple everyday tasks, Strength in hands and fingers are already compromised, feet, knees, elbows and shoulders are affected on a smaller scale at this time.	To eliminate the “major flares” that stop me in my tracks….unable to function at all.	Enbrel is controlling the flares and helping to maintain my ability to function everyday.
20	Patient	Enbrel	No	61270	Medicare	People with disabilities	Juvenile Rheumatoid Arthritis & Iritis	It makes doing everyday tasks more difficult. Opening bottles, putting on socks, tying shoe laces, brushing hair are all made much more difficult. Preparing my own meals is not possible. Showering is impossible some days. Every single task throughout the day takes thought and more time and effort than it takes an able bodied person. I have been unable to work for 20 years. The pain is chronic and never goes away, it’s a constant buzz that’s always there, just some days the buzzing	To be able to keep the ability to walk as long as possible, to stop more deterioration, and to just be comfortable and not in constant pain.	When I was on it, I missed less school and work days, I was able to walk longer distances, go hiking, and keep up with others.

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
								isn't as loud as others. Walking is sometimes impossible and a wheelchair or cane are needed.		

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
21	Patient	Enbrel	No	76133	Medicare	Older adults, People with disabilities	PsA	I have 2-plus hours of stiffness every morning. I live with chronic joint and tendon pain daily. I suffer from joint swelling. I have moderate difficulty performing basic household tasks most days. Walking for an “extended” amount of time is severely difficult. Standing for extended time is extremely difficult. I have anxiety about shopping because of mobility difficulties and pain. I can’t enjoy family time because of chronic pain.	To lessen joint damage and to lessen chronic pain.	I had about 1 year of decreased stiffness, decreased daily pain, and mobility improvement while on Enbrel. Sadly it stopped working at about the 12-14 month mark.
22	Caregiver	Enbrel	Yes	80401	Insured through employer		RA	pain/discomfort	less pain & discomfort	less pain & discomfort

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
23	Patient	Enbrel	No	45236	Medicare	Children and families	Juvenile Rheumatoid Arthritis/Rheumatoid Arthritis	Unable to complete activities of daily living, on bad days unable to get out of bed experience extreme fatigue as well as systemic symptoms comparable to Mono/COVID body aches, sore throat rash fever in addition to joint pain in flare or with over exertion	Ability to function at the very minimum not be in excruciating pain for the entirety of the day	When first used I was in drug induced remission of JRA for several years when enbrel first came out was able to go to college with Accomodations however my body became used to medication stopped working took long break came back to it and it did not work again
24	Patient	Enbrel	No	19703	Medicare	Older adults	Rheumatoid arthritis	Without medication, I would not be able to walk or use my hands.	That the disease is kept under control to avoid more damage to my body.	I used it in the past, and had absolutely no beneficial effects.
25	Patient	Enbrel	Yes	80026	Medicare	Older adults	psoriasis	itcy body, inflamed areas, sores, plaques on my body, skin cancer as a result of previous treatments	reduced inflamation, scalp irritation, plaques on the body	reduction of all symptoms

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
26	Patient	Enbrel	Yes	80126	Individual (private) insurance	Older adults	Rheumatoid Arthritis	I'm not sure if this question reflects when I have good treatment or without treatment? Without treatment, I need care and cannot work. With treatment, I can function with some difficulty, depends on if I'm dealing with a flare up or not, weather, etc. I can say that I struggle to find and keep work due to my RA. It's very easy to have anxiety/depression when dealing with a chronic condition with many factors out of my control.	That I can function without assistance and be employed full-time in a job that meets my educational and skill level and to maintain that mob. I have not been able to do so due to my RA, yet I don't qualify for disability benefits.	This was the most effective drug for me that I took for my RA until it no longer worked for me. I was able to live very normally, and most normal since being diagnosed with RA in 2007. No other drug has had the same therapeutic effects for my RA as Enbrel.

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
27	Patient	Enbrel	Yes	80920	Affordable Care Act (the Exchange/Marketplace)	Older adults, People with disabilities	Rheumatoid Arthritis	Movement is slow, always feel exhausted with no energy and tired, unable to work, random pain and discomfort most severe in hands and feet, experience anxiety and depression throughout the day. Housework is difficult. Unable to participate in many leisure activities. Strength has been affected. Unable to lift and hold objects over 10 pounds safely.	Pain and discomfort management, strength, anxiety and depression.	Less pain and discomfort in joints.
28	Patient	Enbrel	No	93313	Insured through employer	People with disabilities	Psoriatic Arthritis	The psoriasis and psoriatic arthritis just seemed to get worse as I age and the inflammation made it harder to exercise and keep up with daily activities. The pain just seemed to increase and/or take longer to subside. I've since graduated from the Psoriasis and Psoriatic Arthritis and am now being treated for Rheumatoid Arthritis.	Mobility, less pain and discomfort and less stress and anxiety.	The Enbrel worked for almost a uear then stopped working at all.

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
29	Patient	Enbrel	No	97067	Medicare	Older adults	Rheumatoid arthritis	Currently - minimally	Pain and fatigue management with minimal side effects	Both pain and fatigue management
30	Patient	Enbrel	No	14120	Medicare	Older adults	Psoriatic arthritis	It would affect all of the above if it weren't for Enbrel	Mobility and comfort	I am just about back to normal. Much more tolerable to have this condition with Enbrel
31	Patient	Enbrel	No	75034	Medicare	Older adults	Rheumatoid Arthritis	exhaustion, anxiety, depression, suppressed immunity	Pain	Pain has been under control the entire time.
32	Patient	Enbrel	No	70403	VA Healthcare System	Veteran	Rheumatoid Arthritis	Pain/discomfort, fatigue, leisure activities, work, housework, exercise, recreation	Reducing fatigue and pain so I can participate in day to day life	It worked for me for a couple months and then my body stopped responding and we switched to xeljanz after 9 months on enbrel

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
33	Patient	Enbrel	No	22901	Insured through employer		Initially, I was diagnosed with Psoriatic Arthritis and Sjorgrens but recently that was changed to Covid Vaccine Injury. My symptoms present just like the above autoimmune disorders but I do not have any of the markers for them. This all started directly following an anaphylaxis response to my first Moderna vaccine.	HORRIBLY affected. Pain in joints, trigger fingers on both hands, feet hurt all the time, back cracks also no saliva or tears. Very fatigued all the time.	To get back to "doing"....	I went from about 25% of myself to 75%
34	Patient	Enbrel	No	98230	Medicare	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People with disabilities	Rheumatoid Arthritis	I have issues with using my hands, walking, brushing hair and teeth, sleep and overall health	to be able to dress myself, brush my teeth, get in and out of tub, go to bathroom, walk to mailbox, get in and out of a vehicle	it has helped me dress myself, brush my teeth, walk, do errands, button clothes, tie shoes
35	Patient	Enbrel	Yes	80014	Medicare	Older adults	Rheumatoid arthritis	I no longer take it	less pain and swelling with no bad side effects	I had very bad site reactions, so took it a short time

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36	Patient	Enbrel	No	23180	Insured through employer		Rheumatoid Arthritis	Fatigue is the biggest factor for me. Mostly, I am able to do the things I want to do.	Avoid joint damage, avoid pain, and help with fatigue.	Enbrel did not work for me. I needed to switch to another medication in order to achieve treatment goals.
37	Patient	Enbrel	No	98375	Tricare	Veteran, Children and families	Psoriasis	It affects every aspect of my life. I have young children , I work a full time job in healthcare and my spouse is deployed often which leaves the responsibility of the home and stress on myself. Being military I don't have a support system either and all of these aspect affect my personal health which flairs my psoriasis. My skin affects everything from pain/comfort in my clothing , to safety of infection at work, to being able to physically care for my disabled 5 year old. It has caused me as piety and depression through my life and social circumstances due to the visibility of my condition.	Less fatigue, skins clearness , mental health improvements and the ability to be without pain.	Improvements in skin lesions , joint pain and tenderness

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38	Patient	Enbrel	No	07060	Insured through employer	Older adults	RA	Chronic fatigue and joint pain	Remission	None
39	Patient	Enbrel	No	08535	Medicare	Older adults	RA	Requires biologic to function	Quality of life	Quality of life for 7 yrs
40	Patient	Enbrel	No	34275	Medicare	Older adults	ankylosing spondylitis	It limits the range of motion of my spine and sacroiliac joints. Because in my specific case it targets my cartilage, I cannot do strenuous exercises because that much motion will inflame the cartilage all over my body. So this type of inflammation will make me feel like I have the flu.	The ability to walk and perform the daily activities of life. I must also be hyper aware of my eyes (which have a lot of cartilage in them) because there is a specific chance that my eyes could also become inflamed and limit my vision.	It completely erased the low level pain I endured for several decades. The morning after Enbrel was injected at the doctor's office I felt no pain upon wakening. It was a miracle. This drug, Enbrel, also allowed me to eat. The only other drug that I took and was effective - Feldene, generic name Piroxicam - eroded my stomach so much that I was unable to eat. It literally burned a hole in my stomach. I went on Enbrel so I could eat again. I AM NOT EXAGGERATING!
41	Patient	Enbrel	No	48167	Medicare	Older adults	Rheumatoid arthritis	Limits what I used to be able to do - definitely have had to restructure my lifestyle	Less pain -less swelling-more mobility	Less pain -less swelling-more mobility for about a year than benefits faded

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42	Patient	Enbrel	No		Medicare	People of disproportionately affected sexual orientations, gender identities, or sex assigned at birth, Older adults, People with disabilities	Rheumatoid arthritis	Mobility, pain, ability to engage socially	To stay alive	Keeps me alive, reduces pain, helps me to walk, move
43	Patient	Enbrel	No	37922	Insured through employer	People with disabilities	Rheumatoid Arthritis and Sjrogrens	Can't do much and have panic attacks now, anxiety and depression	More mobility	Less pain
44	Patient	Enbrel	No	98513	Insured through employer	People of disproportionately affected sexual orientations, gender identities, or sex assigned at birth, Children and families, People with disabilities	Rheumatoid Arthritis	Unable to work, daily activities very limited. High levels of pain daily. Anxiety about being in pain and being unable to do already limited activities. Anxiety that I will get viral illnesses because my medication suppresses my immune system. Depression over being unable to lead the life I was living before.	Being able to care for and play with my kids, care for my family and household. Being able to do at least some hobbies that bring me joy. I have already given up on being able to work (in the medical field) or do most hobbies (hiking, camping, kayaking, jogging)	Less pain in my joints.

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45	Patient	Enbrel	No	91355	Medicare	Older adults	Rheumatoid Arthritis	Enbrel gave me an almost normal life for 20 years	No pain and enjoying life	Stopped the progression of the disease. I have deformities from living with RA before enbrel.
46	Patient	Enbrel	No	78633	Medicare	Older adults, People with disabilities	Rheumatoid arthritis	My condition forced me to go on disability. My physical and mental health have been and will continue to be affected by this diagnosis. I am gradually losing my ability to do a number things. I need to consider what activities I need to limit or not do at all. I am learning to ask for help — not an easy task for someone who has been independent all of her life.	Maintain my ability to feel like I still have something to offer this world and be as pain free as possible.	My initial inflammatory numbers were significantly high. Once I started Enbrel, those markers dropped to low levels
47	Patient	Enbrel	No		Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People with disabilities	Rheumatoid arthritis	Daily stiffness and pain, struggle to use hands for tasks, chronic fatigue, mobility limited, cognitive effects- "brain fog"	Decrease pain, decrease fatigue, increase ability to use hands	Enbrel was not that helpful and I continued to decline while on it

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48	Patient	Enbrel	No	59405	Medicare	People with disabilities	Rheumatoid arthritis	Every aspect of my life it affects. I can't hold a job because of flare up, pain walking, lifting, carrying anything, climbing ladders, the fatigue is unrelenting. I can't enjoy doing many things with family, I can't run after my grandchildren or lift them much because after repeated tasks like that pain will start in my back and shoulders and the tiredness kicks in. My feet feel like they are breaking when I walk especially on flat surfaces, my neck shoulders and back are so painful to even wash dishes, my jaw hurts so I can't smile as much as I used to which makes me sad because now I just look grumpy all the time.	To be able to live life as pain free as possible.	It helped kick my disease from the pain for about a year.
49	Patient	Enbrel	No	50613	TRICARE	People with disabilities	Rheumatoid Disease	Allows my joints to move.	Long term protection of my joints.	More mobility.

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50	Patient	Enbrel	No	33611	Insured through employer		Rheumatoid Arthritis	Dec 2019, I woke up one day completely crippled. A year later being put on Enbrel made me feel completely pain-free with no physical limitations.	No pain. No physical limitations. I have to work for a living fulltime.	I am no longer crippled. I can sleep. I can walk. I can use my hands again.
51	Patient	Enbrel	No	47421	Insured through employer	American Indians and Alaska natives, Older adults, Children and families, People with disabilities	Psoriatic Arthritis and Psoriasis	Decreased mobility, pain everywhere, itching, extreme fatigue, multiple comorbidities, decreased immune system., isolation.	No itching, stops progression of joint damage.	Treated Psoriasis well. It did nothing for my psoriatic arthritis.
52	Patient	Enbrel	No	95608	Medicare	People with disabilities	Psoriatic arthritis	Pain, limited mobility, disability	Decreased pain, increased mobility	Decreased pain, increased mobility, less days at home - more days out in the world
53	Patient	Enbrel	No	94124	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning	Rheumatoid Arthritis	I have to carefully manage my energy use and commitment. Needing to change my entire lifestyle to minimise disease activity.	Prevent flair and promote a minimum amount of disease activity.	I am able to live my life..
54	Patient	Enbrel	Yes	80537	Medicare	Older adults	Rheumatoid Arthritis		Stop progressing	Reducing Flares

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55	Patient	Enbrel	No	46060	Medicare	Older adults, People with disabilities	Rheumatoid arthritis	Due to RA, I am mobility limited, cannot do most housework, have given up most hobbies and pastimes, and my bones are moving around.	Less pain and stiffness, prevention of further joint damage.	Enbrel has been a life saver. As long as I am able to stay on the drug, pain and stiffness are considerably reduced.
56	Patient	Enbrel	No	02176	Insured through employer		Rheumatoid Arthritis	frequent pain, and fatigue. Many things are more difficult than they should be	Reduce pain, ability to do normal day to day activities	reduction in pain
57	Patient	Enbrel	No	33433	Insured through employer		Rheumatoid Arthritis	At times, soreness in my joints (specifically hands), exhaustion at times	That I can live my life normally and like I did before this chronic illness	I am back to living life (relatively) normally. I can exercise, work, socialize - generally without pain
58	Patient	Enbrel	No	90740	Cobra	Older adults	Psoriatic Arthritis	Pain discomfort mobility of my hands is compromised	Functionality of daily tasks and lower pain	More flexibility and less pain
59	Patient	Enbrel	No	92057	Medicare	Black people, indigenous people, and people of color, American Indians and Alaska natives, Older adults, People with disabilities	RA	It is a dynamic disease that changes from day to day and has impacted every aspect of my life mentioned above. My constant and salvation has ben my steadfast and loyal loving family and spouse.	pain management and stopping further damage	none that I know of with the exception of managing my RA pain

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60	Patient	Enbrel	No	78373	Medicare	Older adults	Rheumatoid Arthtitis	Tremendous impact in relation to mobility, pain, quality of life, and mental health.	Mobility and pain reduction.	Enbrel was the first biologic I tried. It worked well and I felt the impact immediately.
61	Patient	Enbrel	No	55410	Individual (private) insurance		Rheumatoid Arthritis	I have more pain and fatigue. I have painful joints. I have had to have my big toe fused. I can no longer do many of the physical things I used to do before (e.g. running, downhill skiing, rigorous exercises).	Reduce pain, increase energy and slow or ideally stop the progression of the disease.	Hard to know what exactly to attribute to which drug (I am on multiple) but I believe it has helped slow the progression of the disease and reduced my pain significantly.
62	Patient	Enbrel	No	92675	Medicare	Older adults, People with disabilities	Psoriatic arthritis	I'm limited in how I can do anything. Arthritis 50+ years	Pain relief and slowing progression	
63	Patient	Enbrel	No	19015	Individual (private) insurance		rheumatoid arthritis	I have constant pain and fatigue, it makes it hard to work but I generally pushed through	I know there's no cure, I just want to prevent my condition from getting worse	It helped reduce the pain for several years, then it just stopped working so I switched
64	Patient	Enbrel	No	98136	Medicare	Older adults	Rheumatoid arthritis	Fatigue and joint pain	Less pain	Less pain

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65	Patient	Enbrel	Yes	80031	Medicare	Older adults	Rheumatoid Arthritis	My main symptoms are pain and swelling in several joint in my hands. This affects using my hands in most Dailey activities; I work part time and it affects me at work too. So far it has not affected me internally however that's a possibility in the future. No knowing how RA might affect me in the future is always there and causes some anxiety.	RA is a progressive disease that gets worse as time goes on. My main health outcome is to slow the progression and to possibly have long periods of remission.	Enbrel is the 4th RA drug that I have used so far and is the only one that has slowed the progression.
66	Patient	Enbrel	No	33701	Medicare	Older adults	Rheumatoid arthritis	Difficulty working, pain, significant fatigue especially in the morning	Risk versus benefit of improving lifestyle.	Improvement and in some cases elimination of my symptoms.
67	Patient	Enbrel	No	02818	Insured through employer	Older adults	Rheumatoid Arthritis	Joint deformaties	Relief of symptoms, few side effects, long term or slowing of disease process	Taken yrs ago, it was positive in effects but after 2 yrs it was not as effective
68	Patient	Enbrel	No	55076	Insured through employer	Children and families	Rheumatoid arthritis	Few flares, sometimes sore joints	No flares, no soreness	Only a few flares a year

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69	Patient	Enbrel	No	44129	medicare and tricare for life	Older adults, People with disabilities	rheumatoid arthritis	i had to retire at age 40 because this illness, combined with seven others made working full time impossible. i am a lawyer. my career demanded more than i had. today RA makes housework difficult. i am always behind. i live in constant pain, and more joints are becoming affected. i sew, draw, and crochet. it's hard to accomplish those. but i am a constant optimist!	less pain and fatigue. chronic pain consumes a ton of energy as i work to keep it in the background and move forward.	i took enbrel with methotrexate. enbrel helped alleviate morning stiffness in my knees and elbows.

70	Patient	Enbrel	No	12523	Insured through employer	Older adults, People with disabilities	RA	This condition has stolen my life. Mobility, Daily Non-Stop Pain/Discomfort, causes anxiety and depression, melancholy-as it was once referred to. Overall ability to be as independent and self reliant as I once was has diminished and I've become limited in all parts of my life due to RA-Now I believe due to ongoing remnants of CoVSARs virus that grabbed ahold of my immune system, while I was experiencing a major Break in treatment /causing a systemic Flare of disease, my immune system went haywire and now I've had several other issues infections and have been diagnosed with RA & Lupus, also experiencing Big changes in my blood pressure , and my Overall decline in ability to live a normal life without the pain and discomfort from inflammation and my body continues to be out of control, I feel as though everything has gone completely	SUBSTANTIAL NOTICEABLE GAINs QUICKLY- for Overall increase in mobility without constant Discomfort and pain, stiffness, and stop or block the disease(s), progression so I can return to a "normal" functioning person and live a somewhat normal less painfully consumed life.	None

								awry since becoming infected with Covid 19. Nothing works! And yet my physician (s) continue to say that the medications I'm on are helping, my daily life is diminishing and I feel as though this is what I will have to live with or worse from here on out….(?) .		

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71	Patient	Enbrel	Yes	80004	Medicare	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People who have AIDs or HIV	Rheumatoid arthritis	Limited joint mobility	Relief from pain and joint damage	Joint pain relief and strong progression of joint damage
72	Patient	Enbrel	No	60056	Medicare	Older adults	Rheumatoid Arthritis	If the condition is active, my mobility is very poor and I would be in almost constant pain.	Living life to the fullest, mental health, doing my volunteer work., included in family activities.	Very little pain if any. Doing what I want to do.
73	Patient	Enbrel	No	89441	Insured through employer		Psoriasis, Psoriatic Arthritis	On this drug, I did not have joint pain nor did I have flares while I was on it. It also cleared my skin.	Reduction of pain, independence, increased mobility and ability to do ADLs	Significantly clearer skin, reduced joint flares, significantly reduced pain and swelling in joints leading to more indepence, return to near normal activities.
74	Patient	Enbrel	No	92371	Medicare	Older adults	Rheumatoid Arthritis	I do experience some pain/discomfort mostly in my hands and feet but I am still able to do what I want to do.	To be able to feel well enough I don't think much about my condition.	Enbrel has controlled the pain and stiffness Rheumatoid Arthritis causes. It has made my quality of life much better.
75	Patient	Enbrel	Yes	80228	Medicare	Older adults	Rheumatoid arthritis (RA)	affect my life a lot.	mobility, less pain	quit working after a year and half

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76	Patient	Enbrel	No	02360	Insured through employer	Older adults	Psoriasis and Psoriatic Arthritis	Limited mobility in all aspects of life, extreme fatigue, reduced work schedule.	Ability to be active in all daily functions. Less pain and fatigue.	I was on Enbrel for about 2 years 10 years ago and it worked well to reduce my psoriasis and psoriatic pain for about the first year then it started losing efficacy so had to switch to another biologic.
77	Patient	Enbrel	No	46307	Insured through employer		Ankylosing spondylitis	Difficulty daily but manageable 75% of time	Ability to work and care for family	Better manages my symptoms
78	Patient	Enbrel	No	85007	Insured through employer	People with disabilities	Rheumatoid Arthritis	Self care, work, housework, family and leisure activities, chronic pain, anxiety and depression	Less pain, more mobility, affordability of drugs	Increased mobility, less pain
79	Patient	Enbrel	No	56001	Medicare	People with disabilities	PsA & RA	Very much	Be able to live some sort of life	Less joint damage less pain meds needs
80	Patient	Enbrel	No		Insured through employer	Children and families	Plaque Psoriasis	Impacted daily life esp with work and self care. Painful to commute in car, personal outlook and household chores	no side effects.	initially, it was able to control the psoriasis and clear the skin
81	Patient	Enbrel	No	83716	Insured through employer		Psoriatic Arthritis/Spondylitis	Constant pain, mobility issues	Less pain	When I used Enbrel, I felt amazing

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82	Patient	Enbrel	Yes	80015	Insured through employer	People with disabilities	Rheumatoid arthritis	Pain when flares occur, need thumb fusion due to dislocation from RA, difficult to walk at times, typing can be difficult frustration from not being able to do what I want and dropping things	No inflammation, no pain	None
83	Patient	Enbrel	No	13905	Individual (private) insurance	Children and families	Psoriasis and Psoriatic arthritis	Mobility, ability to work, housework, leisure activities, pain, anxiety and depression	Clear skin and less pain and stiffness	I had no bad side effects and it helped my skin a little but did not do anything for my pain and stiffness.
84	Patient	Enbrel	No	28540	Medicare	Older adults	Rheumatoid arthritis	Fatigue, mobility, pain/discomfort, housework	Less pain and fatigue	Less pain
85	Patient	Enbrel	No	29671	Medicare	People with disabilities	Rheumatoid arthritis, and several other autoimmune illnesses	I was mostly bedridden before enbrel. I lived in horrific bone pain. I had no quality of life.	Living with decreased pain and inflammation.	This drug calms my disease activity- stops my body from attacking its own healthy tissues. I have greatly decreased pain and inflammation. I can work my farm and go to the gym. It's a miracle drug for me.
86	Patient	Enbrel	No	17552	Individual (private) insurance		Psoriasis and psoriatic arthritis	Both of my conditions are painful. Enbrel helped reduce the	Decrease in pain	It reduce the pain and swelling in my joints. It cleared my skin of plaques.

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								pain so I can live my life with less pain.		
87	Caregiver	Enbrel	No	23050	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning	Juvenile Idiopathic Arthritis	Occasional joint pain and stiffness, fatigue	Control of inflammation and joint damage prevention	Decreased joint inflammation and decreased pain
88	Patient	Enbrel	No	48910	Insured through employer	People with disabilities	Rheumatoid arthritis	Housework, leisure activities depending on the day I may or may not have the energy, have pain in my hips, legs and feet.	To have the best quality of life possible	Just being able to work and enjoy time with my family
89	Patient	Enbrel	Yes	81611	Insured through employer		Rheumatoid Arthritis	Moderately ++	Continue to have an active life with minimal pain.	I did not do well on Enbrel, I am using a different medication.
90	Patient	Enbrel	No		Insured through employer		rheumatoid arthritis	It impacts every aspect of my life (work, rest, cooking, cleaning, walking, attending events, cleaning myself, etc.)	Reduced symptoms	None
91	Patient	Enbrel	Yes	80015	Insured through employer	Children and families	Rheumatoid arthritis	Pain, limits activity	Less pain and more mobility	Joint pain improvement

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92	Patient	Enbrel	No	62935	Medicaid/Health First Colorado	Children and families	Rheumatoid Disease	Limited mobility, self care, usual activities like work can't work anymore, limited housework, limited family activities, leisure activities, daily pain/discomfort, all anxiety/depression all the time, barely leave the house.	No pain so I can enjoy life again.	Lowered the pain sometimes
93	Patient	Enbrel	No	28081	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People with disabilities	Rheumatoid arthritis	It makes my entire body hurt terribly, and depending on the day I may have issues with one of all of my major joints. My hips are so bad I have to use a cane at times, and I've had surgery on both of them (as well as a knee, an elbow, an ankle, and 11 others)	Better quality of life	Relief from symptoms to a higher degree than existing treatments
94	Patient	Enbrel	No	68521	BCBS	People with disabilities	Rheumatoid Arthritis The pain,	The pain & weakness are debilitating. Taking care of myself is taxing and there are a lot of days I am unable to care for myself.	Accurate diagnoses the first time I see the doctor for the latest problem. Also, it is hard when the doctors keep referring me to other doctors.	None. It didn't work for me.

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95	Patient	Enbrel	No	55304	Insured through employer	Older adults, People with disabilities	Rheumatoid arthritis	Constant pain, unable to work, now require a wheelchair, unable to do household	Stop progression of the disease	It worked. I felt much better and was able to work.
96	Patient	Enbrel	No	78616	I do not have health insurance	Children and families	Psa, RA	Affects alot	Being able to have quality of life	Reduced some issues
97	Patient	Enbrel	No	54220	Medicare	Older adults	Rheumatoid arthritis	Joint pain and swelling	Decreased pain and swelling	Decrease in pain
98	Patient	Enbrel	Yes	80232	Medicare	Older adults, People with disabilities	Psoriatic Arthritis	Constant pain = Depression. I don't like to make plans with people because I don't know how I'm going to feel day to day. Some days are so bad, I just stay in bed. I am limited in what activities I can pursue. If I overdo, I pay. I had to stop working and claim disability due to the discomfort I feel at a computer. I can't do much housework so have to hire someone to help.	Pain relief, fatigue relief	I did not get enough relief from enbrel

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99	Patient	Enbrel	No	44203	Medicare	Older adults, People with disabilities	RA	Without medicine every joint in my body hurt from head to toes. Including jaw, shoulder, wrist , fingers, hips, knees, feet and toes, plus spine. So just moving can cause a constant painsitting to long, standing too long even laying down. I am able to do self care but household chores, to watching grandkids play. I do have better days that I can be more active but then I could be down for a few days.	Pain, swelling and movement	It did help with pain some swelling so I could move more
100	Patient	Enbrel	No	31650	Insured through employer	Older adults	Arthritis AS	Yes	A better range of motion and less daily pain.	It is helping with both.
101	Patient	Enbrel	No	19963	Medicare	Black people, indigenous people, and people of color	Rheumatoid Arthritis	I'm in pain all day. I suffer from insomnia. I have pain in my hips, toes, calf, Achilles tendon. I'm unable to lift the simplest weight or pull and push. I am mildl depressed about my health.	To alleviate my pain. And get a good nights rest sleep. Feel happy about my life	I did not see any improvement so my Rheumatologist discontinued my prescription

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102	Patient	Enbrel	No	68104	Medicare	People with disabilities	Rheumatoid arthritis	I've had the disease for about 40 years. I have had 13 orthopedic surgeries, including 4 joint replacements. I have become unable to work, and require a cane to walk. Household chores have become difficult.	Quality of life. Full stop.	When I started taking it in 1998, it was as if a faucet had been turned on, and my energy came back. In time, my joint inflammation was greatly reduced. Those were hugely important benefits,because at the time I had 3 young children. I continue to experience those benefits, even though my disease is severe. I think I'd have been complete disabled by age 45 if Enbrel hadn't come on the market when it did.
103	Patient	Enbrel	No	44212	Insured through employer	Children and families, People with disabilities	RA	I struggle to complete most daily tasks	be more functioning	not much for me unfortunately
104	Patient	Enbrel	No	306	Individual (private) insurance	People who are lesbian, gay, bisexual, transgender, queer, or questioning, Children and families, People with disabilities	Arthritis	Effects all aspects of daily life	Less pain and stiffness	Less pain

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105	Patient	Enbrel	No	30028	Insured through employer		Rheumatoid Arthritis	With the current treatment of using Enbrel and Hydroxychloriquin, I am very minimally affected. Some days I have pain in my hands and fingers but mostly, as long as I don't over do things, I'm pretty good.	Keep joint damage to a minimum and pain level tolerable for as long as possible.	Enbrel has made my RA symptoms minimal and I am able to mostly function in all of my daily activities.
106	Patient	Enbrel	No	64118	Insured through employer		Rheumatoid Arthritis	Pain	Less pain and reduction of joint damage	None
107	Patient	Enbrel	No	35758	Medicare	Older adults, People with disabilities	Rheumatoid arthritis	Affects mobility, self care, social life, professional career, pain and discomfort, and family relationships	Increased mobility and reduced pain and discomfort	Reduced pain and discomfort. Increased mobility
108	Patient	Enbrel	No	37748	Insured through employer	People with disabilities	Rheumatoid arthritis	Daily activities, leisure activities, anxiety, home duties, ability to work, social activities,	Less pain, less fatigue, quality of life	Some pain relief, better quality of life,
109	Patient	Enbrel	No	27312	Individual (private) insurance		Rheumatoid Arthritis	Pain, swelling, fatigue. Hard to maintain a full time job	To eliminate flare ups	None long term.

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110	Patient	Enbrel	No	93428	Individual (private) insurance	Older adults, People with disabilities	Rheumatoid Arthritis	Affects my mobility and ability to move to exercise, care for self, enjoy life activities. I am retired. But I was a teacher of students who are deaf. It affected my work tremendously as I used sign language. It was very difficult to sign. I retired early. I was not but on Enbrel until after retirement. Enbrel has made a huge difference iny functioning. it is a game changer. I am able to resume about 70 percent of my former activities due to Enbrel.	To be able to be mobile and independent as long as possible.	It helps me tremendously. It is has reduced my flare ups and I am able to do most activities.
111	Patient	Enbrel	No	06085	Medicare	Older adults	Psoriatic arthritis	Chronic pain in base joint of big toes. Mobility compromised.	Mobility and pain reduction	The spread of psoriasis has been slowed

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112	Patient	Enbrel	No	47150	Medicare	Older adults, People with disabilities	Rheumatoid Arthritis	I am on disability now, it became effective last year. I struggle with fine motor use, which made working impossible it seemed and some of my favorite hobbies.	Improved hand function, without serious medication side effects and infections.	I did not feel improved, however I have been off Enbrel since June of 2022. I have declined since then, so perhaps it was doing something. I am seronegative and it is challenging. My doctor thought it caused my uveitis and insisted I stop it.
113	Patient	Enbrel	No	27502	Medicaid/Health First Colorado	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People with disabilities	Ankylosing Spondylitis	Limits my mobility and ability to do house hold chores as well as increase pain and decreased energy.	Joint mobility	None
114	Patient	Enbrel	No	14206	Medicare	People with disabilities	Psoriatic Arthritis	Constant pain, loss of mobility, weight gain, anxiety, loss of job and wages, isolation, strain on relationships	To increase basic function in order to live a more socially acceptable life	None
115	Patient	Enbrel	No	92260	Insured through employer	Older adults, People with disabilities	Ankylosing Spondylitis	Wouldn't be able to live without it. Would need full time care and suffer unbearable pain.	Less pain and be able to move	I am able to maintain a full time job. I still have a lot of pain but it's mostly manageable with other meds. I couldn't work and would be completely disabled

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										without it. Probably wouldn't want to live.
116	Patient	Enbrel	No	79602	Insured through employer		Rheumatoid Arthritis	slight mobility, activites, housework	relief of pain and more mobility	none
117	Patient	Enbrel	No	08083	Medicare	People with disabilities	Psoriatic arthritis	I'm 100% disabled	Lessen the pain and swelling in my joints and slow the damage.	None. I no longer take it.
118	Patient	Enbrel	Yes	80452	Medicare and Medicaid for disabled adults under 65	People of disproportionately affected sexual orientations, gender identities, or sex assigned at birth, People with disabilities	Ankylosing spondylitis and axial psoriatic arthritis	Constant intractable pain and fatigue; Unable to work or perform common chores and errands; severely limited social and recreational activities; unable to do my usual hobbies; had to give up my lifelong career as a dancer and dance educator; not working to my potential as someone with an MFA; lost most of my friends; creates unique challenges in relationships	Management of chronic pain and fatigue so that I can have some quality of life	Pain is more manageable so that I'm not totally bedridden and screaming in agony

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								especially romantic partnerships		
119	Patient	Enbrel	No	17406	Medicare	People with disabilities	RA	Drastically	Being able to do things	Temporary Improved symptoms
120	Patient	Enbrel	No	95205	Medicare	Older adults, People with disabilities	Rheumatoid arthritis	Effects my mobility, painful discomfort of my body along with swelling of feet,hands making it unable to do my job and enjoy life with my family.	Stop or minimize deformity of my hands and feet and help with the rheumatoid arthritis getting any worse.. The Ariel helped with the swelling	The Embrel helped somewhat with the swelling and painful discomfort in my hands and feet.
121	Patient	Enbrel	No	76137	Medicare	People with disabilities	Rheumatoid arthritis	Effects everything I do. There are days when I can't even get out of bed.	The pain and stiffness	Being able to move around

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122	Patient	Enbrel	No	86314	Medicare	Older adults, People with disabilities	Psoriatic disease	I am considered disabled as I have very limited mobility. I suffer from depression as well. Most days my pain level is a 7.	Having clear skin is a plus. No cracking and bleeding. Having less joint pain is a must!	I experienced clear skin and much less joint pain.
123	Patient	Enbrel	No	94015	MediCal	Older adults, People with disabilities	Rheumatoid arthritis and Ulcerative colitis	Both conditions cause pain. RA causes stiffness and make tasks difficult and confine me to my home 95% of the time	Symptom alleviation	i did not respond to this medication
124	Patient	Enbrel	No	85387	United Health Care Medicare Adv	Older adults	Psoriatic arthritis	Housework, family, friends, leisure activities , pain, anxiety.	Less pain, ability to enjoy regular activities	Beneficial for 3-4 yrs then had to switch to a different injectable
125	Patient	Enbrel	No	96161	Insured through employer		Rheumatoid Arthritis	Mobility, housework, family activities, exercise, pain and discomfort	Reduction of pain and inflammation	Taking Enbrel worked for me for about 2 years and then my symptoms of RA came back and I had to change medications.
126	Patient	Enbrel	No	63656	Insured through employer	Older adults	Psoriatic arthritis	Pain/discomfort, no longer able to work, mobility issues, anxiety	Less pain, more mobility	All around results for my health
127	Patient	Enbrel	No	05450	Medicare	Older adults	Rheumatoid Arthritis	Have daily pain in joints and have trouble doing daily things.	Less pain	Always helped with my pain

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128	Patient	Enbrel	No	98366	Tricare	People with disabilities	Psoriatic arthritis	I'm wheelchair bound	Slowing of progression and pain	None
129	Patient	Enbrel	No	33815	Spouse's employer insurance (I am on disability)	People with disabilities	Psoriatic Arthritis	Mobility, activities of daily life, pain, self care, housework, hobbies, career, driving	Movement, joint pain	At first, I had instant relief, I was able to bend over and walk freely and turn my head
130	Patient	Enbrel	No	60097-9172	Medicare	Older adults	Psoriasis & psoriatic arthritis	I have mobility issues & pain/discomfort	At that time, I was amidst a flare-up. I wanted clear skin.	My skin cleared up.
131	Patient	Enbrel	No	98030	Insured through employer		Psoriatic arthritis	Joint pain, cardiovascular disease	Pain reduction, no inflammation	Reduce inflammation
132	Patient	Enbrel	No	75211	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People with disabilities	Rheumatoid Arthritis and Antiphospholipid Disorder	Every part of my life is affected.	Less pain, better mobility, quality of life	Better quality of life, less pain, more social and family time
133	Patient	Enbrel	No	02360	Insured through employer		Psoriatic arthritis	Limits mobility, depression	Resolution of symptoms	Increase in mobility compared to prior. Almost complete resolution of deformed digits. Almost complete clearing of skin lesions.

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134	Patient	Enbrel	No	30720	Medicare	People with disabilities	Rheumatoid arthritis	Makes it very hard to do normal activities	Getting the right medication for me	It helped a lot
135	Patient	Enbrel	No	30728	Medicare	Older adults, People with disabilities	rheumatoid arthritis	I have limited accessibility in all walks of life because of distance necessary to walk. uneven paths, lack of handicap facilities, including grocery stores, restaurants and retail stores, activities including learning and spiritual renewal, recreation facilities,	My functionality as an older adult. Sometimes, being functional includes access to pain management.	Enbrel keeps the action of the RA from causing more deterioration of bones and helps me not feel so fatigued.
136	Patient	Enbrel	No	27705	Insured through employer	Children and families	Psoriatic Arthritis	This disease weakens tendons and has led to me rupturing my tendon with little to no symptoms. It causes multiple area joint stiffness and low level discomfort that impacts mood and sleep. Occasional increases in pain level at random times	The ability to get on the ground to play with kids, squat and bend over without stiffness to do my job. Sleep well to prevent other health issues, and exercise consistently to help with weight and healthy behaviors	When on Embral, I have been able To workout consistently with weights and walk daily up to 6 miles. I have hiked 27 miles in a day, and I have not had to seek care for any orthopedic problems over the past 8 years

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137	Patient	Enbrel	No	34689	Medicare	Older adults, People with disabilities	Rheumatoid Arthritis	Mobility limitations using walker, Unable to drive, Require assistance household chores & cooking meals, Chronic Pain, Depression & Unable to participate in outside activities, Depression.	Management of symptoms. Increased mobility, Adequate nutrition.	Management of symptoms, better mobility, pain management.
138	Patient	Enbrel	No	72070	Individual (private) insurance	Older adults, People with disabilities	Ankylosing Spondylitis	Pain, mobility, housework, recreation, work	Being able to have some semblance of a normal life	Less pain, somewhat improved mobility
139	Patient	Enbrel	No	28752	Medicaid/Health First Colorado	Older adults, Children and families, People with disabilities	Rheumatoid arthritis	It affects every aspect of my life I can't play with my grandchildren work or even leave the house very often	To keep my rheumatoid arthritis under control	It controlled my rheumatoid arthritis for 10 years

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140	Patient	Enbrel	No	43229	Medicaid/Ohio		Rheumatoid Arthritis	BEFORE Enbrel, I was unable to dress, bathe, eat, brush my teeth, lift my arms, work... do ANY normal activities (due to excruciating joint pain). I was pretty depressed and had involuntary suicidal thoughts. I couldn't even imagine living the rest of my life in so much pain. I knew I was a burden on my family, and that it would get worse. Now on Enbrel, I hope to live and enjoy a long life. My pain is manageable most days, with a rare "flare up" of extreme pain. Mobility and pain improved 90%+.	Good mobility and minimal pain.	Good mobility and minimal pain.
141	Patient	Enbrel	No	77868	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning	Psoriatic Arthritis	painful joints, problems moving etc	relief of pain and stopping arthritis from shortening my life	none
142	Patient	Enbrel	No	34453	Insured through employer	People with disabilities	RA	Pain, exhaustion and disability	Function	Clearing of brain fog some easing of pain

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143	Patient	Enbrel	No	49079	Medicare	Veteran, Older adults, People with disabilities	Rheumatoid arthritis	Difficulty with household chores, daily living, walking, lifting, carrying.	Reduction of PAIN and fatigue	It reduced my pain and fatigue and allowed me to work.
144	Patient	Enbrel	No	02081	Insured through employer	Black people, indigenous people, and people of color, People who are lesbian, gay, bisexual, transgender, queer, or questioning	Rheumatoid arthritis	Daily fatigue making it hard to concentrate at work and home and remember things, hard time putting clothes on in the morning and getting out of bed from stiffness, random flares make it hard to schedule get togethers because I might not feel well	Reduced pain and slowed progression of disease	Less pain and reduced flares
145	Patient	Enbrel	No	37013	Insured through employer		Rheumatoid arthritis	It's very difficult.	Less pain and fatigue	It helped alleviate swelling and pain
146	Patient	Enbrel	No	74743	Medicare	Older adults, People with disabilities	Rheumatory Arthritis	Limits all daily living activities moderately	Lower pain, slow down progression	Increased energy, greater flexibility
147	Patient	Enbrel	No	97055	Medicare	Older adults, People with disabilities	rheumatoid arthritis	It affects all of the things listed! In cold weather they are even worse.	independence	Enbrel did not help me.

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148	Patient	Enbrel	No	14580	Medicare	Older adults	Psoriasis. Psoriatic ArthrInterferesitis	Interferers with all aspects of daily living.	to be free of constant pain	less joint pain, less embarrassment over large patches of ugly skin and flaking hair debris
149	Patient	Enbrel	No	53511	Medicare	Older adults	Rheumatoid Arthritis	Stiffness in hands on occasion makes housework difficult at times	Relieve pain and stiffness	Didn't help me that much
150	Patient	Enbrel	No	58501	Insured through employer		Rheumatoid Arthritis	Fatigue	Less pain and swelling of joints	More mobility
151	Patient	Enbrel	No	60201	Insured through employer		Ankylosing spondylitis	This condition affects me in every way possible. Cronic pain affecting my mobility and mental health. I am so tired after a simple day of work and unable to do housework or socialize with friends and family. I often need help from my aging parents for simple things because I am so tired from working all day and have pain from just sitting at my desk. I need to work to afford health insurance and I still can't afford the cost	Reduction of chronic pain, more energy and lowered inflammatory markers (which means inflammation is doing less damage to my body).	Decreased pain, more energy and increased mobility.

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								of medication so my parent help me out financially.		
152	Patient	Enbrel	No	76087	Insured through employer	Older adults	Rheumatoid Arthritis	Mobility	Anti inflammatory and mobility	Anti inflammatory and mobility
153	Patient	Enbrel	Yes	80602	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning	Rheumatoid Arthritis	Occasional pain and discomfort, daily fatigue.	Remission	Reduction in symptoms for the very brief period I was on it.
154	Patient	Enbrel	No	53045	Medicare	Older adults, People with disabilities	Arthritis	Mobility, balance in selfcarek	Improved balance and flexibility	Balance and strength for employment

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155	Patient	Enbrel	No	02668	Insured through employer		Psoriatic Arthritis	Currently is under control	Better mobility, reduced joint swelling, less pain.	Almost complete remission
156	Patient	Enbrel	No	98338	Medicare	People with disabilities	Rheumatoid arthritis	I had to quit working I have a hard time with my daily activities of life and sometimes I get depressed	To stop the progression of the disease and to not have to use my cane for walking	I haven't had to use my cane for Almost a year and a half It just better Mobility and it's disease is not progressing very fast at all
157	Patient	Enbrel	No	61072	Insured through employer	Older adults	Rheumatoid arthritis	Low level content pain and fatigue interfere with high activity levels.	Comfort and control of progression	None
158	Patient	Enbrel	No	33762	Medicare		Rheumatoid arthritis	Somewhat	Relief	It helped for a year
159	Patient	Enbrel	No	85716	Insured through employer	Black people, indigenous people, and people of color	Rheumatoid arthritis	Brain fog/ Short term memory loss. Flair unable to be mobile. Vacation causes fatigue.	Fatigue, and flair pain management	Slowing progress of disease, prolonged in between flairs.
160	Patient	Enbrel	No	63119	Medicare	Older adults	Rheumatoid arthritis	Currently in remission. Rarely affects me lately.	Pain relief and range of motion increases	Moderate improvement in te condition.

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161	Patient	Enbrel	No	15717	Insured through employer	People with disabilities	Rheumatoid Arthritis	Some days I am bed-bound. Other days I can go to the store. I am always in pain.	Less pain, less joint damage.	none
162	Patient	Enbrel	No	28712	Insured through employer	People with disabilities	Rheumatoid arthritis	Condition limits life very much without medication.	Functioning as close to normal as possible.	Decrease in symptoms.
163	Patient	Enbrel	No	47126	Medicare	People with disabilities	Rheumatoid arthritis	Disabled with poor mobility, pain, swelling, and exhaustion. Unable to work, difficult to complete housework, cooking, unable to sleep for more than three hours at a time. Seldom leave the house for leisure activities. Had depression and anxiety when first diagnosed.	Lessening of pain, swelling, and sleep disturbances.	Only had a moderate improvement from it.
164	Patient	Enbrel	No	78735	Insured through employer		Psoriatic arthritis and psoriasis	Pain, limited use of joints, itching and burning	Control pain and long term damage to my joints. Control or eliminate psoriasis lesions	Less pain, psoriasis free slowing down progression of permanent joint damage
165	Patient	Enbrel	No	85611	I do not have health insurance	Older adults	Rheumatoid Arthritis	Moderately affected	less pain	Less pain, Increased mobility

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166	Patient	Enbrel	No	73012	Insured through employer		Rheumatoid Arthritis	My condition affected my daily life including mental physical ability to conduct daily activities including work.	To be pain-free, and able to conduct daily activities	Embrel dramatically change my life. It helped me get my life back.
167	Patient	Enbrel	No	23059	Insured through employer	Older adults	Psoriasis and psoriatic arthritis	Pain, fatigue	Mobility, mental health	Skin improvement, Mobility
168	Patient	Enbrel	No	48823	Medicare	Older adults, People with disabilities	Psoriasis, psoriatic arthritis	Mobility, self conscious of appearance, extremely painful, can not work	Mobility, gaining some pain relief	Did work for a while to clear up psoriasis
169	Patient	Enbrel	No	47392	Medicare	Older adults	Psorasis	Pain/discomfort	Pain free	Ability to do daily activities
170	Patient	Enbrel	No	34480	Medicare	Older adults, People with disabilities	Rheumatoid Arthritis	A lot	Reversal and less pain	More mobility
171	Patient	Enbrel	No	55114	Individual (private) insurance	People with disabilities	Rheumatoid arthritis	Pain, depression, fatigue	Less pain	Less pain and flareups

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172	Patient	Enbrel	No	95215	Through the school	People with disabilities	Rheumatoid arthritis	Always in pain especially with the continuous progression which affects other joints. I have depression. Some activities are difficult for me and when I have flare-ups, I would need assistance. Walking is difficult and standing is even worse.	Less pain or at least more manageable to be able to work.	Less flare ups and swelling especially on my hands
173	Patient	Enbrel	No	74036	Medicare		RA		Slow progression	
174	Patient	Enbrel	No	03104	Medicare	People with disabilities	Rheumatoid Arthritis	Moderately	Mobility	Mobility, Pain, Stiffness
175	Patient	Enbrel	No	52803	Insured through employer	Black people, indigenous people, and people of color, Older adults, Children and families, People with disabilities	RA	unable to do simple daily living task, unable to walk more than a block, unable to stand for 10 min or longer, pain level is always between a 6-9, unable to participate in leisure or exercise. suffer from anxiety and depression	improvement in mobility	not much of anything
176	Patient	Enbrel	No	83655	Medicare	Older adults, People with disabilities	RA, polyarthritis	Limits activities, fatigue, insomnia, depression, pain	Pain, mobility	Pain lessening, more mobility

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177	Patient	Enbrel	No		Individual (private) insurance		Rheumatoid Arthritis	Condition cause daily pain, episodes of extreme fatigue, difficulty dressing myself and preforming routine, daily tasks.	Decreased pain, limited or no fatigue, increased mobility	Decreased pain, limited or no fatigue, increased mobility
178	Patient	Enbrel	No	46835	Insured through employer	Older adults, People with disabilities	Rheumatoid arthritis	Affects every aspect of my life, at work and home. Any physical task is more difficult and often accomodations must be made.	To continue to be active, independent, able to work and pursue other activities	Enbrel allowed me to.vontinue to work at a demanding full-time for 22 more years until retirement.
179	Patient	Enbrel	No	33065	Individual (private) insurance	Older adults	Rheumatoid Arthritis	When I have flare ups, my mobility can be limited, i.e., limited use of hands or shoulder. Most often it is for limited timeframe. This can impact work, housework, cooking meals, and is usually associated with a moderate level of pain/discomfort.	The ability to lead a fully productive life. Ability to handle normal household activities, moderate exercise and full self care.	I have been on this drug for 20+ years. It has greatly limited the progression of my disease and I've lead a fully productive life. From the first day after taking Enbrel, my life improved dramatically.
180	Patient	Enbrel	No	73554	Insured through employer		RA	pain/sleep	lessen pain and sleep more restfully	none - I quite taking it because it did nothing.

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181	Patient	Enbrel	No	38555	Medicare	Older adults, People with disabilities	Rhumatoid Arthritis	Affects me greatly, even in minor everyday activities. I have to use a rollater to ambulate.	Less pain and more mobility.	None - allergic due to having Alpha gal syndrome.
182	Patient	Enbrel	No	93063	Insured through employer	People with disabilities	Rheumatoid Arthritis	Yes	Easing my symptoms so I can function day to day, prevention of further damage caused by my illness, remission would be the ultimate dream.	Less inflammation in my body, ability to walk easier, ability to start to enjoy my life again.
183	Patient	Enbrel	No	19081	Individual (private) insurance	People with disabilities	Psoriatic arthritis	Daily pain that limits the ability to do PT, function, work, recreation, and social aspects	Reducing pain to be able to help myself and be less dependent on others. Including being able to go to PT.	The disease has not progressed to permanently destroy my joints which is what my Dr said would happen if untreated.
184	Patient	Enbrel	No	98329	Insured through employer	People experiencing homelessness, People with disabilities	post streptococcal reactive arthritis	I am much less active and mobile.	Being able to work and keep food on the table.	It reduced flares, but I had to switch a couple years ago because it was no longer affecting me. I did take it while pregnant, though.
185	Patient	Enbrel	No	95747	Insured through employer	People with disabilities	psoriasis and psoriatic arthritis	Constant chronic pain in the joints. Loss of flexibility and mobility. Psoriasis puts a crimp on social activities.	Less pain and more flexibility. A lower visual observance of psoriasis scales.	Some degree of pain relief. Some relief from psoriasis.

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186	Patient	Enbrel	No	92126	Medicate Advantage	Black people, indigenous people, and people of color, People with disabilities	Psoriatic Arthritis	Enabled me to lead a somewhat normal life with less pain	To reduce pain and inflammation, no visible signs of psoriasis, to live life with a greater degree of independence	Same as above
187	Patient	Enbrel	No	67648	Medicare	People with disabilities	Rheumatoid Arthritis	Rheumatoid Arthritis for me is a painful disease. Many of my joints are inflamed and painful. It is difficult for me to do normal activities as basic as standing from a seated position and walking. I am no longer able to work.	Stop bone erosion. Reduce swelling.	My health benefits experienced from using this drug were limited so I was only on it for a short time before moving on to a different medication.
188	Patient	Enbrel	No	29356	Veteran's Health & Medicare	Veteran, People with disabilities	Rheumatoid Arthritis	In all aspects from cooking, cleaning to dressing & sleeping. It affects every tiny part of my life.	mobility - the ability to move without extreme pain	I have mobility back. From the time i took the first shot till now - I am able to walk
189	Patient	Enbrel	No	77433	Medicare	Black people, indigenous people, and people of color, Older adults, People with disabilities	Rheumatoid Arthritis	It affects my mobility, my ability to do housework and ability to focus due to pain.	The health outcome most important to me is reduced pain and inflammation.	Enbrel did help reduce pain. I was able to function almost normally.

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190	Patient	Enbrel	Yes	81413	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning, Older adults, People with disabilities	Rheumatoid Arthritis	This condition reduces my mobility, requires me to be on oxygen, causes pain and anxiety/depression. It creates an overwhelming fatigue that is mostly persistent.	Ability to carry out ADLs by myself and to do my hobbies (like gardening).	None
191	Patient	Enbrel	No	05477	Insured through employer	Older adults, People with disabilities	Rheumatoid arthritis	Pain, limitations of joint usage, difficulty in self-care and mobility	Reduce pain, reduce joint damage, increase joint mobility and strength	Enbrel greatly increased my joint mobility and strength, and reduced pain immensely
192	Patient	Enbrel	No	72076	Medicare	People with disabilities	Rheumatoid Arthritis	It affects every part of my daily life and I am currently disabled due to it.	Remission	None
193	Patient	Enbrel	No	10990	Insured through employer	Older adults, People with disabilities	Psoriatic arthritis	24 hrs a day 7 days a week for over 40 years	Reduced inflammation and disease progression	Slowed disease progression and clearing of psoriasis

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194	Patient	Enbrel	No	34491	Medicare	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People with disabilities	Rheumatoid arthritis	I have constant pain, depression, anxiety, guilt, fatigue, brain fog. I have trouble sleeping due to pain. I have trouble doing stuff like cleaning my home, especially the shower and floors. I usually order stuff online and either do drive up or have it shipped to me because going to the store is exhausting.	Manage pain and fatigue	Enbrel did not work for me, but I had to try it because my new insurance wouldn't approve the drug that I was already taking until I failed 2 of 4 drugs they preferred.
195	Patient	Enbrel	No	95125	Medicare	Older adults	RA	pain/discomfort; disruptive to daily living	Remission, if not cure	Was not effective
196	Patient	Enbrel	Yes	81007	Medicare	Older adults, People with disabilities	Psoriatic arthritis	Unable to engage in meaningful work due to mobility, pain and anxiety issues	Decreased pain	None

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197	Patient	Enbrel	No	37931	Insured through employer	People with disabilities	It was prescribed for Rheumatoid Arthritis	I have pain/aches 24/7. I have limited grip strength and arthritis in my knuckles so opening doors, cabinets, bottles, medications, and packaging are difficult. I am only able to stand for about 10 minutes. My walking is only indoors due to balance issues. My toes, ankles, hips, shoulders are all affected by RA. I have to use a stool to cook. I rarely am able to go out for fun. I am being treated for depression. I just don't have the stamina I used to have.	Being able to work and have a little energy when I get home.	It helped some. Pain relief was good.
198	Patient	Enbrel	No	20109	Medicare		arthritis	mobility but it didn't work well enough	mobility, pain	

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199	Patient	Enbrel	No	75009	Insured through employer	Black people, indigenous people, and people of color, Children and families	Rheumatoid arthritis	I have mild to moderate RA so I am able to complete all of my daily activities. If I am in a flare I am less likely to do those activities even if I could do them with some discomfort. I try to prioritize rest during flare ups so I may cancel plans etc. RA has affected me the most mentally and emotionally. I feel out of control and helpless sometimes.	Minimize pain and joint damage.	Greatly reduced pain and inflammation
200	Patient	Enbrel	No	60085	Medicare	Older adults	rheumatoid arthritis	It is slowly taking away my ability to physically care for myself. I have suffered severe pain, depression and considered suicide.	Reasonable mitigation of the limitations the disease has brought on. See above answer	The drug over the course of two years showed no health benefit and I had to add a second injectable which also left me without symptomatic relief or health benefit.
201	Patient	Enbrel	No	75006	Individual (private) insurance	People with disabilities	Rheumatoid arthritis	Pain, limited mobility, reduced motor skills, fatigue	Reduction of disease activity	None

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202	Patient	Enbrel	Yes	80021	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People with disabilities	psoriatic arthritis	severely limits my ability to move regularly, in constant pain from joint inflammation	reduction of pain and arthritic flares	reduction in some pain (from a 9 to a 5-6)
203	Patient	Enbrel	No	56258	Medicare	People who are lesbian, gay, bisexual, transgender, queer, or questioning	Psoriatic Arthritis and Psorisis	Stiff and painful joints, patches of skin scales and patches and itching	Able to move and control skin patches	Able to move, swelling has gone down, able to live without pain and use of arms hands legs
204	Patient	Enbrel	No	14607	Medicare	Older adults, People with disabilities	RA	Decreased mobility, chronic pain, anxiety, difficulty doing normal activities	Stop deformities in hands.feet, reduce pain	Reduced pain, stopped new deformeties
205	Patient	Enbrel	No	19446	Insured through employer	Older adults	rheumatoid arthritis, reactive arthritis	causes pain & discomfort and prevents participation in some activities	pain relief, better sleep	

206	Patient	Enbrel	No	38134	Insured through employer	Black people, indigenous people, and people of color, Older adults, People with disabilities	Ankylosing spondylitis	This condition significantly affects my physical, mental, emotional, and financial abilities. Physically I struggle with doing every day tasks that most are able to perform effortlessly. I have difficulty just getting out of bed independently. I struggle with showering and dressing. I still work but can only work part-time because the work I do as a nurse are long hours and physically demanding. It takes me 2 days to recover from working 1 12- hour shift which impacts my physical and financial well-being. I can't plan house cleaning activities unless I am not working for at least 2 days before or after a work shift, so my home is not as clean as I would like it to be which again impacts me emotionally. I suffer with the ability to focus my mind, because most things like reading and performing tasks are exhausting. I am not able to get restorative	Decreased pain, the ability to think clearly and focus, perform and complete tasks in a timely manner. To just feel productive and like a normal person.	For the time I used Enbrel it helped to slow the progression of the disease process which I didn't know at the time, but having not used it in a while I now know that Enbrel was very effective at allowing me to continue with living my life as normal as possible.

								sleep when I rest because I am in pain all the time. I could continue with how this dis- ease in my body impacts me and my life, but you get the picture.		

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207	Patient	Enbrel	No	20688	Insured through employer	Older adults	Undifferentiated Spondyloarthopathies-RA,PA & AS	Each day is unpredictable, but I am affected each day in some way, physically. Most parts of my body is affected by arthritis in one way or another and weather is a huge contribution to overall symptoms. Dont handle winter well, nor summer due to barometric pressures and humidity.	How much pain means more to me rhan I'm my ability to do things. I no longer carry expectations for activity.	Started in 2013 after an unsuccessful year with Humira and MTX. I'd like to think my weekly use of Enbrel is helping to control deterioration to a point. I'm certainly in more pain without it. It's also kept the ankylosing of my spine to a minimum so far. It did stop my chronic urinary tract infections.
208	Patient	Enbrel	No	23112	Insured through employer	Black people, indigenous people, and people of color	Rheumatoid Arthritis		being free from pain)	Just started but I'm starting to feel better.
209	Patient	Enbrel	No	86004	Insured through employer	Older adults, People with disabilities	Rheumatoid Arthritis	Fatigue, limited mobility, pain/soreness, anxiety and depression, flares prevent any activities.	Less fatigue, slowing down disease progression, preventing heart and lung damage caused by inflammation, less frequency of flares.	Less fatigue, caring for myself and family, exercising (low impact) improved mental health.
210	Patient	Enbrel	No	54452	Individual (private) insurance		Rheumatoid arthritis	Pain, stiffness, fatigue	Less pain and fatigue	Partial relief of symptoms

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211	Patient	Enbrel	No	01801	Insured through employer		Rheumatoid arthritis	Helps me do my everyday tasks	No pain	No or little pain less fatigue
212	Patient	Enbrel	No	43560	Insured through employer		Psoriatic arthritis	It affects all aspects of my daily life when I'm in a flare. I find most tasks difficult to get through.	Quality of life, getting back to as close to normal as possible.	I've experienced less overall flares, it's the closest to normal I've felt.
213	Patient, Caregiver	Enbrel	No	59750	Insured through employer	Older adults, Children and families, People with disabilities	Rheumatoid arthritis	Daily pain, inability to completely clean my house, I don't run anymore, or hike or hunt. Showers and baths are a major undertaking and exhausting.	I want less pain, more energy, ability to walk more.	For sometime, it worked with pain and inflammation. Then it stopped working for me.
214	Patient	Enbrel	No	77355	Husband retired from Shell Oil	Older adults	Rheumatoid Arthritis	Much better now, more energy, less achy-ness, full mobility	Less achy-ness and fatigue	Less achy-ness and fatigue, slowed joint damage
215	Patient	Enbrel	No	20852	Kaiser and Medicare Advantage	Older adults	Rheumatoid Arthritis	Until recently, I functioned fairly well.	Being able to live a relatively normal life.	Kept most of the RA issues controlled.

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216	Patient	Enbrel	No	84043	Medicare	Older adults	Rheumatoid arthritis	Fatigue painful hand joints and loss of grip	To prevent more joint involvement	I had a severe reaction which immobilized me in bed with a headache which was the most severe I had ever experienced. I reported to Enbrel pharmacy
217	Patient	Enbrel	No	55119	Medicare	Older adults	Psoriasis/Psoriatic arthritis	Pain and discomfort, itchiness, inflammation	Being able to move more easily, reduce the scales and itchiness of lesions	At the time it mostly cleared my skin and somewhat slowed the progression of the arthritis.
218	Patient	Enbrel	No	87507	Medicare	Older adults	rheumatoid arthritis	Painful joints restricting usage of hands.	remission of disease or at least slow progression	slowed disease progression

219	Patient	Enbrel	No	94110	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People with disabilities	rheumatoid arthritis	I don't have as much energy as other people my age. I can't walk as far as most people my age. I can't work as many hours as most people my age (because of both fatigue and pain from sitting at a computer). I don't make as much money as I would if I could work more hours. I struggle with a lot of household tasks, and my husband has to pick up the slack. I have to carefully decide what to do with my free time because my energy is so limited. When it comes to doing physical activities for fun, I am limited to walking (slowly), tai chi, and swimming. I've had both knees replaced; each surgery entailed months of not being able to work and only being able to work a little as I rehabbed, resulting in major income loss. With the ups and downs of RA and being immune compromised because of medications (and thus getting sick more often and for longer than my able-bodied	Reduction of pain; increased mobility; reduction of fatigue.	Enbrel worked really well for me for a few years. It reduced my pain, gave me more energy, and increased my mobility. Then, it just stopped working.

								peers), I experience income loss. RA has affected every single aspect of my life, including my choice of career (I quit classroom teaching because it was too physically tiring), my choice of where to live (in a temperate climate), and my social circle (people who are willing to be patient and understanding with my limitations). I experience some level of pain every day, all the time. It fluctuates, and I'm pretty good at blocking it out unless it's really acute. I often feel like a failure because I am not able to live up to society's standards of what someone my age should be able to do. Society doesn't see me as disabled because I often look able-bodied and healthy, and even people who know me well often seem to expect that I'll be able to function as if I don't have RA. That makes me stressed and depressed. I feel like I'm constantly disappointing others. I		

								feel like I'm constantly scrambling to just try to keep up. I have near-constant anxiety about my health and about my ability to earn enough money.		

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220	Patient	Enbrel	No	24382	Insured through employer		Rheumatoid arthritis	Before taking Enbrel, RA significantly affected all aspects of my life…walking was difficult, self care (washing & brushing my hair), housework was difficult, working as a teacher was increasingly difficult.	Quality of life.	I am able to move, care for myself and do everything I want to without pain.
221	Patient	Enbrel	No	78633	Medicare	Older adults, People with disabilities	Rheumatoid arthritis	All the ways listed. I have numerous problems and they get progressively worse.	Control the debilitating effects, relieve pain and help maintain ways to improve health.	It has helped to control or slow the symptoms of my disease
222	Patient	Enbrel	No	11704	Insured through employer		Rheumatoid	Pain	Limiting pain	Limited benefit
223	Patient	Enbrel	No	15229	Insured through employer	American Indians and Alaska natives, People with disabilities	Spondyloarthritis	Severe fatigue (affects work and all aspects of personal life), increased anxiety and depression, Difficulty engaging in social activities due to mobility, fatigue and pain.	Consistent pain/inflammation management and manageability of the fatigue	Consistent pain management, decreased fatigue, more independence in self care and housework.

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224	Patient	Enbrel	No	36305	Medicare/United Health Care for retired state employees	Older adults, People with disabilities	Rheumatoid Arthritis	Pain/discomfort - mobility - depression	Decrease in pain and increased mobility	This medication did not help me
225	Patient	Enbrel	No	19609	Medicare	Older adults	Rheumatoid arthritis	Fatigue and pain	Prevent damage	Pain relief
226	Patient	Enbrel	No	91304	Medicare		Rheumatoid arthritis	I have pain and swelling in the joints in my hands and feet. I have limited strength and flexibility of my fingers. My right hand is worse with my fingers deviating laterally.	Prevention of further joint destruction, less pain and increased mobility	Enbrel has decreased my finger/hand swelling and improved mobility
227	Patient	Enbrel	No	61822	Medicare	Older adults	Rheumatoid Arthritis	On a good day I do well but during flare ups I can hardly walk. (I use paper plates all the time because I tend to drop things and I use a rollator.)	Being able to stay in my home and not getting to the point where I have to rely on my children to take care of me.	I have experienced fewer flare ups and have not had much joint damage. This is important to me because I play piano and violin and would like to keep doing so.

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228	Caregiver	Enbrel	No	03842	Insured through employer		Juvenile Arthritis	The disease causes my child to experience profound fatigue and joint pain that causes them to miss school and fall behind in their academics. It also prevents them from working full time and interferes with their ability to eat.	Prevention of symptoms and protecting joints from irreversible damage.	Remission of all symptoms
229	Patient	Enbrel	Yes	81001	Medicare	Older adults, People with disabilities	R.A.	Work, leisure activities, pain and discomfort	To not be in pain and discomfort	Don't have pain and no swollen joints
230	Patient	Enbrel	No	63367	Insured through employer	People with disabilities	Ankylosing Spondylitis	Constant pain causes me to lose sleep, be in a bad mood, and have difficulty moving,	Better energy and more ability to function	Short term lower pain and mobility
231	Patient	Enbrel	No	38305	Insured through employer		rheumatoid arthritis	Before RA, I ran 6-8 miles daily and had multiple other hobbies alongside working full time as a professor, wife, and mother. Now, I do well to complete daily tasks in online teaching and some household chores.	prevention of further disability and accidents (especially falls because of risk from co-morbidities associated with RA)	decrease in RA symptoms - fatigue, pain, swelling, stiffness

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232	Patient	Enbrel	No	47802	Medicare	Older adults, People with disabilities	Rheumatoid Arthritis	My arthritis has greatly affected my mobility. I am very limited to all activities, in my life. My wife has become my caretaker.	I would say that the best thing I could hope for, is that the medicine. Would help me achieve at least 30 to 40 percent of my comfort.	This drug greatly helped relieve my discomfort and mobility.
233	Patient	Enbrel	No	24538	Medicare	Older adults	Psoriatic arthritisYrs and psoriasis	Y es	Pain relief and Mobility	Decreased psoriasis and some pain
234	Patient	Enbrel	No	78260	Medicare	Older adults	RA and Ankylosing Spondylitis	Yes	Reduced pain, stop progression of diseases, increase daily living activities	It did stop progression and helped reduce pain
235	Patient	Enbrel	No	08021	Medicare	Older adults, People with disabilities	Psoriatic Arthritis, psoriasis	Mobility, self-care, housework, leisure activities, pain, discomfort, depression	Less pain, more activity	It helped with my pain and cleared my psoriasis
236	Patient	Enbrel	No	30504	Medicare	Older adults	psoriatic arthritis	During flares, there is low back pain plus several peripheral locations of pain and inflammation. It can limit my activities during the flare.	pain reduction/elimination and non-serious side effects	pain reduction/low inflammation activity
237	Patient	Enbrel	No	44216	Insured through employer		Rheumatoid arthritis	Not able to work, pain, discomfort, limited mobility	Slowing the progression of the disease	It didn't work as well as my rheumatologist has hoped

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238	Patient	Enbrel	No	49426	Insured through employer	Older adults	Phsoriatic arthritis [8]	Pain gave up water-skiing, ice skating and tubing behind a boat. Daily life I tire quicker but still excell in my job.	Less pain, stop joint damage, and hopefully remission.	Much less pain, less fatigue, able to do my job and also yard work.
239	Patient	Enbrel	No	61114	Insured through employer	People with disabilities	RA	Mobility	More mobility	Sinus infections
240	Patient	Enbrel	No	28752	Medicare	People with disabilities	Rheumatoid Arthritis	I am affected in my everyday living activities. I struggle with physical & mental limitations such as no longer being able to work (I was a nurse) bathing, cleaning my house, doing errands outside of home, (the going out part), fixing my food, doing laundry, etc. This is difficult due to being in constant varying degrees of pain & the constant struggle with fatigue, & the mental aspects of both of those - depression etc. Everything as a whole varies day to day & does not always seem to have a rhyme	What is most important to me is to be in less pain overall, leading to less damage occurring & possible reversal, which leads to less fatigue, less mental issues, & I can then do more for myself & feel better doing it.	Less overall pain & inflammation

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								or reason to it which is difficult to overcome & cope with.		
241	Patient	Enbrel	No	32789	Medicare	Older adults, People with disabilities	Rheumatoid arthritis	In constant pain cannot do daily activities	Pain control, mobility	None

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242	Patient	Enbrel	No	72103	I do not have health insurance		Rheumatoid arthritis	I causes me daily pain and stiffness in various degrees, a lot of fatigue, which decreases my mobility some days to the point I have to be in bed. Other days it just slows me down in my daily activity. But it's enough to stop me from working and to require help on basic daily things. It has caused me a great deal of anxiety for the future, something I'm working on at the moment.	Increased mobility and less pain, less flares.	Slightly less "bad" days (flare days); I believe it has slowed down the progression, since I don't feel worse than before, even if I don't feel better.
243	Patient	Enbrel	No	77807	Insured through employer	People with disabilities	Rheumatoid Arthritis	Constant pain, lack of strength in hands, eye issues, digestive issues, mobility issues, skin irritation.	Reduced pain and increased mobility	Reduced pain
244	Patient	Enbrel	No	91362	Insured through employer	Older adults, Children and families, People with disabilities	Rheumatoid Arthritis	Deal with daily fatigue and occasional flares	Improve symptoms or reduce inflammation of joints	Medication reduced inflammation and has help decrease other symptoms
245	Patient	Enbrel	No	98102	Medicare	People who have AIDs or HIV, Older adults	Psoriasis	Uncomfortable and embarrassing but not truly disabiling	Clear skin	Initially total clearing almost miraculous

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246	Patient	Enbrel	No	38068	Medicare	Older adults, People with disabilities	Rheumatoid arthritis	Pain, fatigue, anxiety, depression, loss of mobility, inability to work, to do housework,inability to engage in leisure activities, inability to make commitments about any physical activity	Reduction of pain, fatigue, and joint deformity.	Reduction of pain and fatigue
247	Patient	Enbrel	No	04357	Medicaid	Older adults, People with disabilities	PsA	It effects all parts of my life quite a bit.	Pain	Pain, inflammation, sleep, rash, gastro issues, and mental health
248	Patient	Enbrel	No	38018	Insured through employer	People with disabilities	Psoriatic Disease	I'll try not to let it affect my life as much as possible but it's dibilitating days I can't get out of bed.	Not having joint damage	It worked for me for about two years and did a decent job
249	Patient	Enbrel	No	87005	Individual (private) insurance	People with disabilities	Rheumatoid Arthritis	This disease attacks more than just joints. Mobility from joint pain & damage does limit basic daily living, but so does the connective tissue damage, the pain and blurriness of severe dry eye, and most importantly, the debilitating chronic fatigue. Feeding oneself, let alone	Reduce/slow down the damage and, hopefully, ease the fatigue and pain.	It reduced some of the swelling, pain and fatigue.

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								working, can be impossible.		
250	Patient	Enbrel	No	34286	Medicare	People with disabilities	Rheumatoid Arthritis	Caring for myself in most aspects as my hands, shoulders, back, legs, feet, and vascular systems are all affected	At this point in time...pain	None...my lungs filled with fluid & was hospitalized twice in 4 months

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251	Patient	Enbrel	No	12413	Insured through employer		Rheumatoid arthritis	I have daily joint pain and stiffness. I am more tired and have less stamina and strength, and drop things a lot. I need to rest more and take breaks during many activities. I'm unable to do things I enjoyed such as hiking and volunteering as a firefighter. I've had to modify how I do things or ask for help because I'm not strong enough. Many activities cause pain, like walking or standing for extended periods. My anxiety and depression have become worse, I believe, because of the limitations I have. I worry about the changes in my body that I can't see, such as joint damage and the effects of RA on my heart. I also think about becoming a burden on my family because of my limitations. When the pain, stiffness and swelling are bad I	The most important outcomes for me are relief/reduction of pain, swelling, and stiffness and longer term prevention of damage to my body.	I have seen a reduction in pain and stiffness and fatigue along withfewer flares since being on Enbrel.

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								have to rest for days and take more medication to get through the flares. I fear becoming trapped in my own body someday because of RA.		

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
252	Patient	Enbrel	No	23322	Insured through employer	Children and families	Rheumatoid Arthritis	pain/discomfort, work, leisure activities, some mobility	to lesson pain and discomfort and allow me to live a regular life	I only used drug for 3 weeks because I developed allergic reaction to injection and had raised hives and itching at injection sites. The drug was working on condition though.
253	Patient	Enbrel	No	24184	Individual (private) insurance	Older adults, People with disabilities	rheumatoid arthritis	my mobility is affected, as are housework, family and leisure activities.	To be pain-free, and to enjoy life much more.	I didn't think there were any until I had to forego one weekly dose of my Enbrel. The difference was terrible, as the pain was greatly increased, as was the necessity to limit my life and leisure activities due to the pain and inflammation. My life enjoyment was severely impacted.
254	Patient	Enbrel	Yes	80004	Medicare	Older adults	Rheumatoid Arthritis	Affects usual activities	Relief from pain of	Some relief from pain
255	Patient	Enbrel	No	10036	Insured through employer	Older adults, People with disabilities	Rheumatoid arthritis	I am now disabled	Having my condition under control	It didn’t help me
256	Patient	Enbrel	Yes	80207	Individual (private) insurance	People who are lesbian, gay, bisexual, transgender, queer, or questioning,	rheumatoid arthritis	periodic flares that keep me from moving my limbs freely or without pain, depending on severity	lack of pain and inflammation and protecting the long term health of my joints	Keeps my flares to a minimum

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						Children and families				
257	Patient	Enbrel	Yes	80907	Insured through employer	Children and families, People with disabilities	Rheumatoid arthritis	It is completely debilitating affecting mobility (ambulatory wheelchair driver), limited use of arms/hands, organ damage, multiple reconstructive surgeries, extreme care needs.	The ability to work and function.	The ability to work again.
258	Caregiver	Enbrel	Yes	80121	Insured through employer	Children and families	Juvenile arthritis	She has mild pain daily but mostly does everything she wants to do.	Getting to remission	Massive pain reduction, full range of motion w affected joints
259	Patient	Enbrel	Yes	80004	ACA Plan		RA and switched when I developed UC as well	Chronic, Pain and fatigue	Living a more normal	Remission
260	Patient	Enbrel	Yes	80130	Individual (private) insurance	Older adults, Children and families	Psoriatic arthritis	Unsightly skin condition that affects mental health and perception by others. The sore stiffness in joints is also debilitating at times	A more normal lifestyle free from ridicule or pain	Actually I have taken Humeria, Enbrel, Cosentyx, Stelera and Tremfya at one time or another for various periods of time with varying results. Enbrel the longest. It helped

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
										me manage the negative effects of my condition.
261	Patient	Enbrel	Yes	80524	Medicare	Older adults, People with disabilities	Rheumatoid arthritis	It affects my physical abilities. It can be difficult to exercise or play any kind of sport. I also fight fatigue.	Painlessness, no fatigue and more energy would be great!	Less pain, less fatigue & more stamina.
262	Patient	Enbrel	Yes	80122	Insured through employer	People with disabilities	rheumatoid arthritis	Enbrel was one of the drugs that I have been on to treat my RA. This biologic did help me to continue to function and work, care for my family. I have had been on a lot of biologics and know that this one makes a huge difference for many. In my situation, I had burned through all of the drugs in that class and it was time to move onto a different class of biologics.	The ability to function daily with decreased to no pain and slowing or stopping of the disease progression. Remission is the goal.	Ability to live a normal life due to decrease inflammation and pain

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
263	Patient	Enbrel	Yes	80027	For most of the time I was on Enbrel, I had student insurance through the University of Colorado. This is when I encountered the most difficulties affording the medication. After I was married and on my husband's private insurance, it was easier.	Children and families	rheumatoid arthritis	When my rheumatoid arthritis is not well controlled, I have extreme difficulty functioning in my daily life. Depending on which joints are impacted, I can have difficulty walking, doing housework, sitting at my desk, typing (which is extremely problematic as I work as a writer), driving, sometimes even lifting a mug to my mouth to drink. Uncontrolled RA can also come with intense fatigue, which makes it very difficult to care for myself and my three children. All of this can come with a great deal of guilt and anxiety. Uncontrolled RA impacts not just me, but my entire family.	I need to be able to function in my daily life. Pain and fatigue need to be minimized so that I can complete my work, take care of my family, and enjoy my life.	I am a working mom of three small children, and an effective biologic is essential for me to be able to function well enough to care for myself and my family. Enbrel was the first biologic that ever got my RA under control after my diagnosis. It allowed me to finish my dual degree graduate program and earn a law degree and a masters, which would not have been possible with uncontrolled RA. Enbrel was also the medication that eventually got my postpartum flare under control after my first son was born, and allowed me to experience being a new mom without the added burden of pain and fatigue from RA (on top of pain and fatigue from just being a new mom!). Enbrel also controlled a terrible flare during my difficult second pregnancy, allowing me to care for my first toddler son and significantly reducing

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
										the uncontrolled inflammation that my second son was exposed to in utero.
264	Caregiver	Enbrel	Yes	80920	Insured through employer and Medicaid	People with disabilities	Psoriasis	Extreme skin breakdown/itching, capacity to attend school, pain in joints	Consistent management of symptoms to minimize breakthrough episodes	Psoriasis is fully managed - instead of plaques head to toe my son experiences very few outbreaks now

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265	Patient	Enbrel	Yes	80246	Medicare	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People who have AIDs or HIV, People with disabilities	Rheumatoid Arthritis	All areas asked to considered are all daily challenges I face with this and other health challenges I have: TBI, HIV, post hip replacement and fusions due to the condition treated.	Remission! Ability to be mobile with least amount of pain	I have had no flares or major events while on Enbrel. I have tried 4 or 5 other brand names which produced no results that Enbrel has. I changed many years ago from enbrel to attempt to get the best results and returned to enbrel for the best I've experienced results.
266	Patient	Enbrel	No	82801	Insured through employer		Ankylosing Sponylitis	Quit job due to lack of accommodation, stiff joints, light sensitivity, more fatigue, anxiety	Being able to live a fulfilled life	Less joint pain, less occurrences of uveitis
267	Patient	Enbrel	Yes	80204	Medicare	People with disabilities	Psoriatic arthritis	I am bedridden without it	No pain equals healthier lifestyle	My joints are helped to the point I can work out

Survey Responses Continued

ID#	What adverse health effects have you experienced from using this prescription drug, if any?	What factors led you to the prescription drug you are currently taking? Select all that apply:	Have you tried taking other prescription drugs to treat your condition? If so, how many?	If you have tried other prescription drugs to treat your condition, what were they? Were there any beneficial or adverse health effects of these other prescription drugs?
1	None	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Humira and Enbrel worked well when I was on corporate insurance or Obamacare. but are absolutely unaffordable on Medicare (between $4,000-$7,000/MONTH WITH insurance!!). Not an option on a fixed budget. Or any normal person's budget. It is ridiculous that Medicare patients cannot go through the manufacturers copay assistance program. And that Medicare cannot negotiate drug prices. This is putting all the cost burden on the most vulnerable populations - elderly and disabled people. I am on Remicade now which isn't as effective and I have a lot of joint pain. Also my veins are getting scar tissue from Remicade IV infusions and it's getting difficult if not impossible to give me an IV. Remicade is currently THE ONLY afford and arthritis medication other than methotrexate which made all my hair fall out. But soon I will no longer be able to take Remicade

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				due to my veins. And I will be bedridden again.
2	injection site reactions	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Humira, Enbrel, Taltz, Stelara, Cosentyx. All but Stelara worked for me. Currently on Cosentyx and have seen the most improvement from it.

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3	none, aside from the fact that it only worked for me for about 2 years.	I cycled through other medications that didn't work before finding this one., i started on methotrexate (which made me too sick) and then transitioned to embrel which stopped working. I am now on Humaria.	Yes, two other treatments.	Methotrexate and Humaria. Both work(ed) very well to reduce inflammation and pain. Methotrexate just made me too sick. Humaria is my current drug.
4	None	It's the drug my provider prescribed and it works for me., It was required by my insurance company.	Yes, two other treatments.	Methotrexate and humira
5		first one available in 1990	Yes, three other treatments.	Atonel,
6	Stomach issues first few doses	It was required by my insurance company.	Yes, one other treatment.	Humira. Not effective, no adverse effects
7		It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Remicade, Humira, cimzia, Xeljanz, Rinvoq
8	None	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., It was required by my insurance company.	Yes, two other treatments.	Methotrexate caused liver damage. I took Enbrel for 10 years before it stopped working for me. That was 10 years of relief though.

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9	Local swelling and itching	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Simponi, humira, Avsola, Xelzanj
10	None	It was required by my insurance company.	Yes, more than three other treatments.	Methotrexate, humaria, hydroxycortaquine
11	Injection site bruising and temporary pain after administration	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Methotrexate- didn't work Plaquenel - didn't work Humira - didn't work and I broke out in a rash over my entire body
12	Lower immune system. That's with all the Biologics I've taken.	The 1st home given Biologic and I had done some research on it. My Rheumatologist thought it was a good decision.	Yes, three other treatments.	MTX(still taking) Remicage- it didn't work well Orencia-worked for a while Plaquenil- bad stomach upset I'm currently on Rutuxin which is working, I've had to raise my dose. Fir all of them, a shot at home(if it works, is stomach easier and you'd think cheaper. My GI track is done with pills.

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13	none	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Humira, Enbrel, Remicade, Cosentyx, Xeljanz, Rinvoq, Otezla, Orencia, and now Simponi Aria
14	I have not noticed anything more than occasional injection site redness or itchiness which fades after a few hours	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Methratrexate(kidney issues),avara (allergic), humerus (anaphylactic reaction), Orencia, Rituxan, Actemra(too low white blood cells)Rinvog (too low white blood cells)Several other drugs I can't try because of other drug allergies or they work with similar mechanism so rheumy won't try them. Xeljam worked well until it didn't and then I tried rinvog and rheumy won't let me go back to it because of rinvog low white blood cell and they are similar(Jak)
15	Decreased ability to fight infextions	It was required by my insurance company.	Yes, more than three other treatments.	Humira, cimzia
16		I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	

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17	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Naproxen, meloxicam, and other nsaids
18	Chills	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Humira-stopped working after 1 year. Xelganz - didn’t work very well Actemra-on this one now. It’s only been 3 weeks
19	None.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., It was required by my insurance company.	Yes, more than three other treatments.	Don’t remember all the names. I had allergic reactions with my skin, itching, pigmentation reaction, skin peeling.
20	N/A	I went through all of the medications and now we’re retrying previous medications.	Yes, more than three other treatments.	Gold Injections, Methotrexate, Weekly Solumedrol IV’s, Humira, Actemra, Orencia, Remicade, Rituxin

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21	None	I'm currently not on a medication for my PsA due to insurance and affordability	Yes, three other treatments.	Stelara, it worked quite well but my insurance changed and it was no longer covered. Otezela, could not tolerate due to it causing SEVERE depression. Taltz, by far the best medication so far in decreasing my stiffness, my chronic pain, joint swelling, and helping my mobility. Unfortunately I became severely ill with an antibiotic resistant pneumonia and had to stop Taltz to treat it. My rheumatologist decided it was no longer good for me to take due to risk of severe infections/antibiotic resistant infection.
22	Chance of MS	It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	Actermra

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23	None	I cycled through other medications that didn't work before finding this one., The method of delivery or injection works best for me., Affordability	Yes, more than three other treatments.	Methotrexate, Orencia, Humira, Symponi, Benlysta, Rituxan, Actemera. Extreme side effects to all of these I can only do Actemra at home not IV infusions developed hives immediately as well as to Benlysta IV, anaphylaxis reaction to one treatment had to have epinephrine shots given then had re bound episode at home the following day, Methotrexate made me extremely nauseated still can’t take it since taking as child
24	My RA doctor had me take Embrel for a very limited time, I believe for 2 weeks and took me off it quickly as I had a bad reaction. Within a day of the shot, I would get a pain in an area on my back and then a large whelt would pop up. It last for a few hours and would then disappear. The whelts were the size of a lemon. I am currently taking Xeljanz for my RA.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Methotrexate-heart side effects, sulfasalizine-dr. decided to try another drug, hydroxychloraquin-eye issues, Embrel-whelts with pain, Humira-injection site reactions, Orencia-headaches, Cimzia-did not work at all, Xeljanz-seems to work to keep the RA under control.

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25	none	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	puva and light treatments resulted now in numerous precancer or cancerous skin
26	none	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Orencia, Remicade, Humira, and a couple of others I don't remember their names. Had anaphylaxis reactions to Orencia and Remicade. Humira was ineffective.
27	Not sure if the depression is from this medication.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, one other treatment.	Methotrexate. After 9+ years on this medication non reversible, untreatable blurry eyes occurred
28	None that I can remember.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Enbrel, Arava, Otezla and others I can't remember anymore
29	Multiple skin cancers, including two melanomas	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Aspirin, methotrexate, Humera, gold shots, Remicade, Enbrel, Orencia

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30	Initially a rash at injection site that went away the longer I used it	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Methotrexate and leflunomide, methotrexate just made me feel ill, leflunomide did help some, but not enough
31		It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Hydroxychloroquine, steroids. Still take half the lowest dose of hydroxychloroquine . Steroids helped but addictive, side effects and hard to stop.
32	None	I cycled through other medications that didn't work before finding this one.	Yes, two other treatments.	Plaquenil, methotrexate (still take these) added enbrel. Now I added xeljanz and discontinued enbrel.
33	Immune suppression	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Humira, Enbrel, Methotrexate, and now on double dose of Cosentyx
34	none	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Methotrexate (caused liver issues needing hospital stay), minocycline (ineffective), Actemra (blood counts went crazy, had to stop), Humira (ineffective), Remicade (anaphylaxis), Orencia (ineffective), Simponi (increased serious infections), Cimzia (increased infections), Prednisone,

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				works but causes other health issues
35	Large black and blue area at injection site, which took more than two weeks to heal	It's the drug my provider prescribed and it works for me.	Yes, three other treatments.	Methotrexate injections work well with a little nausea; malaria meds weren't effective; other injection type gave me lung infection-don't remember the name.
36	Nothing beyond it not working for me.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Sulfasalazine, plaquenil, methotrexate, prednisone, enbrel, humera, symponi, orencia. Currently taking orencia which has worked the best.
37	Stomach related pains/ infection/ headaches/ dizziness	It's the drug my provider prescribed and it works for me., It was required by my insurance company.	Yes, more than three other treatments.	Topical steroids / oral steroids/ other injectables and methotrexate- all of which caused me severe adverse reactions such as anaphylactic
38	None	It did not work as well as desired	Yes, more than three other treatments.	Humira, actemra, Rinvoq, orencia, kevzara

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39	Need to monitor liver	I cycled through other medications that didn't work before finding this one.	Yes, two other treatments.	Enbrel, humira and ACTEMRA currently
40	None.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me., It made me feel like I had no disease at all - a small miracle	Yes, more than three other treatments.	Feldene (the generic name is piroxicam) - severely eroded my stomach making it impossible for me to eat. I am taking Lansoprazole for decades because of this. Lansoprazole is expensive. I still cannot drink a quarter cup of regular coffee or anything high in acid or any type of alchoholic beverage. In the late 1990's I tried 2 other NSAID drugs, Celebrex and another one I can't remember. I immediately had heart palpitations. I was screened by my internal medicine doctor who then sent me to a heart specialist who did a stress test which came up with no indications that needed to be treated, which left me very puzzled. UNTIL I saw a TV report on 60 Minutes which discussed the heart related death of a healthy 33 year old woman from these same drugs. The pharmaceutical companies hid the evidence. I also

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				tried several other NSAID's which did absolutely nothing except take money from me. Tylenol and ibuprofen did not help much.
41	None	It's the only one designated for my condition., I cycled through other medications that didn't work before finding this one., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Humira, Embrel, Orencia, Xeljanz, Simponi Aria, Rituxan (current). Methotrexate, Leflunomide, Placquenil (current). Prednisone (current). Aleve and Arthritis strength Tylenol (current). Most stopped benefits after a period of time-Methotrexate and Leflunomide caused hair loss.

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42	None	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., It was required by my insurance company.	Yes, more than three other treatments.	Methotrexate alone, clinical trial meds
43	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	
44	Chronic diarrhea, fatigue.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Methotrexate- headaches, fatigue, nausea, hair loss. Enbrel was next. Then Xeljanz, experienced fatigue, stomach pain, and painful rashes. Then Humira- only fatigue, but stopped it stopped helping my condition after 2 years. Currently on Cimzia, where I experience episodes of fatigue. All medications have caused me to contract viral and bacterial illnesses MUCH more easily.
45	Lymphoma - my rheumatologist had me stop enbrel. I am on prednisone and rituximab infusions	It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Gold injections and sulfasalizine- broke out in a rash after 6 months with each

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46	I needed to give myself the injections. Not terrible, just something new. Once I went onto Medicare, I needed to switch to a different drug since Medicare required me to pay around $1000/month. I'm now taking something else. That requires me to drive an hour there and back once a month for the treatment. My markers are okay, but I am losing more function in joints gradually. I know that may happen regardless of drug choice, but it sometimes makes me question the change.	It's the drug my provider prescribed and it works for me., Cost was a factor in change of drug choice	Yes, one other treatment.	
47	None specifically from the drug but my disease got worse while on it	I cycled through other medications that didn't work before finding this one., It was required by my insurance company.	Yes, more than three other treatments.	Plaquinel, steroids, enbrel, humira, actemra, xeljanz. Now currently on rinvoq and methotrexate. Actemra helped somewhat. Xeljanz worked well but abruptly stopped working after about a year and half- have been on rinvoq since (~3yrs) and it

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				is working well. Have been on methotrexate since 2017.
48	None	I cycled through other medications that didn't work before finding this one., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Xeljanz, Humana, orensia, kevzara, symphoni Aria, methotrexate, luflunamide, hydroxychloroquine, Prednisone and a few others I can't remember right now. They all had kick started my disease back down instead of full flare up till they stopped working and had to switch. I had an allergic reaction to a couple of them that caused an itchy rash.
49	None.	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Prednisone; methotrexate; kineret;

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50	I have experienced no adverse affects thus far.	It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	In the first year until I could get into the RA doctor, my PCP put me on Etodolac. I had to take it morning and night and it allowed me to walk like I was very old, but I could walk. I could use my hands, even if only like claws. My doctor said due to the dangers of staying on that med they wanted me to see the RA doctor to get me on another more effective with less ill heath effects.
51	Increased blood pressure and glucose.	It was chosen by my doctor. I had to switch though due to the side effects of the blood pressure and glucose.	Yes, three other treatments.	Cosentyx, Tremfya, Humira
52	None	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Only a series of anti inflammatories then methotrexate then another I can’t recall the name of
53	None	It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	MTX
54	Bruising at injection site	Affordability on Medicare, I had to change to a new biologic therapy	Yes, two other treatments.	Inflectra once I had an eye detachment from hydrochloride

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55	None that I know of.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Prednisone, methotrexate, Celebrex, Naproxysn,
56	immuno compromised	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Leflunimide, Methotrexate,
57	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Sulfasalazine (rash), Prednisone (for a year and a half - I had many odd side effects), I tried a few other pills that I can't recall (but didn't work as I tried to stage off steroids)
58	Sometimes it doesn't go far enough to reduce pain and lack of function	It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	I used methotrexate for a few years after first diagnosed but it made me tired and prevented me working to my best capacity
59	unknown	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	methotrexate, quinine, NSAIDS, goldsalts injections, Humira, Remicade

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60	None but it stopped working after six weeks.	It's the drug my provider prescribed and it works for me., No longer taking it.	Yes, more than three other treatments.	Methotrexate-(MTX) initial drug I took. Didn't offer symptom relief by itself. When dosage increased and paired with Enbrel, had good results. When Enbrel stopped working, came off MTX. Later had to switch from pills to shots for better symptom control. After achieving remission, took MTX shots only, but didn't hold back the disease. Dosage was increased but caused gastric distress so had to be reduced. Had to pair with another biologic. Leflunomide- worked well but had an allergic reaction (rash). Steroid shots- worked well for short term symptom relief but negatively impacted eye pressure and sped up cataract development Humira- did not control symptoms until paired with MTX. Reached remission in symptoms but then

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				immune system became too depressed and began having infections. Had to discontinue. Orencia- current medication. Works very well paired with MTX. Beginning to reduce MTX.
61	None besides occasional injection site reaction.	It's the drug my provider prescribed and it works for me.	Yes, three other treatments.	Methotrexate, an antibiotic, and Humira.

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62	Didn’t have but it lost it’s effectiveness so I changed my meds	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Limited benefit, Otezla caused a dangerous high fever 6 months after starting. Rare issue
63	very few, just mild injection site reactions	It was the first we tried beyond methotrexate and it worked well for several years. I no longer take it	Yes, more than three other treatments.	I tried humira but it never worked for me. I tried Cimzia and it worked for a while, then I got cancer and was taken off it. I tried planquenil for a while, but I worried about my eyes. I currently take methotrexate and simponiaria
64	None	It's the drug my provider prescribed and it works for me.		Predisone
65	I have not had any adverse effects using Enbrel so far. The only downside is that using Enbrel means any vaccines I get might not provide as much protection as others. I am always up to date on vaccines as Enbrel does	I cycled through other medications that didn't work before finding this one., The method of delivery or injection works best for me.	Yes, three other treatments.	I have used Humira, Orencia and Xeljanz previously. I was on Humira when I got MERSA and then went to Orencia. My symptoms got worse and then tried Xeljanz. My doctor said new studies showed Xeljanz could worsen heart issues; my brother and sister have Afib so I’m now on Enbrel.

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	compromise my immune system.			
66	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Methotrexate, prednisone, leflunomide, sulfasalazine, hydroxychloroquine. Nausea/vomiting with sulfasalazine; severe diarrhea lasting months after stopping leflunomide; infections with prednisone; and none worked even close to as well as Enbrel for my symptoms. With Enbrel I was able to get off of disability (both my employer disability policy and social security disability)and go back to work as a physician.
67	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Several biological- respiratory side effects

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68		It's the drug my provider prescribed and it works for me., It was required by my insurance company.	Yes, one other treatment.	Sulfasalazine, I am allergic
69	no adverse effects except it just didn't do anything to stop or slow RA progression.	I cycled through other medications that didn't work before finding this one., i tried everything available. some did nothing. some i was allergic to.	Yes, more than three other treatments.	cimzia, simponi, orencia caused allergic reactions. kevzara adversely affected my white blood cells. the rest didn't help enough: humira, xeljanx, and i don't recall the others.
70	Discomfort from injections- I DO NOT LIKE NEEDLES (of ANY sort),& therefore these medications are NOT a good fit for me overall, without QUICKLY NOTICEABLE& SUBSTANTIAL RESULTS- in How I Feel.	At the time it was newer and a main trial or fail drug, I was on for a bit of time it did not help my disease.	Yes, more than three other treatments.	I am a longtime RA patient who tends to be unique in a sense that it seems Nothing has worked for all of my issues, I tend to have these meds work for a time and then they just DONT, and so I've tried and failed Many medications for this diese over my many torturous years of living with RA- but grateful for every trial, hopeful there with be one that works… someday! Too many to list.
71	None	I cycled through other medications that didn't work before finding this one., It was required by my insurance company.	Yes, three other treatments.	Methotrexate, Humira, they stopped working

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72	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	prednisone, methotrexate, others I can't remember the names
73	Reduced immune response and sicker longer.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Plaquenil, never saw improvement, Otezla, worked great for multiple years but significant GI issues impacting life, Methotrexate, increased liver enzymes, Humira, worked well for years but got sick and had to stop short term and never worked after, Cimzia, developed Palmar Plantar Pustular Psoriasis and had to stop.
74	Just mild itching at the injection site.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Orencia wasn't beneficial at all. Hydroxychloroquine, Azathioprine, Arava was prescribed prior to Enbrel. I have taken methotrexate since 2007 when I was first diagnosed with RA and haven't had any adverse health effects.
75	RA flares	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Methotrexate - caused liver damage

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76	Weight gain and difficulty sleeping.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Several biologics (Humira, Orencia, Cosentyx, Otezla, Remicade, Simponi, Tremfya) that all lost efficacy quickly and any oral drug have adverse effects on my liver. Currently on Taltz.
77	None	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Humira, remicade, symzia,
78	Infections	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Humira made me worse, Orencia made me worse, Actemra made me worse, Hizentra is the only drug that has helped but is on the bottom of the “fail first” list
79	Redness at injection site	I cycled through other medications that didn't work before finding this one.	Yes, two other treatments.	I don't remember the pills
80	dont know!	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, one other treatment.	Light therapy, homepathy and Naturopathy

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81	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Humira, Stelara, Otezla, Remicade, Tremfya. I had anaphylaxis with Remicade, infections with Stelara and Humira. I also have had several skin cancers.
82	Painful injection site	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, three other treatments.	Methotrexate (currently taking), Orencia (by infusion, currently taking), Humira (didn't work, Enbril (didn't work), Remicade(infusion, worked well at first and then plateaued and stopped working) The combination on orencia and methotrexate is working best currently
83	None	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Diclofenec, lyrica, Gabapentin, Humira, Enbrel, now taking Skyrizi and it's working for me. Humira worked for almost 3 years and t then started making my symptoms worse. Enbrel didn't do anything really. The others helped a little but not enough.

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84	None	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Enbrel, Orencia, actemra, kevzara all worked for months then lost their effectiveness. I had an allergic reaction to Orencia
85	None that I know of.	It was one of the few biologics that my rheumatologist could get free samples of. At the time I started the drug I could not afford it. This was before the drug company “charities”.	Yes, more than three other treatments.	Methotrexate made me feel like I got hit by a bus. Orencia didn’t work. Simponi gave me an anaphylactic reaction. Cinzia worked if I took more of the drug than was prescribed, but it didn’t work well. And I took a whole host of older drugs which the insurance company required before I could try a biologic, but I don’t remember their names. I want to say that one was Arava. They didn’t work for me.
86	None	It's the drug my provider prescribed and it works for me.	Yes, three other treatments.	Humira, methotrexate, taltz
87	None	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Methotrexate: no benefit, caused nausea; prednisone: worked well, but caused weight gain; steroid joint injection: worked very well, but can’t have repeatedly

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88	None	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Mtx, Humira, xeljanz, remicade and simponi
89	I had significant injection site reactions and little benefit from the medication at the time I was taking it.	I cycled through other medications that didn't work before finding this one., Only one approved with a history of cancer.	Yes, more than three other treatments.	Sulfasalazine, Methotrexate, Plaquenil, Orencia, Enbrel, Humira, Rituxan, Celebrex, Prednisone, Meloxicam, Sulindac, Cymbalta
90	Suppressed immune system	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Methotrexate, humira, orencia, sulfasalazine, Rituxan. The only medication I have EVER responded to is Rituxan. (I took Enbrel for 3 months and then stopped because it didn't work for me.)
91	Sick more often	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, three other treatments.	Plaquenil, methotrexate, humira. Plaquenil and humira stopped working, methotrexate made me nauseous
92	It stopped working.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Avera, methotrexate, enbrel, xeljanz, plaquenil, none of these worked.

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93	Migraines	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Celebrex, Otezla, Cosentyx, Skyrizi
94	Continuing pain when the medication did not work for me.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Humira, Enbrel, Remicade, Rituxiban, and a couple more
95	Extreme neuropathy in feet and legs, and loss of balance both continue after stopping the drug more than 10 years ago. The slurred speech, clouded thinking and visual disturbances cleared up fairly quickly after stopping the drug.	I cycled through other medications that didn't work before finding this one., I am not taking a biologic, just methotrexate and prednisone	Yes, one other treatment.	Orencia-no effects at all
96	None	I cycled through other medications that didn't work before finding this one.	Yes, one other treatment.	Humira, organ shutdown

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97	None	I cycled through other medications that didn't work before finding this one.	Yes, two other treatments.	Methotrexate no adverse effects, Hydrochlorothyazide noadverse effects
98	None that I know of however I have to be tested several times a year to be sure my kidneys aren't being compromised by a biologic	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Methotrexate = severe fatigue and nausea Remicade = no relief Enbrel = was effective for a brief period then no longer worked on my condition. Xeljanz = nausea, rash Cosentyx = current med
99	I had injection site redness and huge hives and itching	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Rutuxan-throat and eyes closed, itching, it worked but wasn't with the side effects Xeljanz worked the best with no side effects. Cost too much Humira same as enbrel for side effects Methotrexate cause upset stomach and nausea Many more but can't fermenter the names

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100	No bad effects	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Celebrate, methotrexate, meloxicam
101	None that im aware of	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me., I get the medication free due to my income	Yes, three other treatments.	Methotrexate, Humira and packwanil
102	None	It's the drug my provider prescribed and it works for me., It was required by my insurance company.	Yes, three other treatments.	My health insurance dictated that I also try Remicade (no effect); Kineret (intolerable GI side effects), and Cimzia (worked well, but insurance company took it off approved drug list).
103	none	It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, three other treatments.	humira, infusions,
104	None	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Meloxicam, Robaxin, ibuprofen,

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105	None.	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Methotrexate, Leflunomide, Prednisone, and also Hydroxychloriquin (which I take with the Enbrel)
106	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	
107	Makes me more at risk for things like COVID, flu, and other diseases	It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, two other treatments.	Plaquinal and methotrexate
108	Allergic reaction at injection site, issues taking them with other drugs for other conditions	It was required by my insurance company.	Yes, more than three other treatments.	Humira, Enbrel, Cimzia, Rutixan, xeljanz, Rinvoq, olumiant, orencia. Some were not covered by insurance after a year, many didn't work at all.
109	It stopped being effective.	It's the drug my provider prescribed and it works for me.	Yes, three other treatments.	Humira, methotrexate
110	None.		Yes, two other treatments.	Arava, methotrexate

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111	None that I know of	It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	Benefit was modest at best. No adverse reactions.
112	I had infections and felt ill. Several starts and stops. It was the pharmacist who suggested we try the pediatric dose because of my body weight. The 25mg injections were better. After a long bit of those I was able to tolerate 2 of the 25 mg injections per week.	I am only taking prednisone now as I refused Humira and I had tried a number of others. Now there is dispute between my specialists.	Yes, more than three other treatments.	Methotrexate, Leflunomide, Sulfasalazine, Enbrel. Infections, weight loss, GI issues, headaches.
113	Migraine, nausea	It was required by my insurance company.	Yes, two other treatments.	Humira - adverse migraine reaction, Rinvoq - benefits of decreased pain
114	Permanent damage to and decreased function of my lungs	I cycled through other medications that didn't work before finding this one., It was required by my insurance company.	Yes, two other treatments.	Cosentyx and Skyrizi
115	Bad nasal congestion daily.	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Diclfenac sodium. Then Enbrel when pain & stiffness got worse.

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				Muscle relaxers and other anti inflammatory meds too.
116	n/a	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Humira, Orencia
117	NA	Tried it but it didn't work.	Yes, more than three other treatments.	Many.
118	Get sick easily due to suppressed immune system, dry mouth leading to dental issues, frequent painful infections on my fingertips	It's the drug my provider prescribed and it works for me., Enbrel was the first drug I was prescribed for my condition, after about a year is lost efficacy and I changed to a different medication	Yes, more than three other treatments.	Humira (had benefit until it stopped working after a year or two, same adverse effects as enbrel), Cosentyx (have been taking this for years and it seems to still work, same adverse effects as enbrel), Indocin (some pain relief, coffee ground stools), Mobic (some pain relief), amitryptaline (no benefit, lowered seizure threshold a leading to my first seizure incident), gabapentin (some pain relief but caused sensory issues and had to lie down on with eyes closed all the time), various muscle relaxants (tend to make pain

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				worse, very unpleasant side effects) etc etc
119	none	I cycled through other medications that didn't work before finding this one., It was required by my insurance company.	Yes, more than three other treatments.	
120	The only effects that I had was that it stopped working for me, and I needed something stronger or different.	I cycled through other medications that didn't work before finding this one.	Yes, two other treatments.	Humira injections was not effective for me
121	The pain and being able to get up and move around	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Steroids

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122	After using for about 4 years ot stopped working for me.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	I've tried many and they work very well, until they don't. While using I did get many infections as these meds inhibit your immune system.
123	none	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Orencia, Simponi, Remicade, methotrexate, Xeljanz and others, both IV and oral
124	It stopped being effective	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, two other treatments.	Humira, Tremfya
125	None	trying to find a medication that works for me	Yes, more than three other treatments.	Orencia, Xeljanz, Rinvoq, Intracept, Humira, plus more
126	Stopped working	Provider suggested & worked for 2 years	Yes, more than three other treatments.	Methotrexate, simponi, otezla, xeljanz
127	None	It was required by my insurance company.	Yes, two other treatments.	Hummers, Orencia

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128	Pneumonia bruising flu symptoms	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Humira cosentyxmotrin celebrex
129	The effects of the drug ended cold turkey after around 8 weeks	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Enbrel was the 1st, I'm on Cosentyx, I've done otezla, Remicade, Skyrizi, and many others (21 yrs)
130		I cycled through other medications that didn't work before finding this one.	Yes, two other treatments.	Methotrexate
131	Injection site reaction	I cycled through other medications that didn't work before finding this one., It was required by my insurance company.	Yes, more than three other treatments.	Enbrel, Humera, methotrexate, xeljanz, Otezla
132	More cautious during pandemic and if exposed to sick people	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., It was required by my insurance company., The method of delivery or injection works best for me.	None	Oral and injections of Methotrexate

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133	Pain during injection. Not from the needle, but a burning sensation from the drug.	It's the drug my provider prescribed and it works for me.	Yes, three other treatments.	NSAIDS, sulfasalazine, methotrexate alone
134	I didn't have any jus couldn't afford it	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	They seem to help for awhile and then stopped helping
135		I developed Giant Cell Arteritis and Enbrel was one drug that addressed that condition.	Yes, more than three other treatments.	methotrexate caused long term adverse GI conditions, Humira, Cimsys, several more
136	Occasional discomfort at injection site	I cycled through other medications that didn't work before finding this one.	Yes, one other treatment.	Methyltrexate It caused me to have severe Anemia at the dose that was effective and it is a severe immune system suppressor
137	Immune suppression	It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, two other treatments.	
138	None	I cycled through other medications that didn't work before finding this one.	Yes, two other treatments.	Methotrexate, other biologics

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139	I got infections very easily I had a couple that was pretty serious	It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, three other treatments.	Remicade gold treatments orencia
140	None.	It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	Methotrexate - still use it along with Enbrel. Methotrexate pills made me very nauseous - switched to injectable and that solved the problem. Methotrexate gave me some relief, but only some (better than nothing). The Enbrel changed my life: it made life worth living again.
141	I am unsure of how or if I suffered any negative effects from Enbrel	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Otezla
142	6hr headache and fatigue	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Don't remember all 7 of them
143	None	I cycled through other medications that didn't work before finding this one., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Humira-worked but developed cancer, rituxan-didn't help, Orencia-allergic,

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144	Possibly fatigue, diarrhea day after injection	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Methotrexate (no benefit, severe nausea), Humira (benefited for a week only but only a biweekly injection was approved), Rinvoq (no benefit)
145	Recurrent sinus infections	It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Prednisone , methotrexate, meloxican
146	None	It was required by my insurance company.	Yes, more than three other treatments.	Lots of bad side effects. Plaquenil seems to be helping some
147	none it just didnt help.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Enbrel didnt work, Humera, angioedema , one I dont remember, Xeljanz works!, Xeljanz XR works
148	none	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	most recent is Cosentyx which is causing thrush

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149	None	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Remicade,Cimzia,Cellcept,Orencia, Leflunomide and Methotrexate currently taking Hydroxychloroquine only it works well for me initially gave me GI problems but have since resolved.Remicade worked well but developed a rash and so had to stop the medication.Got a UTI from Cimzia had to stop that medication too.Had a adverse reaction to Cellcept had some abnormal blood tests while on it.
150		I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Methotrexate chronic nausea, sinus issues
151	Localized swelling at the injection site, swelling of the tongue and hives.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Humira, enbrel, cimzia and rinvoq

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152	Brain fog - diarrhea- non reduction of inflammation.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Rinvoq and Ibuprofen is my current drug and is working great to treat my symptoms of RA, with minimal adverse effects. These drugs I have used in the past- Enbrel, Plaquenil, methotrexate, steroids, Humira, Cimzia, Orencia, Celebrex, hydroxychloroquine, meloxicam, sulfasalazine, - Adverse effects with all of these past drugs.
153	None.	It was required by my insurance company.	Yes, one other treatment.	Methotrexate. I experienced extremely severe side effects and could not continue.
154	None	It's the drug my provider prescribed and it works for me.	None	None
155	Problems with my teeth	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Gold, plaquinal, methotrexate, humira, Enbrel
156	Sometimes I have a hard time falling asleep on the day of injection	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	I first tried Humira but I kept getting sick all the time on it

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157	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	
158	Pain at injection site	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	
159	Reaction at injection sight, and it made me sleepy like taking a sleeping pill.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Humira, kezvara (reaction)simponi, xeljanz, (effective 1yr)paquil methotrexate orencia(current)
160	Injection site reaction.	Transferred to Remacade Then stopped treatment all together.	Yes, more than three other treatments.	Prednisone Plaqunil. Reaction to sunlight. Methotrexate. Made me very nauseated for days didn’t help Enbril. Injection site reactions moderate improvement of symptoms Remicade.suspended use due to cancer diagnosis. Worked well though.
161	none	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Actemra helped, but it gave me heart palpitations and made me

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				tired. Rinvoq did not help. Humira did not help.
162	esinophilia cellulitis	It was required by my insurance company.	Yes, more than three other treatments.	Remicade, Arava, Olumiant, Xeljanz, plaquenil, orencia, rynvoq, etc Improve condition for awhile.
163	None.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Orencia, Remicade, Rituxan, Renvoq, Methotrexate. Mild increase in liver function, flushing of face, mild stomach upset, mouth ulcers.
164	Overall none but knowing it decreases body to fight infection especially when COVID was bad just had to be real careful about who or what I was around.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	I've tried a lot since I was 23 when I was diagnosed but enbrel was one that I used for many years before having to switch. It was the best one to control my overall pain and cleared my skin 100% outside of the one I'm currently using.
165	none	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Methotrexate, Plaquenil, major side affects

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166	None	It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	I tried methotrexate, was on Embrel for a year, then took Humira and now I'm on Orencia.
167		It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Methotrexate, Cosentyx - I prefer medications that don't have documented adverse effects
168	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Humira, cosyntex, remicade, simponi aria, talts
169	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	It was several years ago and I don't remember what they were.
170	None	It's the drug my provider prescribed and it works for me.	Unsure	?
171	None	It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, one other treatment.	Methotrexate

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172	Pain at the injection site	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, two other treatments.	Methotrexate - nausea Hydroxychloroquine - worse nausea
173		It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	
174	After about 18 months it stopped working	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Many! At least 8. Most worked well at first then stopped.
175	increased UTI	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Remicade, Leflunomide-gave me Auto-immune Hepatitis, Methotrexate, Humira, currently taking Azathiopine. will be evaluated in a month to start a new RA drug because nothing is working for me
176		I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Arava-hair loss; methotrexate-not effective enough:sulfasalazine-not effective: hydroxychloroquine-not effective

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177	Minor bruising at the injection site. Lack of appetite 24-48 hours after injection. Occasional upset stomach or loose stool 24-48 hours after injection.	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Rinvoq, humeria, methotrexate. Similar side effects. Methotrexate also caused blisters on the tongue.
178	None		Yes, three other treatments.	Methotrexate was ineffective and caused intense nausea and side effects. When I lost prescription coverage for enbrel I switched to simponi and then remicade, which have not been quite as effective as enbrel..
179	I have to be very careful when I get sick. I got Covid in July 2022. I didn't recognize the initial symptoms and took my normal dose of Enbrel which suppressed my immune system. I think I got sicker as a result requiring monoclonal antibody treatment.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Methotrexate - potential lung issues. Initially worked well in conjunction with Enbrel. Currently taking Sulfasalazine in conjunction with Enbrel. Naproxen didn't work. I took Celebrex but stopped due to potential heart risks. Currently take prednisone as needed when addressing flare ups. Cortisone shots in joints when needed during on-going flare ups. Arava didn't work after about 9-12 months and

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				created increased liver enzymes over a few consecutive months.
180	none	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Simponia Aria, Methotrexate, I can't remember the others
181	Allergic signs at second does.	My rheumatologist went through several medications before finding one that I was not allergic to.	Yes, more than three other treatments.	I honestly don't remember as my treatment has been going on for 5+ years now.
182	Headaches first few injections, after maybe two months they stopped. Had on-site rash reactions, waiting to inject until after I showered helped limit the rash.	My dr wanted to provide me relief without damaging my body with harsher options	Yes, one other treatment.	Humira, yes it was beneficial. Had stomach issues the first few injections, after that was ok.

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183	Zero	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., Biologics stop working after a while and need to be switched. I've been on one for 18 years	Yes, more than three other treatments.	Methotrexate, Enbrel, Humira, Simponi, Stelera. No notable side effects. They work until they don't and need to change. Only exception was switching from Humira to Simponi was insurance motivated not drug effect.
184	No immune system.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, three other treatments.	They work until they don't. Overall they're all the same.
185	Sick too often before the pandemic.	It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Humira and methotrexate along with a bunch of different topical creams and shampoos.
186	None, as far as I know	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, two other treatments.	Prednisone tabs, Xeljanz, Humira injections. Health effects were mostly beneficial, except for Prednisone - made me put on weight and also weakened my bones

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187	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Plaquenil, methotrexate, arrava, sulfasalazine, humira, motrin. Adverse health effects with both methotrexate and arrava. I continue n sulfasalazine and motrin as they have both been beneficial. Humira worked for a long time as I was able to use it for seven years and it reduced inflamed joints and was slowing bone erosion.
188	There are side effects, most manageable so far.	The method of delivery or injection works best for me.	Yes, more than three other treatments.	sulfasalazine, hydroquarline ? sp, celebrex, methotrexate, + more i can't recall at mo
189	Continuous sinus infections, colds and pneumonia.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Since I've been living with RA since age 5, I've tried most of the common anti-inflammatory drugs, such as Gold Injections, Arava, Ibuprofen, Methotrexate, Humira and more.
190	Injection site inflammation controlled with allergy medication.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Humira, Enbrel, hydroxychloroquine, methotrexate, Actemra, Orencia, Kevzara (with reaction of blisters at the injection site). Actemra and Orencia worked well until they didn't. Currently I am on azathioprine orally and

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				Rituxan infusions which are working well.
191	After many years of normal lab results, my neutrophils dropped dramatically. I had to stop Enbrel due to this. I waited several months and restarted it, but the issue persisted so I had to stop permenantly.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Methotrexate, prednisone, Plaquenil - all beneficial, just not adequate.
192	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Methotrexate works but caused pancytopenia. Sulfasalazine was stopped due to kidney failure. Plaquenil didn't work. Enbrel worked a few months and then stopped same with Humira. I am now on Rinvoq which worked for 2 months and seems to be not working anymore.

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193	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Gold, asulfadine, methotrexate many others
194	It was extremely painful to inject. I have been on several medications that I had to inject so it wasn't giving the injection that I had a problem with. Enbrel felt like I was injecting fire.	I cycled through other medications that didn't work before finding this one., It was required by my insurance company.	Yes, more than three other treatments.	Rituxan, methotrexate, plaquenil, arrava, Simponi(both the IV version and the injection version),sulfasalazine, orencia and xeljanz. I am currently taking xeljanz, methotrexate, and plaquenil. I had digestive issues with sulfasalazine. Rituxan worked really well for several years, but stopped working. A few years ago, I was taking several medications for my RA and got an infection that they couldn't get to clear up, but I don't remember what those meducations were. The other medications either didn't work, stopped working, or the insurance company refused to approve.
195	N/a	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Methotrexate, 2 others and Embrel

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196	Didn’t work	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Stelara, Simponi Aria,
197	I had to stop Enbrel at 3 months, because I felt like bugs were crawling all over me. I reported this to the pharmacist at Enbrel.	I cycled through other medications that didn't work before finding this one., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Sulfasalazine-no improvement. Methotrexate-no improvement, severe fatigue. Humera-minimal improvement, severe leg cramps. Xeljanz-amazing improvement for 4.5 years, then it quit working. Olumiant-minimal improvement, headache, chest pain, leg cramps. Leflunomide-numbness/tingling in fingers, increased blood pressure, balance issues. Rinvoq-worked moderately well for a short time then quit working. Orencia-currently taking. Noted improvement.
198	do not remember since it was years ago	dr prescribed when other meds did not work. when it didn't work well enough moved on to other drugs	Yes, more than three other treatments.	methotrexate- mouth sores, orencia- difficult to find veins, xyljenz- quite due to cost, cimzia taking primarily because of cost in the medicare system

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199	No adverse effects with the exception of site injection minor irritation	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Methotrexate and hydroxychroquine. Both had several adverse effects like hair loss, headaches, dizziness and nausea.
200	The medication absolutely failed to remediate any of my sequelae of rheumatois srthritis.	It's the drug my provider prescribed and it works for me., My sed rate improved	Yes, more than three other treatments.	opiod pain medication, NSAIDS, sleeping medication
201	Frequent infections, increased fatigue, injection site inflammation	I cycled through other medications that didn't work before finding this one., It was required by my insurance company.	Yes, more than three other treatments.	Methotrexate, remicade, rituxan, humira, arava, actemra, orencia- medications did not work and caused various side effects including nausea, vomiting, frequent infections, hives, extreme fatigue, diarrhea, muscle pain, injection site inflammation. I have also taken xeljanz and Olumiant. Neither caused side effects and did reduce disease activity.

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202	pain at injection site, did not work as effectively as I had hoped	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	methotrexate (was unable to live on this - severe adverse health effects, including severe nausea and fatigue, constant sores in mouth); Humira (worked well to reduce my arthritic pain and psoriasis but stopped working after a year); Taltz (current biologic - working the best of the four meds to reduce my pain and number of flares)
203	None	It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	Methotrexate liver test were not good discontinued it
204	Prone to infections unless I'm very careful	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Methotrexate, hydroxychloroquin, Arava, Imuran, sulfasalazine, Humira
205	none	I cycled through other medications that didn't work before finding this one., Enbrel works for me. Humira did not work. Enbrel worked for daughter, so I gave it a try.	Yes, more than three other treatments.	Steroids caused depression, NSAIDS didn't work, oral drugs did not work or caused a rash

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206	I began to have allergic reactions to the medicine over time, I guess from the autoimmune aspect of the disease as I used it more over time my body began to reject it.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., It was required by my insurance company.	Yes, more than three other treatments.	Remicade- I eventually began having unmanageable allergic reactions to the medicine so I was switched by my provider. Humira- also began having unmanageable allergic reactions to this medication. Prednisone has always been a part of my medication regime. Leflunomide- has been a mainstay medication for my treatment also.I tried Otezla but the nausea was to difficult to tolerate.
207	My hair did get a litter thinner, but whether that's the Enbrel I cant say for sure	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Humira and methotrexate
208	None	It's the only one designated for my condition., It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Methotrexate, predine zone,Humira and Leuflafidid.
209	None so far.	It's the drug my provider prescribed and it works for me.	None	None
210	None	It was required by my insurance company.	Yes, three other treatments.	Orencia, Xeljanz XR, Humira

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211	None	It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Methotrexate and plaquennel
212	Slight rash at the injection site and mild hair loss.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Methotrexate and Humira
213	More infections.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Humira, Kineret, Orencia, Actemra,
214	None	It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	Did take Methotrexate but have stopped taking it about 3 months ago
215	None when it was working.	I cycled through other medications that didn't work before finding this one., It stopped working after 23 years.	Yes, two other treatments.	Azulfidine and methotrexate. Alergeric to sulfa and methotrexate made me very sick.
216	Severe headache, nausea and vomiting. Have reacted the same to other biologics	Using rinvoq methotrexate and leflunomide	Yes, more than three other treatments.	Rinvoq Methotrexate inj, prednisone leflunomide. Tried humira not able to tolerate

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217	I was more susceptible To colds, pneumonia.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Orencia, Humira, Remicade, Taltz
218	none	It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Cimzia and 1 other. Cimzia works the best for me. Am not taking Embrel or the other injectible (can't remember the name). No adverse health effects.
219	Nausea, diarrhea, tingling in extremities, hot flashes.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Humira (same deal as Enbrel; it worked really well for several years, then just stopped working); Xelganz (I had an anaphylactic reaction to it and couldn't take it); methotrexate (I currently take it; it's the only thing that's reliably helped me over the years; terrible side effects: nausea and diarrhea, exhaustion...but it's the only thing that really keeps the RA under control); Orencia (I currently take it and it works about as well as Enbrel did before Enbrel stopped working); Nabumetone (I currently take it; it helps with pain and inflammation).

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220	I know it makes me more prone to infections, but I have not experienced any change. I am careful to boost my immune system regularly.	It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	Prednisone…elevated my pain and inflammation, but I didn't like the side effects.
221	The weekly injection is painful and since it requires refrigeration it is difficult to travel.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Kiniret, humira, orencia, all we not controlling the progress of the disease. Remicade caused hives. Methotrexate, meloxicam, tramadol, metrol.
222	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Humira, Actemra, Orencia , Simponi, Rinvoq, Kevzara and others. Had stomach issues with Rinvoq.
223	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Methotrexate (both injection and pills) - Adverse effects: Digestive issues, headaches, inflammation not well managed). Humira injection - didn't manage pain and inflammation well enough. Celebrex - only assists in the management of inflammation and some pain.

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224	None	I cycled through other medications that didn't work before finding this one.	Yes, two other treatments.	Methotrexate - severe nausea. / Currently taking Humira and Leflunomide without problems.
225	None	I researched it	Yes, one other treatment.	Methotrexate, I still take
226	None	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	I could not tolerate methotrexate as the starting dose gave me severe abdominal pain and diarrhea for 24 hours after taking it. It wasn't even the dosage that I would eventually be on and it was not worth it to me to be that sick once a week for the rest of my life. I took methotrexate twice. I was on hydrocholoquin which was stopped by the rheumatologist because it was hard to know if it had any benefit. It was the first drug I was started on for my RA. I took Orencia weekly for about two years and it stopped working and was the. Started on Enbrel and Leflunamide. I started to get basal cell carcinomas every three months. I had a stage 1 melanoma on my ear and I stopped the medication. I also had a lot of

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				loose stool and stool urgency with the Leflunamide. I have been on Enbrel weekly for about 10 years
227	I suspect that this affects my immune system and therefore I still mask when out in public.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., It was required by my insurance company.	Yes, two other treatments.	I tried Humira and prednisone. Humira worked for a while. Steroids also worked and I took them for about two years. My doctor and I both wanted to stop steroids and we reduced the dose until I no longer needed them. At this time, I cannot take steroids at all because it makes my wet macular degeneration worse.

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228	None	It's the only one designated for my condition., I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, three other treatments.	Plaquenil (didn’t work), methotrexate (caused liver inflammation), OTC and prescription NSAIDS (liver inflammation).
229	The shots was very painful to take	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Humira it works better than enbral
230	Doesn’t last as long	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Too many to list! Maybe 30 in all. Short of some not working well, no real side effects
231	periodic infections at injection site and not anywhere as much benefit to reducing RA symptoms as I would've liked and increased frequency of migraines on injection days	I cycled through other medications that didn't work before finding this one., It was required by my insurance company.	Yes, more than three other treatments.	plaquenil, methotrexate, orencia, rinvoq, colchicine

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232	N/A	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., It was required by my insurance company.	Yes, more than three other treatments.	Methotrexate, Humira, Voltarin, Azthropiren, Skyrizi.I am currently taking Rinvoc. All worked for periods of time them didn't. The above list of drugs I have taken is a partial list I have taken.
233	None	It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Methotrexate and Cosentyx
234	Because of the mice DNA or whatever my body rejected Enbrel after 10 months	I cycled through other medications that didn't work before finding this one., Purely human	Yes, three other treatments.	Cimzia, Cosentyx, Taltz and now I am on Simponi Aria
235	none, however after several years it ceased to help	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Remicade, Humera and now Cosentyx
236	none	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Humira and Cosentyx, methotrexate and imuran
237	None other than it didn't work for me	I cycled through other medications that didn't work before finding this one.	Yes, two other treatments.	Methotrexate, Humira

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238	None	I cycled through other medications that didn't work before finding this one.	Yes, one other treatment.	Some help, but fell short 2-4 day's before the next injection.
239	More sinus infections	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Humira, 3difderent types pills.
240	None	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Arava, methotrexate, prednisone, humira, kevzara, meloxicam, opioid pain medication, plaquenil. I cont to take plaquenil (just started) & prednisone which works well for me, but the side effects are less than ideal & harmful in its own way but my RA is more harmful tho. The goal is to need to take the least amt of prednisone possible or even not at all & still function. The rest of the meds have either helped to a point then stopped helping or didn't help at all with only the Arava giving me undesirable side effects.
241	Gained weight	It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, two other treatments.	Cimzia no good Orencia worked

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242	Weight gain, infections are hard to clear.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Methotrexate, leflunomide, hidroxicloroquine, and humira
243	digestive issues, increased liver enzymes	Initial drug provider put me on	Yes, one other treatment.	Methotrexate
244	No real adverse effects	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Humuria, Cimza, Xeljanz, Rinvoq, plaquenil, and others; I dealt with rashes on Plaquenil, some medication caused racing heartbeat but can’t remember which ones
245	None	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Donovan, clobetasol
246	None known	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., Severe side effect to previous medication	Yes, more than three other treatments.	I’ve had my condition for approximately 40 years. I have not kept a list of all the Rx I’ve tried over the years. The worst side effects were to Remicade. It reduced my immune system to a life threatening level so that I required hospitalization and surgery and high levels of antibiotic and anti fungal medication.

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247	None	I cycled through other medications that didn't work before finding this one.	Yes, one other treatment.	Humera, it didn't work well, and I got a cancer
248	As With any biological medication, I get sick a lot easier my body hurts constantly but my joints are kind of okay	I cycled through other medications that didn't work before finding this one., It is working better than the rest of the meds I have tried	Yes, more than three other treatments.	Methotrexate (still on it) puked everyday for 6 months, but I lost 60 lbs. Humira 4 yrs (then Enbrel for 2) Humira, worked about as well as the Enbrel. Then Rinvoq for 6 mths. Didn't work and caused major shingles outbreaks for the entire 6 months! Now I'm on Cimzia, and it's working better than anything so far. I'm also (still and have been since 2014): Diclofinac sodium, prednisone , folic acid(for the MXT), amitriptyline , Duloxitine (1yr now)
249	Unfortunately, I think it was the latex in the pen that ended up causing really bad injection site reactions.	I cycled through other medications that didn't work before finding this one., It was required by my insurance company., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Step therapy starting with hydroxychloroquine, helped a tiny bit. Sulfasalazine, made me desperately ill. Methotrexate, helped a little more, but fatigue got worse. Humira, helped a lot, almost felt back to normal, but efficacy was waning before a year had passed. Prednisone, helps the

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				most, but not allowed to use it long term.
250	See above	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Cimzia, orencia, rituxin, humira, xeljanz, stelara(?), Arava, etc. I failed all due to not working or affected lungs.
251	The only adverse effect I have had is itching and redness at my injection site the day I take Enbrel.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Humira worked well for about 2 years and unfortunately lost its effectiveness. I also tried Rinvoq and Xeljanz which did help at all. I was on sulfasalzine and plaquinil but didn't see any results.
252	Only used for 3 weeks due to allergic reaction at injection site of raised hives and itching.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Remicade- it worked for more than 10 years before it suddenly no longer worked, Orencia- it never worked for me, Rituxin- it never worked for me, Simponi- it worked for me for 2 to 3 years and then stopped working. I now take Actemra infusions, Plaquenil pills

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				and Methetrexate injections and they seem to be working.
253	None that I am aware of.	It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Gabapentin. I am also taking methotrexate in addition to my Enbrel.
254	Drowsiness, nausea	I no longer use Embrel	Yes, one other treatment.	Hydroxychloroquine works the best
255	None	It was part of a long list of meds tried for my condition that didn't work	Yes, more than three other treatments.	Some drugs helped for a time but then stopped. One drug made my condition worse but most did nothing.
256	none	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Plaquenil wasn't strong enough, and diclofenac is not safe for long term use
257	Slight increase in sinus infections	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	I've literally been on all of them.

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258	Site injection reaction	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Methotrexate, meloxicam, humira, arava & naproxen. As well as steroid injections. Adverse Health effects: nausea, headaches, injection pain/burning, tiredness, liver inflammation.
259	Infections	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Stelara, Humira, Rinvoq and now Infelctra
260	None. Some worked better than others, but all of these biologicals worked way better than pills or creams.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Humeria, Enbrel Cosentyx Stellera. Tremfya
261	Just the delivery system. A shot.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	NSAIDs, Humira, rinvoq, xeljanz, plaquenil, methotrexate
262	none, really. It just wasn't as effective for me as it could be.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Remicaid, Humira, Cimzia, Simponi, Orencia, methotrexate, arava, plaquenil

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263	None. I was disappointed when Enbrel lost its effectiveness shortly after my second son was born, because it had been a miracle medication for me for many years by then.	I cycled through other medications that didn't work before finding this one., It was required by my insurance company.	Yes, more than three other treatments.	Methotrexate - not effective on its own. I hate the side effects of this medication. While on this medication, I usually had to dedicate an entire day each week to feeling gross (fatigue, nausea, blurry mind) after my dose. It also caused hair loss. I eventually reached a point where the negatives outweighed the positives. Remicade - never worked for me Orencia - never worked for me Rituxan - probably the most effective treatment I was ever on. The only reason I moved on from this medication was that I wanted a third pregnancy and there wasn't enough safety data for this medication Cimzia - was very effective for me and was a pregnancy-safe option for my third pregnancy. Being able to be on a medication for the entirety of my third pregnancy resulted in a vastly different experience than my first two pregnancies, one of which was completely untreated and one that

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				was only treated at the end. I had a much better pregnancy and no postpartum flare, which was an amazing blessing as a mom of three including a newborn. Arava - currently taking concurrently with the Truxima. Truxima - I wanted to go back to Rituxan after the Cimzia stopped being effective, but my insurance wouldn't approve the name brand medication.

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264	Cellulitis and more prone to infections	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Topical steroids, oral steroids, other biologics as injections
265	None that I'm aware of	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Remicade, humira, methotrexate, forgot two more names
266	Injection site lumps, lowered immune system so able to catch contagious illness often, longer recovery time	I cycled through other medications that didn't work before finding this one., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Sulfasalazine - no improvement in symptoms. Humira - stopped working. Taltz - was getting sick too often. Cimzia - was getting sick too often
267	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Remicade, Humira, Methotrexate, sulfasalazine, Otezla, others

Survey Responses Continued

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
1	More than $1000 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	No			My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	
2	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day	

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								supply option) or number of refills I am able to get.	
3	$500-$1000 per month	Yes						My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
4	$500-$1000 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Had to fundraise to cover costs so we could pay mortage. Missed work at least twice a month.

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5	$500-$1000 per month	Yes	double dosed and still not helping	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription.	I'm off all bios and needing a ligament replacement, knee, and foot and ankle fusion
6	$0-$50 per month	No			Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	No
7	$500-$1000 per month	Yes	I have skipped doses of the drug in order to save money., I have reduced the dose of the drug in order to save money., I have stretched time between doses of the drug in order to save	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	Yes	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			money., I have changed prescription drugs to treat my condition due to cost.					raise my insurance premium.	
8	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	I have had reduced impact to my life from my condition because of Embrel. It allowed me to support my family mostly unhindered.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
9	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor.	Yes	Prescription drug manufacturer	Yes	My insurance plan requires prior approval to fill the prescription.	Absence from work which my employer doesn't like
10	$0-$50 per month	No	None	Out-of-pocket costs have caused me to accrue medical debt.	Yes	Prescription drug manufacturer	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
11	$0-$50 per month	No			Yes	Internet search	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	I can no longer work

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
12	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription.	Yes, I spend so much time on the phone. Mostly dealing with meds that aren't covered. It's exhausting being a full time patient. Insurance is usually the reason. I went Bankrupt thanks to my condition. Yes, on co-pays
13	$0-$50 per month	No		Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	Internet search	No	My insurance plan requires prior approval to fill the prescription.	Not for Enbrel. It was taken at home.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
14	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Husband switched jobs and thus new insurance this year. I don't know if they will approve but my copay will be 2600 a month until I use up the copay card amount and then I will have to worry about whether they use accumulators and will have to pay the full copay amount or worry about being approved for Patient assistance if they haven't run out of funds. If I have to pay the full copay I will not be able to afford a medication that works for me and doesn't cause reactions, side effects or allergic reactions. It's also on my insurances formulary and that limits my options further. That's why it's important to have several types of drugs from which a doctor and patient to choose from
15	$0-$50 per month	Yes	I have reduced the dose of the drug in order to save money.	This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor.	Yes

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
16	$50 - $100 per month	No			Yes	Prescription drug manufacturer	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	
17	$250 - $500 per month	Yes	I have skipped doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the hospital or needing surgery., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Ho mc

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
18	$0-$50 per month	Yes	Dealing with insurance I've had to jump through many hoops. Sometimes there is a delay because the insurance company takes a while to approve new meds. It's stressful!	This medication allows me to work and help support my family.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	I miss work for pain, appointments, and my rheumatologist is over 2 hours away.
19	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day	Once I am off my commercial insurance, I am terrified at the expense of this drug. I will NOT be able to afford without the current Assistance Program that is offered. Why does that have to stop?

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
								supply option) or number of refills I am able to get.	
20	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	No		No		

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
21	$50 - $100 per month	Yes	I have stretched time between doses of the drug in order to save money.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	Prescription drug manufacturer	Yes	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	No
22	More than $1000 per month	Yes	I have skipped doses of the drug in order to save money.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	denial of other medications that would help my disease!

23	$500-$1000 per month	Yes	I have skipped doses of the drug in order to save money., I have reduced the dose of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost., Still paying on a credit card from a biologic I took several years ago when you are on Medicare you cannot use co pay assistance cards even	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	Yes	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	Unable to work, unable to pay back student loans not yet fully disabled hoping to get better some day but still at this time can't function and debt is just piling up for our family because of my medical condition, traveling to appts, medications, husband taking time off work taking me to infusions taking, when I have to go to the hospital etc.

			if you have spouses private health insurance for RX benefits so you are being asked to pay astronomical co pays						

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
24	$0-$50 per month	No			Yes	Prescription drug manufacturer	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	Not necessarily, but I worry about the pharmaceutical company changing the rules for the Patient Assistance Program that would make me ineligible to receive the drug at no cost to me. The older RA drugs are generic and out of pocket costs, at least for me, would be OK, cost wise, but I can't take them due to side effects and basically, because they wouldn't work for me now. The "newer" drugs are very expensive and would be difficult for me to affort without the PAP from the drug company. I also worry that Xeljanz will stop working for me. What is available after that? I rely on the meds to help me live a realtively normal life.
25	$0-$50 per month	Yes	I have stretched time between doses of the drug in order to save money.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	Prescription drug manufacturer	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	none

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
26	$0-$50 per month	Yes	I received this drug with a special drug manufacturer patient assistance program. Had to jump through hoops with the drug manufacturer and dr office in order to qualify. Otherwise it was close to $6,000/month for this medication that of course no one can afford.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	Absolutely!! Especially when I was caring full-time for a daughter with a rare disease and disability herself.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
27	$0-$50 per month	No	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My doctor provided a brochure	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	Unable to work, no income. Please help with Compound Drugs (eye serum) not on drug formulary. Out of pocket is 100% with no assistance from anywhere.
28	$50 - $100 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription	This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will	Yes, my whole cost of living and supporting my family.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			drugs to treat my condition due to cost.					raise my insurance premium.	
29	$250 - $500 per month	No		This medication reduces the amount of time and money spent going to the doctor.	No		No	My insurance plan requires prior approval to fill the prescription.	No
30	$0-$50 per month	No			Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription.	
31	More than $1000 per month	Yes			Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	Manufacturer assistance was great, but stopped five years ago when I started on Medicare.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
32	$0-$50 per month	No	I am 100% disabled veteran and all my care/preacriptions are covered by VA		No		No		
33	$500-$1000 per month	Yes		Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	It costs a fortune!! Definitely impacts our thoughts on retirement as the prescription assistance programs do not apply when you switch to Medicare.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
34	$150 - $250 per month	Yes	I have skipped doses of the drug in order to save money., I have reduced the dose of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	No	Prescription drug manufacturer	Yes	My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	as a person on medicare, I am not eligible for financial assistance, which is very difficult
35	$0-$50 per month	No	insurance covered		No				no

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			complete cost						
36	$0-$50 per month	No	No	This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No
37	$0-$50 per month	No	I have skipped doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	Friend or family member	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
38	$0-$50 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	All of the above
39	$500-$1000 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication allows me to work and help support my family.	Yes	Friend or family member	No	My insurance plan requires prior approval to fill the prescription.	Fortunate that i can afford $6K annually now that I have retired

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
40	$500-$1000 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	When I was re-ordering the drug from Accredo (which is part of Express Scripts which is part of CIGNA) I asked if financial help was available & they gave me a list of groups to contact. I spent days contacting them and Amgen came through with substantial assistance last year (2023).	Yes	My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	I have always been single and always worked for over 40 years to support myself. I was extremely aware that I could not be seen walking with a limp out of fear of being fired or not hired. I spent a LOT of time hiding my pain and indeed working overtime to convince my employers to keep me. Upon retirement I moved to a hot climate (southern Florida) to help with my movement and it has really worked. The hot weather is easier on my body than the cold weather and I can swim more easily (the only exercise which does not hurt my body) because of the climate. I got this disease at 30 years old. I asked my rheumatologist about having children. He said I might be OK with taking prednisone. I researched it on my own and decided having children would negatively affect my body and general overall health and I might pass along the possibility of this disease to my children so I decided not to have children. Since most men want a family I also decided not to get married. And I have heard much worse from people in groups where we discuss the impacts of the disease on our personal lives. It only took me 15 months and 5 doctors to get the first diagnosis which was ALMOST correct. Several years later after having more severe symptoms I was given another

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
									diagnosis which was ALMOST correct. And several years after that I finally got a correct diagnosis and Enbrel. In Support Group sessions I have heard much worse from many other people so I consider myself lucky.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
41	$0-$50 per month	No	Not applicable	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	My insurance company	No	My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Not at this time
42	More than $1000 per month	Yes	I have skipped doses of the drug in order to save money., I have reduced the dose of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	Transportation costs

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
43	$250 - $500 per month	No		This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	Expensive disease
44	$0-$50 per month	No			Yes	Prescription drug manufacturer	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	Well, the drug and all subsequent drugs have not worked well enough to allow me go return to work. This drug was inexpensive after insurance AND the manufacturers assistance program. However, my current drug is prohibitively expensive and I have had to spend months on phone calls and paperwork to get assistance from the prescription drug company for it. In general, these types of drugs are expensive, only somewhat effective, and have horrible side effects. I feel strongly that better medications can be developed, but more immediately it needs to be easier for patients to access these medications and any assistance programs to get help paying for them.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
45	$0-$50 per month	No	Always affordable with Kaiser	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	No		No		No
46	$500-$1000 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	No		Yes	My insurance plan requires prior approval to fill the prescription.	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
47	$150 - $250 per month	Yes		Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My pharmacist	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	Unable to work due to disability from conditions since 2021; prior to that was missing a lot of work and was not getting paid for sick days. One year my salary was cut about $15k due to unpaid sick time. Copay assistance cards limit yearly benefits, so most months copay for rinvoq is $5/mo, but at the end of the year is $180-200/mo, which we cut other costs to cover. Even though enbrel didn't work for me, insurance at the time dictated we try another TNF inhibitor (humira) before moving on to other drug classes. Both had to be >4 months before moving on, so that was about a year of treatment that didn't work at all, in which my disease got significantly worse (2017-2018.)

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
48	More than $1000 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	Absentee from work, cutting groceries and other essential bills or household necessities, not able to marry my fiancee or they won't cover my medication, not able to fill up my car with gas due to outrageous medication costs.
49	$50 - $100 per month	No	None	This medication reduces the amount of time and money spent going to the doctor.	Yes	Friend or family member	No	My insurance plan requires prior approval to fill the prescription.	No.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
50	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan has dropped or switched my drug coverage after the plan year started.	My employer changed health insurance effective 1/1/2024. The new insurance company never sent the memo that our company agreement covers Enbrel as well as other medications to their partner Rx company. Since the RX company said Enbrel is not covered, despite me insisting that it is, they sent my RX to a pharmacy in Minnesota and charged my $10,000 copay card $3,500 which is much more costly than the past copays which range from $50 to $80.The rep at Veracity RX told me if I don't like that and I want to keep picking my Enbrel up in Tampa I will have to pay for it myself. I did let her know she is wrong that Enbrel is covered and asked her once she gets that memo, how shall we now proceed now that we are in the middle of this debacle? In Florida, we refer to this as a real Cluster Fxxk. I am waiting for all of this to be straightened out by my HR team.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
51	$0-$50 per month	No	My insurance perpetually asks for prior authorizations during the year which causes delays in my medication delivery.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription.	I can no longer work as a nurse due to my condition.
52	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor.	No		No	My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
53	$150 - $250 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	No		No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
54	More than $1000 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	When I qualified for Medicare and I investigated the cost on Medicare I had to go off Enbrel due to cost and no longer qualified for help.	Yes	My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	I've switched drugs and my co-pay is currently affordable.
55	$0-$50 per month	No	None	This medication reduces the amount of time and money spent going to the hospital or needing surgery.	No		No		No. I have Tricare for Life which provides my prescriptions at a reasonable cost.
56	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	Internet search	No	My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
57	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family.	Yes	My provider	No		
58	$0-$50 per month	Yes		This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	I'm nervous that when I have to change insurance that it won't be covered like it is now.
59	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor.	No		No	My insurance plan requires prior approval to fill the prescription.	Yes. I have comorbidities like Shogrens and COPD and have been unable to access due to the co-pay cost which are in the hundreds of dollars each.
60	$0-$50 per month	No	None		No		No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No- retired. I have excellent insurance (Medicare Advantage Plan) which has kept the medication affordable. I would be lost without it's

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
61	$0-$50 per month			This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No		I retired early because of my health but I fortunately can afford private insurance and have two co-pay assistance programs that pay for my Enbrel so that I don't have to.
62	$0-$50 per month	No	Insurance has covered	This medication reduces the amount of time and money spent going to the doctor.	Yes	My insurance company	No		No
63	$0-$50 per month	No	no, I was on the program from the manufacturer that reduced my copay to $10 a month		Yes	my rheumatologist, the one who proscribed the medication told me about it	No		no
64	$250 - $500 per month	No	I can afford my medication but only because I saved my money	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	No		No	My insurance plan requires prior approval to fill the prescription.	None

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
65	$50 - $100 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family.	No		No	My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No
66	$250 - $500 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	Yes	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	To clarify- when I was on disability, the only way I could afford my Enbrel was through their patient assistance program. When able to work, I then still needed good insurance coverage to keep using it. It gave me back my life and continues to make a huge difference in my life.
67	$0-$50 per month	No	None of the above	This medication allows me to work and help support my family.	No		No	My insurance plan requires prior approval to fill the prescription.	No

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68	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	
69	$0-$50 per month	No	no		No			My insurance plan requires prior approval to fill the prescription.	no

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
70		Yes	I have skipped doses of the drug in order to save money., I have reduced the dose of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost., I have refused medication due to costs&	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	I have since disease flare and then Covid now lupus and ongoing issues with “post covid”, Lulus, and inability to calm my system, lost my ability to work, due to loss of physical mobility/strength, as well as the emotional and mental health issues and challenges I’ve had to endure, accept that I would be fired or retire- and so I have retired due to employers refusal to accept my disability as documented.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			coverages, I have had to pay completely out of pocket for costs with no coverage and I have been denied several.						

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71	$500-$1000 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	Forced to choose between prescriptions sometimes
72	$50 - $100 per month	No	I had to change drug due to bloodwork changes	This medication allows me to work and help support my family.	No			I worry that the cost of my prescription will raise my insurance premium.	

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73	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family.	Yes	My pharmacist	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	My only impact is when the specialized pharmacy can't seem to get their act together and acknowledge the active order they have and send it on time. This has caused significant joint flares and then takes time to get it under control again.
74	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor.	No				No
75	$500-$1000 per month	Yes	had to limit my budget to afford it once on Medicare	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	No	I worry that the cost of my prescription will raise my insurance premium.	I had assistance from drug company until I was on Medicare and then all assistance stopped.

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76	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor.	Yes	Internet search	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	No
77	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	Numerous surgeries taking me out of work. Occasionally days I am unable to work due to pain/inability to move

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
78	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
79	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed	This medication reduces the amount of time and money spent going to the doctor., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	Prescription drug manufacturer	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor.	Damage become so severe I'm disabled now fully

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			prescription drugs to treat my condition due to cost.						

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
80	$500-$1000 per month	Yes	I have skipped doses of the drug in order to save money., I have reduced the dose of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	Prescription drug manufacturer	Yes	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	Had to be on short term disability before using Enbrel.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
81	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	I can't work like I need to.
82	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	

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83	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money., Needed to find patient assistance plans to cover copays ranging from $1500 - $18,000	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My pharmacist	No	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	Inability to work Fulltime and sometimes not able to work at all.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
84	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	Unable to work
85	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	
86	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	My provider	No		No

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87	$0-$50 per month	No	None	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No
88	$0-$50 per month	No	No	This medication allows me to work and help support my family.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription.	Yes. Missing work due to my condition
89	$150 - $250 per month	Yes	I have changed prescription drugs to treat my condition due to cost., I no longer take Enbrel, but the cost of all of these medications is high and challenging.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., I worry that the cost of my prescription will raise my insurance premium.	I currently use Rituxan, which require me to drive 4+ hours away (each direction), get a hotel and take time off of work several times a year.

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90	$150 - $250 per month	Yes			No			My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	
91	$500-$1000 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	Internet search	No	My insurance plan requires prior approval to fill the prescription.	
92	$0-$50 per month	No			No		No	My insurance plan requires prior approval to fill the prescription.	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
93	More than $1000 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My pharmacist	Yes	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	Yes - it makes it extremely difficult to manage when something that worked well for me is $1600 a month AFTER insurance and assistance 😣

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
94	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	I'm no longer able to work due to my condition causing a financial burden on my family and all of the meds & doctor appointments also cause financial burdens in & of themselves.
95	$0-$50 per month	No	I'm not taking an expensive biologic. But when I was taking Embrel my insurance covered it.	This medication allows me to work and help support my family.	No		No	My insurance plan requires prior approval to fill the prescription.	No financial impact
96	$50 - $100 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	Prescription drug manufacturer	Yes	My insurance plan has dropped or switched my drug coverage after the plan year started.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			doses of the drug in order to save money.						
97	$0-$50 per month	No	None	This medication reduces the amount of time and money spent going to the doctor.	No		No		No
98	More than $1000 per month	Yes	I have skipped doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost., My doctor has given me samples to	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or	I am now on disability. The cost of these meds take away from my retirement savings. The copay card paid my copay when I had private insurance. This payment even applied to my deductible. However, once I recieved disability, and went on Medicare, I am no longer eligible foe the copay card. This is so wrong. When I was working my deductible was paid but now that I'm on a fixed income, I'm required to pay $2000/month for treatment until I meet my ridiculous deductible amount. Medicare drug coverage is so confusing and seriously awful

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			help with cost					number of refills I am able to get.	
99	$50 - $100 per month	Yes	I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor.	Being on Medicare prevents medicine to be free of charge or using company coupons/cards for discount

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
100	$0-$50 per month	No	Not applicable	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My pharmacist	No		Yes
101		No	I get my medicine free	This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	I'm retired
102	$100 - $150 per month	Yes		This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g.	The drug itself became more expensive to me when I turned 65, because the manufacturer's copay assistance is not available to Medicare subscribers.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
								only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
103	$500-$1000 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to	This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My pharmacist	No	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			treat my condition due to cost.						
104	$0-$50 per month	No	I have changed prescription drugs to treat my condition due to cost.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	Internet search	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	None

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
105	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	My insurance company	No	My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No
106	$0-$50 per month	No			Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription.	
107	$50 - $100 per month	Yes	have always been able to afford the meds but have done with other things	This medication reduces the amount of time and money spent going to the doctor., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My pharmacist	Yes	My insurance plan requires prior approval to fill the prescription.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
108	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	
109	$100 - $150 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription.	no

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
110	$0-$50 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	
111	$0-$50 per month	No	No	This medication reduces the amount of time and money spent going to the doctor.	No		No		No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
112	$0-$50 per month	No	I was on Indiana Medicaid previously and they paid 100% for my medications. It is a big factor now on Medicare. I would not be able to afford any RA biologics. I looked at the cost and thought maybe it was a blessing the doctor discontinued Enbrel as no way could I have continued this drug.		No				Yes RA issues made working no longer possible. Prescription drug costs on Medicare are very high. I don't think I can afford anything except Prednisone now. It is very cheap. Continuing to go to specialists costs co-pays, more tests and no one agrees. The specialists don't communicate with each other leaving me and probably others without answers. It just costs me more time and money, both of which are running out. Then if they did prescribe a medication I wouldn't be able to afford it. What a broken system we have. I wish it were improved and the road had not led me to being disabled. I would much like to find the answers that would lead me back to life. Thank you.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
113	$0-$50 per month	No			Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	

114	$0-$50 per month	Yes	I have had to deal with specialty pharmacies that cannot deliver medications reliably. I have spent hours and hours in the phone chasing down medication shipments and renewals and repeating the same information over and over again to multiple people and being told my medication will be shipped or that my account is accurate and fine only to find out it wasn't and have to do it all over again over and over again. Specialty	Out-of-pocket costs have caused me to accrue medical debt.	Yes	Prescription drug manufacturer	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Disabled so no living wage income.

			pharmacies are useless. There are too many layers in our healthcare system and it only makes access to care more difficult for people who truly need it.						

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
115	$0-$50 per month	Yes	I've been very lucky but it came very close to me not being able to afford it.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	I am just changing to a plan where I need to rely on patient assistance program. Not 100% sure what I'll end up paying. Already struggling with copays for Dr visits and other meds. It's very hard & scary!
116	$0-$50 per month	No			Yes	My provider	No		no
117	$0-$50 per month	No			Yes	My insurance company	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
118	$0-$50 per month	No			No			My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Unable to work more than 10 hours per week, meaning I'm not doing jobs in my potential as a person with an advanced degree because it's hard to find anything like that with such few hours or accommodations for my spine condition; unable to drive on highways due to neck fusion which severely limits my transportation; can't afford my own car so have to borrow partners or rely on medical rides which severely limits my independence
119	$250 - $500 per month	Yes	I have reduced the dose of the drug in order to save money.	Out-of-pocket costs have caused me to accrue medical debt.	No			My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
120	$50 - $100 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	Internet search	No		Inability to do my job caused lack work, returned to school to learn a new type of job.
121	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	No		Yes		No
122	$0-$50 per month	No	I have stretched time between doses of the drug in order to save money.		Yes	Doctor	No		I'm blessed that my husband is a disabled vet. In addition to Medicare I have CHAMPVA which pays for my medication otherwise I would not be able to afford it!

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
123	$0-$50 per month	Yes	I cannot afford to pay out of pocket for medications so do not take a drug if it's not insurance paid	This medication reduces the amount of time and money spent going to the doctor., Out-of-pocket costs have caused me to accrue medical debt.	Yes	Prescription drug manufacturer	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	My social security income is small and my constant illnesses make it impossible to work
124	$150 - $250 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
125	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	My pharmacist	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	It's very difficult to deal with insurance with medications that cost this much and there are times when I have a lapse in medication due to insurance issues.
126	$0-$50 per month	No			Yes	My provider	No		No
127	$0-$50 per month	No	None of the above		Yes	Prescription drug manufacturer	No		No. But I want to say that I loved Embrel and how it helped me but Medicare made me take a different drug by infusion. I would go back to Embrel if I could!

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
128	$50 - $100 per month	Yes	No	This medication reduces the amount of time and money spent going to the hospital or needing surgery.	No		No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No
129	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	I used to - before I retired I had to miss an increasing amount of work due to the pain and stiffness/fatigue that comes with autoimmune diseases. I was a professor and my employer worked around the morning stiffness but I did have to take early retirement.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
130	$0-$50 per month	No	My cost was minimal: a $20 copay	This medication reduces the amount of time and money spent going to the doctor.	No	Friend or family member	No	My insurance plan requires prior approval to fill the prescription.	no
131	$0-$50 per month	No	I used copay assistance. Would not be able to afford without it	This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	Internet search	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	Specialty pharmacy process can be challenging for delivery of medication

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
132	$50 - $100 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	Prescription drug manufacturer	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	My employer wanted me to quit or fire me to remove me from their insurance plan in case it raised his costs, and me obtain my own plan. I ended up quitting to work for another company that never questioned my illness.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
133	$0-$50 per month	Yes	Blue Cross/ Blue Shield of MA decided that my copay would be over $2600.00 unless I joined a shady copay assistance thing. (1 star Google rating). It took several months without Enbrel to clear that mess up.	This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	Forced to participate by insurance company	No	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No
134	$250 - $500 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	All expenses are hard now can't afford to live and take care of my self for all the medical bills

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
135	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.		No				I no longer drive and I live in a rural area. A relative must take time off work to take me to my infusion.
136	$0-$50 per month	Yes	I had to change pharmacies in order to have it covered and that has caused me to delay doses	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
137	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	Internet search	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
138	$0-$50 per month	No	I applied for help through the manufacturer in order to afford this treatment	This medication allows me to work and help support my family.	Yes	Internet search	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., I worry that the cost of my	I had to stop working a full time job

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
								prescription will raise my insurance premium.	
139	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	If I didn't have Medicaid to pay for this medicine I couldn't even begin to describe what my disease would do to me Medicaid pays for most but you have to get prior approval and you're only limited to so much a month but I have help through the department of Social Services North Carolina

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
140	$0-$50 per month	Yes	I have skipped doses in order to accumulate it in case of being denied medicaid: I could never afford it without that.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	No			My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	I need to keep my income low enough to qualify for medicaid: there's never been a time in my life that I could have afforded the cost ($6-7000 per month last I checked), copays, etc.
141	$50 - $100 per month	Yes	I feel the whole prescription was cost prohibitive but I received help from the company that makes Enbrel		Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number	no

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
								of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	
142	$50 - $100 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., I worry that the cost of my prescription will raise my insurance premium.	No
143	$150 - $250 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
144	$0-$50 per month	No			Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	
145	$0-$50 per month	No	None	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	Unplanned flare ups , pain , fatigue affect my work schedule
146	$50 - $100 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication allows me to work and help support my family., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	Yes	My insurance plan has dropped or switched my drug coverage after the plan year started.	All of the above

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
147	$250 - $500 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	Internet search	Yes	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	no
148	More than $1000 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	Yes	I worry that the cost of my prescription will raise my insurance premium.	My Enbrel treatment was in a clinical trial so the financial hit did not hit for a while. I have been on biological drugs for over 20 years. The financial picture changed several times depending from free (clinical trials) to $1100/mo. since I lost NYS EPIC this month. I am choosing to go off Cosentyx due to finances.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
149	$50 - $100 per month	No	None	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No	I worry that the cost of my prescription will raise my insurance premium.	No
150	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	My insurance company	No	My insurance plan requires prior approval to fill the prescription.	No
151	$250 - $500 per month	Yes		Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription.	Absences from work, being restricted to what jobs I am able to do for work (not a lot of lifting and can't be on my feet all day), having to afford multiple medications to manage my condition, paying more co-pays for seeing multiple specialists, paying out of pocket for treatments and tests that aren't covered by medical insurance.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
152	$0-$50 per month	No	Held the drug only when sick and on antibiotics	This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	Retired and have not had any financial impacts yet
153	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	
154	$50 - $100 per month	No	I have changed prescription drugs to treat my condition due to cost.	This medication allows me to work and help support my family.	Yes	Drug study	No	My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
155	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription.	
156	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	My insurance company	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
157	$50 - $100 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
158	$0-$50 per month	Yes	RX help		Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor.	
159	$50 - $100 per month	Yes	I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor.	Yes, have been terminated due to call out with no FMLA available due to being with company less than a year.
160	$250 - $500 per month	No	None	This medication allows me to work and help support my family.	No		No	My insurance plan requires prior approval to fill the prescription.	I no longer take Enbrel

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
161	$0-$50 per month	No			Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	no
162	$0-$50 per month	No	no	This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	Missing work.
163	$500-$1000 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	I became disabled and am no longer able to work. Had to pay for insurance and all related medicines without help until I could access Medicare plans. Wouldn't have been able to access medical care if I hadn't had savings accounts to use during this transition. No one should have to live in pain because they lack access to medical treatment due to costs. I urge you to help those in need of these drugs due to lack of funds.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
164	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	Gals in getting prescriptions due to changing coverage for medications like these however once It was sorted out was able to get the medication at no cost through help with RX help centers.
165	More than $1000 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	No				Do not have insurance due to cost so have had to discontinue using Enbrel

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
166	$0-$50 per month	No		Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	No
167	$50 - $100 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family.	No		No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	No
168	$0-$50 per month	No	I have changed prescription drugs to treat my condition due to cost.	This medication allows me to work and help support my family.	No		No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g.	None

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
								only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
169	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication allows me to work and help support my family.	Yes	My pharmacist	Yes	My insurance plan requires prior approval to fill the prescription.	No
170	More than $1000 per month	Yes	I have skipped doses of the drug in order to save money.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	Yes	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	N/A

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
171	$0-$50 per month	No		This medication allows me to work and help support my family.	No			My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
172	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	Yes	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance plan requires prior approval to fill the prescription.	No
173	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor.	Yes	Prescription drug manufacturer	No		

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
174	$0-$50 per month	Yes	None	This medication reduces the amount of time and money spent going to the doctor.	Yes	Prescription drug manufacturer	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	Can't work & on SSDI. Income is minimal. Very thankful for assistance program so at least my symptoms are lessened.
175	$50 - $100 per month	Yes	I have skipped doses of the drug in order to save money., I have reduced the dose of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my	This medication allows me to work and help support my family., Out-of-pocket costs have caused me to accrue medical debt.	Yes	Prescription drug manufacturer	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	yes, unable to work as much as I would like which affects my paycheck, and I am to young mentally for Disability so I just suffer through it financially and make the best of it

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			condition due to cost.						

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
176	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
177	$0-$50 per month	No	No	This medication allows me to work and help support my family.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g.	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
								only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
178	$250 - $500 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my	This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., My insurance plan has dropped or switched my drug coverage after the plan year started., I worry that the cost of my prescription will raise my insurance premium.	Was locked in to a low paying job because I was afraid of losing coverage for the drug if I switched employers. Then my employer eliminated coverage for it anyway and I had to search for a payment grant from the manufacturer.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			condition due to cost.						
179	$500-$1000 per month	Yes	No	This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	In recent years, financial assistance has not been available from the manufacturer since the manufacturer required it to be applied to my out of pocket and the insurance company denied that. This includes both regular financial assistance as well as need based financial assistance.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
180	$0-$50 per month	No			Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	There are no rhuematologists within an hour of my location. Most are 2+ hours away.
181	$0-$50 per month	No	My specific allergies are the major concern in all of my healthcare treatments.		Yes	My case manager.	No	My insurance plan requires prior approval to fill the prescription.	Not at this time.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
182	$100 - $150 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription.	
183	$0-$50 per month	No	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	Internet search	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to	NA

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
								get., I worry that the cost of my prescription will raise my insurance premium.	
184	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	I miss a lot of work and have to travel a ton because of my condition, but it's not Enbrel's fault.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			treat my condition due to cost.						
185	$0-$50 per month	No			No		No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	no
186	$0-$50 per month	No	Cost has not been a problem for me	This medication allows me to work and help support my family.	No		No	My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
187	$0-$50 per month	No	I have had to go thru the process of signing up and using a patient assistance program.		Yes	My provider	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	Financial impact is that I can no longer work so have lost a fair amount of our families annual income.
188	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery.	No		No		none. because of my service-connected diseases Enbrel is paid for
189	$50 - $100 per month	Yes	I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries,	No			My insurance plan requires prior approval to fill the prescription.	The biggest impact is to my finances, as I receive SSDI.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			condition due to cost.	vacations, etc.) to pay for the medication.					
190	$0-$50 per month	No	Not affected adherence.	Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
191	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	Internet search	No	My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	
192	$0-$50 per month	No			Yes	My insurance company	No	My insurance plan requires prior approval to fill the prescription.	No
193	$0-$50 per month	No	No because i qualify for amgen copay program. This will stop with change to medicare and i will need to find a new drug. It will be too costly.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No		Yes, grocery delivery charges because I can't lift heavy items.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
194	$0-$50 per month	No			Yes	My provider	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	I am no longer able to work as a result of my illnesses.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
195	$50 - $100 per month	Yes			Yes	RN		I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	
196	$150 - $250 per month	Yes	None	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	No
197	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication allows	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day	Yes. My co-insurance is 20%, and I am behind. I do miss work frequently and am fatigued all the time. If I did not have patient assistance, I would not be able to afford my medication.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
				me to work and help support my family.				supply with no 90 day supply option) or number of refills I am able to get.	
198	$100 - $150 per month	No							
199	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription.	
200	$0-$50 per month	No	I have not had any difficulties financially to take asn prescribed.	This medication reduces the amount of time and money spent going to the doctor.	No			My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	I am retired, initially medically now based on my age. Financial impact has not been an issue in my rheumatologist and my choice of biologic therapies.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
201	$100 - $150 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	No
202	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	My insurance company	No	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day	absences from work - have had to go on FMLA before to reduce the amount of time I could work in a day + required regular breaks; have difficulty working in an office setting because of the pain, which limits which jobs I can get

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
								supply option) or number of refills I am able to get.	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
203	$0-$50 per month	No	I receive my medication by yearly applying for free meds at Amgen Saftey net and attend of year change does age to every two weeks instead of weekly due to being not enough med to use as prescribed. This year went for nearly a month without medication due to application process I started in Novemebrt		Yes	My provider	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
204	$50 - $100 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	Prescription drug manufacturer	Yes	My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	
205	$250 - $500 per month	No	I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	No		no
206	$0-$50 per month	No	I am no longer using this med, but not due to finances.	This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Yes, the provider I see which is a specialist is not covered/ paid by my insurance company. All costs I incure out of pocket because prior to finding this physician I was not getting any relief from any of the other doctors I saw total number of 12 from 1997-2004. I have been a patient of this physician since 2004, my insurance stopped covering my doctor visits to see him in 2018 when my employer

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
									changed to our current insurance plan.
207	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the hospital or needing surgery.	No				
208	$100 - $150 per month			This medication allows me to work and help support my family.	Yes	Myself	Yes	My insurance plan requires prior approval to fill the prescription.	Yes if it wasn't for will my meds I would not be able to afford my medication. Thank GOD
209	$0-$50 per month	No	No	This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
210	$0-$50 per month	No	I have changed prescription drugs to treat my condition due to cost.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	Internet search	No	My insurance plan requires prior approval to fill the prescription.	No
211	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No		No
212	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	My provider	No		

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
213	$0-$50 per month	No	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Prescription plan changed so that patient assistance copay assistance can no longer be counted towards deductible or out of pocket. One they use the copay money up, I'm responsible for the entire amount. Also they reclassified specialty meds to require a 30% copay no matter what.
214	$0-$50 per month	No	I have assistance from Enbrel	This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription.	Not right now but worried when I turn 65 years of age
215	$0-$50 per month	No	No	This medication reduces the amount of time and money spent going to the doctor.	No		No	My insurance plan requires prior approval to fill the prescription.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
216	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes		No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	Live frugally on fixed income
217	$100 - $150 per month	No	No	This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No
218	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
219	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No		I estimate that if I didn't have RA, I could probably earn twice the amount of money I actually do.
220	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	No.
221	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money.		Yes	Physician	No	My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	I have retired early because of my disability. I think that is the ultimate impact.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
222	$0-$50 per month	No	No	This medication allows me to work and help support my family.	No			My insurance plan requires prior approval to fill the prescription.	No
223	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My insurance company	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
224	$50 - $100 per month	No	N/A	This medication reduces the amount of time and money spent going to the doctor.	Yes	My pharmacist	No	My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No
225	$0-$50 per month	No	None of above		Yes	My insurance company	No	My insurance plan requires prior approval to fill the prescription.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
226	$0-$50 per month	No	No	This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	I used the Enbrel co pay card when I had private insurance through my employer. When I turned 65 and went to Medicare I was dropped from the co pay assistance through Amgem and paid more out of pocket. I have a close friend on Medicare who said that her plan considered Enbrel a category 5 drug and her co pay would be over $2,000 and she can't afford that. She has failed other drugs
227	$0-$50 per month	No	I have never done any of the above but I did go without it for about six weeks to see if I still needed it. Yes, I discussed it with my doctor and yes I still need it.	This medication reduces the amount of time and money spent going to the doctor.	Yes	My insurance company	No		Not Embrel. I did experience a shortage of Sulfasalazine in our area and going without it for a few weeks sent me into a particularly bad flare up that lasted six month!

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
228	$0-$50 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Our family had experienced significant financial impacts of the condition of our child. Specifically, my husband and I were self employed but we could not afford the estimated copay for Enbrel if we used an ACA health insurance policy. So we had to shutter our small business and take jobs that offered private health insurance plans because our copay assistance program could not be used with a ACA policy, only with private employers offered policy. In doing so, my husband took a significant pay cut to get a job that offered health insurance coverage.
229	$50 - $100 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Missed some work
230	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
								supply option) or number of refills I am able to get.	
231	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	no

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
232	$500-$1000 per month	Yes	I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	Yes	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	Yes, cost of transportation to Doctors, Pharmacy etc.
233	$0-$50 per month	Yes		This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	While working.PSA was a large factor in choosing to retire

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
234	$0-$50 per month	No	Medicare covers this however when I first started with Cimzia, Cosentyx and Taltz I paid $5000 per month for the first 3 months to meet deductible	This medication reduces the amount of time and money spent going to the doctor.	No		No	My insurance plan requires prior approval to fill the prescription.	I did retire early because of absences from work
235	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My insurance company	No	My insurance plan requires prior approval to fill the prescription.	No
236	$0-$50 per month	Yes	no, because I had a copay assistance program at the time	This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day	This drug was used by me in the past, and as long as I had the copay assistance program, it did not impact me financially. My current situation is quite different on Medicare.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
								supply with no 90 day supply option) or number of refills I am able to get.	
237	$0-$50 per month	No			Yes	Internet search	No	I worry that the cost of my prescription will raise my insurance premium.	No
238	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	My insurance company	No		No
239	$250 - $500 per month	Yes	I have skipped doses of the drug in order to save money.	This medication allows me to work and help support my family.	Yes	My pharmacist	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No. Just sick days from the condition of my RA.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
240	$0-$50 per month	Yes	None, only its more of a hassle to jump thru the hoops to obtain it, which greatly adds to my stress which I don't need cause it's bad enough already	This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	My provider	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	I can no longer work and it took 2 & a half years to get disability at which I had zero income for me & my husband, furthermore now that I'm on disability the income amount is less than half of what it was while I could still work. That is extremely hard to cope with as well.
241	$0-$50 per month	Yes			Yes	My provider	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
242	$0-$50 per month	Yes	I have stretched time between doses of the drug in order to save money.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	No		I had to quit my office job because the long hours sitting down in front of the computer were causing me a lot of pain and flares.
243	$50 - $100 per month	No		This medication allows me to work and help support my family.	Yes	My insurance company	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	I have two days a week when I'm exhausted and can't do much and require a nap.
244	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	No
245	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost., I had to stop when I	This medication reduces the amount of time and money spent going to the doctor.	No		Yes	My insurance plan has dropped or switched my drug coverage after the plan year started.	I just have live with uncontrolled psoriasis

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			entered Medicare						
246	$150 - $250 per month	Yes	No, but sacrifices were made by me and my family in order to purchase the drug.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	Dr.'s nurse	Yes	My insurance plan requires prior approval to fill the prescription.	
247	$0-$50 per month	No			No		No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
248	$0-$50 per month	No	I'm very fortunate to have the needed funds for my condition. My job and occupation help with that greatly!	This medication allows me to work and help support my family.	Yes	My provider, insurance co. And the drug mfg.	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	Yes, I have to go to my rheumatologist qtly and monthly, I'm on more meds than I can remember, the monthly cost of meds, proper diet for my condition also, somehow ridiculously more expensive, and on top of that, the otc's I have to take on top of the prescriptions, is just so much fun…
249	$500-$1000 per month	Yes	Missed doses because insurance didn't want to pay anymore, which would have left me paying $7k out of pocket each month.	This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Can't work full-time, if at all. Travel to see the rheumatologist or other specialists requires a 80+ mile drive, sometimes requiring a hotel room ($200+ a night if you need somewhere with an elevator). Lots of doctor visits, imaging and lab work due to the medication. I count on hitting my max out-of-pocket each year. Then I get to argue for hours with insurance to get the remaining costs covered as they should be.
250	$0-$50 per month	No	Have always used as directed		No		No	My insurance plan requires prior approval to fill the prescription.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
251	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	I am unable to work full time because of RA. I have to be careful about my spending because of this and unfortunately am behind in some bills because of lost time at work.
252	$0-$50 per month	No	I am able to get financial assistance from the drug company	This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
253	$250 - $500 per month	Yes	I have purchased the medication, but it put a definite financial strain on my life.	This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes		If my copay card were to go away, I would not be able to get this medication at all.
254	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My pharmacist	Yes	I worry that the cost of my prescription will raise my insurance premium.	Cannot use this prescription because of costs and side effects
255	$0-$50 per month	No	I have had to wait to start a drug while my doctor appealed the declination from	This medication allows me to work and help support my family.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor.	I have been very fortunate in that my insurance and the copay program made it financially possible to take the medication. It is frustrating that the insurance companies have a say in what drug I try first.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			insurance company.						
256	$0-$50 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication allows me to work and help support my family., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	Yes	My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
257	$0-$50 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	No	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	The entirety of our financial issue is from medical debt. Without access, my body shuts down and I slowly start to die. My RA is one of the most aggressive forms and I've had to stop medication several times because we can't afford it unless there is coverage assistance. During those times, I become unable to work, unable to walk, and unable to care for myself at all.
258	$50 - $100 per month	No	No	This medication reduces the amount of time and money spent going to the doctor.	Yes	Prescription drug manufacturer	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., My insurance plan requires prior approval to fill the prescription.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
259	$100 - $150 per month	Yes		Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	No	I worry that the cost of my prescription will raise my insurance premium.	Yes no access to private insurance and I'm paying 1200 a month for a plan that had good prescription coverage
260	$0-$50 per month	Yes	I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost., Costs did vary by prescription and some had copay assistance but when that runs out my costs	This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	As noted the copay assistance runs out before end of year and then insurance does not cover so cost can be near $5000.00

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			were in the thousands						
261	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication allows me to work and help support my family.	Yes	My provider	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	I only take what I can afford. That does limits me at times.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
262	$50 - $100 per month	Yes		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My insurance company	No	My insurance plan requires prior approval to fill the prescription.	
263	$500-$1000 per month	Yes	My rheumatologist provided me with samples so I wouldn't miss doses while I figured out how to cover the cost of the medication.	This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	When I was a student at the University of Colorado and on Enbrel, I had a $750-800 copay per month. I also had a $5,000 annual cap on ALL prescription medications under my insurance, and the cap would be easily reached prior to the end of the year, leaving me without prescription coverage from my insurance. Another cost was the many, many hours I had to spend on the phone with insurance, specialty pharmacies, and copay assistance programs to figure out how to afford the medication I needed.
264	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not	Yes, transportation costs, absence from work

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
								recommended by my doctor.	
265	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	None that I'm aware of, although a 90 day supply would help with running back n forth from my doctor and pharmacy. I can no longer drive due to health and pay Uber ti get me everyehere
266	$0-$50 per month	No	No		Yes	Originally my provider but now i just know to look for a co-pay card be my current dr does not mention it	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Loss of second income When I was working I was missing a lot of days which lead to resentment in the workplace and added anxiety.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
267	More than $1000 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Cannot do copay assistance with Medicare.

Appendix I

Enbrel: Input from Individuals with Scientific or Medical Training

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider input from individuals who possess scientific or medical training with respect to a condition or disease treated by the prescription drug that is under review by the Board. (C.R.S. § 10-16-1406(4)(h)(II)).

Rule: Individuals with Scientific or Medical Training: The Board will seek input from individuals who possess scientific or medical training with respect to a condition or disease treated by the prescription drug that is under review by the Board, including:

- The impact of the disease,
- Perspectives on benefits and disadvantages of the prescription drug, including comparisons with therapeutic alternatives if any exist, and/or
- Input regarding the prescription drug utilization in standard medical practice, as well as input regarding off label usage. (3 CCR 702-9, Part 3.1.E.2.h.ii).

Off-label usage means the use of a prescription drug for a disease or medical condition that is outside the FDA-approved indication(s) (3 CCR 702-9, 1.1.C).

Policy: Staff will gather input from individuals who possess scientific or medical training through outreach and holding a public meeting(s).

- Individuals who possess scientific or medical training with respect to the condition or disease may continue to provide input via verbal public comment and written public comment.
- During the following Board meeting(s), Staff will present input provided by individuals with scientific or medical training and will report such information in their final report. (PDAB Policy 04, p. 8).

Underlying Methodology: Board staff compiled data for Enbrel for the Board's consideration in the following manner:

1. Documented information provided during the stakeholder sessions to gather input from individuals with scientific and medical training specific to Enbrel. Staff attempted to compile information directly related to the information outlined in rule during stakeholder meetings and from the survey.
2. After the survey deadline and public input sessions have concluded, Board staff aggregated responses, identified high-level themes, and presented findings to the Board in the form of a short report.

Data Source(s): Board staff compiled information from individuals with scientific or medical training for selected prescription drugs from the following sources:

- Results from public input sessions and surveys from individuals with scientific or medical training.

Considerations and Data Limitations: Input provided both via stakeholder meetings and surveys is voluntary. Such qualitative data may not capture information from all individuals with scientific and medical expertise.

Enbrel: Input from Individuals with Scientific or Medical Training Evidence

Background

Board staff gathered input from individuals with scientific or medical training in two ways: meetings and surveys. Input was gathered from two individuals at a public meeting on September 19, 2023. In addition to input gathered through the public meeting, three individuals completed surveys regarding the health and financial effects of Enbrel. Additional input was gathered from five individuals with scientific or medical training via three additional small group meetings.[1]

At the initial time of survey release, the Board received three responses from individuals with scientific or medical training. Board members requested more information from patients and voted to reopen the surveys at the December 15th meeting. After reopening, the Board received zero responses from individuals with scientific or medical training.

To qualify to participate in meetings or surveys, respondents had to have scientific or medical experience with Enbrel. Outreach was conducted via the public listserv and website.

Input summaries are presented below in a manner similar to how meetings and the survey were conducted: health effects of Enbrel and financial effects of Enbrel. Specifically, staff collected information in a manner that encompassed the categories required by Board rule, including the impact of the disease, perspective on the benefits and disadvantages of the prescription drug, including comparisons with therapeutic alternatives if any exist, and/or input regarding the prescription drug utilization in standard medical practice, as well as input regarding off label usage. This appendix also contains links to the public meeting audio recording, the survey, and survey results.

There is additional information contained in Appendix F and Appendix J which may contain additional input from individuals with scientific or medical training not captured in this appendix. The Board may want to weigh information from all three appendices.

Health Effects of Enbrel

Individuals with scientific or medical training stated in public meetings and in survey responses that Enbrel is an anti-TNF biologic therapy that has been used to treat more than a million people with serious inflammatory diseases. It's been studied in more than 100 clinical trials and has a well established safety profile. Enbrel is approved for treatment of the following five indications: severe rheumatoid arthritis (RA), psoriatic arthritis (PsA), moderate to severe plaque psoriasis (PsO), ankylosing spondylitis (AS), and moderate to severe juvenile idiopathic arthritis (JIA).

Individuals with scientific and medical training reported in public meetings and surveys that Enbrel provides the following beneficial health effects:

- Reduction in signs and symptoms of approved indications
- Improved overall function and quality of life
- Potentially lowered risk of developing other comorbid health conditions
- Prevention of irreversible joint damage
- Improvement of inflammatory arthritis and inflammatory back pain
- Skin improvement
- Flexibility in managing conditions with or without methotrexate
- User-friendly, prefilled syringe

[1] The referenced small group meetings included discussion of multiple drugs currently undergoing affordability reviews by the Board, including Enbrel.

- Enbrel does not need to be stopped as far in advance by people wishing to conceive

Participants stated that Enbrel is primarily used for patients with RA, which causes functional impairments and deformities of the joint and has major impacts on quality of life. Treatment is necessary to improve physical function and slow the progression of joint damage. When treating for RA, participants often begin by prescribing an agent like methotrexate. If that does not produce a full response, the combination of Enbrel and methotrexate has shown to be optimal for the management of RA, as well as prevention of structural joint damage. One participant stated that with methotrexate, there is a risk of incomplete response which leads to triple therapy, a complicated all-pill regimen. Given the side effects of triple therapy, the participant claims that anti-TNFs like Enbrel become a safer alternative.

When prescribing Enbrel to patients with psoriasis, participants noted that patients not only suffer from itchy, painful skin, but psoriasis can be embarrassing for patients, affecting overall wellbeing and leading to depression and anxiety. Comorbidities include metabolic syndrome, cardiovascular disease, and psoriatic arthritis. Psoriasis is also a chronic condition, so long-term management is necessary to keep disease activity under control and to lower the risk of developing other comorbid health conditions.

Participants also discussed treating pediatric patients for JIA, polyarticular JIA, and other JIA subtypes. Complications that come with JIA include not being able to go to school, play sports, or move without a wheelchair. Participants reported that some infants with JIA are unable to crawl, and some children get arthritis of the jaw or contract uveitis, which left untreated can cause a child to lose their eyesight. Providers stated that there is a lack of pediatric rheumatologists in the nation and that families will fly or drive long distances to be seen. Participants discussed the continuum of patients with JIA into adulthood, where patients are diagnosed with RA and gain access to more FDA approved medications for 18 and older.

Though Enbrel is approved for a broad population with multiple indications, some participants described off-label usage. One participant stated that Enbrel is frequently used off-label in pediatrics, particularly in rarer conditions such as Behcet's disease and Chronic Non-bacterial Osteomyelitis (CNO). Enbrel has also been prescribed for Lupus with inflammatory arthritis.

Side Effects

Individuals with scientific and medical training reported that the most common side effect of Enbrel was increased risk of serious infections compared to synthetic disease-modifying antirheumatic drugs (DMARDs). Survey respondents also stated that side effects could include risk of developing skin cancer and lymphoma and risk of flare of Multiple Sclerosis (MS) or congestive heart failure (CHF).

Therapeutic Alternatives

The most common therapeutic alternatives to Enbrel include other anti-TNFs, such as Humira, Remicade, Cimzia, and Simponi. Participants discussed the development in monoclonal antibodies and loss of response to particular drugs, resulting in TNF cycling or secondary failure. Because patients will often cycle off these medications over time, several participants emphasized the importance of patient access to multiple anti-TNF agents. One participant specifically highlighted that both physicians and patients need access to multiple options over time, as the manifestations and outcomes of these diseases vary among patients and each treatment has its unique benefits.

One participant stated that some providers are comfortable switching between the same drug class as Enbrel because they are more concerned that the patient has no delay in medication versus the patient being without medication. Another participant stated that intravenous infusions are a good TNF alternative, though transportation issues are often a barrier to patients.

When speaking specifically of psoriasis, one participant stated that many topical and systemic treatment options exist and the individual patient must be taken into consideration. Individuals may not be candidates for therapeutic alternatives due to age, systemic medical diseases or history of malignancy, mental health

conditions, other medications/medication interactions, allergies, lifestyle habits, and prior treatment failures or experiences with other psoriasis medications. Common therapeutic alternatives may or may not exist for the patient, depending on these factors.

Financial Effects of Enbrel

Individuals with scientific and medical training were asked three types of questions related to the financial effects of Enbrel: (1) patient out-of-pocket (OOP) costs for Enbrel; (2)relative financial effects of Enbrel on health, medical, or social services costs; and (3) patient and provider experience with utilization management requirements. Information from all types of questions are summarized below.

Patient Cost and Relative Financial Effects

Participants were asked if patients raise concerns about the cost of Enbrel. One participant stated that patients are paying up to $3,000 to $4,000 out of pocket without insurance, and many times the co-pays are as high as $1,000 per month. Another participant emphasized that with Medicaid, self injectables like Enbrel, are almost inaccessible. There are a variety of high copayments with commercial insurance, especially if a patient has multiple comorbidities.

One participant stated they are not seeing huge out-of-pocket costs for patients that are commercially insured due to the robust savings program through the manufacturer. They stated that they rely heavily on manufacturer and patient assistance programs, but patients aren't always aware of assistance programs or have difficulty navigating the process. Some providers stated that they employ patient navigators who connect patients with resources in the community. One participant stated that the annual maximum copay amount that is awarded decreased significantly in the last couple of years. One provider stated this is due to copay maximizers, and another stated that Amgen has decreased their Enbrel copay amount because they are allocating resources for their other medicines.

Participants stated that people who are undocumented can access financial assistance programs despite not being a US citizen. 70 to 80 percent of the drug companies do not request US citizenship, and only request a US address for the last six months to get access to a free drug. For infusions, providers end up taking on the cost because the 340B program helps offset the cost and serve that patient population.

Utilization Management

Utilization management issues reported by participants include step therapy, denials for off-label usage due to the very few FDA medications, and appeals to insurance companies. Participants also stated that patients have so many hurdles when it comes to disease management, navigating insurance, and patient assistance, that they become overwhelmed and want to give up. One participant also stated that once a patient is doing exceptionally well on a medication like Enbrel, having to switch to a different medication due to insurance changes runs the risk of them having uncontrolled disease, effectively worsening their condition.

Audio from Public Meetings with Individuals with Scientific or Medical Training

The audio from the October 10, 2023 public Zoom meeting is found via the following link: https://us06web.zoom.us/rec/play/hwZNw_NQ10uRLT-f0n8YrihtCZQ0roOSO_5hc5gtw076I8rN4GkSt9Zh0BmIH9Hd-72b2OPDkfac5Yte.T2SBIB-NSYozncnS

Individuals with Scientific or Medical Training Survey

The Scientific or Medical Training Survey was initially live on the Prescription Drug Affordability Board website from September 12 to October 3. At the December 15th PDAB meeting, Board members requested more information from patients and voted to reopen the surveys until January 21, 2024. Though survey results are not a representative sample of all individuals with scientific or medical training, the results can still provide important input from individuals with scientific and medical training.

Figure I-1
Individuals with Scientific and Medical Training Survey

Personal Information

I am answering this survey as an individual with scientific or medical training who mainly utilizes my expertise: *

- [ ] In research of this drug for prescription drug development for a manufacturer.
- [ ] In research of this drug in an academic setting.
- [ ] As a prescriber of this drug to patients.
- [ ] As a prescriber of this drug to patients in a safety net setting.
- [ ] Other:

My expertise directly relates to patients who live: *

- [ ] In Colorado
- [ ] Nationally
- [ ] Other:

Health Effects

Please list the conditions that are treated by the prescription drug for which you are providing expertise.

Your answer

Please list the conditions that are treated by the prescription drug for which you are providing expertise.

Your answer

From your experience, how is this drug used in standard medical practice?

Your answer

From your experience, describe any off-label usage of this drug.

Your answer

In your experience, what are the health benefits of this drug?

Your answer

In your experience, what are the health disadvantages of this drug?

Your answer

From your experience, are there any common therapeutic alternatives to this prescription drug? If so, please list them.

Your answer

In your experience, what are the benefits or disadvantages between therapeutic alternatives and this prescription drug?

Your answer

Financial Effects

In your experience, do patients raise financial concerns when being prescribed this prescription drug?

Your answer

Do you discuss this drug's expense with patients when prescribing?

- ◯ Yes
- ◯ No
- ◯ Not applicable

When do you discuss financial effects with patients related to this drug?

- ◯ At the point of prescribing.
- ◯ After the appointment, before the patient reaches the pharmacy.
- ◯ After the patient has been to the pharmacy.
- ◯ Someone else in my organization discusses financial effects with patients.
- ◯ I do not discuss financial effects with patients.
- ◯ Other:

At the point of prescribing, do you discuss any of the following with your patients related to this prescription drug? Select all that apply.

- [ ] Plan specific cost of the drug
- [ ] Patient deductible information
- [ ] Plan formulary alternatives
- [ ] Cost for uninsured patients
- [ ] Pharmacy specific pricing
- [ ] Manufacturer assistance programs
- [ ] Other:

In your experience, have utilization management policies (e.g., insurance requirements related to step therapy or prescription drug formulary tiers) impacted your patients' ability to access this drug?

- ◯ Yes
- ◯ No
- ◯ Other:

If you are a safety net provider, does your clinic/facility provide this prescription drug to patients? If not, why?

Your answer

Individuals with Scientific and Medical Training Results

Survey results are provided for Personal Information, then Health Effects, followed by Financial Effects.

Table I-1
Individuals with Scientific and Medical Training Survey Results

Personal Information, Health Effects and Financial Effects

ID#	I am answering this survey as an individual with scientific or medical training who mainly utilizes my expertise:	My expertise directly relates to patients who live:	Please list the conditions that are treated by the prescription drug for which you are providing expertise.
1	Pharmacist	In Colorado	Psoriatic arthritis, rheumatoid arthritis
2	As a prescriber of this drug to patients.	In Colorado	Psoriasis
3	As a prescriber of this drug to patients., As a prescriber of this drug to patients in a safety net setting.	In Colorado, Nationally	Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis
ID#	What is the impact of this condition(s) on your patients?	From your experience, how is this drug used in standard medical practice?	From your experience, describe any off-label usage of this drug.
1	Can be debilitating	Treatment of psoriatic or rheumatoid arthritis in combo with other meds	N/A
ID#	What is the impact of this condition(s) on your patients?	From your experience, how is this drug used in standard medical practice?	From your experience, describe any off-label usage of this drug.

2	The appearance of psoriasis can be embarrassing. The symptoms associated with psoriasis, including itch, pain, flaking skin, can directly impact patient wellbeing, patient sleep, and ability to complete activities of daily living. Psoriasis is also well known to have systemic medical associations including metabolic syndrome, cardiovascular disease, mental health conditions like depression and anxiety, and psoriatic arthritis, a potentially debilitating inflammatory arthritis. Having active psoriasis can lead to decreased work productivity, decreased interpersonal relationships, and impact emotional wellbeing. Patients often feel the need to hide their skin with clothing or other accessories. In addition, psoriasis is a chronic condition, there is no cure, so long-term management to keep disease activity under control is necessary. Treatment can improve skin disease and it can also potentially lower the risk of developing other comorbid health conditions. Psoriasis treatment is highly individualized and dependent on many factors including disease severity, location of active disease, and the presence of other comorbid medical conditions such as psoriatic arthritis, inflammatory bowel disease, history of malignancy, and depression and/or anxiety. Not all psoriasis patients respond to the same medications and oftentimes trying multiple different treatments before finding the one that works is needed. In addition, patients may lose response to a medication over time, and because again psoriasis is a chronic condition, they need to switch to another therapy. These situations can be frustrating to the patient, but we can also provide hope that multiple treatment options are FDA-approved and available (others are also being researched), and our goal is to find that one that works to control their disease.	Enbrel is an effective medication to treat moderate to severe psoriasis. Enbrel is also approved for pediatric psoriasis down to age four and psoriatic arthritis, so it can be used to manage patients who have both skin and joint psoriatic disease.	(No response)
3	Huge quality of life, morbidity and mortality	RA: second line after methotrexate and PSA and AS: first line drug	RA: second line after methotrexate and PSA and AS: first line drug
ID#	In your experience, what are the health benefits of this drug?	In your experience, what are the health disadvantages of this drug?	From your experience, are there any common therapeutic alternatives to this prescription drug? If so, please list them.

1	Reduces signs and symptoms of the conditions	Increased risk of serious infections	Humira
2	The health benefits include improved psoriasis disease control which often leads to improved quality of life, amelioration of symptoms, and as above, psoriasis disease control can also potentially lower the risk of developing other comorbid health conditions. When treating psoriasis patients with psoriatic arthritis, it can prevent irreversible joint damage and destruction.	As with many systemic medications to treat psoriasis (biologic and traditional systemic medications), there is an increased risk of infections. Enbrel also carries a risk of developing skin cancer and lymphoma.	This is a challenging question to answer because while many topical and systemic treatment options exist for psoriasis, the individual patient must be taken into consideration. Psoriasis factors to consider include body surface area involved, skin locations affected, special site involvement, nail involvement, other psoriasis subtypes, and whether there is concurrent psoriatic arthritis. Individuals may not be candidates for therapeutic alternatives due to age, systemic medical diseases or history of malignancy, mental health conditions, other medications/medication interactions, allergies, lifestyle habits, and prior treatment failures or experiences with other psoriasis medications. Common therapeutic alternatives may or may not exist for the patient, depending on these factors.
3	Significant improvement of inflammatory arthritis and inflammatory back pain along with skin improvement	Increased infection risk, risk of MS or cHF flare in the wrong patient population	All other TNFs, third line drugs
ID#	In your experience, what are the benefits or disadvantages between therapeutic alternatives and this prescription drug?	In your experience, do patients raise financial concerns when being prescribed this prescription drug?	Do you discuss this drug's expense with patients when prescribing?
1	Biosimilars are available for Humira	Yes	N/A
2	As above, this is a challenging question to answer. All medications have risks and benefits but whether the benefits outweigh the risks for the therapy I choose, and their alternatives, depends on the psoriasis patient in front of me.	Yes	Yes
3	I like the weekly prescription as patients can sometimes remember better than every other week or once monthly	Yes. 3000-4000+ out of pocket without insurance and many times co pays are $1000 per month	Yes

ID#	When do you discuss financial effects with patients related to this drug?	At the point of prescribing, do you discuss any of the following with your patients related to this prescription drug? Select all that apply.	In your experience, have utilization management policies (e.g., insurance requirements related to step therapy or prescription drug formulary tiers) impacted your patients' ability to access this drug?
1	Usually when prescription has been processed	Assistance programs, plan formulary alternatives	Yes
2	At the point of prescribing.	Plan formulary alternatives, Manufacturer assistance programs	(No response)
3	At the point of prescribing.	Patient deductible information, Plan formulary alternatives, Cost for uninsured patients, Manufacturer assistance programs	Yes
ID#	If you are a safety net provider, does your clinic/facility provide this prescription drug to patients? If not, why?	If you are a safety net provider, do you receive a 340B discount for this prescription drug?	In your experience, are there any other financial effects of the condition and prescription drug you think the Board should consider?
1	(No response)	(No response)	No
2	(No response)	(No response)	(No response)
3	I work at the dawn clinic and work closely with stride pharmacy to get drugs like this for our patients	Yes	Co pay coverage is really lacking for these meds!

Appendix J

Enbrel: Voluntarily Submitted Information

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider any other information that a manufacturer, carrier, pharmacy benefit management firm, or other entity chooses to provide. (C.R.S. § 10-16-1406(4)(i)).

Rule: Information Voluntarily Submitted from a Manufacturer, Carrier, Pharmacy Benefit Management Firm, or Other Entity:

- The Board will consider information voluntarily provided by a manufacturer, carrier, pharmacy benefit management firm, or other entity.
- Manufacturers, carriers, pharmacy benefit management firms, or other entities shall have 60 days from the date of selection to provide such information to the Board for its consideration. (3 CCR 702-9, Part 3.1.E.2.i).

Policy: Staff will prepare information voluntarily provided by a manufacturer, carrier, pharmacy benefit management firm, or other entity for the Board's consideration.

- After selection of a prescription drug for affordability review, the Board will notify interested parties, including members of the PDAAC, using its listserv and by posting on its website, of the ability to submit information pursuant to section 10-16-1406(4)(i), C.R.S., if such interested parties are manufacturers, carriers, pharmacy benefit management firms, or other entities. (PDAB Policy 04, p. 8).

Underlying Methodology: None.

Data Source(s): All information that is voluntarily provided to the Board by Oct. 3, 2023 will be provided to the Board for consideration during affordability reviews. Board staff plan to summarize which entities submitted information and the nature of the submitted information.

Considerations and Data Limitations: Some voluntarily submitted information may be confidential, proprietary, or trade secret. Such data will not be made public and can only be discussed by the Board in executive session. Though the deadline for voluntarily submitted information is 60 days after selection (October 3, 2023), the Board voted to extend the voluntarily submitted information for patients and caregivers until October 12, 2023.

This component's information is voluntary. While the Board may request clarification of voluntarily submitted information, there will not be an assessment of the accuracy of voluntarily submitted information or the extent to which it applies to Coloradans. To the degree that voluntarily submitted information is different from information presented in other affordability review components, the Board will need to decide how to evaluate such discrepancies.

Enbrel: Voluntarily Submitted Information Evidence

In compliance with Board policy, on August 10, 2023, Board staff emailed a listserv announcement to subscribers to the PDAB listserv and posted on an announcement on the PDAB website that interested parties had the ability to voluntarily submit information related to Enbrel for 60 days following selection of Enbrel for an affordability review.

Information from Manufacturer

Submissions from Amgen Inc.	Page #s
Affordability Review of Enbrel	J3-J11

Information from Other Entities

Submissions from Other Entities	Pages #s
AiArthritis	J12-J17
Arthritis Foundation	J18-J22

Proprietary Information

Confidential Submissions	Page #s
[redacted]	J23-J49

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October 2, 2023

Via email (*dora_ins_pdab@state.co.us*)

Colorado Department of Regulatory Agencies
Division of Insurance
ATTN: Colorado Prescription Drug Affordability Review Board
1560 Broadway, Suite 850
Denver, CO 80202

Enbrel® Submission Pursuant to 3 Colo. Code Regs. § 702-9-3.1(E)(2)(i)

Amgen is a company that is committed to improving the lives of patients by discovering and developing treatments and cures for serious diseases. **Amgen understands that the cost of prescription drugs is a concern for many Coloradans and has programs in place to ensure affordability, while avoiding access hurdles from pharmacy benefit managers (PBM) and others to the extent possible**. Amgen is committed to the responsible pricing of our medicines, and we price products based on the value they deliver, while aiming to employ flexible pricing approaches to ensure patient access. The list price of a medicine is only one potential factor in determining the ultimate cost to the patient, and all parts of the supply chain have a role in ensuring the affordability of medicines like Enbrel® to Colorado consumers.

The introduction of Enbrel® effectively redefined the clinical course of moderate to severe rheumatoid arthritis (RA). Many patients who previously would have endured progressive and painful deformities and immobility now live for years or decades with lower pain, less progression, and greater function. Since introduction, Enbrel® has been approved in four more disease areas, owing to the broad utility of tumor necrosis factor (TNF) inhibition in transforming the clinical course of many inflammatory diseases.

Across moderate to severe RA, psoriatic arthritis (PsA), and plaque psoriasis (PsO), Enbrel® has demonstrated clinically meaningful improvements in outcomes, such as reductions in joint pain and damage, improved physical functioning, and reduction in skin-related symptoms. Enbrel® is effective for long-term control of disease and has demonstrated these benefits in head-to-head as well as standalone studies. For example, Enbrel® monotherapy in moderate to severe RA has shown greater efficacy than methotrexate monotherapy, the previous standard treatment, in achieving American College of Rheumatology (ACR) criteria, low disease activity (LDA) response, and reduced radiographic progression. Looking at head-to-head performance in PsA, combining methotrexate with Enbrel® did not improve Enbrel® efficacy, distinguishing the TNF pathway as uniquely important and Enbrel® as an effective monotherapy.

In PsO, where safety of systemic treatments is particularly important in the risk-benefit calculation, Enbrel® improves multiple measures of skin signs and symptoms, as well as a number of patient reported outcome (PRO) measures. Improvements in disease activity and PROs with Enbrel® were maintained long-term (up to 96 weeks). Finally, looking at Enbrel® compared with other TNF agents and non-TNF systemic therapies, numerous claims analyses using a validated algorithm have consistently shown Enbrel® to have the highest proportion of "effectively" treated patients compared to adalimumab and infliximab. This has been confirmed in three network meta-analyses (NMA) in RA, helping to differentiate Enbrel® from other biologics.

Enbrel® achieves disease transforming efficacy while also offering an established safety profile. There is not a single therapeutic alternative for Enbrel. Although there are number of biologicals that are indicated for the treatment of moderate to severe RA and other autoimmune disorders treated by Enbrel, **Enbrel and its competitor products do not provide the same response in all patients and they are not simply interchangeable**. More than 600 distinct therapy sequences have been observed for the course of care for moderate to severe RA. This underscores the vital importance of having a wide range of therapeutic choices for patients in this population. The therapeutics most similar to Enbrel are TNF inhibitors – adalimumab, certolizumab pegol, golimumab and infliximab. In RA, Enbrel® patients experience fewer adverse reactions, including infections, compared to those on methotrexate (MTX). Enbrel® may also require less MTX supplementation than other biologics, which could reduce the additional side effects. Real-world evidence (RWE) has shown Enbrel® to have fewer adverse reactions than infliximab and adalimumab as well, with Enbrel® patients having higher adherence as a result. Finally, Enbrel® improves PROs and productivity in adults with moderate to severe RA, PsA, and PsO, boosting patient wellbeing and reducing costs for employers.

Looking beyond Enbrel®, in reviewing the information reflected in the "CO PDAB 2023 Eligible Drug Dashboard" and the criteria to be considered by the Board in assessing the affordability of medicines to Colorado consumers, three elements are critical to developing a more complete picture of innovators' impact on consumer affordability.

- **First,** list prices have become increasingly misleading as the gap between list prices and net prices, known as the "gross-to-net bubble," has become significantly wider in recent years.
- **Second,** in fueling this gross-to-net bubble, the complex system around paying for medicines has not led to corresponding improvements in patient affordability. The extent to which each player in this system may influence a particular medicine's affordability to the patient can vary significantly.
- **Finally,** Amgen has a deep interest in supporting access to life-changing therapies for patients. To this end, Amgen provides financial support information and resources, regardless of a patient's current financial situation or type of insurance they have, to help eligible patients access their prescribed Amgen medication.

Net Prices Declined as List Prices Increased

Much of the public debate about the cost of medicines has been largely focused on list prices. Pharmaceutical companies set the Wholesale Acquisition Cost (known as "WAC"), which is often referred to as the "list price." While the WAC for each of Amgen's products is in part anchored to a medicine's value-driven price, which represents the value a medicine is likely to deliver to patients, to payers, and to society, the price is frequently established against a competitive backdrop. The list price is the price Amgen charges to wholesalers and distributors who purchase medicines, but it does not reflect the true price of the medicine after the rebates and discounts are negotiated with the complex web of wholesalers, distributors, hospitals, providers, pharmacies, pharmacy benefit managers (PBMs), health plans, and other entities in the supply chain. Such price concessions are often necessary to ensure a medicine's appropriate formulary placement and otherwise facilitate patient access without burdensome utilization management hurdles, such as requiring a patient to complete a course of therapy with a drug that may not be the best suited for his or her particular condition.

Since 2019, Amgen's aggregated net prices have declined by 4.7 percent. Amgen is also taking steps to address patient affordability, including providing $19.9 billion in discounts, fees, and rebates to supply chain intermediaries in 2021. Since 2019, these payments to intermediaries have grown by 65 percent. Again, the list prices of Amgen's medicines reflect, among other things, the economic value delivered to patients, providers and payers, the unmet medical need, the size of the patient population, the investment and risk undertaken, and the need to fund continued scientific innovation.

Because of the way PBMs structure relationships with pharmacies and patient-enrollees, increases in list prices generally have a limited impact on net prices, while significantly increasing total rebates paid to the PBMs. In light of this environment, Amgen has increased list prices over the years in response to competitor list price increases to remain available as a choice on PBM formularies. If Amgen had not done so, a likely outcome would have been the removal of Enbrel® from formularies in favor of a competitor who provided a higher rebate to the PBM. Since Enbrel® and its competitor products do not provide the same response in all patients, they are not simply therapeutically equivalent. If taken off formulary, many Enbrel® patients would not have access to the medicine that they and their doctor had determined worked best for them.

For Enbrel®, as of January 4, 2023, the list price is $1,762.34 per weekly 50 mg dose, but, as previously discussed, this does not reflect price concessions. In addition to price concessions, Amgen has invested capital studying Enbrel® for additional indications and introduced new, more patient-friendly formulations and administration methods, such as the easy-to-use, self-injection device specifically designed to meet the needs of moderate-to-severe rheumatoid arthritis patients and psoriatic arthritis patients.

Again, a significant factor for increases in the list price of Enbrel® is that the market for innovative products is structured in a way to benefit intermediaries and not in a way to get lower prices to patients. Enbrel® is in a highly competitive marketplace that includes a number of other medications that are competing for formulary position with PBMs to enable patient access,

including the largest pharmaceutical product in the world Humira®. In such highly competitive marketplaces, companies are forced to simultaneously compete both on lowest net price (i.e., the "all in" price to the PBM) and highest total rebate. In a competitive market, Amgen often must pay increasingly higher rebates to remain on the formulary, even as list prices rise and the net price to the PBM often decreases.

Patient Affordability is a Result of Numerous Inputs in a Complex System

Unlike other categories of healthcare, the list price serves as a primary basis of determining patient out-of-pocket costs for prescription medicines. As a result, the negotiated savings of the market-based healthcare system do not reach patients at the pharmacy counter, especially as co-payments and deductibles on medicines have increased and as high-deductible health plans become more prevalent. The problem is not that the market-based negotiations are not effective at generating savings, it is that the savings never make their way to patients in the form of reduced out-of-pocket costs.

Payers, including healthcare insurers, PBMs, integrated healthcare delivery systems (e.g., vertically-integrated organizations built from consolidations of healthcare insurers and PBMs) and group purchasing organizations, increasingly seek ways to reduce their costs. With increasing frequency, payers are adopting benefit plan changes that shift a greater proportion of drug costs to patients. Such measures include more limited benefit plan designs, high deductible plans, higher patient co-pay or coinsurance obligations and more significant limitations on patients' use of manufacturer commercial co-pay assistance programs.

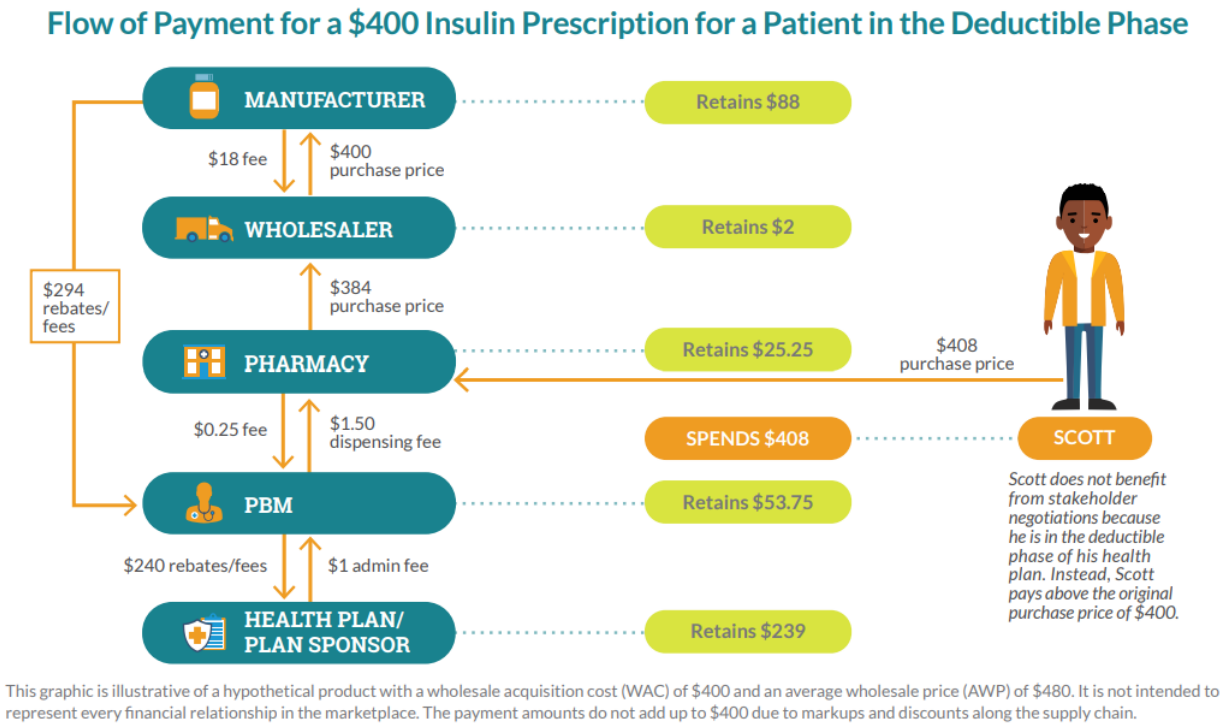
This structure facilitates the current rebate system in the United States, in which companies like Amgen pay billions of dollars in rebates to insurers and PBMs based on the list price, creating a situation in which remaining on-formulary often requires counterintuitive pricing behavior. As discussed later, PBMs can receive lower net prices while consumers see prices increase with little relief at the pharmacy counter, as these savings from the PBMs are rarely, if ever, passed on to any significant extent. While Amgen disapproves of a system where one can lower a medicine's net price and patients pay more and is advocating to change it, this is, unfortunately, the system as it now stands, and Amgen must operate within it to stay competitive and ensure patients have access to Enbrel®.

Despite these structural barriers to reducing patient out-of-pocket costs, due to Amgen's patient assistance programs, commercially insured Coloradans may pay as little as $0 out-of-pocket for each dose with no income eligibility requirements. In fact, roughly two-thirds, or 67 percent, of prescriptions nationally, including those where the Enbrel® Co-Pay Card[1] was used, cost $10 or

[1] Eligibility criteria program maximums apply. For more information about this program, visit www.AmgenSupportPlus.com.

less per month.[2] The remaining one-third of prescriptions cost an average of $341 per month. Overall, only 14 percent of prescriptions cost more than $100 per month.[3]

Exhibit 1. Flow of Payment for Medicines in a Competitive Drug Class in the U.S. Commercial Biopharmaceutical Supply Chain[4]



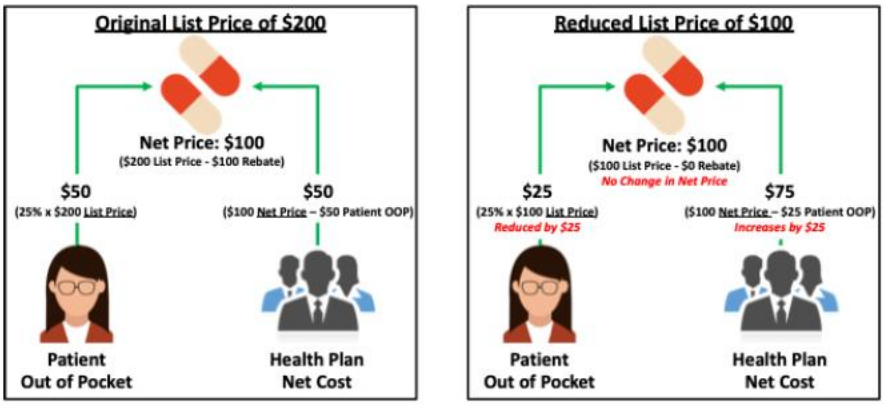
This graphic is illustrative of a hypothetical product with a wholesale acquisition cost (WAC) of $400 and an average wholesale price (AWP) of $480. It is not intended to represent every financial relationship in the marketplace. The payment amounts do not add up to $400 due to markups and discounts along the supply chain.

Furthermore, barriers to reducing list prices are created by the manner in which a PBM determines a drug's "net cost," which serves as an important figure for a PBM's current and potential payer-clients. PBMs calculate plan "net cost" by taking the net price of the drug (e.g., the list price reduced by all applicable rebates) then reducing it further by the patient's out-of-pocket cost. Thus, the more the patient pays out of pocket, the greater the reduction in the net price, meaning a more desirable "net cost" figure for the PBM's client. Because patient out-of-pocket cost is increasingly based on list price, higher list price drugs often result in higher patient out-of-pocket costs and, consequently, even lower "net cost" figures. This means a list price reduction that results in a corresponding reduction in the patient's copayment may be viewed negatively by a PBM as

[2] These data are based on Enbrel® Co-Pay Card paid claims data and paid claims data from national data providers for the period 1/1/2019–12/31/2019. A 1-month supply of ENBREL is typically 4 weekly 50 mg doses.
[3] These data are based on Enbrel® Co-Pay Card paid claims data and paid claims data from national data providers for the period 1/1/2019–12/31/2019, but an individual patient's actual cost may vary depending on the dose, insurance coverage, and eligibility for support programs.
[4] Pharmaceutical Research and Manufacturers of America. *Follow the Dollar: Flow of Payment for a $400 Insulin*. Nov. 29, 2017. Available at: https://phrma.org/en/resource-center/Cost-and-Value/Follow-the-Dollar-Flow-of-Payment-for-a-400-Insulin.

increasing plan "net cost." In other words, where net price to the healthcare system remains constant, a lower list price drug may be viewed by a PBM or payer as increasing plan "net cost" if the patient pays less out of pocket at the pharmacy counter.

Exhibit 2: A Fifty Percent Reduction in List Price Can Result in an Increase in the Net Cost, Contrary to PBMs' and Plan-sponsors' Interests.



One source of client savings increasingly relied on is a rebate guarantee, a fixed dollar amount that is paid to the PBM's clients for each prescription. PBMs receive these rebates from manufacturers. The rebates are based on eligibility criteria, depending on access, utilization management controls and product placement on formulary. The goal for manufacturers with these rebates is to secure a favorable formulary placement, which may lower patients' out-of-pocket costs. Rebate guarantees put pressure on manufacturers to increase list prices, since rebates are based on the difference between list and net prices. However, because patients' out-of-pocket costs are often a percentage of the list price, not net price, all the rebates provided by manufacturers may not actually help patients pay a lower price for their medicines.

PBMs have also introduced new administrative fees to generate revenue, in addition to rebates. New analyses published by Nephron Research found that while the value of rebates paid to PBMs continues to grow, fees and specialty pharmacy now drive a greater share of PBM profits.[5] This is because PBMs have faced criticism for keeping a portion of rebates as revenue for themselves. As a result, they may now pass nearly all rebates on as savings to many clients. As with rebates, however, PBMs base administrative and other fees on drug list price. Due to this dynamic, similar to rebates, manufacturers provide more dollars to PBMs, but these fees are not necessarily passed on to plans, client groups or patients. The Nephron Research found that fees that PBMs charge biopharmaceutical companies doubled in the commercial market over the past five years and were

[5] Eric Percher, Nephron Research. *Trends in Profitability and Compensation of PBMs and PBM Contracting Entities*. Sept. 18, 2023. Available at: https://nephronresearch.com/trends-in-profitability-and-compensation-of-pbms-and-pbm-contracting-entities/.

fueled by increases in traditional administrative fees as well the emergence of new data and PBM contracting entity fees (referred to as "vendor fees").[6]

Some in the healthcare system may assert that these factors are applied to keep health insurance premiums low. Understanding the proportion of rebate dollars, however, applied to maintain more affordable premiums versus other uses has become an increasingly difficult task. This dynamic essentially results in sick patients, who take innovative medicines, subsidizing the healthy patients, which is counter to the purpose of insurance. As you can see in the below illustration, without changing the net price to the healthcare system, the lower list price drug is viewed as increasing plan "net cost" because the patient pays less out of pocket at the pharmacy counter. If the PDAB seeks to address this and similar incentives impacting list prices, more information from PBMs will be necessary, though legislative policy interventions may include mandates on passing through rebates to patients and, among other things, addressing the link between list prices and PBM revenue.

Finally, despite these challenges, maintaining patient access to Enbrel® provides benefits to the broader system, including health, medical, and social services systems.

Amgen's Assistance to Patients Addresses Affordability Challenges

Amgen strives to ensure that every patient who needs our medicine can get access to it. We understand that the dynamics that exist in today's supply chain, such as high coinsurance and deductible levels, can make needed therapies expensive for patients. This is why we sponsor industry leading patient support programs that provide medicine for free to those who cannot afford their medicine. In addition, Amgen offers generous copay assistance to reduce out-of-pocket costs for commercially insured individuals regardless of income.

As previously noted, the out-of-pocket costs commercially insured patients pay for Amgen medicines, like Enbrel®, have changed very little over the decades. Through Amgen's co-pay card programs, out-of-pocket expenditures for our advanced medicines are significantly reduced – **as little as $0 out-of-pocket for each dose with no income eligibility requirements**. In fact, **roughly two-thirds, or 67 percent, of prescriptions, including those where the Enbrel® Co-Pay Card[7] was used, cost $10 or less per month**.[8] The remaining one-third of prescriptions cost an average of $341 per month. Overall, **only 14 percent of prescriptions cost more than $100 per month**.[9]

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[6] *Id*. at pg. 11.

[7] Eligibility criteria program maximums apply. For more information about this program, visit www.AmgenSupportPlus.com.

[8] These data are based on Enbrel® Co-Pay Card paid claims data and paid claims data from national data providers for the period 1/1/2019–12/31/2019. A 1-month supply of ENBREL is typically 4 weekly 50 mg doses.

[9] These data are based on Enbrel® Co-Pay Card paid claims data and paid claims data from national data providers for the period 1/1/2019–12/31/2019, but an individual patient's actual cost may vary depending on the dose, insurance coverage, and eligibility for support programs.

Although Medicare beneficiaries are not eligible for co-pay cards, approximately three-quarters, or 76 percent, of prescriptions cost $50 or less out-of-pocket per month, and the remaining quarter, or 24 percent, of prescriptions cost an average of $395 per month.[10] **For Medicaid beneficiaries, 93 percent of prescriptions cost $10 or less out-of-pocket per month**, and the remaining 7 percent of prescriptions cost an average of $293 per month.[11]

We also recognize that many uninsured and vulnerable patients need extra help affording their medicines. For that reason, Amgen established the Amgen Safety Net Foundation to provide access to Amgen medicines at no cost to qualifying patients in the U.S. (including Puerto Rico) who have a financial need and are uninsured or have an insurance plan that excludes the prescribed Amgen medicine.[12] Since 2008, the Amgen Safety Net Foundation (ASNF) has provided nearly $13 billion worth of Amgen medicines to help hundreds of thousands of qualifying patients gain access to their therapy in the United States.

Amgen Efforts Have Achieved Both Access to and Affordability of Enbrel® for Patients

The leading driver of healthcare costs is the underlying burden of disease, and innovative biopharmaceuticals are part of the solution to addressing this disease burden through lifechanging treatments. What we need is more innovation, not less. Changes are needed to encourage innovation while ensuring patients have access to these innovative medicines.

As our experiences with Enbrel® show, Amgen has implemented reforms to address affordability for our patients. Significantly increasing the rebates paid for a medicine to lower the net price, as was done with Enbrel®, will still leave cost-sharing hurdles for patients, requiring structural reforms to address.

These challenges are not something a single manufacturer or even an industry can make happen. Transforming this system requires the collaboration of all stakeholders, and such broad-based solutions must move beyond a focus on a medicine's list price or else risk unintended consequences for access and innovation. A credible starting point for reform would be to change how PBMs operate in the US marketplace. Specifically, we support policy reforms that would ensure manufacturer rebates are reaching patients at the pharmacy.

The need for innovative medicines has never been greater, driven by a rapidly-aging global population. Industry's ability to innovate and treat patients with medical breakthroughs has never

[10] These data are based on paid claims data from national data providers for the period 1/1/2019–12/31/2019. A particular patient's out-of-pocket costs may vary throughout the year, depending on the Part D benefit phase. Medicare Part D drug coverage is divided into four phases, each with a different cost sharing amount. Such amounts may vary depending on Extra Help program eligibility. For more information, please visit Extra Help with Medicare Prescription Drug Plan Costs from the Social Security Administration (SSA) at https://www.ssa.gov/benefits/medicare/prescriptionhelp.

[11] These data are based on paid claims data from national data providers for the period 1/1/2019–12/31/2019, and any individual patient's out-of-pocket costs may vary throughout the year and be dependent on individual circumstances.

[12] For more information, please visit the Amgen Safety Net Foundation at https://www.amgensafetynetfoundation.com/.

been greater, driven by remarkable advances in science and technology. Stakeholders must partner to drive policy solutions to help improve access and affordability for patients without sacrificing innovation.

Amgen appreciates and shares Colorado's interest in ensuring medications are affordable. Though we have concerns about the delegation to the Review Board of the ability to make a determination on affordability, as well any resulting upper price limit, and we do not release any positions on which we may later rely with respect to the scheme overall, we recognize the importance of dialogue on this topic and remain driven by our mission to serve patients.

AiARTHRITIS
INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS

"We don't represent the patient voice, we *are* the patient voice."

September 30th, 2023

Colorado Division of Insurance
1560 Broadway, Suite 850
Denver, CO 80202

RE: Colorado Prescription Drug Affordability Board (CO PDAB) Voluntary Information Submission - Patient/Caregiver and Patient Organization Engagement for Consideration During Affordability Reviews

Dear Prescription Drug Affordability Board Members,

The International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis), a patient organization led by people affected by AiArthritis diseases, is excited about the opportunity to participate in your drug affordability reviews. As such, we had patient representatives participate in all three public comments sessions relevant to our community (Enbrel, Stelara, and I - as a person on Cosentyx - was a participant) and shared the survey with many in Colorado and nationwide.

We appreciate how much the PDAB worked to include patients and associated testimony. As people who did participate, we would like to take this opportunity to provide feedback for the Board to review prior to your review. We hope you will consider our suggestions as you continue navigating this process.

About AiArthritis. We are the only patient organization in the world focusing solely on this group of diseases, whose leadership consists of those diagnosed with or caring for persons with our diseases, and who specialize in designing innovative, patient-inspired solutions. Our leaders are also public policy, education, and research experts. Given the evolving landscape of health affordability and economic assessments to request direct patient voice participation, in conjunction with the need to fine tune the associated processes, AiArthritis feels positioned to help.

The following comments are divided into two sections: Participation Feedback and General Process Comments.

Participation Feedback

- **Preparation Assistance.** Given new processes breed confusion and questions, there is no surprise Patient Organizations (who were largely responsible for getting the word out to potential patient participants) were unclear about participation (i.e., "Can patient organizations representing the patient voice participate, or only those diagnosed/care partners?" or "How would a patient prepare for participation in an online session?"). The Office Hours, hosted by Callie Shelton and Lila Cummings, were exceptionally helpful addressing these questions. They were equally available and willing to answer additional questions via email outside of scheduled office hours.

Recommendations: Continue the open office hours. Create and publish a FAQ document based on inquiries this initial round.

- **Participation of patients and care partners.** AiArthritis, as an organization who connects patients/care partners to opportunities to have a voice in matters that impact their health,[1] is excited about the evolving landscape to bring more people with lived experience to the conversation. In saying this, our organization is led by those affected by these diseases. We also understand challenges associated with inviting community participation *(i.e., they may feel uncertain they are answering the question correctly, uncertain how their perspectives will be interpreted, not fully clear of the purpose for participation/broader issue, fine line between wanting help developing speaking points and feeling 'scripted')*. While this is not the case with advocates, who are used to speaking publicly, there is a push to bring additional patients 'to the table,' including those who historically are not accustomed to sharing their stories or perspectives.

  Identifying patients/care partners who reside in Colorado, and taking or have taken a specific drug for an indicated disease, has proved difficult. AiArthritis and other organizations struggled to locate people to participate, particularly in online sessions. While part of the challenge likely involves known participatory barriers (as outlined above), there is concern how patient/care partner data will be included if the representation was small. *Note: We are uncertain how many patients/care partners participated via survey or email, but this information will be important to understand when planning for future reviews.*

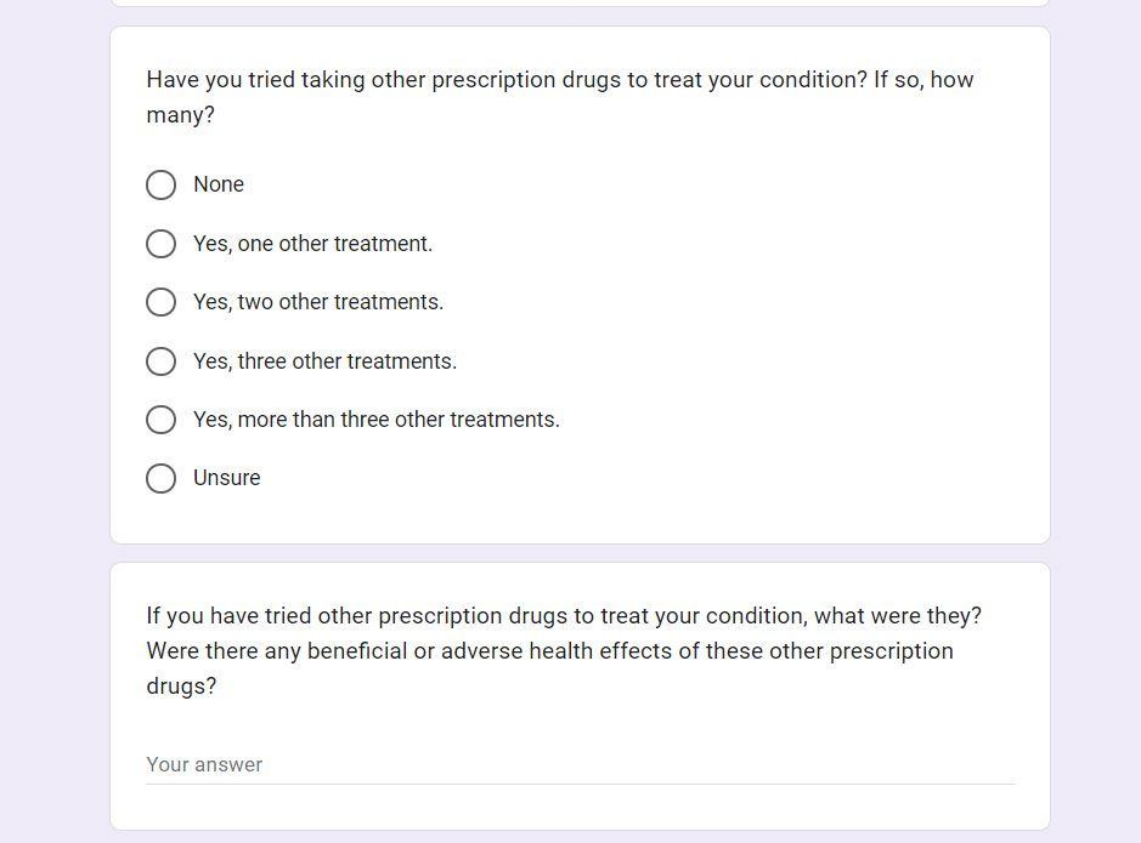
  - **Colorado residents versus those not residing in Colorado**. We appreciate the Board's willingness to permit non-Colorado residents to participate, particularly given that identifying Colorado participants was challenging. However, how their testimony will be weighted is unclear.

  Recommendations: We encourage the Board to release data collected from surveys and email participation, including demographic information, to access participatory challenge and guide efforts to recruit patient/care partner participants. If the percentage of CO participants is low (and additionally, what is considered 'low' should be established), future PDABs should increase outreach efforts to ensure sufficient participation.. Examples may include designing brochures or invitations to share with patients/care partners, Patient Organizations, clinics, or health practitioners.

- **Survey and associated polling design.** AiArthritis is pleased the Board considered many ways to capture patient/care partner perspectives. However, we are concerned about the question design, which may have resulted in inaccurate data collection.

[1] https://www.aiarthritis.org/aiarthritisvoices

- For example, one series of questions asks if a patient ever skipped a dose or stretched out a dose *due to drug affordability issues*. Patients may answer 'yes' to this question if they have skipped a dose or stretched out a dose, dismissing the 'why' at the end of the sentence. *However, as heard several times in the online sessions, this often occurs due to disruption in care caused by utilization management practices (i.e., prior authorization, step therapy) or formulary changes (including non-medical switching).* This is particularly true if the patient participates in the drug manufacturer's assistance plan.
- The following questions were asked in the survey version and discussed in the online sessions:



For those living with AiArthritis diseases and on biologic treatments, answering these questions could cause Board reviewers to feel, "Well, this person has done well on other drugs, so there is no real reason this one drug they are doing well on (or did well on for years) is that valuable." *That is not what Board reviewers should take away from this data.*

What the Board needs to understand is that the current practice of finding the treatment that will work best for us is often a long process. When it works, our disease is not progressing, comorbidities are not forming, and we are living our best lives. The number of times we tried another drug is irrelevant. The number of times it worked or did not work is irrelevant. What matters is finding one that works and, if it fails naturally - not if the

insurance company pulls a patient off of it for company gain - finding another one that works. This is the only way to avoid unnecessary disease activity and potentially permanent damage.

It may take between 1 and 9 years for a patient to get diagnosed, depending on several factors (failure to be referred to a specialist, dismissed due to negative blood work, etc.). After 6-12 months from onset, the window of opportunity to achieve remission closes without proper treatment. Once on a biologic, it can take three months or longer to realize if it will work. If not, the trial-and-error process continues. In the meantime, the patient is dealing with pain, fatigue, brain fog and other symptoms that compromise their ability to lead full, functional lives. But then it happens - the one drug that works. Suddenly, the patient may be able to work full time again, go to school regularly, or do simple things like carry their child or attend a ballgame

Biologics will not work for all people with a shared diagnosis. The goal is to find the right one, and hang on to it until it stops working on its own - as it may be years before another works. So whether a person tried and failed three and two worked or failed five and three worked, the data does not matter. *The only data that matters is if a patient is stable now and, if so, don't disrupt it.*

Recommendations: The Board should consider recruiting patients during the development of questions to identify potential issues prior to publication. Patients can identify issues that a person not living with the condition would not realize. The Board should consider the uniqueness of AiArthritis diseases and the associated challenges patients face to find the right treatments (outside of affordability factors).

- **Lack of other stakeholder participation.** Similar to our concerns regarding lack of patient/care partner participation (particularly from the state of Colorado), we are equally concerned regarding the lack of physician/health professional participation.

  Additionally, while we understand the movement towards involving the voices of only those diagnosed with diseases and who have real world experience using the treatments in review, Patient Organization's bring a perspective that could help ensure data collected is viewed with the proper context. For example, the average patient/care partner may not have supplemental references that show how long on average it takes to be diagnosed or how subgroups within diagnoses matter.

  Recommendations: AiArthritis suggests polling healthcare specialists who prescribe the drugs under review to inquire why they would or would not participate (in the case of our diseases, this could be led by groups like the Coalition of State Rheumatology Organizations/CSRO). We also suggest inviting representatives from Patient Organizations to the listening sessions and then offering them an

opportunity to meet with Board representatives to weigh in on patient/care partner comments, specifically to add context or supplemental information.

- **Disclosures and clarification**. AiArthritis understands there is concern from certain parties that involvement of Patient Organizations who are funded by the manufacturers of the drugs in review could be biased in their testimony, guidance, or feedback. While it is true that organizations, including AiArthritis, obtain financial support from pharmaceutical companies, they are not permitted to (nor do they try to) influence our voice.

  Recommendations. If there is any question regarding who influences Patient Organization perspectives, as clearly outlined in these submitted comments, the people affected by the conditions we serve- who are at the heart of our missions - influence our words.

General Process Comments

- **Regarding upper limit payments.** We understand the Board has the authority to review prescription drug costs and evaluate their impact on Coloradans through affordability reviews of prescription drugs. As a result of these reviews, the Board may then recommend ways to address those costs, which may set an upper payment limit for certain prescription drugs.
  - We question how this process may deter innovation and the development of new pharmacologic therapies. There are many people affected with AiArthritis diseases who have exhausted all current medications and are waiting for new treatments to surface.
  - We also are unclear how this will impact the introduction of biosimilars to the market and how the reference drugs may be impacted.
  - We question how precision medicine will be factored into this process, as we are beginning to identify which types of biologics may or may not work best for different subgroups.
- **How much will patient/care partner perspectives be considered in determining affordability?**
  - In the introduction to the survey, it states, "The PDAB will use the information you provide as part of the affordability review process to determine if a prescription drug is unaffordable for Colorado consumers." At least during the live sessions (as we have not viewed the survey data), patients overwhelmingly agreed Enbrel, Cosentyx, and Stelara were affordable if accessed with help from the manufacturer; but could be inaccessible and even cause harm as a result of insurance practices. How will these perspectives be counted and weighted?
    - Given the difficulty to recruit patients/care partners in Colorado, we are grateful the Board opened comments to a broader population. However, how will the data collected outside of the state be considered during the review?

In closing, I would like to extend gratitude again on behalf of AiArthritis, and all persons living with our diseases, for this opportunity to participate in your review process and to provide comments that we hope can help as you evolve it. Thank you for considering our suggestions and do not hesitate to reach out to me at tiffany@aiarthritis.org with any questions.

Sincerely,

Tiffany Westrich-Robertson

Tiffany Westrich-Robertson
Chief Executive Officer
Person living with non-radiographic axial spondyloarthritis
International Foundation for Autoimmune & Autoinflammatory Arthritis

October 12, 2023

Colorado Prescription Drug Affordability Board
Department of Regulatory Agencies
Division of Insurance
1560 Broadway, Suite 850
Denver, CO 80202

Dear Members of the CO Prescription Drug Affordability Board and Advisory Council:

On behalf of the Arthritis Foundation, representing the nearly 60 million Americans and nearly 950,000 Coloradans living with doctor-diagnosed arthritis, we appreciate the opportunity to comment on the ongoing work of the Colorado Prescription Drug Affordability Board (PDAB) to conduct affordability boards for five drugs, including three indicated for various forms of arthritis.

We thank the PDAB for holding opportunities for patients to provide input on their experiences taking these drugs, including listening sessions, surveys, and small group meetings. We also appreciate that PDAB staff have provided ample opportunities for stakeholders to ask questions and provide feedback, including through weekly office hours and individual calls. We would like to provide feedback on the following:

1. The process of soliciting patient feedback
2. Our data and insights on the patient experience taking biologic medicines
3. Examples of our work with value assessment to inform your methodological considerations for determining affordability

Patient Engagement Process

We were able to recruit two patients to participate in the Enbrel stakeholder meeting, and though we disseminated the survey through our state newsletter channels, it is unknown how many patients completed it. We found it difficult to generate a significant number of patients to participate in either the PDAB staff-led stakeholder meetings or a small group meeting. We do not know definitively why this was the case, but through internal conversations with our CO-based staff and state advocate leaders, we speculate it was likely due to a combination of limited scope (i.e., CO residents with experience on those specific drugs); difficulty relating to or understanding the purpose or process; a lack of time or bandwidth; or limited scope in our outreach. These are questions we would like to explore further in concert with the PDAB to improve response rates for future patient participation opportunities. In the meantime, we encourage PDAB staff to prioritize the following for future efforts:

- Coordinating with the patient advocacy community well in advance so we can collectively determine effective outreach practices.
- Working closely with the health care provider community to recruit patients; providers have the most consistent and wide-reaching touchpoints with patients and are in a unique position to communicate with patients on those specific

drugs. Providers have limited time, so having pamphlets or even a QR code they can give patients could make a substantial difference in recruitment efforts.

For immediate next steps we recommend that you combine the survey data with the focus group insights to form a more holistic picture of the patient experience. In our experience surveys can provide critical insights but often lead to more questions as to why a patient may have answered a question a certain way or about the outcome of their experience. We hope the focus group insights help fill in those gaps, but if there are remaining gaps in understanding what leads to affordability and accessibility challenges for patients, we urge the PDAB to collaborate with patient advocacy organizations to conduct follow-up patient stakeholder opportunities.

AF Data and Insights

We regularly collect survey and focus group data from patients on their experiences with prescription drugs, including impacts of out-of-pocket costs, impacts of step therapy and prior authorization, and general experiences finding the right treatment.

Out-of-pocket Costs

The list price of Rheumatoid Arthritis (RA) biologics ranges from $5,000 to $8,000+ per dose, and patient cost-sharing varies depending on their plan type. These drugs are typically placed on specialty tiers with either co-insurance or higher co-pays. For those paying co-insurance, costs can reach into the thousands for one fill. Many patients with commercial insurance rely on some sort of copay assistance to help afford their cost-sharing, which can cause significant problems when they enroll in Medicare or experience restrictions in the use of copay assistance.

In a survey conducted by the Arthritis Foundation in 2021, patients cited out-of-pocket costs as one of the top three barriers to accessing care. Of all surveyed, 37% have had trouble affording their out-of-pocket costs this past year. Of those, 54% say they have incurred debt or suffered financial hardship because of it. Out-of-reach costs can lead to non-adherence which results in myriad negative impacts to health. In our survey, trouble affording out-of-pocket medical expenses had negative impacts on care: 45% delayed refilling a prescription, 41% say their health care worsened, and 41% switched medications as a result.

Utilization Management

Arthritis Foundation data demonstrates that inappropriate use of utilization management (UM) such as step therapy and prior authorization can lead to delays in care, resulting in negative financial, emotional, and physical consequences. Patients living with arthritis are particularly susceptible to these kinds of insurance practices, and many utilization management protocols tend to apply policies that do not adequately align with clinical guidelines or what the provider deems is in the patient's best interest. Inappropriate use of UM practices can lead to treatment delays and disease worsening. When inappropriately used, step therapy can undermine the clinical judgment of health care

providers and put patients' health at unnecessary risk. Many patients must try multiple drugs before finding one that works for them, so the ability to remain on a drug that works is critical.

A 2023 Arthritis Foundation survey on utilization management issues found the following:

- Nearly 60% of patients reported having difficulty getting their doctor-prescribed medication.
- Over 70% of patients surveyed have experienced step therapy multiple times, with 12% having experienced it 5 or more times.
- Nearly half of patients indicated they experienced joint damage due to the step therapy protocols,
    - 25% developed non-joint related health complications, and
    - 70% of patients reported suffering from stress, depression, and anxiety as a result.
- More than half of patients indicated their arthritis was at least somewhat well-managed prior to step therapy.
- While more than half of patients requested an exception to the step therapy requirement, it was only granted about 1/3rd of the time with the most likely reason cited for the exemption request was due to having already tried and failed the drug the health plan was requiring.

Over 70% of patients had to go through prior authorization process because their health plan required it.

Value Assessment Examples

The Arthritis Foundation has engaged in two RA-specific value assessment-related efforts since 2016:

Institute of Clinical and Economic Review (ICER) RA Review 2017

The Arthritis Foundation participated in an Institute of Clinical and Economic Review (ICER) review of RA drugs in 2016-2017 and as part of this effort we conducted a survey of RA patients' experience with taking biologics. Among the findings: a majority had taken multiple biologics over the course of their RA and many switched early in treatment, including 56% of respondents who had been on or taken Enbrel for less than two years. The most cited reason across all biologics was the drug did not work. Specific to Enbrel, 48% cited it did not work, 19% had bad side effects, and 9% had insurance changes. 35% of respondents indicated challenges accessing their medications and when asked the impact of insufficient treatment, 57% cited they had to take additional medications for things like pain, depression, and anxiety; 42% missed work or school; 40% experienced joint damage or worsening of disease; 22% developed non joint-related symptoms related to their disease; 19% had to leave their job or school; and 11% had to be hospitalized.

As a result of this survey, ICER took into consideration the high level of variability in treatment efficacy and the consequences of disruptions of treatment and indicated in the final report that step therapy is not appropriate in all cases.

Innovation and Value Initiative (IVI) RA Model and White Paper 2021
In its update to its RA model in 2019, IVI worked with the Arthritis Foundation to identify RA patients with whom to conduct a focus group in order to better incorporate patient experience data into their modeling. The focus group yielded important and invaluable insights and as a result we co-authored a white paper highlighting the key themes and best practices for this patient-centered approach. From the paper:

- Traditional clinical trials and research do not always capture the full complexity of living with RA, including comorbid conditions, fatigue, mental health, and the impact of hormonal changes.
- Access to effective treatment may be driven by insurance coverage or haphazard testing of treatments rather than by clinical guidelines.
- Costs related to RA include far more than direct medication costs and need to be captured.
- While RA is a progressive disease, people living with it are seeking independence and normalcy versus just symptom management.

The focus groups revealed a diverse range of experiences. From the paper:

- While severity of RA and response to treatment vary among individuals, commonly experienced symptoms include significant joint pain and weakness, stiffness, and fatigue.
- Most participants described fatigue as a largely unaddressed impact of RA, and a factor further exacerbated by many of the RA treatments as a side effect.
- Multiple individuals pointed to hormonal changes (puberty, pregnancy, menopause, etc.) as "triggers" to the onset of symptoms or treatment failures.
- Nearly every participant described significant psychological impacts of the disease, including depression, anxiety, and social isolation.
- Co-occurring conditions are common, and when present, complicate outcomes. Multiple participants reported co-occurring health conditions, including type 1 diabetes, fibromyalgia, spondyloarthropathy, lupus, anxiety, and depression.

The paper noted that even with only 14 participants, there was wide diversity in time to diagnosis (between 6 months and 5 years) and time to finding an effective treatment (between 1 year and never); treatment experiences from the paper:

- Participants reported that treatment choices appeared to be based on trial and error or insurance coverage, rather than clinical guidelines or assessment by their clinician.
- Many had difficulty finding effective treatment over time. Most were concerned about the durability of treatment and the lack of clarity about what might trigger sudden change or failure of a treatment. Several reported never finding a fully effective treatment option despite extensive regimen testing.

- Multiple individuals were concerned about running out of treatment options; there was a sense that each treatment had a "shelf life" or limited time horizon.
- Participants reflected a common experience or understanding that insurance coverage, socioeconomic status, and race impact the quality of and access to treatment.
- Participants described the impact of treatment on choices to have children, how having children impacts treatment options, and the ability to have children.

Also from the paper:
Other areas of less frequently measured costs that have high impact on patients' experiences and outcomes include:

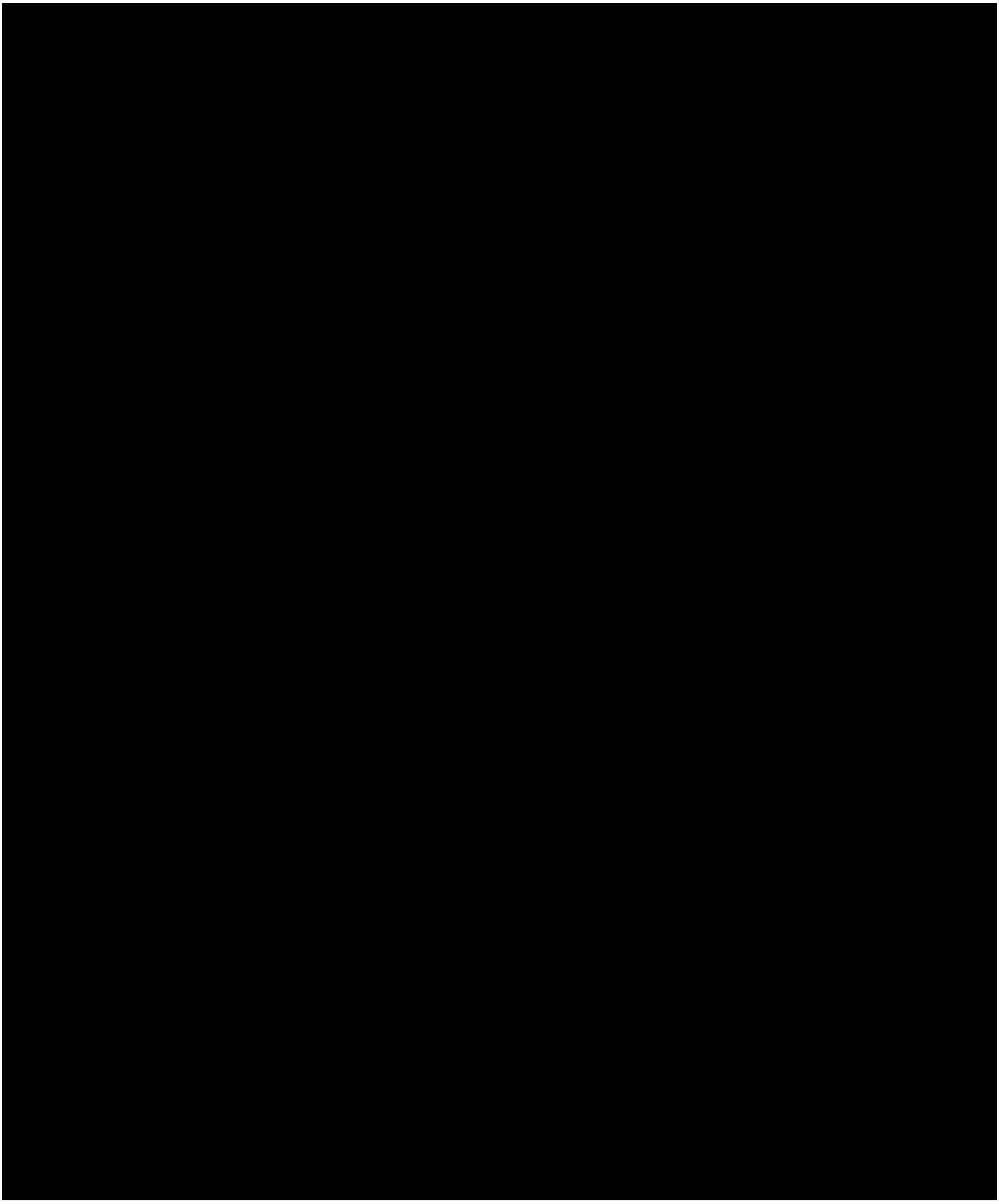
- Time spent in seeking, receiving, and recovering from treatment, with some calculating this cost to be upwards of a month a year.
- Diminished ability to work and lost wages due to early retirement or career impact, including choosing lower paying jobs to ensure health insurance access.
- Heavy burden of RA on caregivers (spouses, parents, and siblings), such as anxiety, missed work time, childcare, and job choice based on health insurance.
- Ancillary costs of seeking and receiving treatment, including transportation costs, non-medical supportive expenses (e.g., assistive devices), and non-covered benefits.

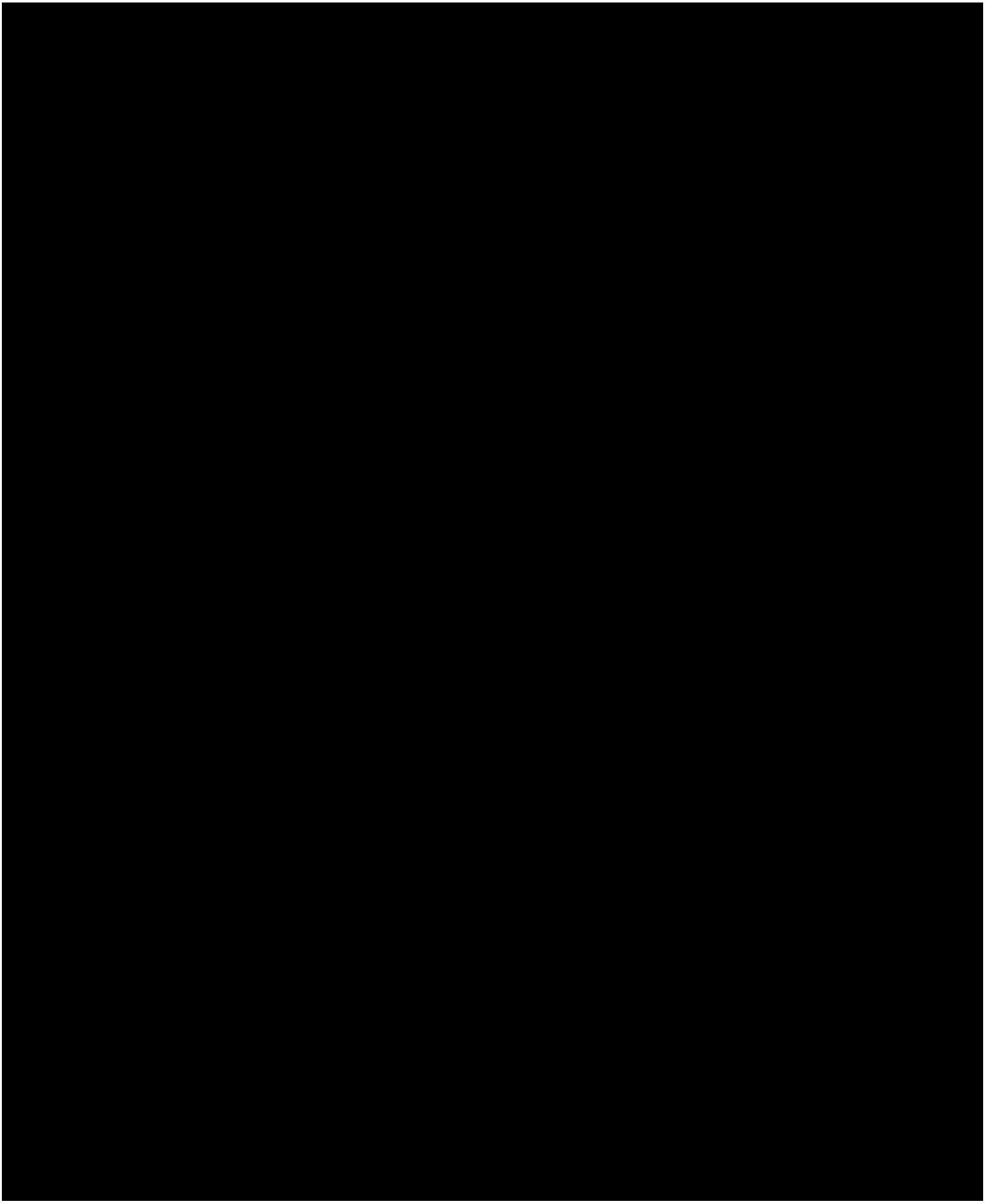
We hope these insights and examples will be valuable to the PDAB as it embarks upon the next phase of affordability reviews. We welcome the opportunity to provide further insights and to serve as a resource to the PDAB in the coming weeks and months. Thank you for your consideration, and we look forward to engaging with you in the future.

Sincerely,

Anna Hyde

Anna Hyde
Vice President of Advocacy and Access
Arthritis Foundation





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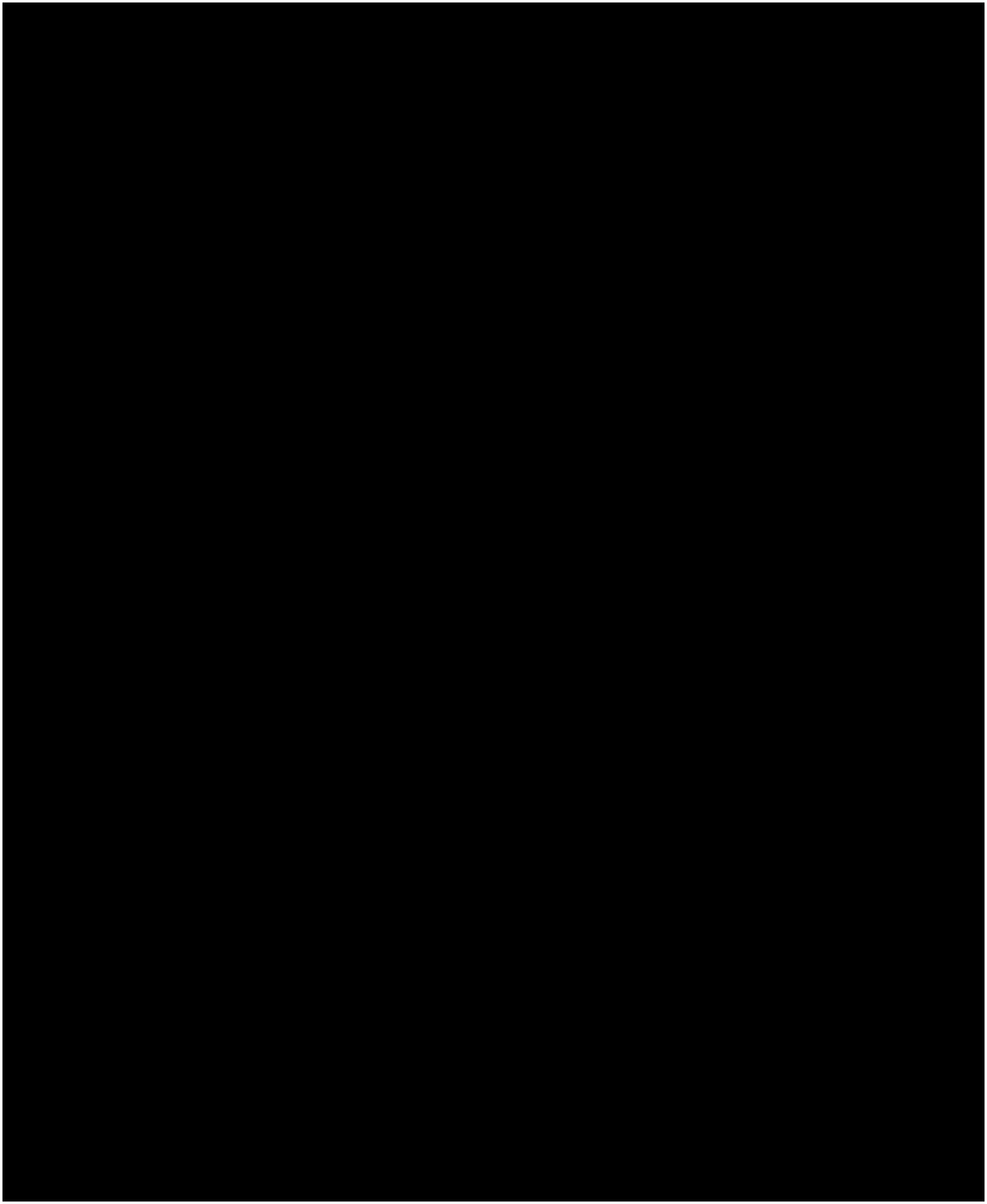

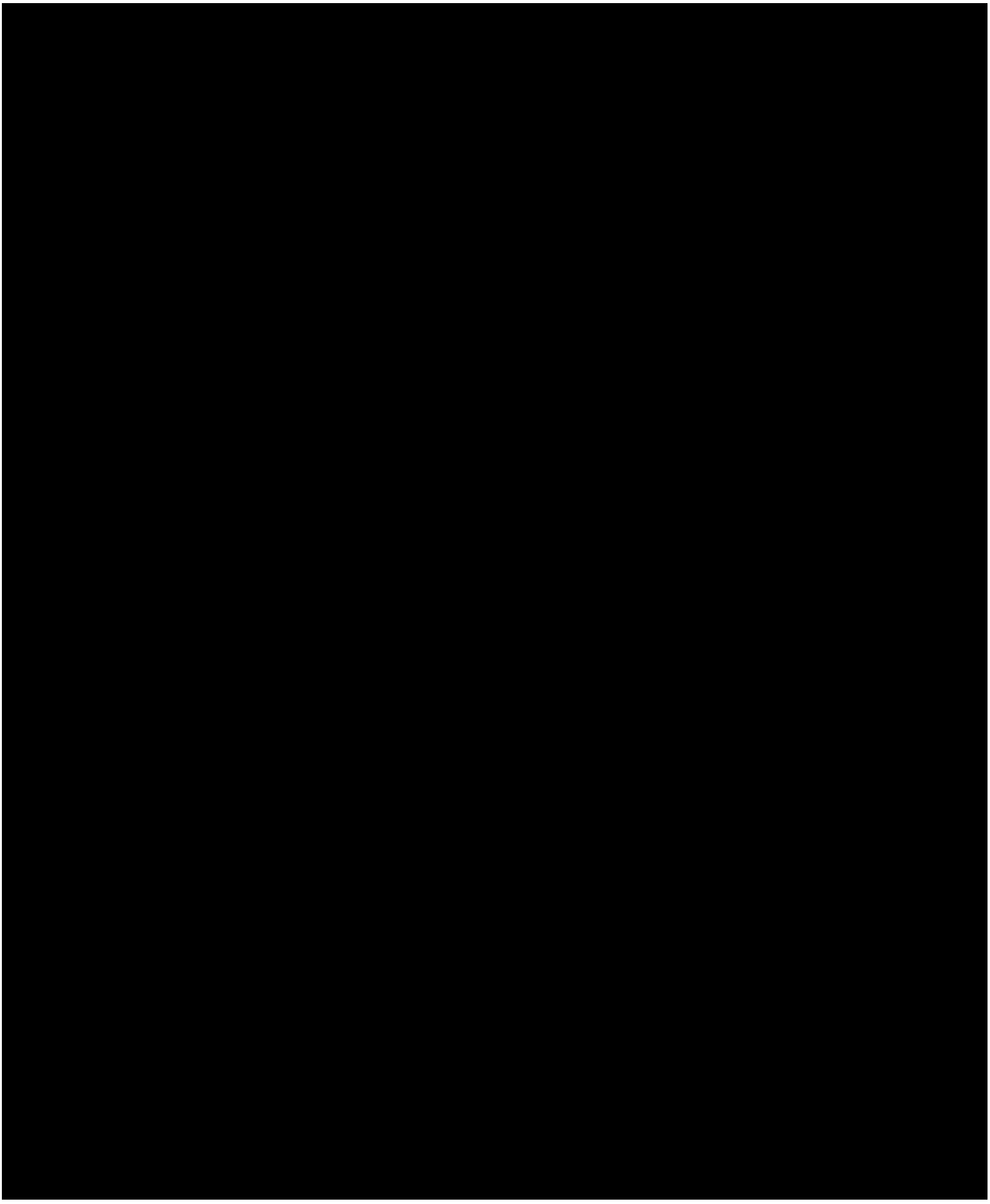

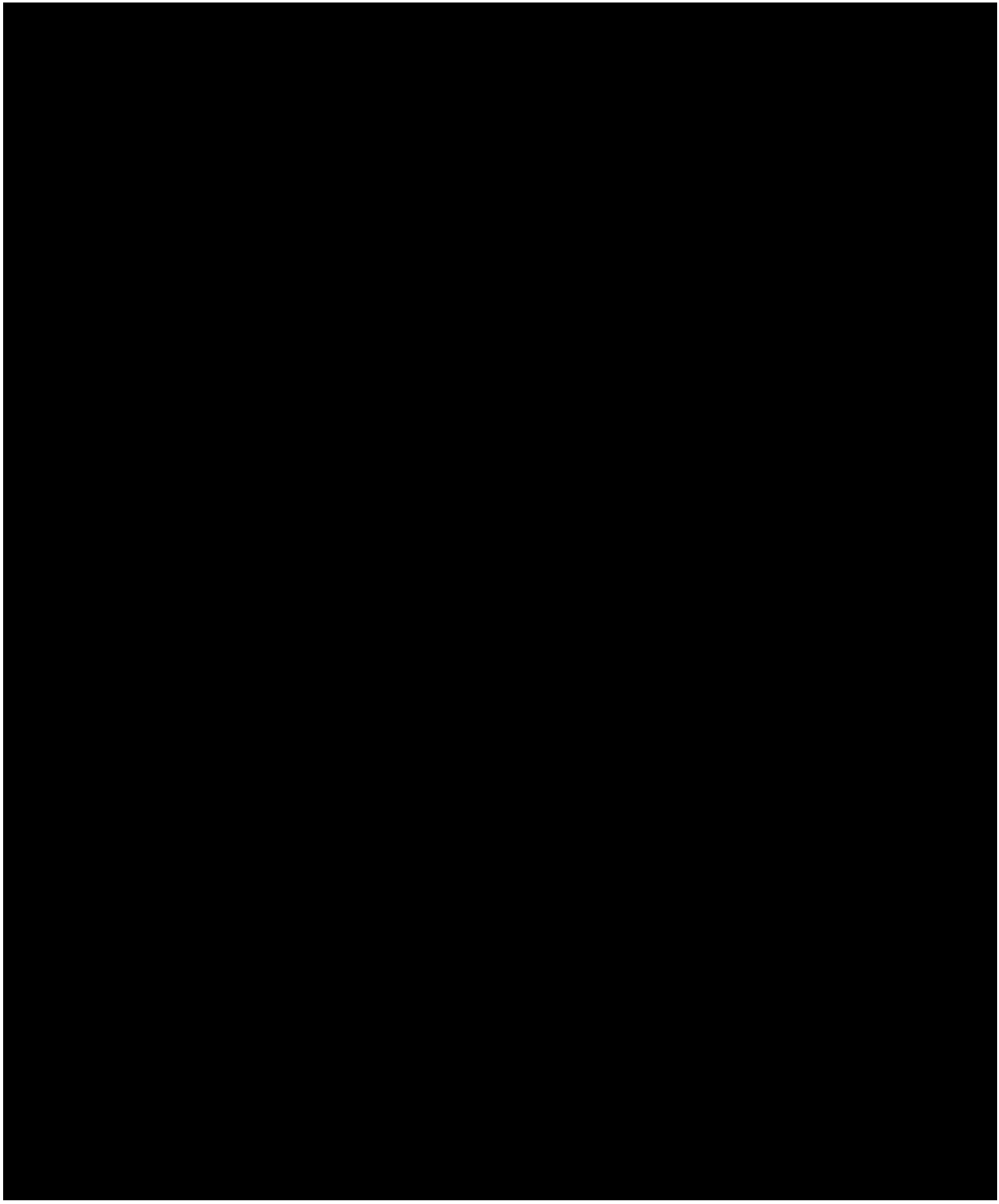

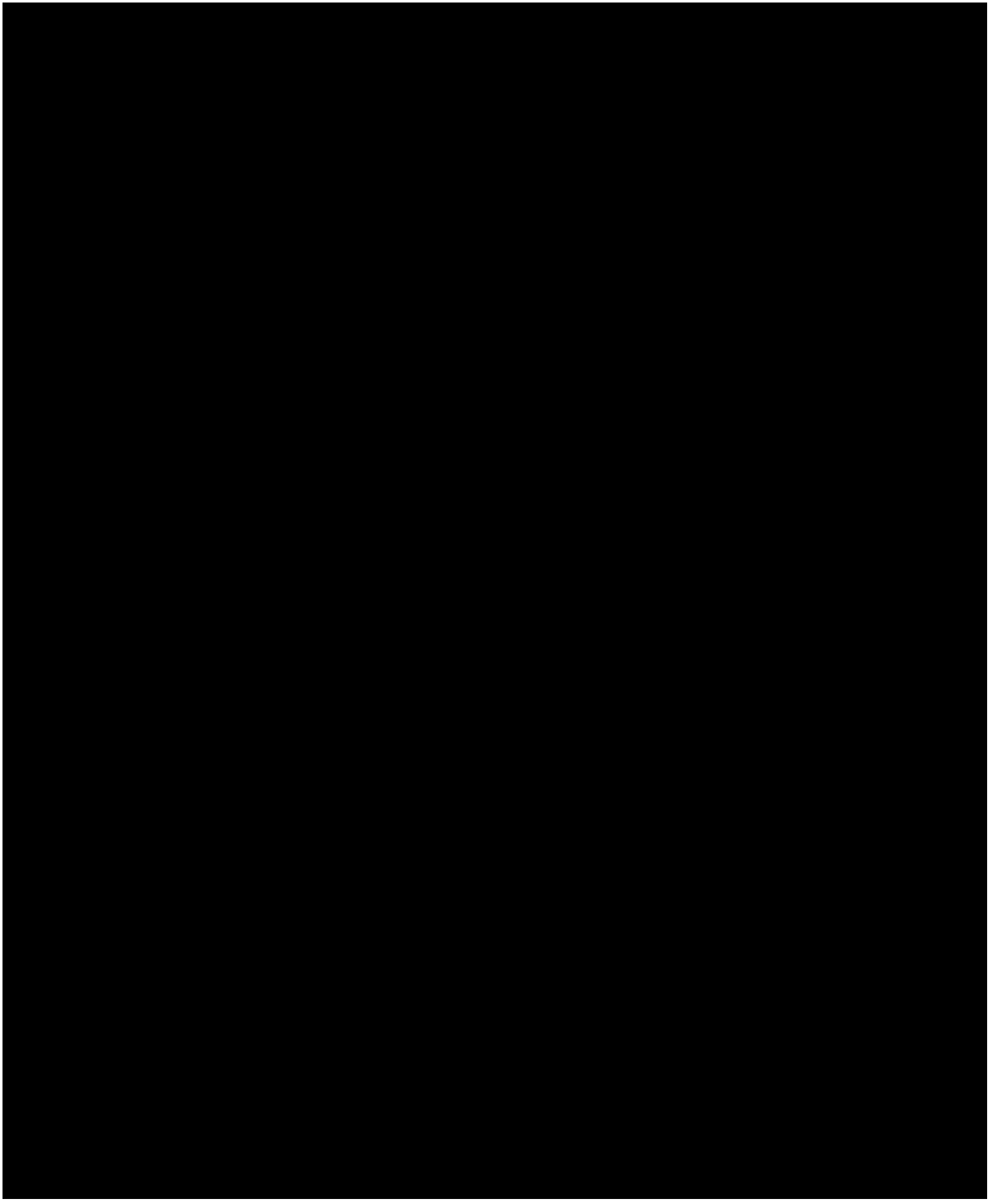

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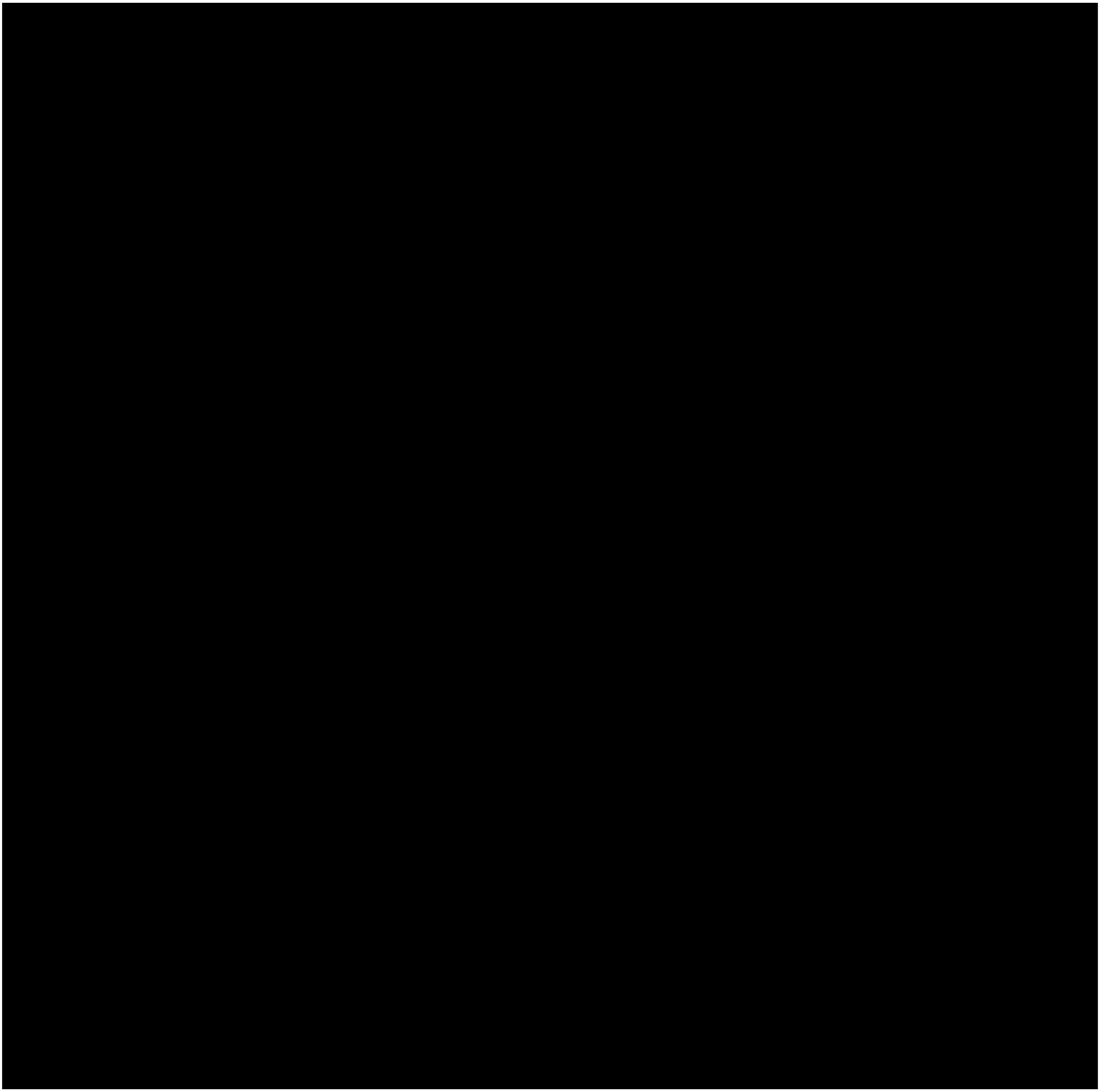

Appendix K

Enbrel: Rebates, Discounts, and Price Concessions

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider any other factors as determined by rules promulgated by the board pursuant to section 10-16-1403(5). (C.R.S. § 10-16-1406(4)(j)).

Rule: To the extent practicable, the Board may consider estimated manufacturer net-sales or net-cost amounts (including rebates, discounts, and price concessions) for the prescription drug and therapeutic alternatives.

The Board may consider manufacturer financial assistance the manufacturer provides to pharmacies, providers, consumers, and other entities. (3 CCR 702-9, Part 3.1.E.2.j.i).

Policy: To the extent the Board has funding, information may be prepared from an external database regarding estimated manufacturer net sales and net costs (including rebates, discounts, and price concessions) for the prescription drug under review and, to the extent practicable, for therapeutic alternatives under review. Staff may also prepare information regarding manufacturer coupons to pharmacies and/or consumers. (PDAB Policy 04, p. 8).

Underlying Methodology: Board staff compiled data for the selected prescription drug for the Board's consideration in the following manner:

- Board staff contracted with SSR Health[1] to receive their proprietary U.S. prescription brand drug pricing and analytics database, which provides total net revenue and volume estimates for the majority of active brand name prescription drugs in the United States. SSR Health uses net revenues from publicly-available SEC Form 10-K financial reports from drug makers or other public sources to develop a net-sales and gross-to-net estimates quarterly for all drugs.[2] The gross-to-net estimates provide a quarterly estimated gross-to-net percent that is inclusive of all concessions and discounts that manufacturers deduct from gross sales. This is inclusive of all rebates, 340B discounts, and point of sale copayment support. SSR Health provides these estimates on a total, statutory Medicaid, and total less statutory Medicaid basis.
- Board staff gathered these estimates for Enbrel, which are presented below. The estimates are on a rolling four quarter basis.
- Board staff used publicly available information on patient assistance programs to identify manufacturer coupons and discount programs available to patients.

Data Source(s): Board staff compiled information on rebates, discounts, and price concessions for Enbrel from the following sources:

- SSR Health for estimated gross-to-net sales,
- Results of public input sessions and surveys for patients and caregivers, and
- Relevant voluntarily submitted information.

Considerations and Data Limitations:

- SSR Health data is proprietary and confidential. Estimates are national and do not necessarily reflect rebates, discounts, and price concessions in Colorado.

[1] SSR Health: https://www.ssrhealth.com/

[2] "Best Practices Using SSR Health Net Drug Pricing Data", Health Affairs Forefront, March 10, 2022. DOI: 10.1377/forefront.20220308.712815: https://www.healthaffairs.org/content/forefront/best-practices-using-ssr-health-net-drug-pricing-data

- Publicly available patient assistance program information is limited and does not reflect the number of patients who qualify and regularly receive assistance and the process for patients to receive assistance.

Enbrel: Rebates, Discounts, and Price Concessions Evidence

Background

This appendix includes information on gross-to-net estimates, net-sales estimates, and manufacturer financial assistance programs information. For the purposes of this appendix, these terms mean:

- Gross-to-net Sales Estimate means the proprietary estimate as a percentage where SSR Health estimates all price concessions the manufacturer gives, including rebates, 340B discounts, and coupons provided by manufactures compared to gross sales to get a percentage estimate of all discounts. All gross-to-net sales estimates are provided on a four quarter moving average to provide full annual estimates and smooth quarter to quarter variation.
- Net-sales Estimate means the proprietary estimate of net sales based on sales information from 10-K financial reports and other publically available sources including earnings calls, press releases, and investor presentations.[3]
- Manufacturer financial assistance program Estimate. This is different from the broader “patient assistance program” or “assistance program” terminology used in the Summary Report and in other appendices. While those later terms cover any patient assistance programs, information in this summary just pertains to financial assistance programs offered by the prescription drug manufacturer.

Information for gross-to-net estimates and net-sales estimates are provided first, followed by manufacturer financial assistance program estimates.

[3] "Best Practices Using SSR Health Net Drug Pricing Data", Health Affairs Forefront, March 10, 2022. DOI: 10.1377/forefront.20220308.712815: https://www.healthaffairs.org/content/forefront/best-practices-using-ssr-health-net-drug-pricing-data

SSR Health Estimates

Figure K-1
Enbrel Net-Sales and Gross-to-Net Estimates

Figure K-1 shows the net- sales and gross-to-net estimates for Enbrel in 2008. The total gross-to-net estimate in April 2008 was [redacted], which increased to [redacted] in the third quarter of 2023.

Table K-1
Estimated Gross-to-Net for the Third Quarter of 2023

Gross-to-Net Measure	Enbrel	Cimzia	Humira	Remicade	Simponi
Total	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Statutory Medicaid	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Total less Statutory Medicaid	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table K-1 shows the gross-to-net estimates broken out by total (all), statutory Medicaid (reflects most Medicaid rebates, but not all such as best price), and total less statutory Medicaid (commercial and Medicare Part D plans). The statutory Medicaid estimate is likely derived from the base 23.1% rebate required under statute[4] and not the Medicaid best price requirement that generates greater discounts. This means that the Medicaid discounts for Enbrel should actually exceed those provided to non-Medicaid entities. Strength and dosage forms of prescription drugs may be associated with different rebate amounts. What is represented in this table is for all strengths and dosage forms.

[4] 42 CFR § 447.509 Medicaid drug rebates (MDR)

Figure K-2
Estimated Total Gross-to-Net Sales

Figure K-2 shows the total gross-to-net sales estimate for Enbrel and identified therapeutic alternatives. The gross-to-net sales estimate for Enbrel has increased to [redacted] in the third quarter of 2023, [redacted]

Table K-2
Gross-to-Net Estimate (Enbrel and Therapeutic Alternatives)

Quarter Date	Enbrel	Cimzia	Humira	Remicade	Simponi
April 2008	[redacted]		[redacted]	[redacted]	
July 2008	[redacted]		[redacted]	[redacted]	
October 2008	[redacted]		[redacted]	[redacted]	
January 2009	[redacted]	[redacted]	[redacted]	[redacted]	

Quarter Date	Enbrel	Cimzia	Humira	Remicade	Simponi
April 2009	[redacted]	[redacted]	[redacted]	[redacted]	
July 2009	[redacted]	[redacted]	[redacted]	[redacted]	
October 2009	[redacted]	[redacted]	[redacted]	[redacted]	
January 2010	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2010	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2010	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2010	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2011	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2011	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2011	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2011	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2012	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2012	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2012	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2012	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2013	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2013	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Quarter Date	Enbrel	Cimzia	Humira	Remicade	Simponi
July 2013	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2013	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2014	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2014	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2014	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2014	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2015	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2015	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2015	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2015	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2016	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2016	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2016	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2016	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2017	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2017	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2017	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2017	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Quarter Date	Enbrel	Cimzia	Humira	Remicade	Simponi
January 2018	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2018	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2018	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2018	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2020	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2020	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2020	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2020	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2021	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2021	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2021	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2021	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2022	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2022	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Quarter Date	Enbrel	Cimzia	Humira	Remicade	Simponi
July 2022	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2022	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2023	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2023	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2023	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table K-2 lists the quarterly total gross-to-net estimates from April 2008 to July 2023 for Enbrel and identified therapeutic alternatives. If a cell is left empty, there were no estimates for that drug during that quarter.

Figure K-3
Enbrel Net-Sales Estimate as a percent of Amgen Total Net-Sales Estimate

Figure K-3 shows Enbrel net sales estimates (in purple) as a percent of Amgen total net sales from the first quarter of 2018 through the third quarter of 2023. In the third quarter of 2023, Enbrel accounted for an estimated [redacted] of Amgen's total net sales. Additional information of manufacturer-reported information of Enbrel's share of Amgen Inc.'s total sales is contained in Appendix O.[5]

Table K-3
Quarterly Net-Sales Estimate

Year	Quarter	Enbrel	Cimzia	Humira	Remicade	Simponi
2008	Q1	[redacted]		[redacted]	[redacted]	

[5] Appendix O contains information of Enbrel's net sales for national and international sales, whereas this appendix contains estimates for national sales only.

Year	Quarter	Enbrel	Cimzia	Humira	Remicade	Simponi
2008	Q2	[redacted]		[redacted]	[redacted]	
2008	Q3	[redacted]	[redacted]	[redacted]	[redacted]	
2008	Q4	[redacted]	[redacted]	[redacted]	[redacted]	
2009	Q1	[redacted]	[redacted]	[redacted]	[redacted]	
2009	Q2	[redacted]	[redacted]	[redacted]	[redacted]	
2009	Q3	[redacted]	[redacted]	[redacted]	[redacted]	
2009	Q4	[redacted]	[redacted]	[redacted]	[redacted]	
2010	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2010	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2010	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2010	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2011	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2011	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2011	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2011	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2012	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2012	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Year	Quarter	Enbrel	Cimzia	Humira	Remicade	Simponi
2012	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2012	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2013	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2013	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2013	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2013	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2014	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2014	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2014	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2014	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2015	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2015	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2015	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2015	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2016	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2016	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2016	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Year	Quarter	Enbrel	Cimzia	Humira	Remicade	Simponi
2016	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2017	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2017	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2017	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2017	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2018	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2018	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2018	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2018	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2019	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2019	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2019	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2019	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2020	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2020	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2020	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2020	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Year	Quarter	Enbrel	Cimzia	Humira	Remicade	Simponi
2021	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2021	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2021	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2021	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2022	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2022	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2022	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2022	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2023	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2023	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2023	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table K-3 lists the quarterly estimates in net sales for Enbrel and identified therapeutic alternatives from January 2008 to July 2023.[6] These amounts are the same reflected in Figure K-1 above.

Pursuant to section 10-16-1405(1)(a)(VII), C.R.S., each carrier and PBM must report the fifteen prescription drugs for which the carrier received the largest rebates. In 2021, 14 of 25 carriers indicated that Enbrel was in the top 15 drugs for which the carrier received the largest rebate.

Figure K-4
Carrier's Rank of Enbrel Rebates

[6] Any cells without values do not have estimates in SSR Health

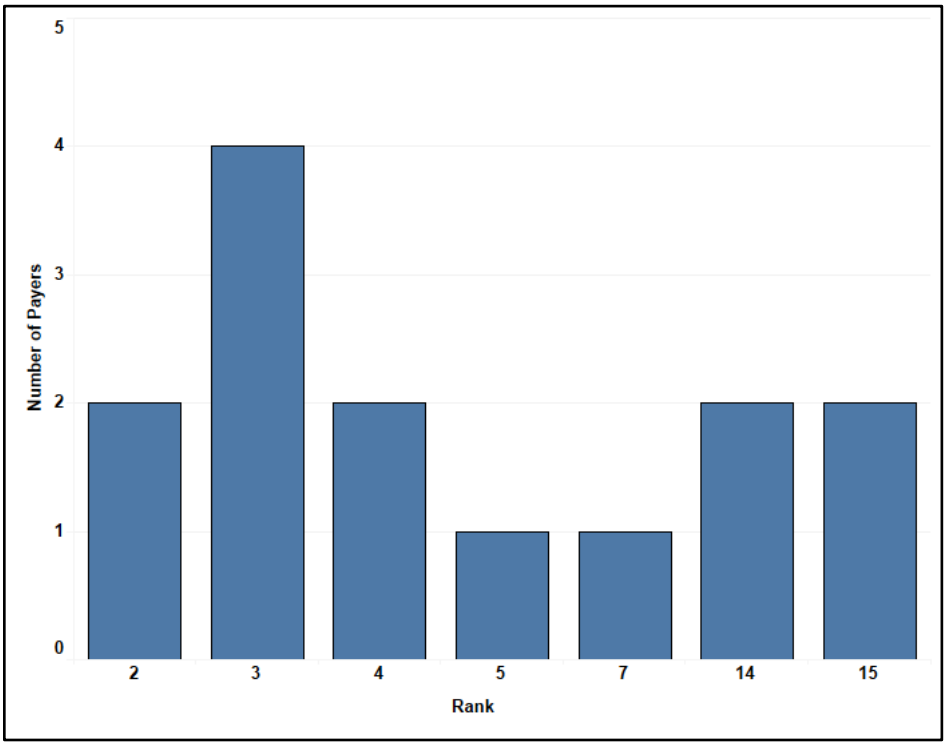

Figure K-4 shows the number of carriers who ranked Enbrel in the top 15 rebated drugs. The x-axis shows the rank and the y-axis shows the number of carriers who ranked Enbrel in that position, for example, two carriers ranked Enbrel as the second highest rebated drug and four carriers ranked it as the third highest drug.

Manufacturer Financial Assistance Programs

As part of voluntarily submitted information from Amgen Inc., the following statement regarding patient assistance was submitted: "Despite these structural barriers to reducing patient out-of-pocket costs, due to Amgen's patient assistance programs, commercially insured Coloradans may pay as little as $0 out-of-pocket for each dose with no income eligibility requirements. In fact, roughly two-thirds, or 67 percent, of prescriptions nationally, including those where the Enbrel® Co-Pay Card was used, cost $10 or less per month. The remaining one-third of prescriptions cost an average of $341 per month. Overall, only 14 percent of prescriptions cost more than $100 per month."[7] Additionally, the statement said, "As previously noted, the out-of-pocket costs commercially insured patients pay for Amgen medicines, like Enbrel®, have changed very little over the decades. Through Amgen's co-pay card programs, out-of-pocket expenditures for our advanced medicines are significantly reduced – as little as $0 out-of-pocket for each dose with no income eligibility requirements. In fact, roughly two-thirds, or 67 percent, of prescriptions, including those where the Enbrel® Co-Pay Card was used, cost $10 or less per month. The remaining one-third of prescriptions cost an average of $341 per month. Overall, only 14 percent of prescriptions cost more than $100 per month." Amgen Inc. stated the following about uninsured and vulnerable patients: "We also recognize that many uninsured and vulnerable patients need extra help affording their medicines. For that reason, Amgen established the Amgen Safety Net Foundation to provide access to Amgen medicines at no cost to qualifying patients in the U.S. (including Puerto Rico) who have a financial need and are uninsured or have an insurance plan that excludes the prescribed Amgen medicine. Since 2008, the Amgen Safety Net Foundation (ASNF) has provided nearly $13 billion worth of Amgen medicines to help hundreds of thousands of qualifying patients gain access to their therapy in the United States."[8]

[7] https://drive.google.com/file/d/1wjNIBWWQoOQe0ufBRWkl0GmqOe381WN2/view?usp=drive_link
[8] https://drive.google.com/file/d/1wjNIBWWQoOQe0ufBRWkl0GmqOe381WN2/view?usp=drive_link

Board staff gathered further information on the Enbrel Co-Pay Program via the drug's public website.[9] According to the website, the co-pay program is open to patients with commercial insurance that covers an Amgen SupportPlus product, regardless of financial need. While there is no income requirement for participation, the maximum program benefit and patient total program benefit are determined by the patient's plan coverage. A patient must meet eligibility criteria for the Amgen Safety Net Foundation assistance including that they: lived in the U.S. or its territories for six months or longer, satisfy income eligibility requirements, and are uninsured or on an insurance plan that excludes the Amgen medicine or its generic/biosimilar. While certain Medicare Part D patients may be eligible, they have to demonstrate inability to afford the medicine and have satisfied all payer guidelines and Prior Authorization (PA) requirements. Patients using Enbrel are able to check if they qualify for assistance through ASNF from their website.[10]

Board staff heard from patients, caregivers, and individuals with scientific and medical training that there are patient assistance programs in addition to the Enbrel Co-Pay Program. See Appendices H, I, and J for more information on both manufacturer financial assistance programs and other patient assistance programs.

[9] https://www.amgensupportplus.com/copay-card-program-terms-and-conditions

[10] https://www.amgensafetynetfoundation.com/eligibility.html

Appendix L

Enbrel: Health Equity Factors

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider any other factors as determined by rules promulgated by the board pursuant to section 10-16-1403(5). (C.R.S. § 10-16-1406(4)(j)).

Rule: The Board will consider whether the pricing of the prescription drug results in or has contributed to health inequities in priority populations. (3 CCR 702-9, Part 3.1.E.2.j.ii).

Policy: Staff will prepare information regarding changes in utilization as compared to changes in WAC and changes in expenditures as identified in APCD data, attempting to understand changes in utilization by:

- People experiencing homelessness;
- People involved in the criminal justice system;
- Black people, indigenous people, and people of color;[1]
- American Indians and Alaska natives;
- Veterans;
- People who are lesbian, gay, bisexual, transgender, queer, or questioning;
- People of disproportionately affected sexual orientations, gender identities, or sex assigned at birth;
- People who have AIDs or HIV;
- Older adults;
- Children and families;
- People with disabilities, including people who are deaf and hard of hearing, people who are blind and deafblind, people with brain injuries, people with intellectual and developmental disabilities, people with other co-occurring disabilities;
- Other populations as deemed appropriate by the Prescription Drug Affordability Board. (PDAB Policy 04, pp. 8-9).

Underlying Methodology: Board staff have compiled data on health equity factors for the Board's consideration in the following manner:

1. Staff conducted an analysis into the Social Vulnerability Index (SVI) score of counties where individuals who used Enbrel live.
2. Staff conducted a literature review to understand if the indications for the selected prescription drug disproportionately impact priority populations.

Data Sources: Board staff compiled information on health equity factors for the selected prescription drug from the following sources:

- The Social Vulnerability Index (SVI), created by the U.S. Center for Disease Control (CDC) Geospatial Research, Analysis and Services Program, which uses 16 U.S. census variables to determine the social vulnerability of counties. This program defines social vulnerability as factors, including poverty, lack of access to transportation, and crowded housing that may weaken a community's ability to prevent suffering and financial loss in a disaster.[2]
- APCD data to identify the county of residence of patients who took Enbrel in 2022.
- Peer-reviewed journals pertaining to the indications treated by the selected prescription drugs and potential impacts on priority populations.

[1] When referring to racial and ethnic groups, Board staff applies the language used in the study being referenced.

[2] https://www.atsdr.cdc.gov/placeandhealth/svi/index.html

Considerations and Data Limitations: The SVI is calculated on a county basis, and does not necessarily reflect the circumstances of the utilizers of the prescription drug. County of residence at the time each prescription was used, if individuals moved during 2022, so their utilization factors into the percent of total patients from each county where they resided throughout the year.

Enbrel: Health Equity Factors Evidence

Social Vulnerability Index (SVI) Information

Board staff calculated SVI scores for patients who utilized Enbrel in the following manner:

1. Staff used 2020 Social Vulnerability Index (SVI) data by county in Colorado and calculated the straight statewide average overall SVI score of 49.95%.
2. Counties with an SVI score higher than 49.95% were classified as higher than the statewide average, meaning that individuals residing in these counties may be more vulnerable to adverse outcomes due to social conditions in their county.
3. Counties with an SVI score lower than 49.95% were classified as lower than the statewide average, meaning that individuals residing in these counties may be less vulnerable to adverse outcomes due to social conditions in their county.
4. Staff aggregated APCD data based on the county of residence of utilizers of Enbrel and calculated a percent of total patients who resided in each county in Colorado in 2022.
5. Staff combined these two data sources to determine the percent of patients who used Enbrel in 2022 who resided in Colorado counties with SVI scores above the statewide average.

Following the methodology outlined above, staff calculated that in 2022, 48.65% of patients who filled a prescription for Enbrel lived in a county with an SVI score above the statewide average of 49.95%, meaning that 48.65% of Enbrel patients lived in a county with higher social vulnerability. This could indicate that patients who utilize Enbrel are located in counties that are more vulnerable to adverse outcomes due to social conditions in their county than patients in the average Colorado county.

Figure L-1

Map of Colorado by 2022 SVI Score for Utilizers of Enbrel

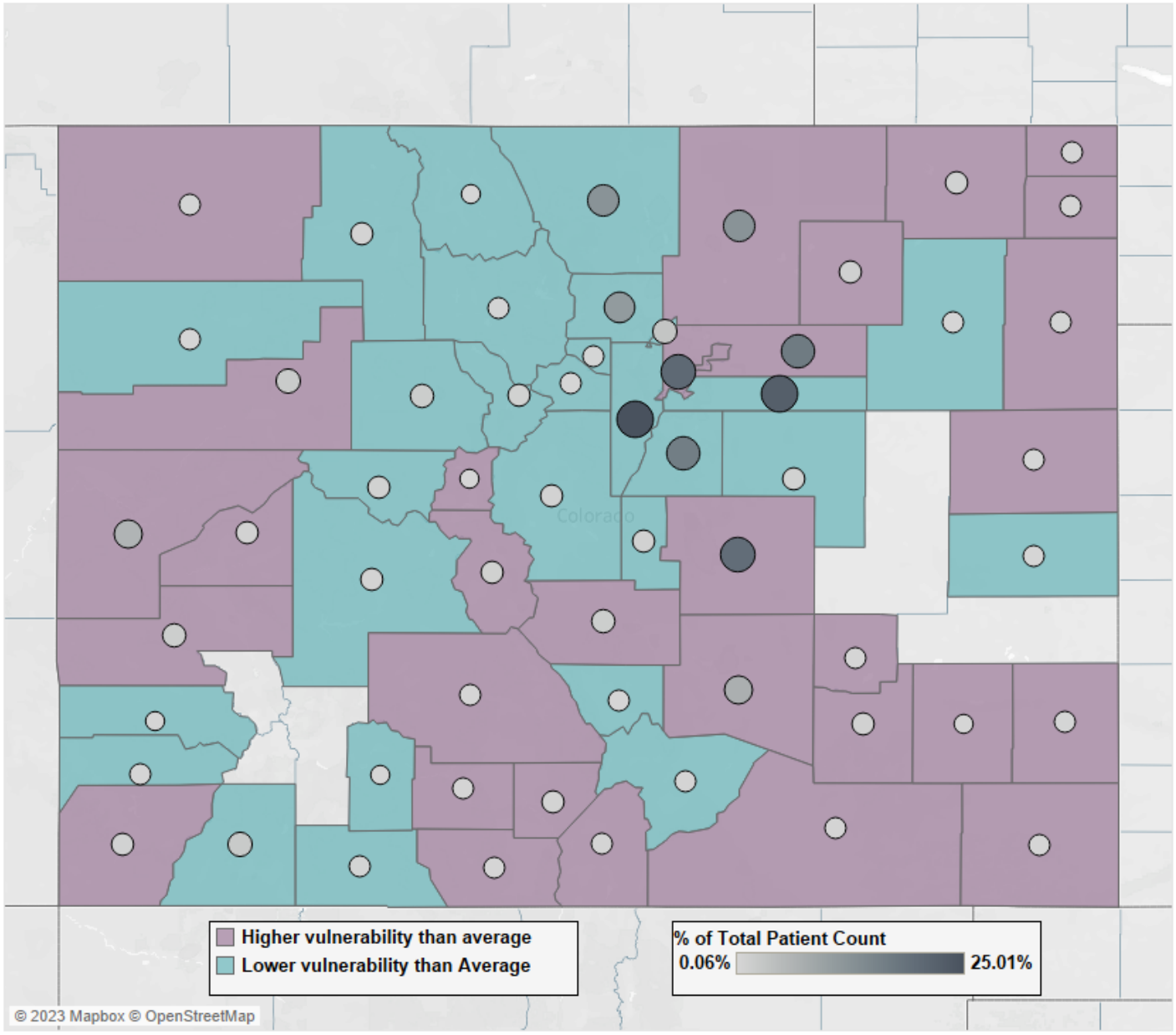

Figure L-1 shows the state of Colorado by county, where purple counties indicate higher than average SVI scores and teal counties indicate a lower than average SVI score, and counties without color did not have any patients who used Enbrel in 2022 residing in them. The dots on each county show the percent of patients who used Enbrel in 2022 by county where a larger, darker dot represents a higher portion of utilizers and smaller, lighter dots represent a smaller portion of the population.

Table L-1

Percent of Patients of Enbrel and Therapeutic Alternatives by County

	County	County SVI Score	Enbrel	Cimzia	Humira	Remicade	Simponi
	ADAMS	80.95%	8.54%	7.16%	8.18%	6.16%	7.43%
	ALAMOSA	100.00%	0.23%		0.35%	0.14%	

Counties with Higher Vulnerability Than Average	BACA	52.38%	0.09%	0.21%	0.07%	0.14%	0.17%
	BENT	82.54%	0.03%		0.04%	0.14%	
	CHAFFEE	63.49%	0.50%	0.63%	0.29%	1.00%	0.17%
	CONEJOS	93.65%	0.06%	0.21%	0.04%	0.29%	
	COSTILLA	95.24%	0.15%	0.21%	0.04%	0.14%	
	CROWLEY	77.78%	0.09%		0.04%	0.14%	0.17%
	DELTA	79.37%	0.35%	1.26%	0.49%	0.43%	0.35%
	DENVER	73.02%	10.31%	10.53%	12.12%	11.89%	10.36%
	EL PASO	53.97%	9.86%	8.84%	10.38%	11.32%	7.43%
	FREMONT	60.32%	0.79%	0.84%	1.00%	0.43%	0.52%
	GARFIELD	61.90%	1.06%	1.26%	1.32%	0.57%	0.86%
	KIT CARSON	69.84%	0.06%		0.12%		0.17%
	LAKE	57.14%	0.03%		0.11%		0.17%
	LAS ANIMAS	85.71%	0.15%		0.32%		0.35%
	LINCOLN	55.56%			0.04%		0.17%
	LOGAN	71.43%	0.47%	0.42%	0.52%	0.29%	0.17%
	MESA	74.60%	3.02%	5.47%	3.23%	2.44%	2.42%
	MOFFAT	90.48%	0.21%	0.42%	0.15%		0.52%
	MONTEZUMA	58.73%	0.38%	0.63%	0.54%	0.72%	0.17%
	MONTROSE	68.25%	0.79%	2.74%	0.69%	0.29%	0.35%
	MORGAN	92.06%	0.53%		0.50%	0.29%	0.35%
	OTERO	87.30%	0.44%		0.41%	0.57%	0.17%

	PHILLIPS	50.79%	0.15%	0.21%	0.07%		0.17%
	PROWERS	98.41%	0.12%		0.21%	0.14%	0.17%
	PUEBLO	84.13%	3.49%	1.89%	4.36%	1.15%	3.63%
	RIO GRANDE	96.83%	0.18%	0.21%	0.39%		0.17%
	SAGUACHE	88.89%	0.06%		0.08%		
	SEDGWICK	76.19%	0.06%		0.03%		0.17%
	WELD	66.67%	6.25%	5.68%	8.08%	8.45%	5.70%
	YUMA	65.08%	0.21%		0.19%	0.29%	
	Total		***48.65%***	***48.84%***	***54.37%***	***47.42%***	***42.49%***
Counties with Lower Vulnerability Than Average	ARAPAHOE		11.30%	9.26%	9.78%	14.76%	12.61%
	ARCHULETA	41.27%	0.21%		0.12%	0.14%	
	BOULDER	39.68%	5.46%	8.42%	5.06%	2.87%	8.12%
	BROOMFIELD	9.52%	1.56%	1.47%	1.33%	1.00%	1.73%
	CHEYENNE	14.29%	0.06%		0.07%		
	CLEAR CREEK	19.05%	0.09%	0.21%	0.15%	0.29%	0.17%
	CUSTER	6.35%	0.06%		0.08%	0.14%	
	DOLORES	12.70%	0.09%				
	DOUGLAS	1.59%	8.28%	5.89%	5.87%	8.02%	8.98%
	EAGLE	44.44%	0.88%	0.63%	0.56%	0.57%	0.35%
	ELBERT	0.00%	0.41%	0.21%	0.23%	0.43%	0.52%
	GILPIN	4.76%	0.12%	0.21%	0.03%	0.29%	
	GRAND	28.57%	0.21%	0.63%	0.17%		
	GUNNISON	25.40%	0.23%	0.63%	0.25%		0.17%

	HINSDALE	38.10%			0.04%		
	HUERFANO	42.86%	0.18%		0.09%		
	JACKSON	31.75%	0.03%				
	JEFFERSON	20.63%	12.51%	16.00%	10.75%	11.03%	19.00%
	LA PLATA	36.51%	1.17%	1.47%	1.38%	0.43%	0.35%
	LARIMER	33.33%	6.19%	3.79%	7.49%	11.03%	3.45%
	MINERAL	22.22%	0.03%		0.03%		
	OURAY	6.35%		0.21%	0.04%		
	PARK	3.17%	0.32%	0.42%	0.21%	0.14%	0.17%
	PITKIN	15.87%	0.41%	0.21%	0.27%	0.14%	
	RIO BLANCO	47.62%	0.06%	0.21%	0.12%	0.29%	0.35%
	ROUTT	11.11%	0.26%	0.21%	0.52%	0.14%	0.52%
	SAN JUAN	44.44%			0.01%		
	SAN MIGUEL	26.98%	0.03%	0.21%	0.13%	0.14%	
	SUMMIT	30.16%	0.41%	0.21%	0.35%	0.43%	0.69%
	TELLER	17.46%	0.44%	0.21%	0.43%	0.14%	0.52%
	WASHINGTON	34.92%	0.09%		0.13%	0.14%	
	Total		***51.09%***	***50.74%***	***45.68%***	***52.58%***	***57.69%***

Table L-1 shows a breakdown of the SVI score of each county, with higher than average vulnerability counties listed first, with the percent of utilizers in each county for Enbrel and identified therapeutic alternatives in 2022. Please note the percent of utilizers may not equal 100% as some patients may have moved throughout the year and might be counted in each location where they lived while filling a prescription.

Figure L-2
SVI Score for Enbrel and Therapeutic Alternatives

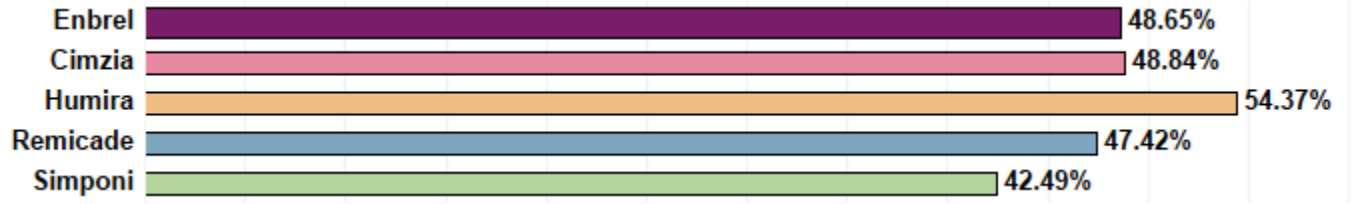

Figure L-2 shows the percent of utilizers of Enbrel and identified therapeutic alternatives that lived in a county with a higher social vulnerability index score than the statewide average.

Health Equity Literature Review

Literature reviews were conducted for each of Enbrel's FDA-approved indications and are meant to provide a broad overview of potential health equity impacts related to the disease or condition. Citations are provided for more information regarding the specific study populations, locations, timeframes, and categories or subcategories of the indication being studied.

Rheumatoid Arthritis (RA)

According to major treatment guidelines, the standard of care for rheumatoid arthritis (RA) includes early assessment, frequent reassessment, and aggressive adjustment of therapy to achieve remission and reduce disease progression.[3] RA therapy is dependent on access to specialty care, insurance coverage, and management of associated comorbidities.[4] One study found that non-Hispanic African Americans and people with low family income had a significantly higher RA risk, while people with high education levels had a significantly lower RA risk.[5]

Delay in diagnosis of RA can lead to more severe disease manifestations and irreversible bone destruction, disability, and loss of function.[6] Geographic distance from a rheumatologist can increase negative health outcomes by delaying diagnosis and making it difficult for patients to receive the frequent reassessments needed to monitor disease activity.[7] One study found that patients with the longest driving distances to rheumatology providers had approximately 30% decreased odds of receiving an RA diagnosis compared with those located nearest to rheumatology care.[8] Remote distance from providers was also associated with a 70% reduction in continuity of care in the first year of disease onset.[9] Additionally, decreased access to RA services can result in accumulation of RA damage, leading to increased need for surgeries.[10]

Type of insurance is also associated with RA disease activity and burden. Some studies have shown that Medicaid coverage can be associated with less access to care. One study found that fewer than 20% of rheumatology practices were caring for more than 50% of RA patients with Medicaid.[11] Another study of patients aged 18 to 64 years found that uninsured and Medicaid patients were 17% and 13% less likely to visit a rheumatologist, respectively.[12]

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[3] https://www.rheumatic.theclinics.com/article/S0889-857X(20)30077-6/fulltext

[4] https://acrabstracts.org/abstract/the-distribution-of-social-deprivation-distance-to-care-and-disease-burden-in-rheumatoid-arthritis-patients-in-the-united-states/

[5] https://www.mdpi.com/2077-0383/10/15/3289

[6] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8009304/

[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8009304/

[8] https://onlinelibrary.wiley.com/doi/abs/10.1002/acr.22333

[9] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3913026/

[10] https://www.jrheum.org/content/42/3/429.short

[11] https://acrabstracts.org/abstract/the-distribution-of-social-deprivation-distance-to-care-and-disease-burden-in-rheumatoid-arthritis-patients-in-the-united-states/

[12] https://www.tandfonline.com/doi/abs/10.1080/03007995.2016.1227775

Currently, there are multiple therapeutic options for patients with RA, but the availability of biological therapy to groups with lower socioeconomic status is a concern given the cost of these therapies to payers.[13] Medicaid patients aged 18 to 64 years had just 9% odds of receiving biological therapy compared with patients with private insurance.[14] Those with Medicaid were more likely than those with private insurance to be unable or delayed in getting prescription drugs, to experience cognitive, social, and physical limitations, and also reported significantly lower general health and health-related quality of life.[15]

Rheumatoid arthritis is associated with progressive disability, and with limitations in work and physical activity. One study revealed that 39% of RA patients were unable to work 10 years after early-stage rheumatoid arthritis. About 30% of RA patients were more likely to need help with personal care and were twice as likely to have a health-related activity limitation.[16] One study found that patients with RA are more susceptible to mental health disorders such as anxiety, depression, or cognitive impairment, which may be contributing to higher disease activity and lower treatment responsiveness.[17]

Ankylosing Spondylitis (AS)

Ankylosing spondylitis (AS), a subset of axial spondyloarthritis,[18] is historically considered a disease predominantly impacting men. However, increasing evidence suggests that it is often under-recognized or misdiagnosed in women. One study found that, on average, women wait about 8 years for an AS diagnosis while men wait about 6 years, and women may have more active disease because of a delay in diagnosis. In addition, men are more likely to receive a correct first diagnosis of AS (30%) compared with women (11%). Many factors are thought to contribute to this longer diagnostic delay, including inadequate healthcare professional knowledge, historical biases, and poor communication between providers, resulting in a lack of awareness of potential gender differences in disease manifestation, leading to misdiagnosis.[19]

Studies have found that white people are more often diagnosed with ankylosing spondylitis when compared with Black and Hispanic people.[20] Multiple researchers have raised concerns about detection bias with regard to diagnosing AS among people of color. Since it has been believed that white people are at higher risk for AS, health care providers may tend to suspect AS more often when treating white people while missing symptoms of spondylitis in people of color.[21] Some researchers have noted that reduced access to diagnostic tests and specialists may also affect the numbers of people of color diagnosed with rheumatic diseases.[22]

Despite being diagnosed at lower rates than white and Hispanic patients, Black patients reported greater discomfort and impairment, had higher levels of inflammation, and showed more joint damage and deterioration on X-rays and MRIs.[23] A study in the Journal of Rheumatology found that Black patients with AS have both higher disease activity and comorbidities compared to white patients.[24] This is further complicated by the fact that people of color are underrepresented in clinical trials for inflammatory arthritis and genetic research as a whole.[25]

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13 https://www.jmcp.org/doi/abs/10.18553/jmcp.2014.20.11.1110
14 https://www.tandfonline.com/doi/abs/10.1080/03007995.2016.1227775
15 https://www.tandfonline.com/doi/abs/10.1080/03007995.2016.1227775
16 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9677290/
17 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9677290/
18 https://www.arthritis.org/diseases/ankylosing-spondylitis
19 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9568456/
20 https://www.jrheum.org/content/jrheum/47/6/835.full.pdf
21 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8475338/
22 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5693696/
23 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5693696/
24 https://www.jrheum.org/content/47/6/835.long
25 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4082969/

As with many other inflammatory diseases, research suggests Black patients are not offered biologics as early on as white patients.[26] One study found that Black patients tended to undergo less treatment with biologic agents, despite having more severe disease.[27]

Plaque Psoriasis

Psoriasis is an immune-mediated disease that affects 3.0% of the US adult population, or more than 7.5 million adults. Plaque psoriasis is the most common subtype of psoriasis, affecting up to 80 percent of those with psoriasis.[28] Psoriasis has higher prevalence among white individuals (3.6%) compared with Asian (2.5%), Hispanic (1.9%), and Black (1.5%) individuals.[29]

Lack of culturally competent care was identified as a key unmet need for psoriasis among people with skin of color. One study reported that Hispanic and Black patients with psoriasis experienced more provider-related bias, stereotyping, misdiagnosis, and delayed diagnosis compared with white patients. The clinical presentation of psoriasis is different in people with darker skin tones compared to those with lighter skin tones and contributes to delayed diagnosis in historically marginalized populations. Additionally, people with skin of color are underrepresented in clinical trials of psoriasis therapies.[30]

Compared with white patients with psoriasis, individuals with skin of color may be less familiar with and have different rates of treatment with biologic therapies for psoriasis, are more likely to be hospitalized for psoriasis, and their access to physicians may differ. One study demonstrated significantly higher odds of hospitalization for psoriasis among Black, Hispanic, and Asian individuals. The same study also found higher rates of hospitalization for psoriasis among Medicare and Medicaid recipients, and uninsured patients compared with privately insured patients.[31] Black patients were less likely to receive biologic treatment or effective medications for their psoriasis compared with white patients. One study found that 8.3% of Black patients received a disease-modifying antirheumatic drug (DMARD) for their psoriasis, and 28% received a biologic therapy. In comparison, 13.3% of White individuals received a DMARD and 46.2% received a biologic therapy for their psoriasis. Additionally, patients of color reported high costs of care as a significant barrier to seeking and receiving treatment. Black, Asian, and other non-Hispanic historically marginalized populations are approximately 40% less likely to see a dermatologist for psoriasis compared with white patients.[32]

Nearly one-third of psoriasis patients are in the pediatric age group. With an annual prevalence of up to 0.71%, childhood psoriasis can be regarded as a frequently seen chronic inflammatory skin disorder having a significant impact on the quality of life. Incidence of pediatric psoriasis varies between different ethnic groups, being highest in white and Black children. International studies have shown that pediatric psoriasis is more common in girls than in boys, but the difference is not always significant.[33]

Children with psoriasis require treatment until adulthood, and prolonged treatment may increase the risk of complications and adverse events, therefore it is crucial to adopt an effective treatment approach that reduces this risk. Long-term comorbidities associated with psoriasis may place a great burden on the physical and mental health of children with psoriasis beyond the effects of psoriasis itself. Pediatric patients with moderate-to-severe plaque psoriasis demonstrated significantly impaired health-related quality of life in relation to physical, emotional, social, and school functioning compared with healthy children, and pediatric psoriasis was associated with significantly worse quality of life than other skin diseases. Children

[26] https://www.ajmc.com/view/black-patients-with-ra-less-likely-than-white-counterparts-to-be-prescribed-a-biologic
[27] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5693696/
[28] https://www.psoriasis.org/locations-and-types/
[29] https://www.sciencedirect.com/science/article/abs/pii/S0733863522000961?via%3Dihub
[30] https://www.sciencedirect.com/science/article/abs/pii/S0733863522000961?via%3Dihub
[31] https://www.sciencedirect.com/science/article/abs/pii/S0733863522000961?via%3Dihub
[32] https://www.sciencedirect.com/science/article/abs/pii/S0733863522000961?via%3Dihub
[33] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5683294/

with psoriasis are at approximately 20% to –30% higher risk of developing psychiatric disorders, such as depression and anxiety, than children without any psoriasis diagnosis. Anxiety or depression may stem from experiences of shame, behavior avoidance, bullying, decreased self-confidence, and social isolation caused by psoriasis.[34]

Psoriatic Arthritis

Often, patients with psoriasis are also diagnosed with psoriatic arthritis (PsA). Up to 30% of psoriasis patients initially present with a skin condition and then eventually progress into joint pain over 10 years following the initial psoriasis diagnosis.[35] The condition typically begins between the ages of 30 and 50, but children with psoriasis may also develop psoriatic arthritis. Though all races can get psoriasis and psoriatic arthritis, it is diagnosed more often in white people than people of other races and ethnicities.[36] One study found that white patients were five times more likely to be diagnosed with psoriatic arthritis compared with Black patients.[37] The disparity in prevalence could potentially be due to underdiagnosis in historically marginalized racial/ethnic groups.[38]

Though psoriatic arthritis is less frequent in Black patients compared to white patients, Black patients had more severe skin involvement, and greater psychological impact and impaired quality of life. One study reported a significantly higher degree of disease severity and lower use of biologics among Black patients compared with white patients.[39] One study found Black patients were 70% less likely to receive biologics than white patients.[40]

Insurance coverage may also impact diagnosis and treatment for psoriatic arthritis. One study found that Medicaid patients were less likely to be diagnosed with psoriatic arthritis, and only 12% of those with Medicaid saw a doctor who specializes in treating arthritis, compared to more than 50% of patients with other types of insurance. Those with private insurance or Medicare were more likely to get a correct diagnosis, see a specialist, and have targeted treatments.[41]

Juvenile Psoriatic Arthritis

In children, psoriatic arthritis is a form of juvenile idiopathic arthritis (JIA). It affects 1-7% of children with JIA. Juvenile Psoriatic Arthritis (JPsA) and its definition has been a matter of debate among pediatric rheumatologists for many years. The few studies that have compared the clinical characteristics and genetic determinants of JPsA with those of the other JIA categories have obtained contrasting findings. The debate on the categorization of JPsA as a distinct entity within JIA classification is still ongoing and has prompted the revision of its current classification.[42]

No research on health equity and JPsA is currently available.

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

Juvenile idiopathic arthritis (JIA) is an umbrella-term describing a group of conditions characterized by chronic arthritis beginning before the age of 16 years, persisting for at least 6 weeks, and having no other

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[34] https://onlinelibrary.wiley.com/doi/full/10.1111/1346-8138.17049#:~:text=International%20studies%20have%20shown%20that,significantly%20higher%20incidence%20in%20men.

[35] https://link.springer.com/article/10.1007/s40744-023-00580-y

[36] https://www.webmd.com/arthritis/psoriatic-arthritis/disparities-psoriatic-arthritis-diagnosis-treatment

[37] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8475338/

[38] https://link.springer.com/article/10.1007/s40744-023-00580-y

[39] https://link.springer.com/article/10.1007/s10067-014-2763-3

[40] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9045033/#:~:text=Another%20study%20found%20that%20Black,worse%20disease%20severity%20%5B10%5D

[41] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8475338/

[42] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9821505/

identifiable cause.[43] Studies suggest that disparities are prevalent among children with polyarticular juvenile idiopathic arthritis (pJIA) and impact different timepoints of disease. Disparities in polyarticular JIA were evident before establishing care with a pediatric rheumatologist, with statistically significant delays among those living in poverty, but disparities exist even for children in the care of a rheumatologist across the first year of treatment.[44]

Children with pJIA are more likely than those with other categories of JIA to experience prolonged periods of active disease.[45] One US study showed that Black children with pJIA were nearly twice as likely to have joint damage than their white counterparts.[46] Studies have also shown that at the initial visit to a rheumatologist, Black children had significantly higher disease activity compared with white children and to all other children combined. Black children also showed significantly higher pain scores and lesser mobility than their white counterparts.[47]

Multiple social determinants were identified as contributing to disparities in pJIA. Lower socioeconomic status was associated with persistent functional disability, race/ethnicity was associated with higher disease activity, and use of public insurance and a guardian's education level of high school or lesser were associated with both functional disability and persistent moderate to severe disease activity across the first year of treatment.[48] In a study of children with new JIA diagnoses, publicly insured children had significantly higher active joint counts and were more likely to have polyarticular arthritis compared to children with private insurance. Prompt escalation to TNF inhibitors is recommended for children with JIA and ongoing disease activity despite treatment with conventional disease-modifying antirheumatic drugs (cDMARDs). Overall TNFi use did not differ between children with different insurance types, but publicly insured children were escalated from cDMARDs to TNFis more quickly, consistent with their increased disease severity.[49]

While selected information has been pulled above, there is additional information contained in Appendix Appendix H: Input from Patients and Caregivers, Appendix I: Input from Individuals with Scientific and Medical Training, and Appendix J: Voluntarily Submitted Information which may contain additional information on health equity effects not captured in this appendix. The Board may want to weigh information from all four appendices when evaluating the health equity of Enbrel.

[43] https://ped-rheum.biomedcentral.com/articles/10.1186/s12969-021-00629-8

[44] https://www.rheumatologyadvisor.com/home/topics/pediatric-rheumatology/disparities-impacting-delays-in-care-and-disease-outcomes-in-polyarticular-juvenile-idiopathic-arthritis/

[45] https://pubmed.ncbi.nlm.nih.gov/36521922/

[46] https://www.jrheum.org/content/40/6/936

[47] https://www.jrheum.org/content/40/6/936

[48] https://ped-rheum.biomedcentral.com/articles/10.1186/s12969-021-00610-5

[49] https://pubmed.ncbi.nlm.nih.gov/36521922/

Appendix M

Enbrel: Information from the Department of Health Care Policy and Financing (HCPF)

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider any other factors as determined by rules promulgated by the board pursuant to section 10-16-1403(5). (C.R.S. § 10-16-1406(4)(j)).

Rule: The Board shall consider information from HCPF as follows:

- Additional analyses HCPF conducts relevant to the prescription drug or therapeutic alternative under review; and/or
- Information regarding safety net providers participating in the 340B, including information to assist with gathering input to assess the impact to safety net providers for a prescription drug under review that is available through Section 340B of the Federal "Public Health Service Act", Pub.L. 78-410. (3 CCR 702-9, Part 3.1.E.2.j.iii).

Policy: Staff will review any additional analyses conducted by HCPF relevant to the prescription drug or therapeutic alternative under review for presentation to the Board. (PDAB Policy 04, p. 9).

Underlying Methodology: None.

Data Source(s): Board staff sought to compile information for the selected prescription drugs from the following sources:

- Publicly available reports from the Colorado Department of Health Care Policy and Financing (HCPF).

Considerations and Data Limitations: If any selected prescription drugs or therapeutic alternatives were mentioned in public HCPF reports, Board staff noted any differences in definitions, the period of time being analyzed, or general characteristics of the prescription drugs or analytics being conducted.

Enbrel: Information from the Department of Health Care Policy and Financing Evidence

Board staff requested any publicly available reports with quantitative or qualitative data related to Enbrel from HCPF and were informed that there are no publicly available reports.

HCPF maintains a preferred drug list (PDL) with prior authorization requirements for self-administered drugs and Appendix P with prior authorization requirements for physician-administered drugs.[1] These lists are developed with recommendations from HCPF's Drug Utilization Review Board.[2]

HCPF's PDL outlines the following information effective as of January 1, 2024:[3]

- For rheumatoid arthritis, all other arthritis (except psoriatic arthritis), and ankylosing spondylitis: Enbrel is a preferred agent with no prior authorization required if diagnosis is met. Of identified therapeutic alternatives, Humira is also a preferred agent, while Cimzia and Simponi are non-preferred agents and require a prior authorization.

[1] https://hcpf.colorado.gov/pharmacy-resources.

[2] https://hcpf.colorado.gov/drug-utilization-review-board.

[3] https://hcpf.colorado.gov/sites/hcpf/files/01-01-24%20PDL-V8.1.pdf.

- For psoriatic arthritis: Enbrel is a preferred agent with no prior authorization required if diagnosis is met. Of identified therapeutic alternatives, Humira is also a preferred agent, while Cimzia and Simponi are non-preferred agents and require a prior authorization.

HCPF's Appendix P outlines the following information effective January 1, 2024:[4]

- Remicade may be approved if certain criteria are met, including a requirement that a Medicaid member has tried and failed one preferred TNF inhibitor.

Additionally, Board staff and HCPF discussed that there was no readily available list or email listserv of 340B covered entities that could be used to facilitate Board staff outreach.

[4] https://hcpf.colorado.gov/sites/hcpf/files/Appendix%20P%2001.01.24%20V2.1.pdf.

Appendix N

Enbrel: Non-Adherence and Utilization Management

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider any other factors as determined by rules promulgated by the Board pursuant to section 10-16-1403(5). (C.R.S. § 10-16-1406(4)(j)).

Rule: The Board may use information regarding non-adherence to the prescription drug, as well as information related to utilization management restrictions placed on the prescription drug. (3 CCR 702-9, 3.1.E.2.j.iv).

Policy: To the extent such information is available, the Board may use information regarding non-adherence to the prescription drug, as well as information related to utilization management restrictions placed on the prescription drug. (PDAB Policy 04, p. 9).

Underlying Methodology: Board staff have compiled data for the selected prescription drug for the Board's consideration in the following manner:

1. Document information provided during the stakeholder sessions to gather input from patients and caregivers and individuals with scientific or medical expertise. Staff attempted to compile information directly related to the information outlined in rule during stakeholder meetings, as well as a survey.
2. Relevant information provided by entities who submitted information voluntarily.

Data Source(s): Board staff compiled information on non-adherence and utilization management for Enbrel from the following sources:

- Results of public input sessions and surveys by patients and caregivers and individuals with scientific and medical training, and
- Relevant voluntarily submitted information.

Considerations and Data Limitations: Input provided both via stakeholder meetings and surveys is voluntary. Such qualitative data may not capture information from all patients and caregivers.

Enbrel: Non-Adherence and Utilization Management Evidence

See Appendix M for more information regarding the Department of Health Care Policy & Financing's (HCPF's) prior authorization requirements for Enbrel and identified therapeutic alternatives.

Stakeholder Input

Through public input sessions and surveys, patients and caregivers disclosed information about non-adherence of Enbrel due to cost. Of the 38 Colorado patients and caregivers surveyed:

- Twenty two participants indicated that cost impacted their adherence to Enbrel and nine respondents indicated that they skipped or stretched doses of the drug to save money.
- Twenty-four participants said their insurance plan requires prior approval to fill the prescription, eighteen said their insurance plan limits the supply of the drug, eight worried that the cost of the prescription will raise their premium, and fourteen said their insurance required them to try a medication they had previously failed.

See Appendices H and I for more information.

Voluntarily Submitted Information

Amgen Inc. voluntarily submitted the following information related to utilization management and adherence:

Utilization management:

- "Net Prices Declined as List Prices Increased: Such price concessions are often necessary to ensure a medicine's appropriate formulary placement and otherwise facilitate patient access without burdensome utilization management hurdles, such as requiring a patient to complete a course of therapy with a drug that may not be the best suited for his or her particular condition." (Amgen Inc. Voluntarily Submitted Information, p. 3)
- "Patient Affordability is a Result of Numerous Inputs in a Complex System: The rebates are based on eligibility criteria, depending on access, utilization management controls and product placement on formulary." (Amgen Inc. Voluntarily Submitted Information, p. 6)

Adherence:

- "Enbrel achieves disease transforming efficacy while also offering an established safety profile: Real-world evidence (RWE) has shown Enbrel® to have fewer adverse reactions than infliximab and adalimumab as well, with Enbrel® patients having higher adherence as a result." (Amgen Inc. Voluntarily Submitted Information, p. 2)

See Appendix J for more information.

Appendix O

Enbrel: Pricing Information

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board may consider any documents and information relating to the manufacturer's selection of the introductory price or price increase of the prescription drug, including documents and information relating to: (a) Life-cycle management; (b) The average cost of the prescription drug in the state; (c) Market competition and context; (d) Projected revenue; (e) The estimated cost-effectiveness of the prescription drug; and (f) Off-label usage of the prescription drug. (C.R.S. § 10-16-1406(6)).

The Board may access pricing information through publicly available pricing information from state entities, the APCD, and other countries. (C.R.S. § 10-16-1406(7)(a)). Pricing information is defined as information about the price of a prescription drug, including information that explains or helps explain how the price was determined. (C.R.S. § 10-16-1401(20)).

To the extent that there is no publicly available information with which to conduct an affordability review, the Board may request that a manufacturer, carrier, or pharmacy benefit management firm provide pricing information for any prescription drug identified. (C.R.S. § 10-16-1406(7)(b)).

Rule: The Board may also consider documents and information relating to the manufacturer's selection of the introductory price or price increase of the prescription drug including information related to:

- Life cycle management;
- Average cost of the prescription drug in Colorado;
- Market competition;
- Projected revenue;
- Estimated cost-effectiveness of the prescription drug; and/or
- Off-label usage of the prescription drug.

The Board may access pricing information for prescription drugs by:

- Accessing publicly available pricing information from a state to which manufacturers report pricing information;
- Accessing available pricing information from the APCD and from state entities; and/or
- Accessing information that is available from other countries.

To the extent there is no publicly available information with which to conduct an affordability review, the Board may request that a manufacturer, carrier, or PBM provide pricing information for any prescription drug eligible for an affordability review.

- Such interested parties shall have 30 days from the date of the request of a prescription drug for affordability review to provide such information to the Board for its consideration.
- Failure of an entity to provide pricing information to the Board for an affordability review does not affect the authority of the Board to conduct the affordability review, as described in this section. (See 3 CCR 702-9, Parts 3.1.E.3, 4).

Policy: The Board may also consider documents and information relating to the manufacturer's selection of the introductory price or price increase of the prescription drug including information related to:

- Life-cycle management;
- Average cost of the prescription drug in Colorado;
- Market competition;
- Projected revenue;
- Estimated cost-effectiveness of the prescription drug; and/or
- Off-label usage of the prescription drug.

The Board may access pricing information for prescription drugs by:

- Accessing publicly available pricing information from a state to which manufacturers report pricing information. Staff will review other state programs and provide such information to the extent it is available.
- Accessing available pricing information from the APCD and from state entities.
- Staff will review pricing information in the APCD and, to the extent such data has not already been utilized in the affordability review, provide such information.
- Staff will review pricing information available from state entities and provide such information to the Board.
- Accessing information that is available from other countries. Staff will review pricing information from other countries and provide such information to the extent it is available. (PDAB Policy 04, pp. 9-10).

Underlying Methodology: None.

Data Sources: Board staff obtained pricing information through public reports and the following data sources:

- APCD data, including APCD data gathered pursuant to C.R.S. § 10-16-1405.
- Other state prescription drug transparency reports.
- U.S. Security and Exchange Commission (SEC) Form 10-K Filings.

Considerations and Data Limitations: Board staff did not recommend the Board specifically request pricing information from manufacturers, carriers, and PBMs since information is already both publicly available and available through the Division of Insurance's contract with AnalySource.[1] However, entities were able to choose to provide information related to the following components by submitting such information through the "Voluntarily Submitted Information" path by October 3, 2023:

- Life-cycle management;
- Average cost of the prescription drug in Colorado;
- Market competition
- Projected revenue;
- Estimated cost-effectiveness of the prescription drug; and/or
- Off-label usage of the prescription drug.

The Division of Insurance did not receive any voluntarily submitted information from entities with additional pricing information.

Information accessed through searches for public reports and data may not always match exactly the type of data being compiled for other affordability review components. Board staff will note when publicly available data cannot be vetted for exact comparability.

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[1] AnalySource data contains information on Enbrel's price - See Appendix A for more information.

Enbrel: Pricing Information Evidence

Other State Transparency Reports

Board staff reviewed prescription drug transparency reports from six other states, summarized below.

West Virginia

The West Virginia legislature passed Senate Bill 689 in 2020, requiring all pharmaceutical manufacturers that sell drugs directly or to wholesalers in West Virginia to submit pricing information to the State Auditor's Office for it to be visualized and transparent for the everyday consumer.[2] In 2023, this resulted in four published reports:

- Pharmaceutical Manufacturers WAC Report - Annual information from 2020 through 2022 is provided in a searchable database for both Enrbel and Amgen Inc., specifically introductory prices and weighted average costs for multiple strengths and dosage forms of Enbrel as reported by the manufacturer in 2020 and 2022.
- Patent Exclusivity Report - Information regarding Amgen Inc., but not Enbrel, is contained in this report.
- WAC Increases - No information regarding Enbrel or Amgen Inc. is contained in this report.
- Research and Development Costs - Information regarding Amgen Inc. is contained in this report, specifically that Amgen Inc.'s 2022 research and development costs were $4.819 billion.

Minnesota

The Minnesota legislature passed a law creating the Prescription Drug Price Transparency Data and Dashboards.[3] In the Reporting Snapshot of data reported by June 2023, the Minnesota Department of Health (MDH) outlined 47 expected reports from Amgen, Inc. with 60 reports received.[4]

The Price Increase - Five Year Price Analysis Dashboard[5] provided the following information regarding Enbrel's price increases:

Table O-1
Information from Minnesota

[2] https://stories.opengov.com/westvirginia/published/kFdN-WMxm.
[3] https://www.health.state.mn.us/data/rxtransparency/dashboards/index.html.
[4] https://www.health.state.mn.us/data/rxtransparency/dashboards/reporting.html.
[5] https://www.health.state.mn.us/data/rxtransparency/dashboards/fiveyear.html

Manufacturer	NDC	Item Description	% Current Change	% Prior Year 1 Change	% Prior Year 2 Change	% Prior Year 3 Change	% Prior Year 4 Change	% Prior Year 5 Change	Prior Year 1 WAC	Prior Year 2 WAC	Prior Year 3 WAC	Prior Year 4 WAC	Prior Year 5 WAC	WAC After Current Change	WAC Effective Date
Amgen Inc.	58406001001	Etanercept 25 MG/0.5ML Solution Prefilled Syringe 0.500 ML UD	7.40%	7.40%	10.00%	7.40%	7.40%		$820	$746	$695	$647		$881	1/4/2023
Amgen Inc.	58406001001	Etanercept 25 MG/0.5ML Solution Prefilled Syringe 0.500 ML UD	2.40%	10.00%	7.40%	7.40%			$746	$695	$647			$820	7/1/2022
Amgen Inc.	58406001004	Etanercept 25 MG/0.5ML Solution Prefilled Syringe 0.500 ML UD	7.40%	7.40%	10.00%	7.40%	7.40%		$3,282	$2,984	$2,778	$2,587		$3,525	1/4/2023
Amgen Inc.	58406001004	Etanercept 25 MG/0.5ML Solution Prefilled Syringe 0.500 ML UD	2.40%	10.00%	7.40%	7.40%			$2,984	$2,778	$2,587			$3,282	7/1/2022
Amgen Inc.	58406002101	Etanercept 50 MG/ML Solution Prefilled Syringe 1.000 ML UD	7.40%	7.40%	10.00%	7.40%	7.40%		$1,641	$1,492	$1,389	$1,294		$1,762	1/4/2023
Amgen Inc.	58406002101	Etanercept 50 MG/ML Solution Prefilled Syringe 1.000 ML UD	2.40%	10.00%	7.40%	7.40%			$1,492	$1,389	$1,294			$1,641	7/1/2022
Amgen Inc.	58406002104	Etanercept 50 MG/ML Solution Prefilled Syringe 1.000 ML UD	7.40%	7.40%	10.00%	7.40%	7.40%		$6,564	$5,968	$5,557	$5,174		$7,049	1/4/2023

Manufacturer	NDC	Item Description	% Current Change	% Prior Year 1 Change	% Prior Year 2 Change	% Prior Year 3 Change	% Prior Year 4 Change	% Prior Year 5 Change	Prior Year 1 WAC	Prior Year 2 WAC	Prior Year 3 WAC	Prior Year 4 WAC	Prior Year 5 WAC	WAC After Current Change	WAC Effective Date
Amgen Inc.	58406002104	Etanercept 50 MG/ML Solution Prefilled Syringe 1.000 ML UD	2.40%	10.00%	7.40%	7.40%			$5,968	$5,557	$5,174			$6,564	7/1/2022
Amgen Inc.	58406003201	Etanercept 50 MG/ML Solution Auto-injector 1.000 ML UD	7.40%	7.40%	10.00%	7.40%	7.40%		$1,641	$1,492	$1,389	$1,294		$1,762	1/4/2023
Amgen Inc.	58406003201	Etanercept 50 MG/ML Solution Auto-injector 1.000 ML UD	2.40%	10.00%	7.40%	7.40%			$1,492	$1,389	$1,294			$1,640	7/1/2022
Amgen Inc.	58406003204	Etanercept 50 MG/ML Solution Auto-injector 1.000 ML UD	7.40%	7.40%	10.00%	7.40%	7.40%		$6,564	$5,968	$5,557	$5,174		$7,049	1/4/2023
Amgen Inc.	58406003204	Etanercept 50 MG/ML Solution Auto-injector 1.000 ML UD	2.40%	10.00%	7.40%	7.40%			$5,968	$5,557	$5,174			$6,563	7/1/2022
Amgen Inc.	58406004401	Etanercept 50 MG/ML Solution Cartridge 1.000 ML UD	7.40%	7.40%	10.00%	7.40%	7.40%		$1,641	$1,492	$1,389	$1,294		$1,762	1/4/2023
Amgen Inc.	58406004401	Etanercept 50 MG/ML Solution Cartridge 1.000 ML UD	2.40%	10.00%	7.40%	7.40%			$1,492	$1,389	$1,294			$1,641	7/1/2022

Manufacturer	NDC	Item Description	% Current Change	% Prior Year 1 Change	% Prior Year 2 Change	% Prior Year 3 Change	% Prior Year 4 Change	% Prior Year 5 Change	Prior Year 1 WAC	Prior Year 2 WAC	Prior Year 3 WAC	Prior Year 4 WAC	Prior Year 5 WAC	WAC After Current Change	WAC Effective Date
Amgen Inc.	58406004404	Etanercept 50 MG/ML Solution Cartridge 1.000 ML UD	7.40%	7.40%	10.00%	7.40%	7.40%		$6,564	$5,968	$5,557	$5,174		$7,049	1/4/2023
Amgen Inc.	58406004404	Etanercept 50 MG/ML Solution Cartridge 1.000 ML UD	2.40%	10.00%	7.40%	7.40%			$5,968	$5,557	$5,174			$6,564	7/1/2022
Amgen Inc.	58406005501	Etanercept 25 MG/0.5ML Solution 0.500 ML UD	7.40%	7.40%	10.00%	7.40%			$820	$746	$695			$881	1/4/2023
Amgen Inc.	58406005501	Etanercept 25 MG/0.5ML Solution 0.500 ML UD	2.40%	10.00%	7.40%				$746	$695				$820	7/1/2022
Amgen Inc.	58406005504	Etanercept 25 MG/0.5ML Solution 0.500 ML UD	7.40%	7.40%	10.00%	7.40%			$3,282	$2,984	$2,778			$3,525	1/4/2023
Amgen Inc.	58406005504	Etanercept 25 MG/0.5ML Solution 0.500 ML UD	2.40%	10.00%	7.40%				$2,984	$2,778				$3,282	7/1/2022
Amgen Inc.	58406042534	Etanercept 25 MG Solution Reconstituted 1.000 EA UD	7.40%	7.40%	339.90%	7.40%	7.40%	6.20%	$3,282	$746	$695	$647	$609	$3,525	1/4/2023
Amgen Inc.	58406042534	Etanercept 25 MG Solution Reconstituted 1.000 EA UD	2.40%	339.90%	7.40%	7.40%	6.20%	9.70%	$746	$695	$647	$609	$555	$3,282	7/1/2022

Manufacturer	NDC	Item Description	% Current Change	% Prior Year 1 Change	% Prior Year 2 Change	% Prior Year 3 Change	% Prior Year 4 Change	% Prior Year 5 Change	Prior Year 1 WAC	Prior Year 2 WAC	Prior Year 3 WAC	Prior Year 4 WAC	Prior Year 5 WAC	WAC After Current Change	WAC Effective Date
Amgen Inc.	58406042541	Etanercept 25 MG Solution Reconstituted 1.000 EA UD	7.40%	7.40%	-72.50%	7.40%	7.40%	6.20%	$820	$2,984	$2,778	$2,587	$2,436	$881	1/4/2023
Amgen Inc.	58406042541	Etanercept 25 MG Solution Reconstituted 1.000 EA UD	2.40%	-72.50%	7.40%	7.40%	6.20%	9.70%	$2,984	$2,778	$2,587	$2,436	$2,221	$820	7/1/2022

Table O-1 shows Minnesota's price transparency for five years of comparative price analysis for all Enbrel NDCs.

The Price Increase - Comparative Price Change Analysis Dashboard[6] provided the following information regarding Enbrel's price increases:

Table O-2

Information from Minnesota

Manufacturer	NDC	Item Description	$ Change 12 Month	% Change 12 Month	$ Change 24 Month	% Change 24 Month
Amgen Inc.	58406001001	Etanercept 25 MG/0.5ML Solution Prefilled Syringe 0.500 ML UD	$209.59	28.1%	$312.39	45.0%
Amgen Inc.	58406001004	Etanercept 25 MG/0.5ML Solution Prefilled Syringe 0.500 ML UD	$838.35	28.1%	$1,249.57	45.0%
Amgen Inc.	58406002101	Etanercept 50 MG/ML Solution Prefilled Syringe 1.000 ML UD	$419.16	28.1%	$624.76	45.0%
Amgen Inc.	58406002104	Etanercept 50 MG/ML Solution Prefilled Syringe 1.000 ML UD	$1,676.66	28.1%	$2,499.10	45.0%

[6] https://www.health.state.mn.us/data/rxtransparency/dashboards/comparative.html

Manufacturer	NDC	Item Description	$ Change 12 Month	% Change 12 Month	$ Change 24 Month	% Change 24 Month
Amgen Inc.	58406003201	Etanercept 50 MG/ML Solution Auto-injector 1.000 ML UD	$419.16	28.1%	$624.76	45.0%
Amgen Inc.	58406003204	Etanercept 50 MG/ML Solution Auto-injector 1.000 ML UD	$1,676.66	28.1%	$2,499.10	45.0%
Amgen Inc.	58406004401	Etanercept 50 MG/ML Solution Cartridge 1.000 ML UD	$419.16	28.1%	$624.76	45.0%
Amgen Inc.	58406004404	Etanercept 50 MG/ML Solution Cartridge 1.000 ML UD	$1,676.66	28.1%	$2,499.10	45.0%
Amgen Inc.	58406005501	Etanercept 25 MG/0.5ML Solution 0.500 ML UD	$209.59	28.1%	$312.39	45.0%
Amgen Inc.	58406005504	Etanercept 25 MG/0.5ML Solution 0.500 ML UD	$838.35	28.1%	$1,249.57	45.0%

Table O-2 shows Minnesota's price transparency comparative price analysis for all Enbrel NDCs.

Maine

The Maine legislature passed two laws related to prescription drug price transparency:

Public Law 2021, Chapter 606 (LD 1636)

This law requires the Maine Health Data Organization (MHDO) to produce an annual report beginning in 2023 that provides information regarding potential savings that could be achieved by subjecting drugs identified as the costliest and most frequently prescribed to a referenced rate as defined in law.[7]

Table O-3
Information from Maine

Potential Savings

[7] https://mhdo.maine.gov/RxReferenceRates.htm.

§8741 2. C. For each drug identified in paragraph A, the organization shall determine the potential savings that could be achieved by subjecting those drugs to the referenced rate as calculated pursuant to paragraph B. The savings must be determined based on the payments reported in the organization's claims database for the most current 12-month period.

Top 100 List	Manufacturer Name	NDC	Item Description	Average WAC Per Unit	Reference Rate	Annual Cost @ Average WAC Per Unit	Annual Cost @ Reference Rate Per Unit	Potential Savings
Brand Most Costly	AMGEN	58406002104	Etanercept 50 MG/ML Solution Prefilled Syringe 1.000 ML UD	$1,741.0440	$1,741.0440	$2,493,320	$2,493,320	$0
Brand Most Costly, Brand Most Prescribed	AMGEN	58406003204	Etanercept 50 MG/ML Solution Auto-injector 1.000 ML UD	$1,741.0440	$1,741.0440	$14,139,843	$14,139,843	$0

Table O-3 shows the potential savings that could be achieved by subjecting Etanercept 50 MG/ML Solution Prefilled Syringe 1.000 ML UD and Etanercept 50 MG/ML Solution Auto-injector 1.000 ML UD to the referenced rate (determined based on payments reported in MHDO's claims database for the most current 12-month period) is $0.[8]

Public Law 2018, Chapter 406

This law requires MHDO to produce an annual prescription drug report that includes:

- The 25 costliest drugs (determined by total amount spent in the state),
- The 25 most frequently prescribed drugs in the state, and
- The 25 drugs with the highest year-over-year cost increase (determined by total amount spent in the state).[9]

Information is provided for three state fiscal years, which run from July 1 through June 30. The most recent report is outlined below (July 1, 2021 through June 30, 2022):

Top 25 Costliest Drugs

- Overall: Enbrel Sureclick appears #5 on the list.

[8] Pulled from Part III of the International Referenced Rate Pricing for Prescription Drugs 2023 Report accessed via https://mhdo.maine.gov/RxReferenceRates.htm.

[9] https://mhdo.maine.gov/tableau/prescriptionReports.cshtml.

- Commercial: Enbrel Sureclick appears #3 on the list.
- Medicaid: Enbrel Sureclick appears #11 on the list.
- Medicare Advantage: Enbrel Sureclick appears #12 on the list.

Figure O-1
Maine: Enbrel Ranking Among Top 25 Costliest Drugs Overall

Rank	NDC	Drug Name	Drug Class(es)	Number of Prescriptions	Number of Prescription Users	Cost	Cost Per Prescription
Top 25 Overall				535,254	107,680	$757,322,271	
State Total				13,928,196	912,598	$2,762,444,684	
5	58406003204	Enbrel Sureclick	Disease-modifying Antirheumatic Drugs; Immunomodulatory Agents	5,206	820	$35,977,557	$6,911

Figure O-1 shows Enbrel Sureclick is the #5 costliest drug overall in 2021-2022.

Figure O-2
Maine: Enbrel Ranking Among Top 25 Costliest Drugs for Commercial Plans

Rank	NDC	Drug Name	Drug Class(es)	Number of Prescriptions	Number of Prescription Users	Cost	Cost Per Prescription
Top 25 Overall				82,865	20,994	$287,743,460	
State Total				3,769,512	400,330	$777,869,615	
3	58406003204	Enbrel Sureclick	Disease-modifying Antirheumatic Drugs; Immunomodulatory Agents	2,887	454	$18,874,090	$6,538

Figure O-2 shows Enbrel Sureclick is the #3 costliest drug for commercial plans in 2021-2022.

Figure O-3

Maine: Enbrel Ranking Among Top 25 Costliest Drugs for Medicaid

Rank	NDC	Drug Name	Drug Class(es)	Number of Prescriptions	Number of Prescription Users	Cost	Cost Per Prescription
Top 25 Overall				253,227	30,589	$151,049,958	
State Total				2,881,698	204,791	$458,079,261	
11	58406003204	Enbrel Sureclick	Disease-modifying Antirheumatic Drugs; Immunomodulatory Agents	640	114	$4,087,416	$6,387

Figure O-3 shows Enbrel is the #11 costliest drug for Medicaid in 2021-2022.

Figure O-4

Maine: Enbrel Ranking Among Top 25 Costliest Drugs for Medicare Advantage

Rank	NDC	Drug Name	Drug Class(es)	Number of Prescriptions	Number of Prescription Users	Cost	Cost Per Prescription
Top 25 Overall				246,271	64,868	$401,992,957	
State Total				7,276,986	317,518	$1,526,495,808	
12	58406003204	Enbrel Sureclick	Disease-modifying Antirheumatic Drugs; Immunomodulatory Agents	1,679	256	$13,016,052	$7,752

Figure O-4 shows Enbrel is the #12 costliest drug for Medicare Advantage in 2021-2022.

Top 25 Most Frequently Prescribed Drugs: Enbrel does not appear on the list overall, nor specifically for commercial plans, Medicaid, or Medicare Advantage.

Top 25 Drugs with Highest Year-Over-Year Increases: Enbrel does not appear on the list overall, nor specifically for commercial plans, Medicaid, or Medicare Advantage.

Oregon

The Oregon legislature created Oregon's Drug Price Transparency program in 2018 to provide accountability for prescription drug pricing through transparency of specific cost and price information from pharmaceutical manufacturers and health insurers.[10] Drug Price Transparency Program Reports are available from 2019-2022.[11] The 2022 report is outlined below.

The report identifies insurer reporting of the most costly drugs reflects the drugs with the highest total payments made on behalf of covered members, including payments made by carriers and member cost sharing, such as co-pays and co-insurance. Enbrel appears #3 on the list (p. 50):[12]

Figure O-5

Oregon: Top 10 Most Costly Drugs in 2022

Figure 21: Top 10 most costly drugs

Drug	Class	Prescriptions
Adalimumab *Brand name: Humira*	Analgesics - Anti-Inflammatory	$76,966,470
Ustekinumab *Brand name: Stelara*	Dermatologicals	$35,999,195
Etanercept *Brand name: Enbrel*	Analgesics - Anti-Inflammatory	$28,675,010
Bictegravir-Emtricitabine-Tenofovir Alafenamide Fumarate *Brand name: Biktarvy*	Antivirals	$23,245,660
COVID-19 (SARS-CoV-2) mRNA Virus Vaccine *Moderna and Pfizer-BioNTech*	Vaccines	$20,679,117
Elexacaftor-Tezacaftor-Ivacaftor *Brand name: Trikafta*	Respiratory Agents	$17,964,545
Secukinumab *Brand name: Cosentyx*	Dermatologicals	$17,770,873
Pembrolizumab *Brand name: Keytruda*	Antineoplastics and Adjunctive Therapies	$16,463,259
Vedolizumab *Brand name: Entyvio*	Gastrointestinal Agents	$14,872,464
Ocrelizumab *Brand name: Ocrevus*	Psychotherapeutic and Neurological Agents	$11,115,070

Figure O-5 shows Enbrel as #3 on the list of the top 10 most costly drugs in Oregon in 2022.

[10] https://dfr.oregon.gov/drugtransparency/Pages/index.aspx.

[11] https://dfr.oregon.gov/drugtransparency/Pages/annual-reports.aspx.

[12] https://dfr.oregon.gov/drugtransparency/Documents/Prescription-Drug-Price-Transparency-Annual-Report-2022.pdf.

Information is also provided in this report regarding drugs with greatest increases in year-over-year health plan spending, as well as the amount of that increase. Enbrel does not appear on the list (p. 51).[13]

California

The California legislature passed two laws related to prescription drug price transparency:

Prescription Drugs Introduced to Market

This dataset provides data for new drugs introduced to market in California with a WAC that exceeds the Medicare Part D specialty drug cost threshold.[14] Prescription drug manufacturers submit information to the California Department of Health Care Access and Information (HCAI), including NDC, a narrative description of marketing and pricing plans, and WAC. For the four years of available data (Q1 2019 - Q4 2022), Amgen Inc. submitted information, but nothing related to Enbrel.

Prescription Drug WAC Increases

This dataset provides data for WAC increases that exceed the statutorily mandated WAC increase threshold of a 16 percent increase for the period including the current quarter and the previous two calendar years for prescription drug products with a WAC greater than $40 for a course of therapy.[15] Amgen Inc. reported NDCs associated with Enbrel in multiple annual reports.

Texas

The Texas legislature passed House Bill 2536 in 2019, requiring pharmaceutical drug manufacturers to report the current WAC of drugs sold in or into Texas to the Texas Health and Human Services Commission (HHSC), as well as separately report specific information related to WAC increases.[16] Amgen Inc. reported WAC information to HHSC in 2020, 2021, 2022, and 2023 and reported price increases in 2023 for prescription drugs other than Enbrel and did not report any qualifying WAC increases in 2021 or 2022.[17]

[13] https://dfr.oregon.gov/drugtransparency/Documents/Prescription-Drug-Price-Transparency-Annual-Report-2022.pdf.
[14] https://data.chhs.ca.gov/dataset/prescription-drugs-introduced-to-market.
[15] https://data.chhs.ca.gov/dataset/prescription-drug-wholesale-acquisition-cost-wac-increases.
[16] https://www.dshs.texas.gov/prescription-drug-price-disclosure-program/about.
[17] https://www.dshs.texas.gov/prescription-drug-price-disclosure-program/data-overview.

Colorado All Payer Claims Database Transparency Reporting Information

Pursuant to section 10-16-1405(1)(a)(IV), C.R.S., each carrier and PBM must report the 15 prescription drugs that caused the greatest increases in the carrier's premiums in a given year. Please find data gathered from 19 payers pursuant to section 10-16-1405(1)(a)(IV), C.R.S., below.[18]

Figure O-6
Payer Rank of Enbrel Impact on Premiums in 2022

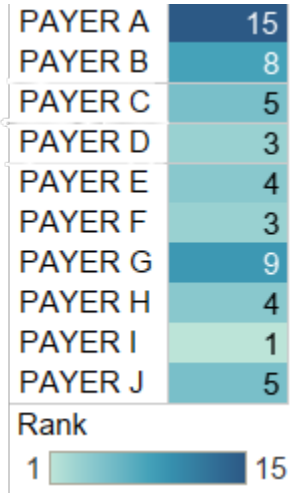

Figure O-6 shows the rank that each payer submitted indicating that Enbrel was a drug in the top 15 prescription drugs that increased premiums. For example, Payer I indicated that Enbrel was the first highest drug responsible for increases to premiums. The box represented shows the rank number and lighter boxes indicate a lower rank, meaning a larger increase in premiums than a lower rank and darker box.

Payers and Pharmacy Benefit Management Firms were required to identify in their submission which 15 drugs caused the highest increases to premiums, however, no additional information was required pursuant to section 10-16-1405(1)(a)(IV), C.R.S. As a result, the specific dollar impact Enbrel had on premiums, or even how its rank compared to other prescription drug premium impacts, is unknown.

While this information can be insightful in understanding Enbrel's impact to a broader portion of the health care system, Board staff do not recommend the Board heavily weigh this information this year. Per section 10-16-1405, C.R.S., only the top drugs are submitted for each reference, and more data and research would be necessary to understand the actual impacts to premiums and relative impact of each drug for each carrier.

[18] Information submitted per section 10-16-1405, C.R.S. is required by all submitters to the APCD. For this submission, 19 submitters provided information.

Manufacturer Pricing Information

The SEC requires all public companies to file a Form 10-K each year, and a Form 10-Q each quarter.[19] These forms provide a financial snapshot of the company's revenues, assets, and liabilities for the previous year. Amgen Inc.'s 2022 10-K details that Enbrel's international Product Revenue decreased from approximately $4.465 billion in 2021 to $4.117 billion in 2022 (p.F-17). Additionally, the 2022 10-K details that Enbrel comprises 17% of total product revenues (p.4). Additional information of estimates of Enbrel's share of Amgen Inc.'s total sales is contained in Appendix K.[20]

[19] United States Securities and Exchange Commission, Form 10-K, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, Transition Report Pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934, Amgen Inc., : https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/data/318154/000031815423000017/amgn-20221231.htm.

[20] Appendix K contains information of Enbrel's estimated net sales for national sales only, whereas this appendix contains information for national and international sales.

Appendix P

Data Sources and Limitations

Data sources and limitations are described in detail here. How these data sources are used and component-specific limitations are outlined in each component's appendix.

All-Payer Claims Database (APCD)

The All Payer Claims Database (APCD) receives claims from Medicaid, Medicare Advantage, and over 40 commercial payers and represents over 4.5 million lives and over 75% of insured Coloradans. The APCD does not have claims data for uninsured Coloradans and some commercial payers and plans. For this affordability review, pharmacy and medical claims from January 2018 through December 2022, which were paid through May 2023, were used for analyses. Drugs are identified on pharmacy claims with their National Drug Code (NDC). APCD claims are categorized by the submitting payer and are categorized as Medicaid, Medicare Advantage, and all other submitters are commercial. Enbrel and identified therapeutic alternatives NDC codes found in the APCD and utilized in these analyses were:

Drug Name	NDC
Enbrel	54868-4782-00*, 54868-5444-00*, 58406-0010-01, 58406-0010-04, 58406-0010-96*[1], 58406-0021-01, 58406-0021-04, 58406-0021-96*, 58406-0032-01, 58406-0032-04, 58406-0032-96*, 58406-0044-01, 58406-0044-04, 58406-0044-96*, 58406-0055-01, 58406-0055-04, 58406-0425-34*, 58406-0425-41*, 58406-0435-01*, 58406-0435-04*, 58406-0445-01*, 58406-0445-04*, 58406-0455-01*, 58406-0455-04*, 58406-0456-01*, 58406-0456-04*.[1]
Cimzia	50474-0700-62, 50474-0710-79, 50474-0710-81
Humira	00074-3799-02, 00074-4339-74, 00074-4339-01, 00074-4339-02, 00074-4339-06, 00074-4339-07, 00074-0243-02, 00074-0616-02, 00074-0817-02, 00074-0067-02, 00074-2540-03, 00074-0124-74, 00074-0124-02, 00074-0554-02, 00074-0554-71, 00074-0124-03, 00074-0124-04, 00074-1539-03
Remicade	57894-0030-01
Simponi	57894-0070-01, 57894-0070-02, 57894-0071-01, 57894-0071-02, 57894-0350-01

[1] (*) inactive NDC. Inactive NDCs were used to gather historical WAC data and any utilization that may have occurred during this time frame if the currently inactive NDCs were active at the time of the claim. Only Enbrel inactive NDCs were included, no inactive NDCs for identified therapeutic alternatives are included.

[2] SSR Health: https://www.ssrhealth.com/

[3] "Best Practices Using SSR Health Net Drug Pricing Data", Health Affairs Forefront, March 10, 2022. DOI: 10.1377/forefront.20220308.712815: https://www.healthaffairs.org/content/forefront/best-practices-using-ssr-health-net-drug-pricing-data

Limitations

- As the APCD does not include claims for all Coloradans, it is a conservative estimate, where utilizers, claims, and associated paid amounts are under-represented.
- Annual estimates of utilization are also likely under-represented as individuals change insurance and move and their entire year of utilization may not be captured in the APCD claims.
- Under federal and state privacy laws, information about drugs with fewer than 12 utilizers in the database must be protected, as it is potentially identifiable at such low numbers. Where utilization is below 12 individuals there will be less information available.
- One commercial payer reported inaccurate units for pharmacy claims. These units were removed, and any calculations using units did not include units from this payer. Dollar amounts and utilization information was reported accurately by this payer and were not removed. The only data element in the affordability review that incorporates units is the course of treatment calculation, which excludes this payer and is therefore an underestimate of the course of treatment.
- Pharmacy claims do not include diagnosis codes. As such, utilization and paid amount analyses were conducted for all Enbrel utilization and separate analyses were not conducted for each FDA-approved indication.

First DataBank AnalySource

AnalySource provides WAC and other pricing benchmarks for all NDCs at current rates and historic levels. Enbrel NDC codes found in AnalySource are listed in table P-1 above.

Limitations

- WAC and other data elements from AnalySource are proprietary and confidential and may only be disclosed through secure channels and may only be discussed by the Board in Executive Session.
- WAC data is updated daily, but other data sources have a greater time lag, meaning that there are NDCs for which there is WAC data, but no utilization data. It is noted when these are included

SSR Health

- Board staff contracted with SSR Health[2] to receive their proprietary U.S. prescription brand drug pricing and analytics net price database, which provides total net revenue and volume estimates for the majority of active brand name prescription drugs in the United States. SSR Health uses net revenues from publicly-available SEC Form 10-K financial reports from drug makers or other public sources to develop a net sales and gross-to-net estimates quarterly for all drugs.[3] The gross-to-net estimates provide a quarterly estimated gross-to-net percent rebate that is inclusive of all concessions and discounts that manufacturers deduct from gross sales. This is inclusive of all rebates, 340B discounts, and point of sale copayment support. SSR Health provides these estimates on a total, statutory Medicaid, and total less statutory Medicaid basis.

Limitations

- Estimates are proprietary and confidential and may only be disclosed through secure channels and may only be discussed by the Board in Executive Session.
- Gross-to-net sales estimates are inclusive of all concessions and discounts that manufacturers deduct from gross sales. This is inclusive of all rebates, 340B discounts, and point of sale copayment support, but cannot provide detailed amounts on these discounts.
- Estimates are for national information and are not specific to Colorado.