COLORADO
Prescription Drug Affordability Board
Division of Insurance

2023 Affordability Review Summary Report: Genvoya

February 23, 2024

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Executive Summary

Affordability Review Summary Report Findings

Genvoya, first approved by the United States Food and Drug Administration in 2015, is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed. The relevant professional medical guidelines identify the following single-dose, in-class therapeutic alternatives for Genvoya: Stribild, Triumeq, Biktarvy, and Dovato. 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.

These stakeholders also noted HIV-1 is distinct from other conditions because HIV can be a communicable disease if not managed properly, making the condition a public health concern. Further, while new HIV diagnoses have declined nationally, there has been a rise in both the number and rate of new HIV diagnoses from 2015-2019 in Colorado, where some priority populations have experienced a disproportionate increase in new diagnoses. The Colorado Department of Public Health and Environment (CDPHE) and other organizations have developed a strategic plan, in part to address this increase in new diagnoses, focusing on prevention, improving outcomes, disrupting and reducing inequities, and achieving integrated, coordinated efforts.

Recommended treatments for HIV are complex and depend on a number of factors, including how long someone has been diagnosed and co-occurring conditions. Clinical guidelines for antiretroviral therapy take into account these factors and make recommendations for medications based on the strength of clinical evidence from best to moderate to weak. Recommendations for Genvoya vary depending on the specific clinical profile of a patient and most commonly are given a moderate recommendation based on the strength of evidence.

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. Genvoya's wholesale acquisition cost has increased 54.46%, from [redacted] per unit at its launch in November 2015 to [redacted] per unit in January 2024, which is greater than the increase in inflation for the same time period. Three of 19 insurance carriers who submitted information to the Colorado All Payer Claims Database (APCD) reported that Genvoya was one of the top 15 prescription drugs that raised premiums for all covered lives. Genvoya is one of the prescription drugs listed as a potential drug for importation in the Colorado Department of Health Care Policy & Financing's (HCPF) Section 804 Importation Program application, which is currently awaiting federal review. HCPF estimates importing Genvoya from Canada would result in nearly $11 million annual savings.

In 2022, Genvoya was the second most utilized drug (879 patients) compared to its in-class therapeutic alternatives, Biktarvy (4,183), Triumeq (738), Dovato (494), and Stribild (20), and has seen a decrease in utilization from 2018 (1,889) to 2022. According to 2022 APCD data, Genvoya cost $32,196 per patient and over $28,300,194 in total. In that year, the average annual out-of-pocket cost for patients with commercial insurance was $1,431 annually, though there is evidence that patients with HIV-1 may have average out-of-pocket costs that are lower than this figure due to assistance programs. In addition to assistance programs offered by manufacturers, non-profits, and discount retail pharmacies, patients in Colorado may utilize discounts offered to patients receiving services from providers who receive federal funding from the Ryan White HIV/AIDs Program (RWHAP).

In 2023, it is estimated that [redacted] of Gilead Science Inc.'s national gross sales for Genvoya was spent on rebates, 340B discounts, manufacturer financial assistance programs, and other price concessions. National net revenue for Genvoya decreased from $2.879 billion in 2021 to $2.404 billion in 2022, which may be partly explained by decreases in Genvoya's utilization.

The following report and its appendices provide detailed evidence necessary for the Board's consideration of whether Genvoya 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 Genvoya affordability review. The Board then deliberated whether the use of Genvoya was unaffordable for Colorado consumers.

During deliberations, Board members noted that availability of federal and state patient cost assistance programs, patient out-of-pocket costs, and downward utilization trend provided evidence that the drug is not unaffordable to patients in Colorado at this time. Specifically, deliberation included discussion of:

- Significant reduction in utilization because other medications became available that were viewed as being better tolerated or more effective;
- Reduction in utilization may continue as newer drugs are introduced;
- Broad coverage from state and federal assistance programs and other programs which include people earning up to 500% of the federal poverty level and those who are uninsured or undocumented; and
- Average patient's out-of-pocket costs have not risen significantly in the past few years.

After deliberations and hearing public comment from six individuals, the Board voted 4-0 that the use of Genvoya consistent with the labeling approved by the FDA or with standard medical practice is not 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, Genvoya.

This report of the affordability review for Genvoya 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.[1] 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 six patients and caregivers at one public meeting on September 20, 2023 and one small-group meeting. Additionally, 22 patients and caregivers completed surveys regarding the health and financial effects of Genvoya, and some of these patients and caregivers also attended the public meetings.
- Input from individuals with scientific and medical training - Board staff gathered input from four individuals with scientific or medical training at one public meeting on September 20, 2023 and two small group meetings. Additionally, one individual with scientific & medical training completed surveys regarding the health and financial effects of Genvoya.
- Voluntarily submitted information - two patients, caregivers, and other entities submitted voluntary information. Gilead Sciences Inc. the manufacturer of Genvoya, also voluntarily submitted 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 Genvoya's clinical efficacy and the people who use it. This section provides information regarding Genvoya'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.

Access to Care Profile

The Access to Care Profile examines potential access to care concerns related to Genvoya and whether there is evidence that the causes of access to care concerns may be related to Genvoya's price or cost. This profile includes an examination of potential relationships of changes between utilization, price, and costs as

[1] Throughout this report different terminology is used to both refer to people living with HIV (PLHIV), as well as PLHIV who are or were specifically taking Genvoya. As seen in this affordability review and other documents supporting the PDAB's work, the term "utilizer" or "patient" is often used to refer to data from the APCD. Additionally, there are times where Board staff have not changed terminology used by stakeholders or published in research. Examples of this include individuals with scientific and medical training using the term "patient" or altering the race and ethnicity language used in research pulled for the Health Equity Literature Review.

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.

Price and Cost Profile

The Price and Cost Profile includes information on what different entities on the prescription drug supply chain charge for Genvoya, as well as what different entities pay for Genvoya. This profile also contains information on Genvoya'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.

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.

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).
Appendix K:	The Board may consider estimated manufacturer net-sales or net-cost amounts (including

Component Name	Component Details
Rebates, Discounts, and Price Concessions	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).

Genvoya Therapeutic and Utilization Profile

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

Indication

Genvoya has one FDA-approved indication for treatment: Human Immunodeficiency Virus or HIV. Genvoya is a four-drug combination of elvitegravir (EVG), an HIV-1 integrase strand transfer inhibitor (INSTI), cobicistat (COBI), a CYP3A inhibitor, and emtricitabine (FTC) and tenofovir alafenamide (TAF), both HIV-1 nucleoside analog reverse transcriptase inhibitors (NRTIs), and is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 25 kg who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Genvoya.[2]

[2] https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/207561s029lbl.pdf

Hiv.gov describes HIV as a virus that attacks cells that help the body fight infection, making a person more vulnerable to other infections and diseases. It is spread by contact with certain bodily fluids of a person with HIV, most commonly during unprotected sex or through sharing injection drug equipment.[3] If left untreated, HIV can lead to the disease AIDS (acquired immunodeficiency syndrome). While the human body can't get rid of HIV and no effective HIV cure exists, effective treatment with medication can reduce the amount of HIV in the blood (also called the viral load) to a very low level called viral suppression.[4] If a person's viral load is so low that a standard lab can't detect it, it is referred to as being an undetectable viral load. People with HIV who take HIV medicine as prescribed and get and keep an undetectable viral load can average lifespans and will not transmit HIV to their HIV-negative partners through sex.[5]

Symptoms related to acute HIV infection (when a person is first infected; Stage 1) can be similar to the flu or other viral illnesses.[6] They include:

- Fever and muscle pains
- Headache
- Sore throat
- Night sweats
- Mouth sores
- Swollen lymph glands
- Diarrhea

While many people have no symptoms during the first stage of HIV, it progresses over weeks or months to become chronic or asymptomatic (Stage 2; no symptoms). This stage can last 10 years or longer, during which a person might have no reason to suspect they have HIV, but can spread the virus to others. If an individual is not treated, almost all people infected with HIV will develop AIDS (Stage 3). Some people develop AIDS within a few years of infection, while others remain completely healthy after 10 or even 20 years.[7]

HIV.gov estimates that approximately 1.2 million people in the U.S. have HIV, with about 13% of them unaware of their diagnosis and need testing.[8] In 2021, an estimated 32,100 new HIV infections occurred in the U.S. Estimated new HIV infections declined 12% from 36,500 in 2017 to 32,100 in 2021. Annual infections in the U.S. have been reduced by more than two-thirds since the height of the epidemic in the mid-1980s.[9] While national trends have shown a decrease in new infections, Colorado has observed a different trend. There has been a rise in both the number and rate of new HIV diagnoses from 2015 - 2019, where in 2019, Colorado's rate of new HIV diagnoses was 8.1 per 100,000 people, with 470 new diagnoses.[10] While outside of the scope of this affordability review, it is worth nothing that CDPHE worked with community partners, recognizing the public health risk new HIV diagnoses poses, to create the Colorado HIV & AIDs Prevention, Care, & Treatment 2022-2026 Strategic Plan that focuses on prevention, improving outcomes, disrupting and reducing inequities, and achieving integrated, coordinated efforts.[11]

Clinical guidelines from the United States Department of Health and Human Services (HHS), Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV, take into account complex clinical

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[3] https://www.hiv.gov/hiv-basics/overview/about-hiv-and-aids/what-are-hiv-and-aids/

[4] https://www.hiv.gov/hiv-basics/overview/about-hiv-and-aids/what-are-hiv-and-aids/

[5] https://www.hiv.gov/hiv-basics/overview/about-hiv-and-aids/what-are-hiv-and-aids/

[6] https://www.pennmedicine.org/for-patients-and-visitors/patient-information/conditions-treated-a-to-z/aids-and-hiv

[7] https://www.pennmedicine.org/for-patients-and-visitors/patient-information/conditions-treated-a-to-z/aids-and-hiv

[8] https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics/

[9] https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics/

[10] https://cohealthviz.dphe.state.co.us/t/STIHIVViralHepatitisPublic/views/HIVinColorado/PublicFacing?%3AshowAppBanner=false&%3Adisplay_count=n&%3AshowVizHome=n&%3Aorigin=viz_share_link&%3AisGuestRedirectFromVizportal=y&%3Aembed=y

[11] https://drive.google.com/file/d/1V4mRtzf-LA2y9DjlZrrED6Yvu01o1yxg/view

factors and make recommendations for medications based on the strength of clinical evidence from best to moderate to weak. Recommendations for Genvoya vary depending on the specific clinical profile of a patient and most commonly are given a moderate recommendation based on the strength of evidence. Genvoya is listed as an alternative, not preferred, regimen for adolescents and adults with a new HIV diagnosis. Additionally, these guidelines highlight that Genvoya is a regimen that should be taken with food, as well as highlighting that Genvoya has been associated with dyslipidemia (abnormally elevated cholesterol or fats (lipids) in the blood.[12]

Utilizer Profile

Genvoya's utilization decreased from 2018-2022, with 879 individuals utilizing Genvoya in 2022, according to Colorado's All Payer Claims Database (APCD). Additionally, data from the APCD indicates that patients who utilize Genvoya are most commonly insured through commercial insurance, followed by Medicaid, then Medicare Advantage.[13] 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 Genvoya

Drug Name	2018	2019	2020	2021	2022
Genvoya	1,889	1,510	1,098	1,017	879

Table 2 shows the number of utilizers of Genvoya by year from 2018 - 2022. From 2018 to 2022 there was a 53.47% decrease in the number of patients utilizing Genvoya.

[12] https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf

[13] Utilization information in this section is from the Colorado All Payer Claims Database (APCD). APCD data limitations are outlined in Appendix P.

Figure 1
Genvoya Utilization by Payer Type

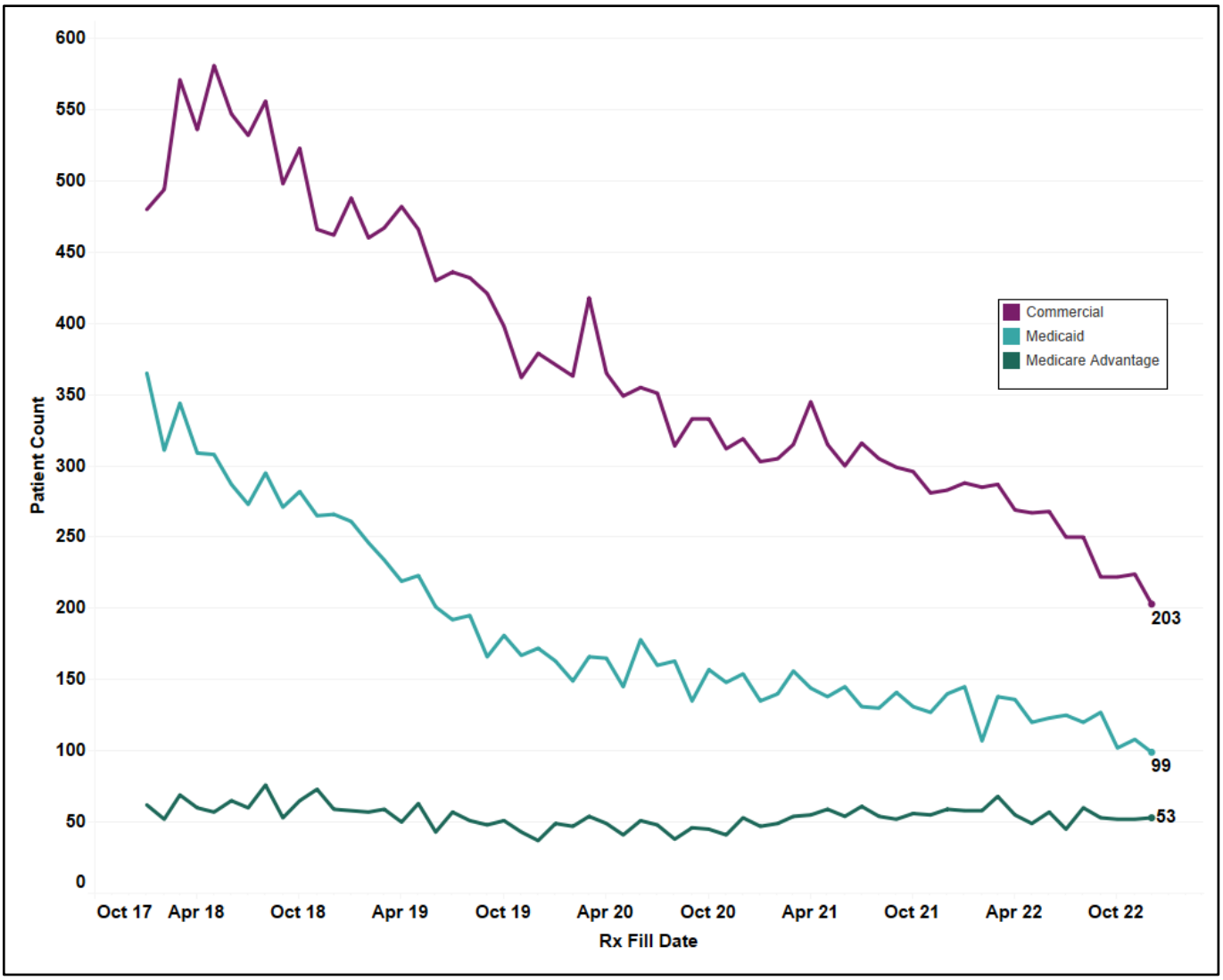


Figure 1 shows the monthly number of patients who filled a prescription for Genvoya each month between January 2018 and December 2022, where the purple line represents the number of commercially insured patients, the teal line shows the number of Medicaid patients, and the green line shows the number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

Figure 2
Insurance Information

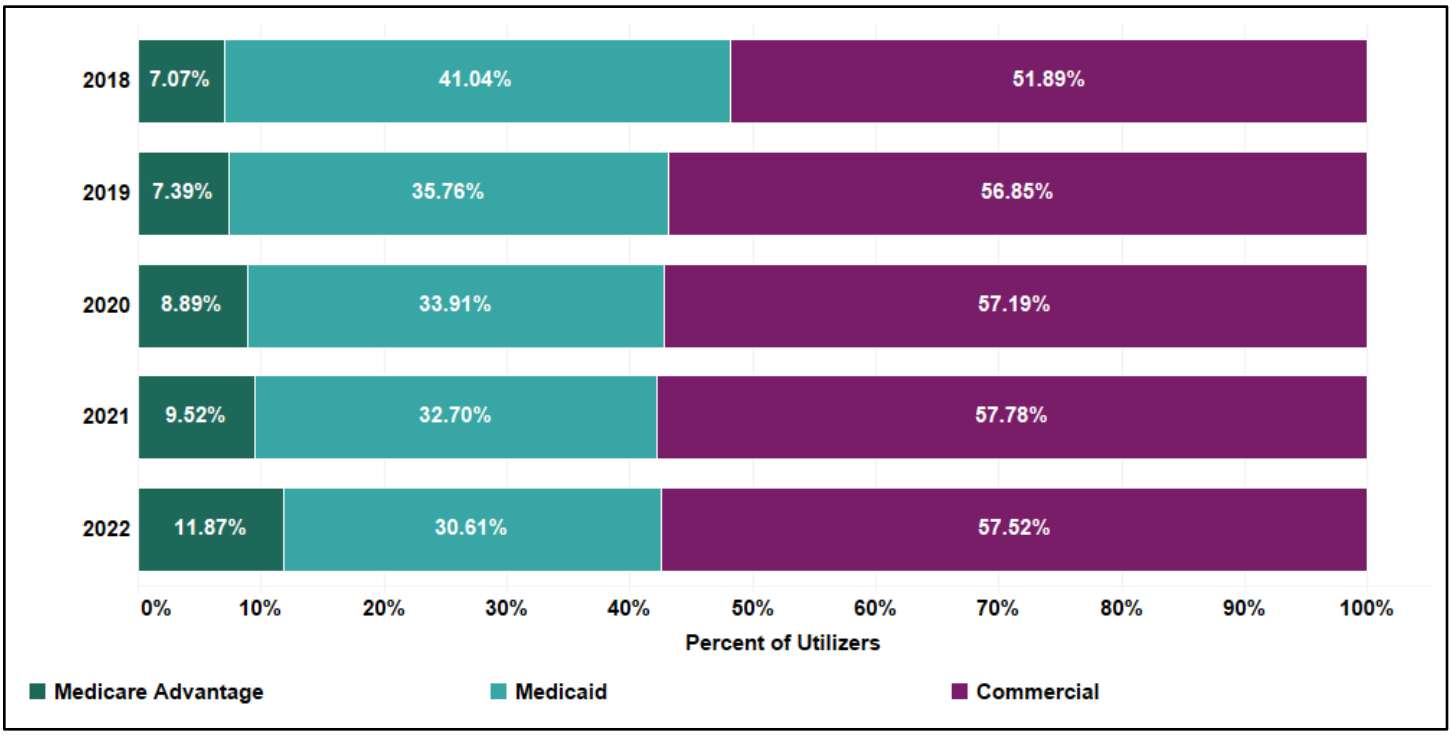


Figure 2 shows Genvoya payer mix percentages from 2018-2022. This figure shows the percent of patients by payer type and year where green represents patients with Medicare Advantage, Teal represents patients with Medicaid, and purple represents patients with commercial insurance. Commercial and Medicare Advantage have both slightly increased in portion of coverage each year.

Health Equity Impact

Obtaining prescription drug-specific information regarding health equity can be a complex task. There is evidence that priority populations[14] 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.[15] 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. However, in the case of Genvoya, there is data regarding HIV. A health equity literature review was conducted and summarized below. See Appendix L for more information.

Black/African American and Hispanic/Latino communities are disproportionately affected by HIV compared to other racial/ethnic groups. In 2021, Black/African American individuals aged 13 and older represented approximately 12% of the U.S. population, but accounted for 40% of people with HIV. Hispanic/Latino persons aged 13 and older represented 18% of the population but accounted for 25% of people with HIV. Gilead Sciences Inc. provided Colorado-specific information that Hispanic/LatinX who make up 22.3% of the Colorado population, are disproportionately impacted by new HIV diagnoses (32%) as shown by the AIDSVu

[14] 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.

[15] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10037618/#:~:text=In%20comparison%20to%20the%20general,16%2C17%2C18%5D.

Colorado data and Black individuals, who make up 4.1% of the Colorado population, are disproportionately represented in both new HIV diagnoses (16.7%) and statewide HIV prevalence (15.2%).

Gay, bisexual and other men who have sex with men (MSM) are the most affected group in the United States by HIV, accounting for 70% of the 32,100 estimated new infections in 2021, even though this population made up only 2% of the overall population, with the highest burden among Black and Latino gay and bisexual men. In 2021, adult and adolescent transgender people and people of additional gender identity were 2.5% (912) of new HIV diagnoses in the United States, despite being approximately 1% of the total US population.

In addition to the information highlighted above and further expanded on in Appendix L, the Board may also want to weigh information from Appendix H: Input from Patients and Caregivers, Appendix I: Input from Individuals with Scientific and Medical Training, and Appendix J: Voluntarily Submitted Information when evaluating the health equity impacts of Genvoya.

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 Genvoya 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 Genvoya and health equity. Rather, it is meant to be a contextual snapshot to better understand if the typical patient who uses Genvoya lives in a county that has a higher vulnerability to adverse outcomes due to social conditions than the average Colorado county.

In 2022, 60.07% of patients who filled a prescription for Genvoya lived in a county with an SVI score above the statewide average of 49.95%, meaning that 60.07% of Genvoya patients lived in a county with higher social vulnerability. This could indicate that patients who utilize Genvoya 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. See Appendix L for more information.

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

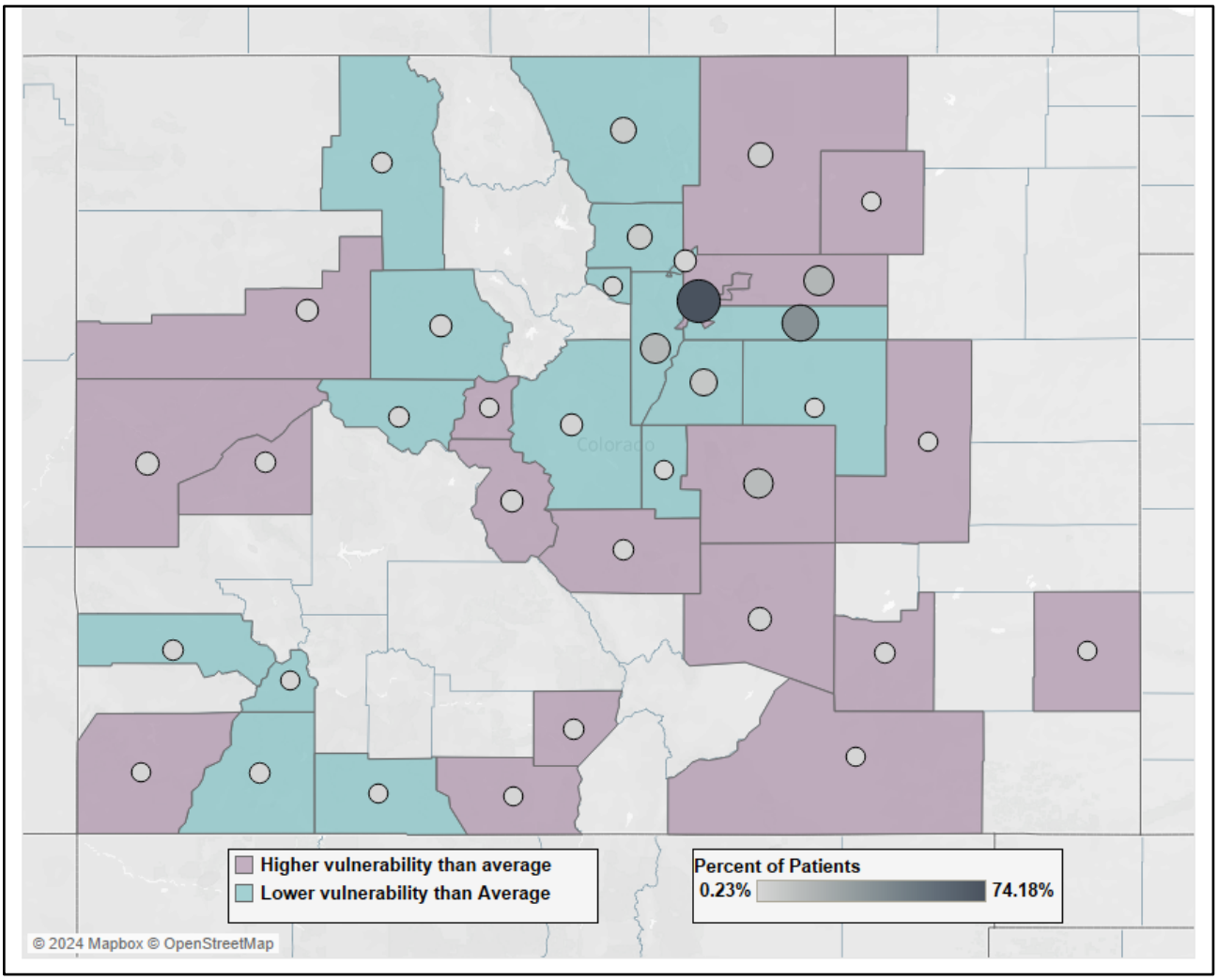


Figure 3 shows the state of Colorado by county, where purple counties indicate higher than average SVI scores and teal counties indicate a lower than average SVI score, and counties without color did not have any patients who used Genvoya in 2022 residing in them. The dots on each county show the percent of patients who used Genvoya 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 patient and caregiver input through public meetings, a small-group meeting, and an online survey aimed at gathering information regarding the health and financial effects of Genvoya.

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. Additionally, during the October 27, 2023 Board meeting, the Board directed staff to only examine single-pill regimens that were in-class therapeutic alternatives. The resulting in-class

therapeutic alternatives are summarized in Table 3 below. Information related to Genvoya's therapeutic alternatives is contained throughout this summary report and appendices.

Table 3
Genvoya Therapeutic Alternatives Details

Non-proprietary name	Brand Name	Mechanism of Action	FDA Approval Date
elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate	Stribild	Integrase Strand Transfer Inhibitor, Two Nucleoside Reverse Transcriptase Inhibitors, Booster	8/27/2012
dolutegravir/lamivudine/abacavir	Triumeq	Integrase Strand Transfer Inhibitor and Two Nucleoside Reverse Transcriptase Inhibitors	8/22/2014
bictegravir/emtricitabine/tenofovir alafenamide	Biktarvy	Integrase Strand Transfer Inhibitor and Two Nucleoside Reverse Transcriptase Inhibitors	2/7/2018
dolutegravir/lamivudine	Dovato	Integrase Strand Transfer Inhibitor and OneNucleoside Reverse Transcriptase Inhibitors	4/8/2019

Table 3 shows details of Genvoya's therapeutic alternatives and FDA approval dates.

Utilization information for Genvoya and therapeutic alternatives is outlined below. While Genvoya, Triumeq, and Stribild saw utilization decreases, Biktarvy and Dovato saw utilization increases.

Table 4
Utilization of Genvoya and Identified Therapeutic Alternatives

Drug Name	2018	2019	2020	2021	2022
Genvoya	1,889	1,510	1,098	1,017	879
Biktarvy	845	2,164	2,815	3,770	4,183
Dovato		66	199	376	494
Stribild	107	53	31	24	20
Triumeq	1,066	981	853	822	738
Total[16]	3,907	4,774	4,996	6,009	6,314

Table 4 shows the number of utilizers of Genvoya and therapeutic alternatives by year from 2018 - 2022.

[16] The total utilizer count has distinct utilization by drug, but any individual who changed between these drugs throughout the year will be counted twice (or as many of these drugs as they filled prescriptions for) in the total estimate.

Figure 4
Insurance information for Therapeutic Alternatives

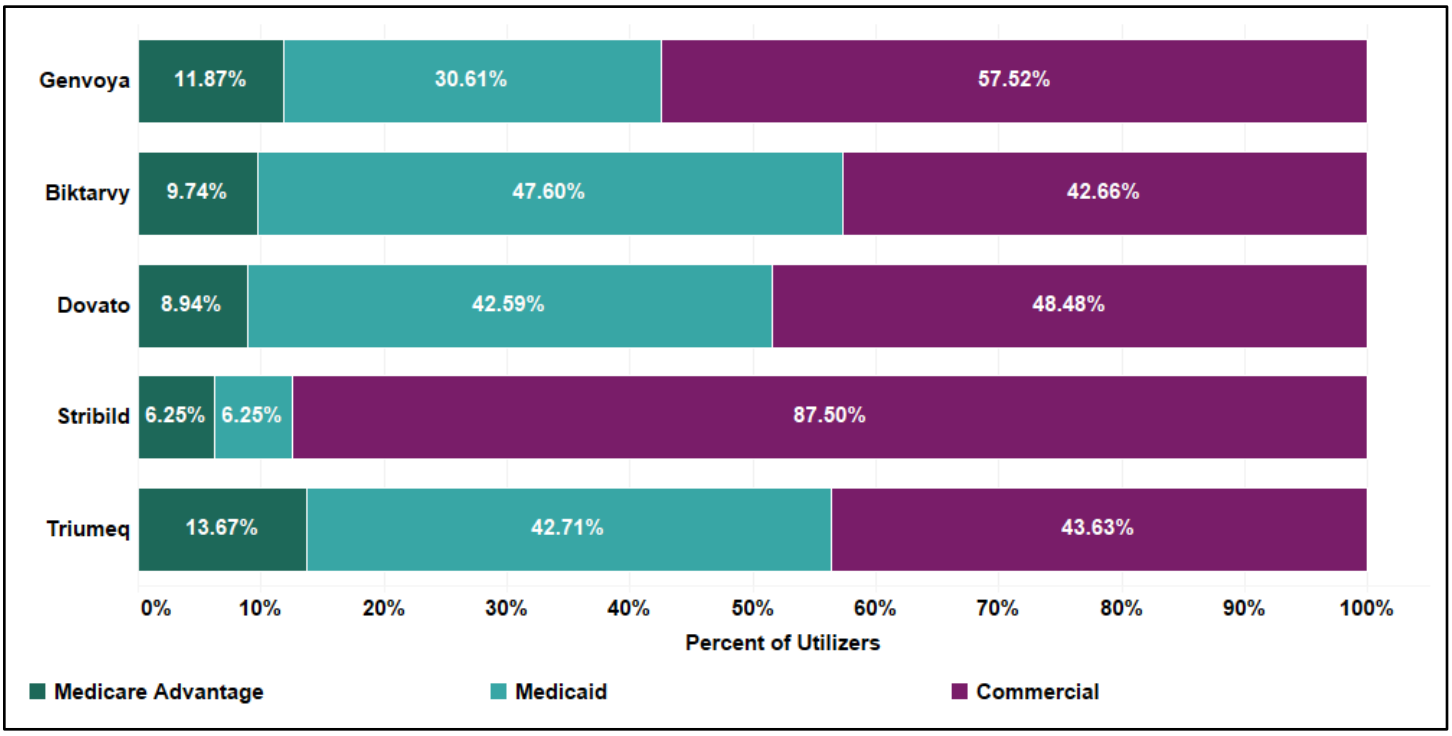


Figure 4 shows the 2022 payer mix for Genvoya and its identified therapeutic alternatives. This figure shows the percent of patients by payer type and year where green represents patients with Medicare Advantage, teal represents patients with Medicaid, and purple represents patients with commercial insurance. Genvoya has the second highest commercial coverage behind Stribild with 57.52%.

Genvoya Price and Cost Profile

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

Table 5
Genvoya's 2022 Price & Cost per Person Statistics

Price & Cost Per Person Statistics	Amount
Average WAC per Course of Treatment per Person[17]	[redacted]
Average Paid per Person	$32,196
APPY - Plan Paid	$30,728
APPY - Out-of-Pocket[18]	$2,616

[17] 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

[18] 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/

Table 6
Genvoya's 2022 Statewide Price & Cost Statistics

Statewide Price and Cost Statistics	Amount
Total Paid Amount	$28,300,194
Total Plan Paid[19]	$27,009,981
Total Medicaid Paid	$7,337,498
Total Patient Paid	$886,852
Gross-to-net Estimates	[redacted]

The current WAC for Genvoya is [redacted] per unit, with the most recent update to the WAC in January 2024. The initial WAC was $85.92 in November 2015. This is a 54.46% increase from November 2015 to January 2024, a 28.84% increase in the past five years, and a 4.9% increase from 2023 to 2024. The average course of treatment is 287 units per patient per year, making the current WAC per course of treatment [redacted].[20]

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. Three of the nineteen carriers who submitted data reported Genvoya in the top fifteen drugs that caused the greatest increase to premiums and one submitter reported Genvoya in the top five drugs that caused the greatest increase to premiums. Prescription drug transparency data from other states did not indicate Genvoya is among the costliest drugs in the state, nor does it have price increases above specified thresholds. See Appendix O for more information. Genvoya is one of the prescription drugs listed as a potential drug for importation in the Colorado Department of Health Care Policy & Financing's (HCPF) Section 804 Importation Program application, which is currently awaiting federal review.[21] HCPF estimates importing Genvoya from Canada would result in $10,933,487 annual savings. The savings estimate is derived using HCPF's $101.78 per unit for Genvoya and comparing that to Canadian unit prices with a 50% markup ($49.28). See Appendix M for more information. The SEC requires all public companies to file a Form 10-K each year, and a Form 10-Q each quarter.[22] These forms provide a financial snapshot of the company's revenues, assets, and liabilities for the previous year. Gilead Sciences, Inc.'s 2022 10-K details that Genvoya's international Product Revenue decreased from approximately $2.879 billion in 2021 to $2.404 billion in 2022 (p.60). 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 provides data on the patient portion of the claim paid for the drug, but does not contain any information on

[19] 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.

[20] For course of treatment methodology please see June 6, 2023 PDAB Board staff memo: CO PDAB Resources: PDAB Staff Memo - 2023 Colorado PDAB Eligible Prescription Drug Methodology - Updated June 6

[21] https://hcpf.colorado.gov/drug-importation

[22] 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, Gilead Sciences, Inc.,: https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/data/882095/000088209523000007/gild-20221231.htm

assistance programs. Patients and caregivers provided input regarding their experiences with assistance programs through public meetings, surveys, and voluntarily submitted information. Patients, caregivers, and individuals with scientific and medical training specifically called attention to the federal Ryan White HIV/AIDS Program (RWHAP), which provides funding to states to support people living with HIV to get access to medications and other services. See Appendix F, H, I, and J for more information.

The average annual out-of-pocket cost per person per year for individuals with commercial insurance is $1,431. There was wide variation in monthly average out-of-pocket costs, where 45.24% of Genvoya utilizers paid between $0 and $50, though some individuals paid as much as $10,250 - $10,300.[23] 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

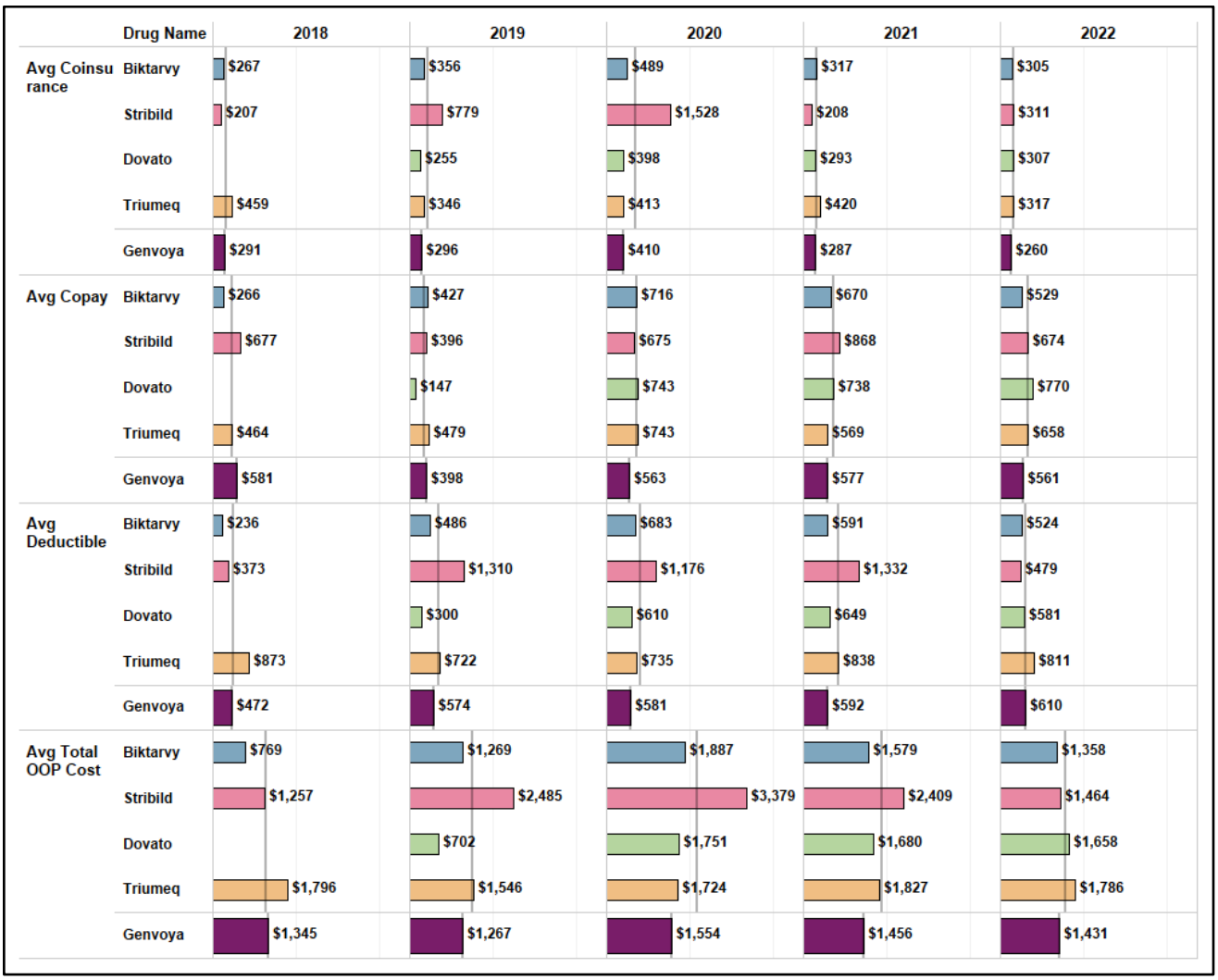


Figure 5 shows each out-of-pocket cost type for commercially insured individuals with Genvoya in dark purple and its therapeutic alternatives by year. A light gray line shows the average of the therapeutic alternatives as a comparison to determine if Genvoya is more or less expensive than the average of its therapeutic alternatives. For example, the bottom right corner shows the average total out-of-pocket cost

[23] 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.

in 2022; Genvoya was $1,431, which is just below the average of the four identified therapeutic alternatives.

Table 7

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

	Genvoya	Biktarvy	Dovato	Stribild	Triumeq
Average Total OOP Cost	**$183**	$174	$207	$149	$205
Average Coinsurance Amount	**$33**	$38	$39	$30	$37
Average Copay Amount	**$75**	$68	$96	$72	$79
Average Deductible Amount	**$75**	$67	$72	$47	$89
Average Days Supply	**45.4**	42.1	39.4	43.4	41.9

Table 7 shows that in 2022, in an average month an individual with commercial insurance paid a total of $183, $75 went towards a patient's deductible, $33 was paid towards coinsurance, and $75 was paid via copayment. These payments were for an average of 45.4 days. Genvoya is higher than Biktarvy and Stribild in total out of pocket payments and is lower than Dovato and Triumeq.

Figure 6

Changes in Commercial Out-of-Pocket amounts by year and drug 2018-2022

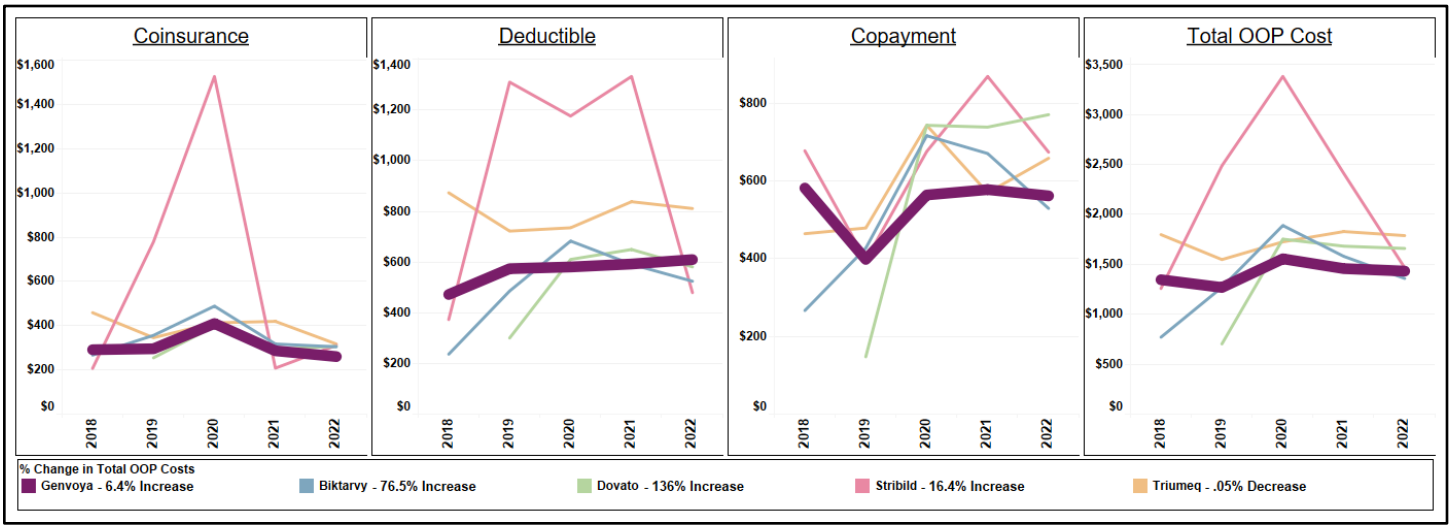


Figure 6 shows the annual change in the annual average oop amounts for individuals with commercial coverage comparing Genvoya (dark purple) to its therapeutic alternatives. Below the graph, the percent change in total out-of-pocket cost from January 2018 - December 2022 for each drug is indicated.

Gilead Sciences Inc. provided information on the Advancing Access and Gilead co-pay coupon card, 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 Appendix J and Appendix K for more information. Board staff received information in surveys that 91% (20 of 22) patients utilize an assistance program, with only one patient having trouble affording Genvoya despite assistance programs. 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.[24] The gross-to-net sales estimate was [redacted] in the fourth quarter of 2015, which increased to [redacted] in the third quarter of 2023. See Appendix K for more information

Figure 7
Estimated Total Gross-to-Net Sales

[redacted]

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

Genvoya'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 Genvoya'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

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

(Appendix I), and voluntarily submitted information (Appendix J). These summaries are structured to focus first on Genvoya's health effects, followed by financial effects.

Genvoya's Health Effects

The FDA label provides information on Genvoya'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.

When asked about health outcomes of Genvoya, the majority of patients said their treatment goal was to remain undetectable and to achieve overall physical health. Thirteen of 22 patients reported that Genvoya kept them undetectable, while five respondents said Genvoya did not work for them or gave them serious side effects. Meeting attendees spoke to the importance of whole-person wellness in addition to medical outcomes when treating patients with HIV. Additionally, meeting attendees discussed the differences in Genvoya and the other drugs under review, namely that Genvoya treats a communicable disease and interruptions in treatment could lead to worries of a broader public health issue. Meeting attendees discussed the importance of patient choice and the critical need for access to multiple medications due to drug resistance. Meeting attendees also discussed the stigma surrounding HIV and the importance for community to have trust, self-determination, and to share in clinical decision making.

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 Genvoya. 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, provide evaluations of both clinical and cost effectiveness of prescription drugs. HTAs can provide consistent and thorough assessments of a prescription drug' clinical effectiveness. A summary of these organizations, the country where they are found, and their conclusions regarding the clinical effectiveness of Genvoya are outlined in the table below.

Table 8
Genvoya Health Effectiveness Analyses by HTA organizations

Institute or Organization (Country)	Summary of Health Effects Findings[25]
CADTH (Canada)	From CADTH - *CDR CLINICAL REVIEW REPORT FOR GENVOYA, 2015, pp 35*[26] In two RCTs, EVG/COBI/FTC/TAF was shown to achieve statistically similar rates of VL suppression compared with EVG/COBI/FTC/TDF among treatment-naive adults with HIV infection after 48 weeks of treatment. In a third RCT, the switch to EVG/COBI/FTC/TAF from another FTC/TDF-containing regimen among virologically suppressed patients was associated with significantly higher rates of virologic suppression at 48 weeks compared with continued therapy with the existing regimen. EVG/COBI/FTC/TAF was associated with relatively similar rates of AEs as the comparator in these trials, among which diarrhea, nausea, URTIs, and headache appeared to be the most common. While EVG/COBI/FTC/TAF had smaller effects on kidney function (eGFR) and BMD compared with EVG/COBI/FTC/TDF, the observed changes are unlikely to be clinically significant in the short term and are of uncertain importance with respect to the risks for kidney failure or fracture in the long term. EVG/COBI/FTC/TAF also demonstrated high rates of virologic suppression in a single-group study of patients with mild to moderate kidney impairment, with minimal changes in median eGFR. High rates of virologic suppression were also observed in a small, single-group trial of treatment-naive adolescents; however, in the absence of a comparative trial against EVG/COBI/FTC/TDF or another STR, there is greater uncertainty

[25] Information in this table are direct quotes from studies referenced in Appendix D.

[26] https://www.cadth.ca/elvitegravircobicistatemtricitabinetenofovir-alafenamide

Institute or Organization (Country)	Summary of Health Effects Findings[25]
	regarding relative efficacy and safety in this population compared with adults.
IQWiG (Germany)	From IQWiG - *Elvitegravir/cobicistat/emtricitabine/ tenofovir alafenamide (HIV-1 infection [children ≥ 2 to < 6 years and with a body weight of ≥ 14 kg]) – Benefit assessment according to §35a SGB V, 2023*[27] Since no relevant study is available for the benefit assessment, there is no hint of an added benefit of EVG/COBI/FTC/TAF in comparison with the ACT for either research question; an added benefit is therefore not proven.

Table 8 shows a summary of health effects findings from HTA organizations. See Appendix D for more information and citations.

Genvoya'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 Genvoya'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 Genvoya 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
Patient Responses: How does Genvoya impact each patient or their family?[28]

Survey Prompt	Patient Responses
This medication reduces the amount of time and money going to the doctor.	13 of 22
This medication reduces the amount of time and money spent going to the hospital or needing surgery.	4 of 22
This medication allows me to work and support my family.	10 of 22
Due to the cost of this medication, I have had to cut costs in other areas of my life.	4 of 22
Out-of-pocket costs have caused me to accrue medical debt.	0 of 22

Similar to Table 9 above, Board staff conducted literature reviews to compile evidence of the cost effectiveness of Genvoya, with only CADTH containing information. See Appendix D for more information.

[27] https://www.iqwig.de/download/a22-116_elvitegravir-cobicistat-emtricitabine-tenofovir-alafenamide_extract-of-dossier-assessment_v1-0.pdf
[28] 3 of 22 survey participants did not answer regarding the impact Genvoya has on the patient or their family.

Table 10
Genvoya Cost Effectiveness Analyses by HTA organizations

Institute or Organization (Country)	Summary of Financial Effects Findings[29]
CADTH (Canada)	From CADTH Reimbursement Recommendation -*CDR FINAL RECOMMENDATION FOR GENVOYA, 2015, pp1*[30] At the submitted price, EVG/COBI/FTC/TAF is similar in cost or less costly than other single-tablet or commonly used treatment regimens for adolescents ($41.38 to $43.78) and adults ($41.38 to $55.57) with HIV-1 infection.

Table 10 shows a summary of financial effects findings (see Appendix D for more information).

Genvoya Access to Care Profile

The Access to Care Profile examines potential access to care concerns related to Genvoya and whether there is evidence that the causes of access to care concerns may be related to Genvoya'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

Genvoya's WAC has increased eight times since it was approved by the FDA in 2015, increasing a total of 54.45% since introduction, which is greater than the increase in inflation for the same time period (Figure 8 below). See Appendix A for more information. From 2018-2022 APCD data shows fluctuations in average annual patient out-of-pocket costs with an increase from 2018 to 2020, with consistent out-of-pocket costs from 2020-2022. Total patient paid amounts have decreased largely due to the fact that the number of patients utilizing Genvoya has decreased (Table 11 below). See Appendices C and E for more information. Meanwhile, APCD data shows a steady decrease in the utilization of Genvoya and increases in two of its therapeutic alternatives (Figure 9 and Table 11 below). While increases in out-of-pocket costs from 2018 to 2022 for Genvoya may have impacted utilization, there are other reasons utilization may have decreased in APCD data, including patients switching to other therapeutic alternatives or other health insurance coverage. See figure 9 below. See Appendices E and H for more information.

Table 11
Annual Utilization and Expenditures

	2018	2019	2020	2021	2022
Patient Count	1,889	1,510	1,098	1,017	879
Total Paid	$44,957,004	$35,348,480	$31,924,430	$30,977,136	$28,300,194

[29] All cost-effectiveness studies in Table H utilize a cost per quality-adjusted life year (QALY) or similar measure. The Board may consider these studies as a part of affordability reviews, but may not use QALY analyses in determining an upper payment limit or other appropriate costs of Genvoya.
[30] https://www.cadth.ca/sites/default/files/cdr/complete/SR0449_complete_Genvoya-March_22-16_e.pdf

Average Paid Per Person	$23,799	$23,410	$29,075	$30,459	$32,196
Total Patient Paid	$1,477,364	$1,222,750	$1,135,290	$1,012,658	$886,852
Average OOP Cost	$1,994	$2,036	$2,666	$2,619	$2,616
WAC per Unit	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table 11 shows the year-over-year increases in the number of patients using Genvoya, the total amount paid for Genvoya, the average paid per person, the total amount that patients paid, and the average amount that each patient paid.

Figure 8

Percentage Change in WAC (Genvoya) Compared to Annual Inflation

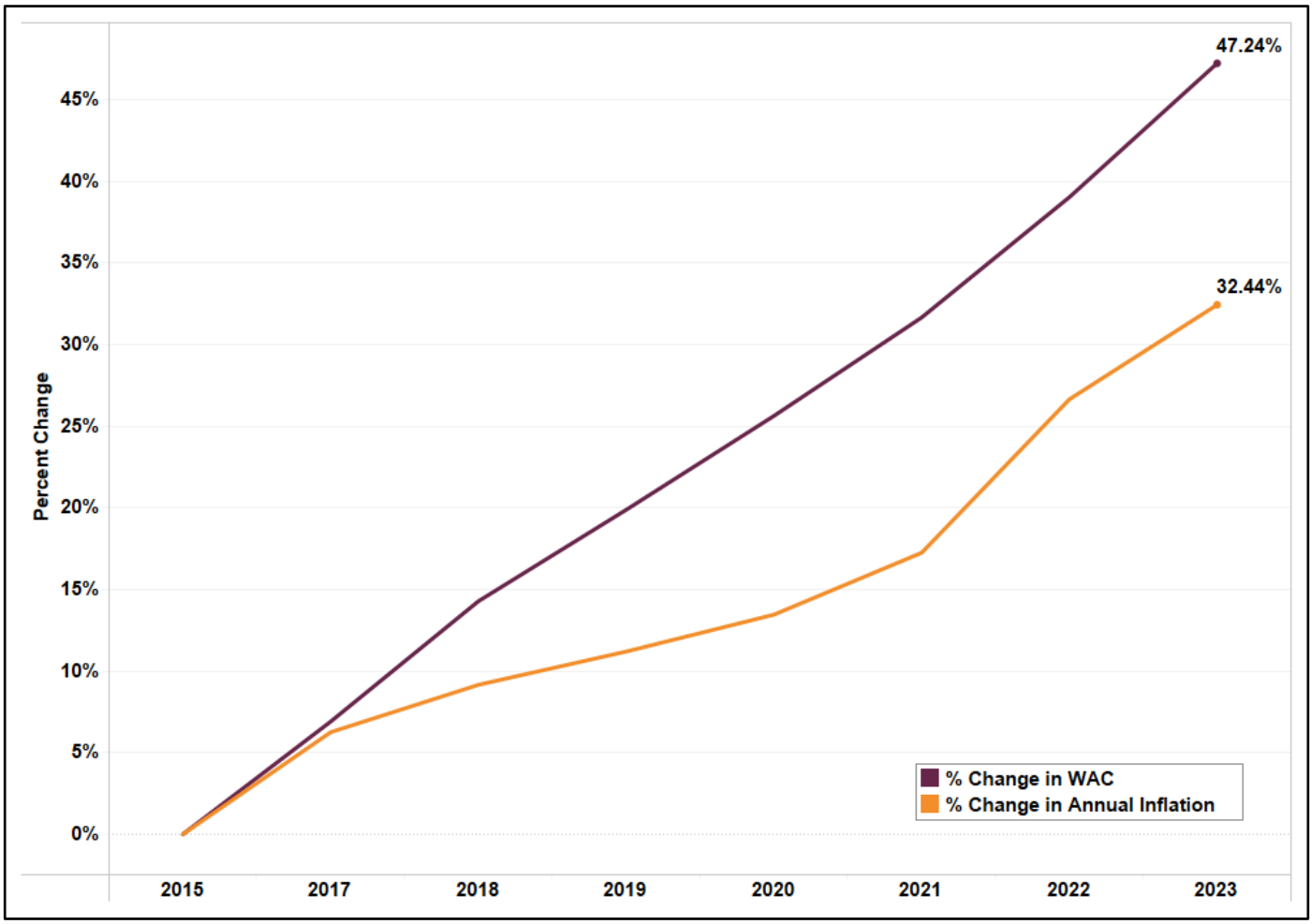


Figure 8 shows the same change in WAC as a percent change (purple) and annual inflation (orange) over the same time frame.[31]

[31] 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 Genvoya and Therapeutic Alternatives

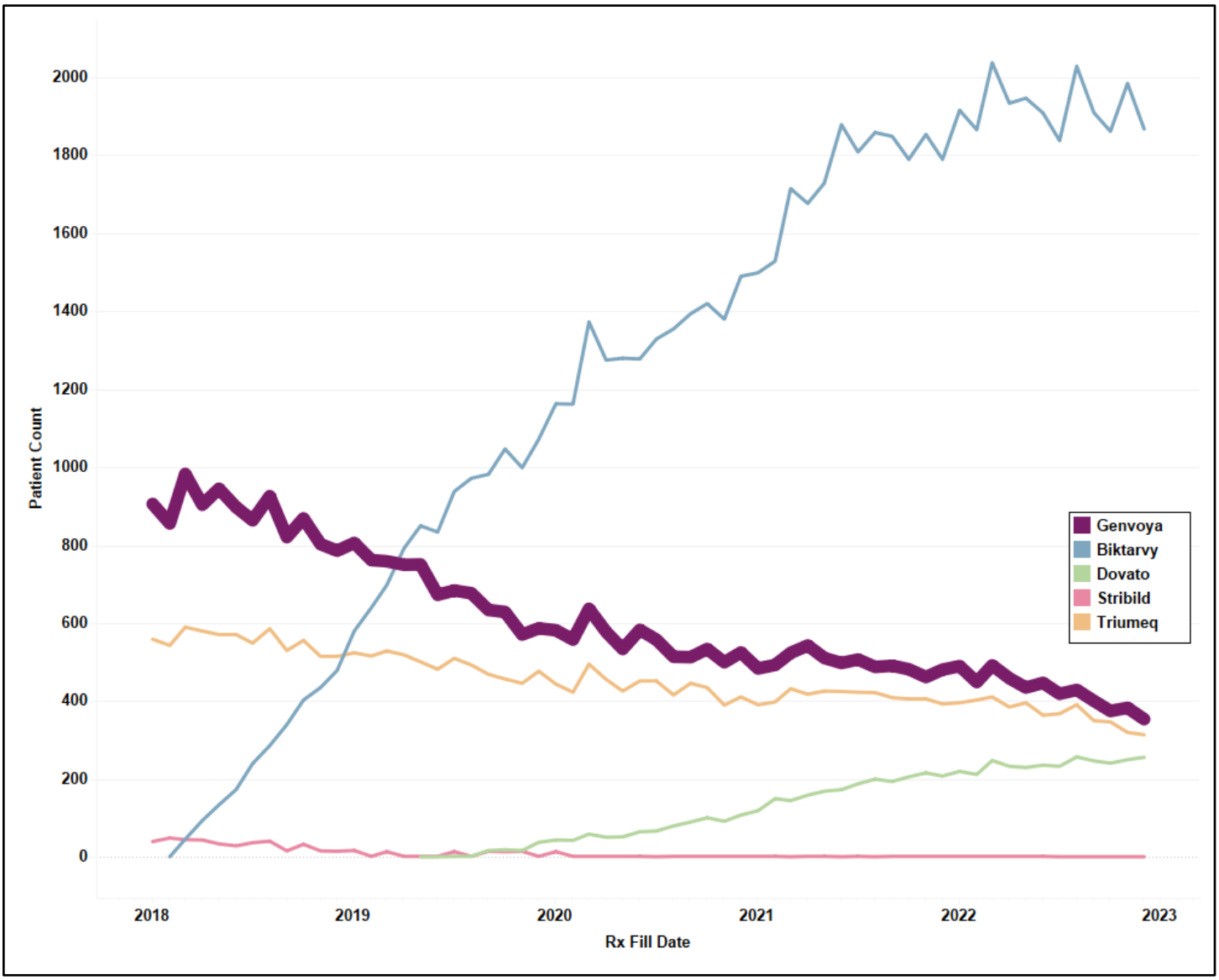


Figure 9 shows the monthly number of utilizers of Genvoya and therapeutic alternatives. Utilization of Genvoya has steadily decreased from January 2019 to December 2022, it is the second highest utilized drug after Biktarvy and is close in the number of utilizers to Triumeq and Dovato.

Figure 10
Monthly Total Paid and Average Total Paid

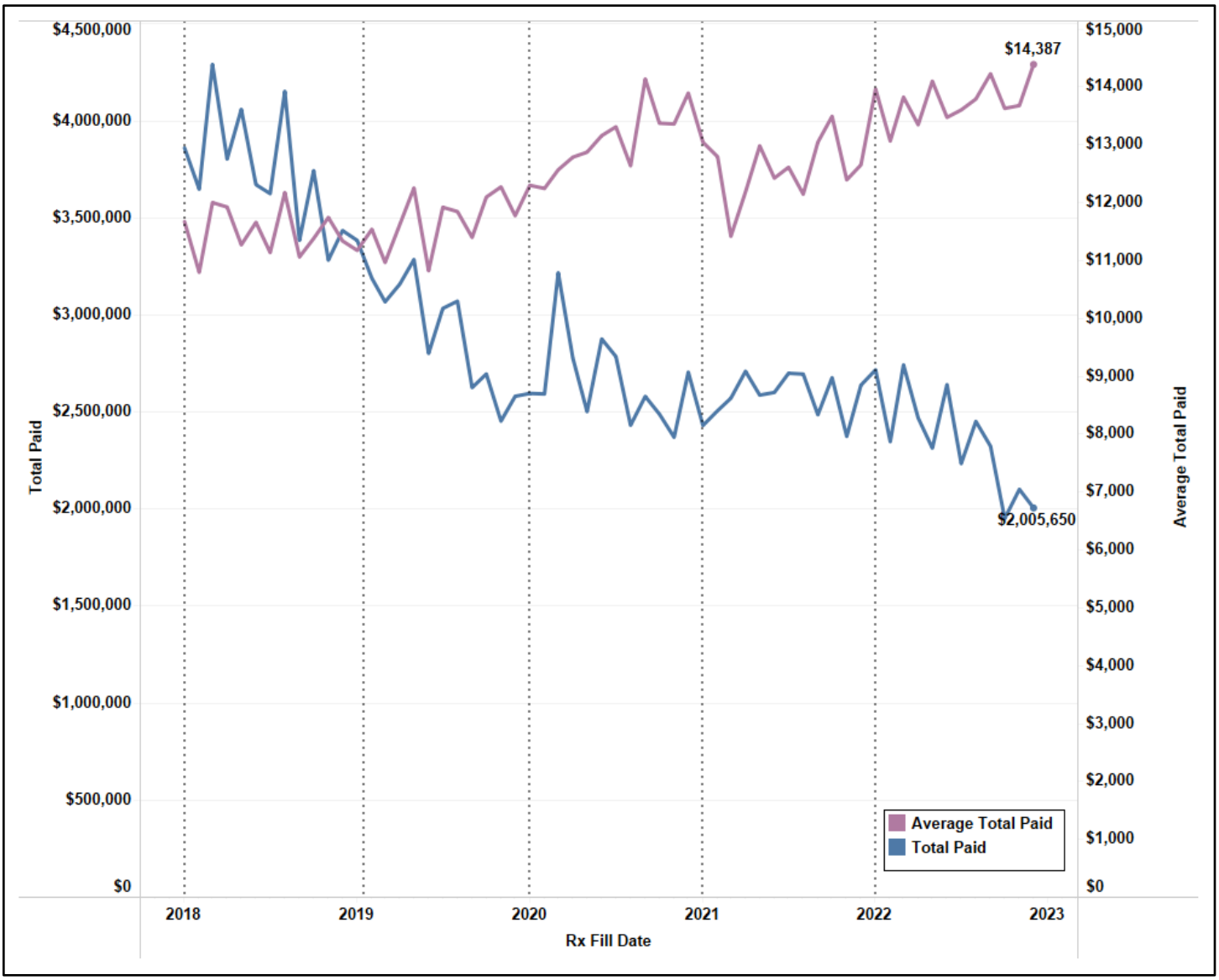


Figure 10 shows the monthly total paid with the blue line (left axis) and the monthly average paid per person with the purple line (right axis) with vertical lines representing increases in WAC. There is no visible correlation between the WAC change and the corresponding change in the APCD paid amounts. During this time frame, the number of patients using Genvoya decreased by 53.46%.

Table 12
Patients' Self-Reported Out-of-Pocket Cost and Access Due to Cost

Out-of-Pocket Cost per Month	Patient Response	Cost Affects Access
$0 - $50	20 of 22	12 of 20 said cost does not affect access. 7 of 20 said cost affects access.
$50 - 100	2 of 22	1 of 2 said cost does not affect access. 1 of 2 said cost does affect access.

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

Patients, caregivers, and clinicians provided input that treatment for HIV may be received at a clinic or provider's office who receives funding from the federal Ryan White HIV/AIDS Program (RWHAP) and that many, if not all, of these clinics are registered as covered entities in the federal 340B Drug Pricing Program administered by the U.S. Health Resources & Services Administration (HRSA). See Appendices F, H, I, and J for more information. These individuals also provided input that these clinics, often referred to as Ryan White Clinics, receive funding for a number of programs, including the State Drug Assistance Program (SDAP) to lower the costs of prescription drugs. The SDAP provides services to help people living with HIV get access to medications and offers assistance with insurance premium payments and covered OOP medical costs. The program is open to Colorado residents living with HIV with incomes equal to or less than 500% of the federal poverty level. See Appendix F for more information.

It is difficult to precisely know how many uninsured patients in Colorado are people living with HIV. indication treated by Genvoya. Twenty one patients who completed surveys identified at least one type of coverage, with one identifying no insurance. See Appendix H for more information.

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

Table 13
Patient responses when asked if they agree with any of the following statements regarding utilization management.[32]

Survey Prompt	Patient Responses
I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	3 of 22
My insurance plan has dropped or switched my drug coverage after the plan year started.	0 of 22
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.	3 of 22
My insurance plan requires prior approval to fill the prescription.	6 of 22
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.	10 of 22
I worry that the cost of my prescription will raise my insurance premium.	5 of 22

Table 13 shows 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.[33] To better understand health benefit plan design coverage and formulary structure, data was

[32] 5 of 22 survey participants did not answer regarding utilization management of Genvoya.
[33] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10398227/#:~:text=The%20intent%20of%20a%20formulary,the%20needs%20of%20patient%20populations.

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.

Utilization management may include practices like step therapy or prior authorization requirements. Colorado Senate Bill 23-189 requires Medicaid and state-regulated commercial plans that cover health services related to sexually transmitted infections include coverage of HIV prevention drugs or cover HIV treatment, like Genvoya, without step therapy or prior authorization requirements.[34] At the federal level, Medicare requires Part D plan sponsors to include on their formulary all drugs in six categories, including antiretrovirals, like Genvoya, and antiretrovirals may not be subject to prior authorizations or step therapy requirements.[35] See Appendix N for more information.

Of the ten carriers in the market, all ten carriers cover this medication with unrestricted access, meaning there is no prior authorization or step therapy. In total, 729 plans provide coverage for Genvoya and the majority of carriers place Genvoya on the middle to lower tiers, meaning a lower portion of the drug is paid by patients than drugs on higher tiers. See Appendix E for more information.

[34] https://leg.colorado.gov/bills/sb23-189

[35] https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-and-part-d-drug-pricing-final-rule-cms-4180-f

Appendix A

Genvoya: 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 Genvoya 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.

[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.

Genvoya: Wholesale Acquisition Cost Evidence

The current WAC for Genvoya is [redacted] per unit, with the most recent update to the WAC in January 2024. The initial WAC was [redacted] in November 2015. This is a 54.46% increase from November 2015 to January 2024, a 28.84% increase in the past five years, and a 4.9% increase from 2023 to 2024. The average course of treatment is [redacted] units per patient per year, making the current WAC per course of treatment [redacted].[2]

If Genvoya were taken in accordance with the FDA label[3], the course of treatment WAC amount for Genvoya would be [redacted] per day (1 unit per per day), [redacted] per month (1 unit per day for 30.437 days), and [redacted] per year (365 units utilized per 365 days). However, utilization and WAC estimates in this appendix reflect utilization reported in the APCD, which can be an under-representation of utilization. See Appendix P for more information.

Table A-1
WAC per Unit: Date, Price, and Percent Increase (Genvoya)

WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	4.80%
[redacted]	[redacted]	4.80%
[redacted]	[redacted]	5.60%
[redacted]	[redacted]	5.90%
[redacted]	[redacted]	4.90%

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

[2] For course of treatment methodology please see June 6, 2023 PDAB Board staff memo: CO PDAB Resources: PDAB Staff Memo - 2023 Colorado PDAB Eligible Prescription Drug Methodology - Updated June 6

[3] https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/207561s029lbl.pdf

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

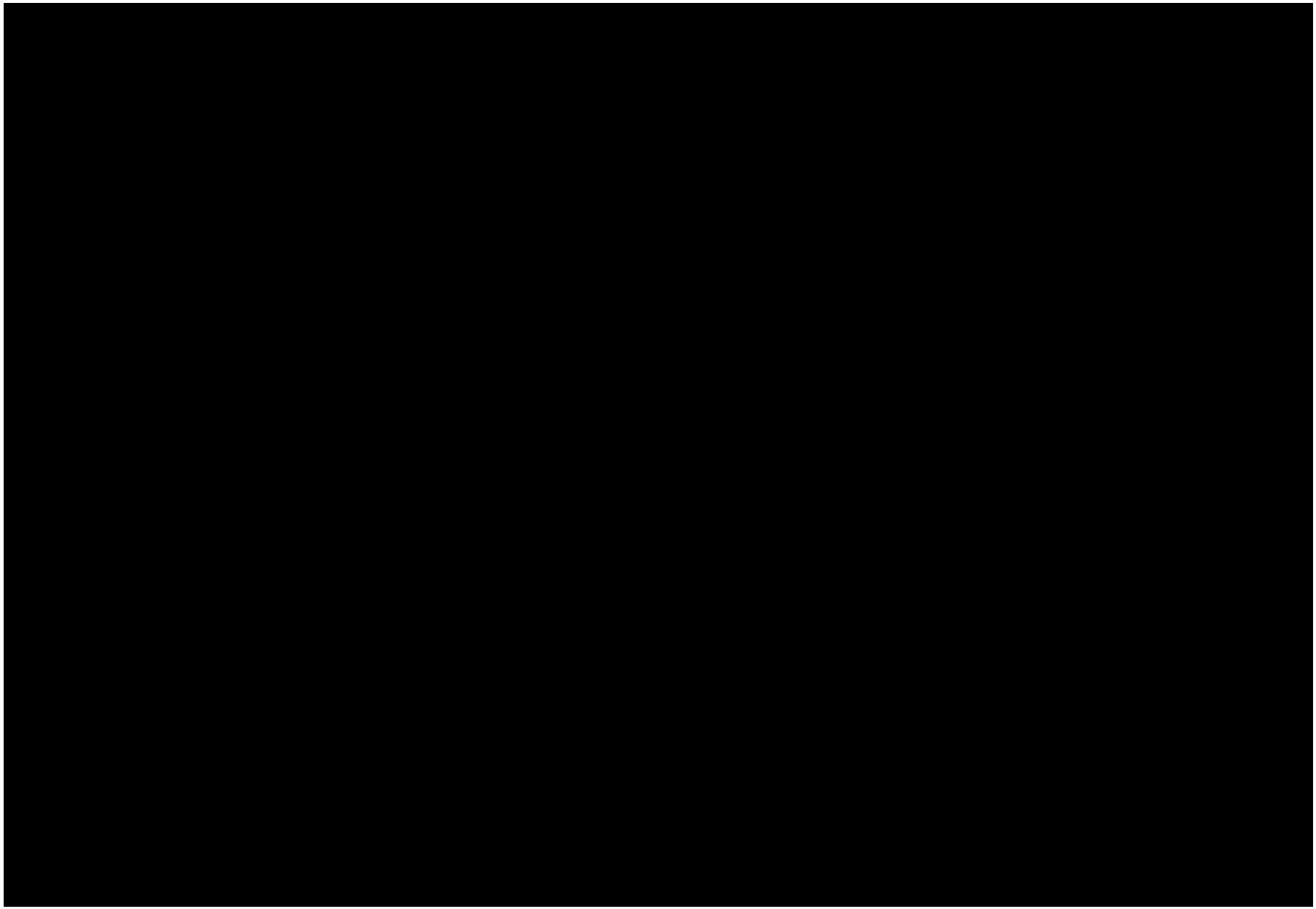
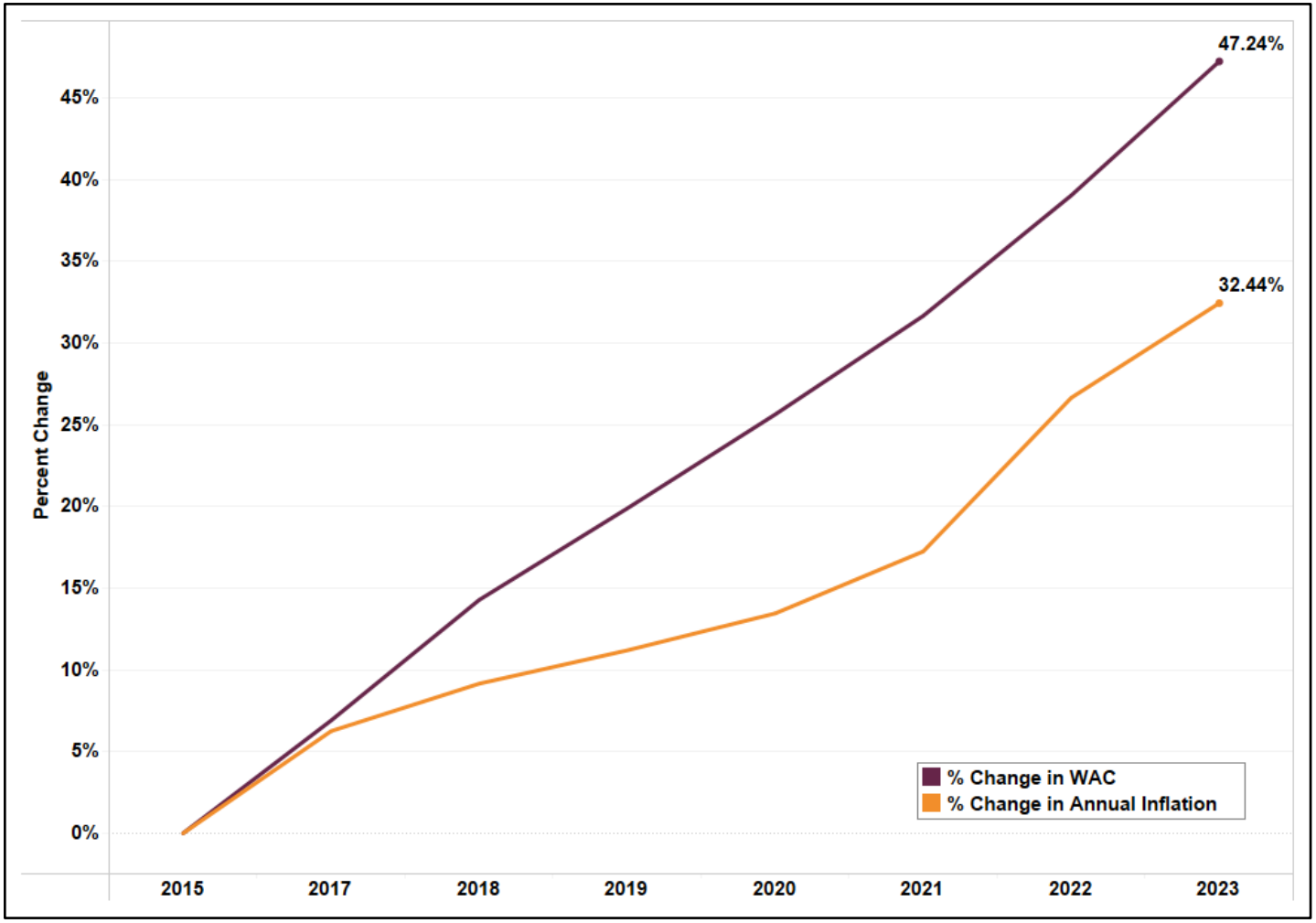


Figure A-1 shows the change in WAC per unit price since its initial WAC price in November 2015.

Figure A-2

Percentage Change in WAC (Genvoya) Compared to Annual Inflation



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.[4]

[4] 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
Changes in WAC for Genvoya and Therapeutic Alternatives

Figure A-3 shows the change in WAC per unit price for Genvoya and identified alternatives. Genvoya and Biktarvy have the same WAC per unit price, which is the second highest WAC per unit after Stribild.

Table A-2

WAC Changes from Initial WAC and Within the Last 5 Years for Therapeutic Alternatives

Biktarvy WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	4.80%
[redacted]	[redacted]	4.80%
[redacted]	[redacted]	5.60%
[redacted]	[redacted]	5.90%
[redacted]	[redacted]	4.90%

Dovato WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	4.94%
[redacted]	[redacted]	4.94%
[redacted]	[redacted]	4.49%
[redacted]	[redacted]	5.94%
[redacted]	[redacted]	5.94%

Stribild WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	38.38%
[redacted]	[redacted]	4.80%
[redacted]	[redacted]	4.80%
[redacted]	[redacted]	5.60%
[redacted]	[redacted]	5.90%
[redacted]	[redacted]	4.90%

Triumeq WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	30.90%
[redacted]	[redacted]	4.94%
[redacted]	[redacted]	4.94%
[redacted]	[redacted]	4.94%
[redacted]	[redacted]	5.94%
[redacted]	[redacted]	5.94%

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

[5] The first percent increase may cover up to 7 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 each identified therapeutic alternative.

Appendix B

Genvoya: 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 Genvoya and identified therapeutic alternatives for the Board's consideration in the following manner:

1. Identified therapeutic alternatives for Genvoya.
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 Genvoya. 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 Genvoya's four identified therapeutic alternatives can be found in Appendices C and E.

[2] Expenditure data for Genvoya'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.

Genvoya: Therapeutic Alternatives Evidence

Therapeutic Alternatives Identification

Members of PORTAL identified therapeutic alternatives in the following manner:

1. Identified the Genvoya'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 Genvoya under this system were evaluated as therapeutic alternatives.
2. Reviewed the current FDA labeling for Genvoya 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 Genvoya 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 identified therapeutic alternative. This date was verified using the Drugs@FDA

[3] https://www.whocc.no/atc_ddd_index/
[4] https://www.wolterskluwer.com/en/solutions/uptodate

database[5]. If drugs 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 Genvoya

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 those therapeutic alternatives that are in the same therapeutic class as Genvoya.[6]

Relevant Medical Professional Guidelines

Genvoya's therapeutic class as defined under the WHO-ATC classification system is Antivirals for treatment of HIV infections, combinations.[7] The following guidelines were used to identify in-class therapeutic alternatives for both of Genvoya's FDA approved indications in Table B-X.

Table B-1

FDA[8] Approved Indications (as of January 17, 2022)	Relevant Guidelines	Guideline Publication Date
Genvoya is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 25 kg who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Genvoya.	Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. 2023.[9] Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. Department of Health and Human Services. 2023.[10]	12/6/2023 1/31/2023

Genvoya Indications and Relevant Guidelines

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

In-Class Therapeutic Alternatives

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

- Stribild
- Triumeq
- Biktarvy
- Dovato

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

[6] The Board also gave staff approval to only look at one-dose regimens if the selected drug was also one-dose. That is not the case for Genvoya.

[7] https://www.whocc.no/atc_ddd_index/?code=J05AR&showdescription=no

[8] www.accessdata.fda.gov/drugsatfda_docs/label/2022/207561s029lbl.pdf

[9] https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/whats-new

[10] https://clinicalinfo.hiv.gov/en/guidelines/pediatric-arv/whats-new

Stribild

- **Non-Proprietary Name:** elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate
- **Brand Name:** Stribild
- **Mechanism of Action:** Integrase Strand Transfer Inhibitor, Two Nucleoside Reverse Transcriptase Inhibitors, Booster

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

Indication	In Guidelines	FDA Approval Date
Stribild, a combination of 1 integrase strand transfer inhibitor, 1 pharmacokinetic enhancer, and 2 nucleos(t)ide analog HIV-1 reverse transcriptase inhibitors, is indicated as a complete regimen for the treatment of HIV-1 infection in adults who are antiretroviral treatmentnaïve.	Yes	8/27/2012

Triumeq

- **Non-Proprietary Name:** dolutegravir/lamivudine/abacavir
- **Brand Name:** Triumeq
- **Mechanism of Action:** Integrase Strand Transfer Inhibitor and Two Nucleoside Reverse Transcriptase Inhibitors

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

Indication	In Guidelines	FDA Approval Date
TRIUMEQ, a combination of dolutegravir (integrase strand transfer inhibitor [INSTI]), abacavir, and lamivudine (both nucleoside analogue reverse transcriptase inhibitors) is indicated for the treatment of HIV-1 infection.	Yes	8/22/2014

Biktarvy

- **Non-Proprietary Name:** bictegravir/emtricitabine/tenofovir alafenamide
- **Brand Name:** Biktarvy
- **Mechanism of Action:** Integrase Strand Transfer Inhibitor and Two Nucleoside Reverse Transcriptase Inhibitors

Table B-4
Biktarvy: In-Class Therapeutic Alternatives by Indication

Indication	In Guidelines	FDA Approval Date
BIKTARVY is a three-drug combination of bictegravir (BIC), a human immunodeficiency virus type 1 (HIV-1) integrase strand transfer inhibitor (INSTI), and emtricitabine (FTC) and tenofovir alafenamide (TAF), both HIV-1 nucleoside analog reverse transcriptase inhibitors (NRTIs), and is indicated as a complete regimen for the treatment of HIV-1 infection in adults who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 3 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of BIKTARVY.	Yes	2/7/2018

Dovato

- **Non-Proprietary Name:** dolutegravir/lamivudine
- **Brand Name:** Dovato
- **Mechanism of Action:** Integrase Strand Transfer Inhibitor and One Nucleoside Reverse Transcriptase Inhibitors

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

Indication	In Guidelines	FDA Approval Date
DOVATO, a two-drug combination of dolutegravir (integrase strand transfer inhibitor [INSTI]) and lamivudine (nucleoside analogue reverse transcriptase inhibitor [NRTI]) is indicated as a complete regimen for the treatment of HIV1 infection in adults with no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of DOVATO.	Yes	4/8/2019

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

Appendix C

Genvoya: 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 Genvoya 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.

Genvoya: 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 Genvoya Utilization, Expenditure, and Gross-to-Net Sales from 2018-2022

	2018	2022	Percent Change
Total OOP Costs	$1,994	$2,616	31.19%
Total Paid Amount	$44,957,004	$28,300,194	-37.05%
Patient Count	1,889	879	-53.47%
Gross-to-Net Sales	[redacted]	[redacted]	[redacted]
WAC	[redacted]	[redacted]	[redacted]

Table C-1 shows the total Out-of-Pocket costs, the Total paid amount, the total number of patients utilizing Genvoya, and the Gross-to-Net Sales estimate in 2018 and 2022, with the percent change over that time period. In this timeframe there was a 53.%47% decrease in patients, and a 37.05% decrease in total paid amounts, but out-of-pocket costs increased by 31.19%, the WAC increased by 30.06%, [redacted] Patients, caregivers, and individuals with scientific and medical training specifically called attention to the federal Ryan White HIV/AIDS Program (RWHAP), which provides funding to states to support people living with HIV to get access to medications and other services. See Appendices F, H, I, and J for more information.

Table C-2

Annual Utilization and Expenditures

	2018	2019	2020	2021	2022
Patient Count	1,889	1,510	1,098	1,017	879
Total Paid	$44,957,004	$35,348,480	$31,924,430	$30,977,136	$28,300,194
Average Paid Per Person	$23,799	$23,410	$29,075	$30,459	$32,196
Total Patient Paid	$1,477,364	$1,222,750	$1,135,290	$1,012,658	$886,852

Average OOP Cost	$1,994	$2,036	$2,666	$2,619	$2,616
WAC per Unit	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table C-2 shows the year-over-year increases in the number of patients using Genvoya, the total amount paid for Genvoya, 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 increases in 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 Genvoya decreased by 53.46%.

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	OOP Cost	Average Deductible Amount	Average Coinsurance Amount	Average Copay Amount	Average days supply
Jan-18	907	[redacted]	[redacted]	$3,860,760	4,257	$772	$344	$274	$153	46
Feb-18	857	[redacted]	[redacted]	$3,648,007	4,257	$572	$198	$258	$115	42
Mar-18	984	[redacted]	[redacted]	$4,290,816	4,361	$530	$107	$183	$241	46
Apr-18	905	[redacted]	[redacted]	$3,803,514	4,203	$263	$36	$114	$113	45
May-18	946	[redacted]	[redacted]	$4,059,435	4,291	$213	$29	$71	$113	43
Jun-18	899	[redacted]	[redacted]	$3,671,533	4,084	$228	$25	$105	$98	44
Jul-18	865	[redacted]	[redacted]	$3,625,109	4,191	$206	$38	$81	$86	43
Aug-18	927	[redacted]	[redacted]	$4,152,380	4,479	$188	$26	$78	$83	46
Sep-18	822	[redacted]	[redacted]	$3,384,571	4,117	$152	$4	$61	$87	42
Oct-18	870	[redacted]	[redacted]	$3,743,612	4,303	$189	$22	$75	$93	43
Nov-18	804	[redacted]	[redacted]	$3,282,553	4,083	$139	$35	$48	$56	44
Dec-18	787	[redacted]	[redacted]	$3,434,708	4,364	$145	$22	$81	$42	42
Jan-19	807	[redacted]	[redacted]	$3,384,063	4,193	$982	$471	$362	$149	42
Feb-19	763	[redacted]	[redacted]	$3,189,456	4,180	$467	$148	$192	$126	44
Mar-19	760	[redacted]	[redacted]	$3,067,787	4,037	$396	$121	$155	$120	41
Apr-19	751	[redacted]	[redacted]	$3,158,542	4,206	$263	$49	$151	$63	42
May-19	752	[redacted]	[redacted]	$3,285,576	4,369	$181	$32	$91	$58	44
Jun-19	674	[redacted]	[redacted]	$2,802,106	4,157	$182	$41	$81	$61	39
Jul-19	685	[redacted]	[redacted]	$3,033,718	4,429	$227	$33	$110	$84	43
Aug-19	678	[redacted]	[redacted]	$3,071,273	4,530	$150	$16	$82	$52	43
Sep-19	635	[redacted]	[redacted]	$2,625,786	4,135	$237	$37	$144	$57	42
Oct-19	630	[redacted]	[redacted]	$2,695,986	4,279	$195	$47	$95	$54	44
Nov-19	572	[redacted]	[redacted]	$2,453,204	4,289	$191	$28	$76	$87	44
Dec-19	588	[redacted]	[redacted]	$2,580,986	4,389	$196	$39	$99	$58	42
Jan-20	583	[redacted]	[redacted]	$2,595,808	4,453	$1,141	$496	$494	$150	43

Month, Year of Rx Fill Date	Patient Count	WAC per unit	Gross-to-net-sales estimate	Total Paid	Average Paid	OOP Cost	Average Deductible Amount	Average Coinsurance Amount	Average Copay Amount	Average days supply
Feb-20	559	[redacted]		$2,592,990	4,639	$760	$161	$434	$165	43
Mar-20	638			$3,217,527	5,043	$493	$74	$263	$157	44
Apr-20	579		[redacted]	$2,777,334	4,797	$302	$32	$141	$129	45
May-20	535			$2,502,000	4,677	$297	$48	$123	$126	45
Jun-20	584			$2,876,203	4,925	$255	$21	$134	$100	45
Jul-20	559		[redacted]	$2,785,802	4,984	$211	$26	$89	$96	46
Aug-20	515			$2,431,792	4,722	$210	$23	$89	$99	45
Sep-20	514			$2,580,382	5,020	$229	$5	$91	$133	48
Oct-20	535		[redacted]	$2,489,261	4,653	$169	$0	$76	$93	47
Nov-20	501			$2,369,918	4,730	$202	$17	$81	$104	47
Dec-20	526			$2,705,406	5,143	$227	$30	$113	$84	48
Jan-21	485		[redacted]	$2,430,731	5,012	$951	$469	$308	$174	45
Feb-21	494			$2,507,012	5,075	$665	$169	$311	$185	45
Mar-21	525			$2,570,975	4,897	$525	$118	$283	$124	42
Apr-21	544		[redacted]	$2,709,771	4,981	$368	$43	$171	$154	43
May-21	512			$2,587,232	5,053	$240	$24	$127	$90	45
Jun-21	499			$2,600,735	5,212	$221	$25	$99	$98	42
Jul-21	508		[redacted]	$2,699,604	5,314	$212	$25	$89	$98	43
Aug-21	489			$2,695,439	5,512	$207	$35	$102	$69	42
Sep-21	492			$2,486,013	5,053	$187	$2	$73	$112	45
Oct-21	483		[redacted]	$2,676,775	5,542	$249	$36	$116	$97	46
Nov-21	463			$2,374,508	5,129	$234	$45	$99	$89	42
Dec-21	482			$2,638,325	5,474	$276	$46	$78	$151	43
Jan-22	491		[redacted]	$2,717,224	5,534	$1,130	$478	$500	$152	45
Feb-22	450			$2,347,352	5,216	$531	$138	$297	$96	41

Month, Year of Rx Fill Date	Patient Count	WAC per unit	Gross-to-net-sales estimate	Total Paid	Average Paid	OOP Cost	Average Deductible Amount	Average Coinsurance Amount	Average Copay Amount	Average days supply
Mar-22	493	[redacted]		$2,742,964	5,564	$422	$34	$188	$200	43
Apr-22	460		[redacted]	$2,469,454	5,368	$306	$28	$159	$119	43
May-22	436			$2,314,025	5,307	$295	$60	$110	$124	43
Jun-22	448			$2,641,046	5,895	$342	$96	$110	$136	45
Jul-22	420		[redacted]	$2,234,218	5,320	$258	$44	$85	$130	44
Aug-22	430			$2,451,587	5,701	$257	$39	$85	$133	45
Sep-22	402			$2,323,704	5,780	$241	$26	$106	$108	45
Oct-22	376		[redacted]	$1,951,266	5,190	$201	$18	$69	$114	44
Nov-22	384			$2,101,714	5,473	$170	$16	$72	$82	44
Dec-22	355			$2,005,650	5,650	$200	$26	$70	$103	47

Table C-3 above shows the monthly amounts of APCD, WAC, and gross-to-net sales estimates for Genvoya. 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 Genvoya 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.

[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

- 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 Genvoya 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.

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 23 approved patents for Genvoya with the latest expiration date of 10/06/2032.[4] 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.[5]

[4] https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=207561&Appl_type=N

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

Appendix D

Genvoya: 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 Genvoya 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.[2] 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 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.

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[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).

[2] Id.

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.

Genvoya: 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 identified 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.[3] 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 big 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

Relative Medical Professional Guidelines and Manufacturer-Reported Benefits

Relevant Medical Professional Guidelines

Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV, 2023.[4]

Manufacturer-Reported Benefits

Information contained in Genvoya's FDA label, Section 14 Clinical Studies, reports on the studies and the resulting primary and key secondary efficacy analyses.[5]

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

[4] https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/whats-new

[5] https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/207561s029lbl.pdf

Figure D-1
Study I, Table 16

Table 16 Pooled Virologic Outcomes of Randomized Treatment in Studies 104 and 111 at Week 144[a] in Treatment-Naïve Subjects

	GENVOYA (N=866)	STRIBILD (N=867)
HIV-1 RNA < 50 copies/mL[b]	84%	80%
HIV-1 RNA ≥ 50 copies/mL[c]	5%	4%
No Virologic Data at Week 144 Window	11%	16%
Discontinued Study Drug Due to AE or Death[d]	2%	3%
Discontinued Study Drug Due to Other Reasons and Last Available HIV-1 RNA < 50 copies/mL[e]	9%	11%
Missing Data During Window but on Study Drug	1%	1%

a. Week 144 window was between Day 966 and 1049 (inclusive).
b. The primary endpoint was assessed at Week 48 and the virologic success rate was 92% in the GENVOYA group and 90% in the STRIBILD group, with a treatment difference of 2.0% (95% CI: -0.7% to 4.7%). The difference at Week 144 was primarily driven by discontinuations due to other reasons with last available HIV-1 RNA <50 copies/mL.
c. Included subjects who had ≥50 copies/mL in the Week 144 window; subjects who discontinued early due to lack or loss of efficacy; subjects who discontinued for reasons other than an adverse event (AE), death or lack or loss of efficacy and at the time of discontinuation had a viral value of ≥ 50 copies/mL.
d. Includes subjects who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
e. Includes subjects who discontinued for reasons other than an AE, death or lack or loss of efficacy; e.g., withdrew consent, loss to follow-up, etc.

Figure D-1 above shows the efficacy and safety of Genvoya included in Genvoya's FDA label.

Figure D-2
Study II, Table 17

Table 17 Virologic Outcomes of Study 109 at Week 96[a] in Virologically-Suppressed Adults who Switched to GENVOYA

	GENVOYA (N=959)	ATRIPLA or TRUVADA+atazanavir +cobicistat or ritonavir or STRIBILD (N=477)
HIV-1 RNA < 50 copies/mL	93%	89%
HIV-1 RNA ≥ 50 copies/mL[b]	2%	2%
No Virologic Data at Week 48 Window	5%	9%
Discontinued Study Drug Due to AE or Death[c]	1%	3%
Discontinued Study Drug Due to Other Reasons and Last Available HIV-1 RNA < 50 copies/mL[d]	3%	6%
Missing Data During Window but on Study Drug	1%	<1%

a. Week 96 window was between Day 630 and 713 (inclusive).
b. Included subjects who had ≥50 copies/mL in the Week 96 window; subjects who discontinued early due to lack or loss of efficacy; subjects who discontinued for reasons other than an adverse event (AE), death or lack or loss of efficacy and at the time of discontinuation had a viral value of ≥50 copies/mL.
c. Includes subjects who discontinued due to AE or death at any time point from Day 1 through the time window if this resulted in no virologic data on treatment during the specified window.
d. Includes subjects who discontinued for reasons other than an AE, death or lack or loss of efficacy; e.g., withdrew consent, loss to follow-up, etc.

Figure D-2 above shows the efficacy and safety of Genvoya included in Genvoya's FDA label.

In Study 112, the efficacy and safety of Genvoya once daily were evaluated in an open-label clinical trial of 248 HIV-1 infected subjects with renal impairment (estimated creatinine clearance between 30 and 69 mL per minute by Cockcroft-Gault method). At Week 144, 81% (197/242 virologically suppressed subjects) maintained HIV-1 RNA less than 50 copies per mL after switching to Genvoya. All six treatment-naïve subjects were virologically suppressed at Week 144. Five subjects among the entire study population had virologic failure at Week 144.

In Study 1825, the efficacy and safety of Genvoya once daily were evaluated in an open-label clinical trial of 55 virologically-suppressed (HIV-1 RNA less than 50 copies per mL for at least 6 months before switching to Genvoya) HIV-1 infected subjects with ESRD (estimated creatinine clearance of less than 15 mL per minute by CockcroftGault method) receiving chronic hemodialysis for at least 6 months. At Week 48, 82% (45/55) maintained HIV-1 RNA less than 50 copies per mL after switching to Genvoya. Two subjects had HIV-1 RNA ≥ 50 copies per mL by Week 48. Seven subjects discontinued the study drug due to AE or other reasons while suppressed. One subject did not have an HIV-1 RNA measurement at Week 48.

In Study 106, an open-label, single arm trial the efficacy, safety, and pharmacokinetics of Genvoya in HIV-1 infected pediatric subjects were evaluated in treatment-naïve adolescents between the ages of 12 to less than 18 years weighing at least 35 kg (N=50) and in virologically-suppressed children between the ages of 6 to less than 12 years weighing at least 25 kg (N=52). In subjects in cohort 1 treated with Genvoya, 92% (46/50) achieved HIV-1 RNA less than 50 copies per mL at Week 48. After switching to Genvoya, 98% (51/52) of subjects in cohort 2 remained suppressed (HIV-1 RNA < 50 copies/mL) at Week 48.

Voluntarily Submitted Manufacturer Information

Gilead Sciences Inc. submitted the following information:

- Genvoya is a single-tablet regimen (STR) that provides differentiated value for patients with HIV, having demonstrated high rates of virologic success in dedicated studies conducted in treatment-naïve and -experienced populations, including a wide variety of PLWH; e.g. virologically suppressed PLWH, women, children and adolescents with HIV, older PLWH, HIV/hepatitis B virus (HBV) co-infected PLWH.
- The broad utility of Genvoya is recognized in DHHS HIV treatment guidelines, which support its use in both treatment-naïve and treatment experienced patients and recommend it as an initial ARV regimen in certain clinical situations, such as for patients with CrCl < 30 mL/min and on chronic hemodialysis.
- Genvoya provides potent, durable, noninferior efficacy through Week 96 with a low rate of resistance (1%) in antiretroviral therapy (ART)-naïve adults from 2 parallel head-to-head clinical trials (Studies 104 and 111) against Stribild.
- In addition to efficacy in ART-naïve patients, switching to Genvoya was associated with superior efficacy at Week 48 compared to continuation of emtricitabine /tenofovir disoproxil (FTC/TDF)-based regimens in virologically suppressed adults (97% vs 93%, respectively; P<0.001).
- In clinical trials, patients using Genvoya demonstrated favorable renal and bone laboratory parameters compared to those treated with other HIV treatments containing TDF (e.g., Stribild) and no associated cardiac risks, which have been associated with treatments containing abacavir.

See Appendix J for more information and citations.

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**[6]: 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 "elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide" and "HIV" and reviewing "Cochrane Reviews" (i.e., not compiling information from Cochrane Protocols, Trials, Editorials, Special Collections, or Clinical Answers).
- **Institute for Clinical and Economic Review** (ICER)[7]: 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 "elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide" and "HIV". ICER cost-effectiveness recommendations are non-binding for any U.S. federal, state, and local governments.
- **National Institute for Health and Care Excellence** (NICE)[8]: 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 "elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide" and "HIV".
- **Canadian Agency for Drugs and Technologies in Health** (CADTH)[9]: 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 "elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide" and "HIV". CADTH's recommendations are non-binding for federal, provincial, and territorial public drug plans and provincial cancer agencies (with the exception of Quebec).[10]
- **Institute for Quality and Efficiency in Health Care** (IQWiG)[11]: 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 "elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide" and "HIV".
- **International Network of Agencies for Health Technology Assessment** (INAHTA)[12]: 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.

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.

Several notes regarding the table below:

- **Priority Populations and QALYs:** The Board considered health equity impacts to priority populations of Genvoya. Please see Appendix H, Appendix J, and Appendix L for more information. QALYs may

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

discount the value of life because of an individual's disability or age and no studies listed in Table D-1 utilize a QALY.

Table D-1
Clinical and Cost Effectiveness Conclusion Summaries

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
Cochrane Library[13]	Not applicable.	Not applicable.
ICER	Not applicable.	Not applicable.
NICE	Not applicable.	Not applicable.
CADTH	*CDR CLINICAL REVIEW REPORT FOR GENVOYA, 2015, pp 35*[14] In two RCTs, EVG/COBI/FTC/TAF was shown to achieve statistically similar rates of VL suppression compared with EVG/COBI/FTC/TDF among treatment-naive adults with HIV infection after 48 weeks of treatment. In a third RCT, the switch to EVG/COBI/FTC/TAF from another FTC/TDF-containing regimen among virologically suppressed patients was associated with significantly higher rates of virologic suppression at 48 weeks compared with continued therapy with the existing regimen. EVG/COBI/FTC/TAF was associated with relatively similar rates of AEs as the comparator in these trials, among which diarrhea, nausea, URTIs, and headache appeared to be the most common. While EVG/COBI/FTC/TAF had smaller effects on kidney function (eGFR) and BMD compared with EVG/COBI/FTC/TDF, the observed changes are unlikely to be clinically significant in the short term and are of uncertain importance with respect to the risks for kidney failure or fracture in the long term. EVG/COBI/FTC/TAF also demonstrated high rates of virologic suppression in a single-group study of patients with mild to moderate kidney impairment, with minimal changes in median eGFR. High rates of virologic suppression were also observed in a small, single-group trial of treatment-naive adolescents; however, in the absence of a comparative trial against EVG/COBI/FTC/TDF or another STR, there is greater uncertainty regarding relative efficacy and safety in this population compared with adults.	*CDR FINAL RECOMMENDATION FOR GENVOYA, 2015, pp1*[15] At the submitted price, EVG/COBI/FTC/TAF is similar in cost or less costly than other single-tablet or commonly used treatment regimens for adolescents ($41.38 to $43.78) and adults ($41.38 to $55.57) with HIV-1 infection.
IQWiG	*Elvitegravir/cobicistat/emtricitabine/ tenofovir alafenamide (HIV-1 infection [children ≥ 2 to < 6 years and with a body weight of ≥ 14 kg]) – Benefit*	Not applicable.

[13] Some Cochrane Reviews met search criteria, but were not publicly available.
[14] https://www.cadth.ca/elvitegravircobicistatemtricitabinetenofovir-alafenamide
[15] https://www.cadth.ca/sites/default/files/cdr/complete/SR0449_complete_Genvoya-March_22-16_e.pdf

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	assessment according to §35a SGB V, 2023[16] Since no relevant study is available for the benefit assessment, there is no hint of an added benefit of EVG/COBI/FTC/TAF in comparison with the ACT for either research question; an added benefit is therefore not proven.	
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 Genvoya, there were no applicable results in the following studies found on ClinicalTrials.Gov:

- Study to Evaluate the Safety and Efficacy of E/C/F/TAF (Genvoya®) Versus E/C/F/TDF (Stribild®) in HIV-1 Positive, Antiretroviral Treatment-Naive Adults, 2018[17]
- Switching From a Tenofovir Disoproxil Fumarate (TDF) Containing Regimen to Elvitegravir/Cobicistat/Emtricitabine/ Tenofovir Alafenamide (E/C/F/TAF) Fixed-Dose Combination (FDC) in Virologically-Suppressed, HIV-1 Infected Adults Aged ≥ 60 Years, 2020[18]
- Study to Evaluate the Safety and Efficacy of E/C/F/TAF Versus E/C/F/TDF in HIV-1 Positive, Antiretroviral Treatment-Naive Adults, 2020[19]
- Phase 3 Open-Label Study to Evaluate Switching From Optimized Stable Antiretroviral Regimens Containing Darunavir to Elvitegravir/ Cobicistat/Emtricitabine/Tenofovir Alafenamide (E/C/F/TAF) Fixed Dose Combination (FDC) Plus Darunavir (DRV) in Treatment Experienced HIV-1 Positive Adults, 2018[20]
- Safety and Efficacy of E/C/F/TAF (Genvoya®) Versus E/C/F/TDF (Stribild®) in HIV-1 Infected, Antiretroviral Treatment-Naive Adults, 2018[21]
- Efficacy and Safety of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide in HIV-1 Infected Adolescents, 2018[22]
- Safety and Efficacy of Switching From Regimens of ABC/3TC + a 3rd Agent to E/C/F/TAF Fixed-Dose Combination (FDC) in Virologically-

[16] https://www.iqwig.de/download/a22-116_elvitegravir-cobicistat-emtricitabine-tenofovir-alafenamide_extract-of-dossier-assessment_v1-0.pdf
[17] https://clinicaltrials.gov/study/NCT01780506?cond=hiv&intr=Elvitegravir%20%2FCobicistat%2FEmtricitabine%2FTenofovir%20alafenamide%20FDC&rank=2
[18] https://clinicaltrials.gov/study/NCT02616783?cond=hiv&intr=Elvitegravir%20%2FCobicistat%2FEmtricitabine%2FTenofovir%20alafenamide%20FDC&rank=3
[19] https://clinicaltrials.gov/study/NCT01797445?cond=hiv&intr=Elvitegravir%20%2FCobicistat%2FEmtricitabine%2FTenofovir%20alafenamide%20FDC&rank=4
[20] https://clinicaltrials.gov/study/NCT01968551?cond=hiv&intr=Elvitegravir%20%2FCobicistat%2FEmtricitabine%2FTenofovir%20alafenamide%20FDC&rank=5
[21] https://clinicaltrials.gov/study/NCT01497899?cond=hiv&intr=Elvitegravir%20%2FCobicistat%2FEmtricitabine%2FTenofovir%20alafenamide%20FDC&rank=6
[22] https://clinicaltrials.gov/study/NCT02276612?cond=hiv&intr=Elvitegravir%20%2FCobicistat%2FEmtricitabine%2FTenofovir%20alafenamide%20FDC&rank=7

Suppressed HIV 1 Infected Adults, 2018[23]
- Open-label Safety Study of E/C/F/TAF (Genvoya®) in HIV-1 Positive Patients With Mild to Moderate Renal Impairment, 2020[24]
- Efficacy and Safety of E/C/F/TAF (Genvoya®) in HIV-1/Hepatitis B Co-infected Adults, 2018[25]
- Efficacy, Safety, and Tolerability of Ledipasvir/Sofosbuvir (LDV/SOF) Treatment for HIV/HCV Co-infected Participants Who Switch to Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (E/C/F/TAF) or Emtricitabine/Rilpivirine/Tenofovir Alafenamide (F/R/TAF) Prior to LDV/SOF HCV Treatment (Co-STARs), 2018[26]
- Study to Evaluate the Pharmacokinetics, Safety, and Antiviral Activity of the Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (E/C/F/TAF) Single Tablet Regimen (STR) in HIV-1 Infected Antiretroviral Treatment-Naive Adolescents and Virologically Suppressed Children, 2023[27]

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.[28] 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 Genvoya, 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 Genvoya 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 Genvoya.

[23] https://clinicaltrials.gov/study/NCT02605954?cond=hiv&intr=Elvitegravir%20%2FCobicistat%2FEmtricitabine%2FTenofovir%20alafenamide%20FDC&rank=9
[24] https://clinicaltrials.gov/study/NCT01818596?cond=hiv&intr=Elvitegravir%20%2FCobicistat%2FEmtricitabine%2FTenofovir%20alafenamide%20FDC&rank=10
[25] https://clinicaltrials.gov/study/NCT02071082?cond=hiv&intr=Elvitegravir%20%2FCobicistat%2FEmtricitabine%2FTenofovir%20alafenamide%20FDC&page=2&rank=12
[26] https://clinicaltrials.gov/study/NCT02707601?cond=hiv&intr=Elvitegravir%20%2FCobicistat%2FEmtricitabine%2FTenofovir%20alafenamide%20FDC&page=2&rank=13
[27] https://clinicaltrials.gov/study/NCT01854775?cond=hiv&intr=Elvitegravir%20%2FCobicistat%2FEmtricitabine%2FTenofovir%20alafenamide%20FDC&page=2&rank=15
[28] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/benefit-risk-assessment-new-drug-and-biological-products

Appendix E

Genvoya: 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 Genvoya and relevant insurance coverage information for the patients on those claims 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 Genvoya.

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.

Genvoya: 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 Genvoya's manufacturer provided some information. See Appendices H and J for more information.

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.

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

Figure E - 1

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

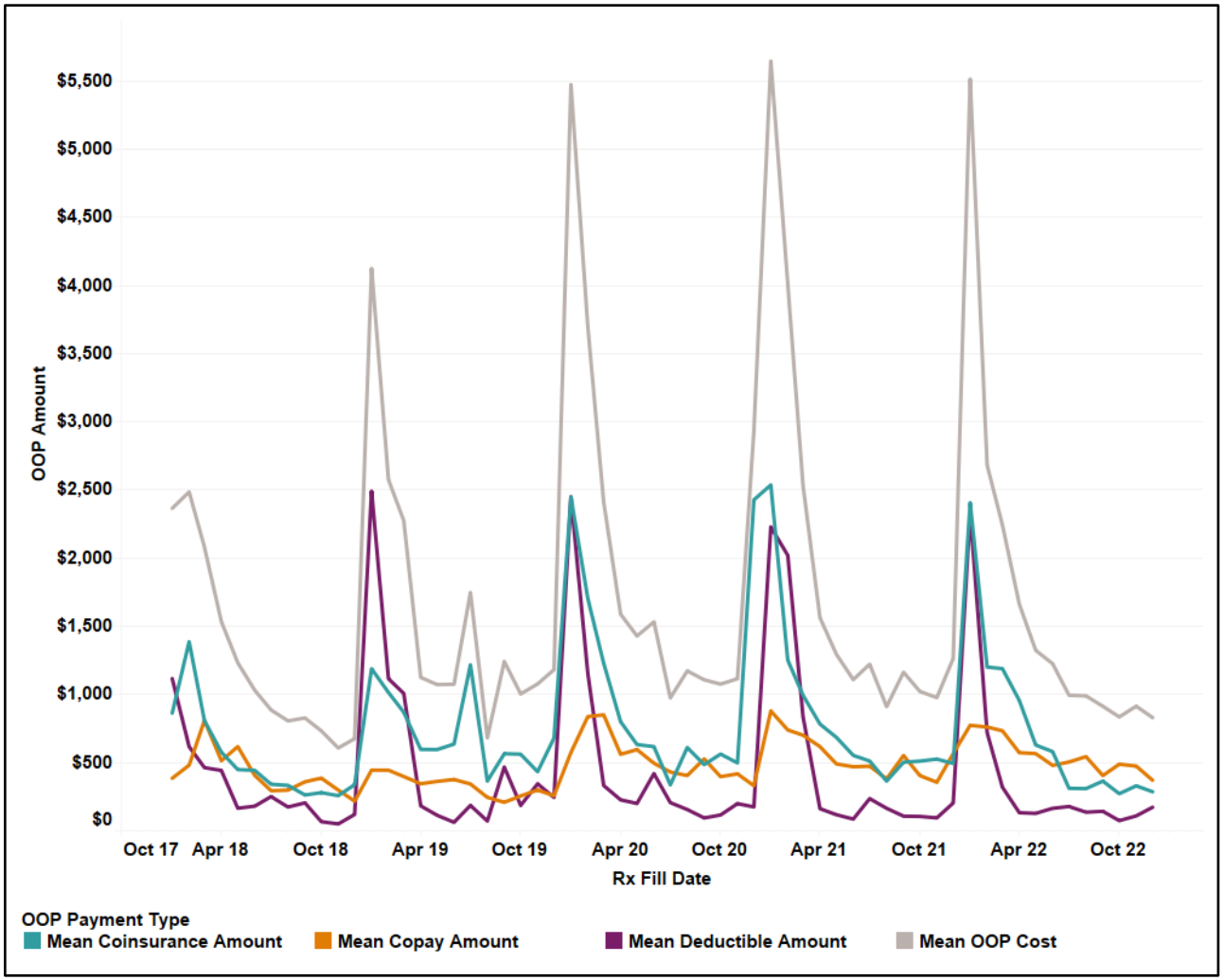


Figure E-1 shows the average out-of-pocket amount for commercially insured patients, where the orange line shows the monthly average copayment amount, the purple line shows the monthly average deductible amount, the teal line shows the monthly average coinsurance amount, and the gray line shows the monthly 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. From 2020 through 2022, there is also a large increase in coinsurance each January.

Figure E-2
Average Commercial Out-of-Pocket Cost Comparison

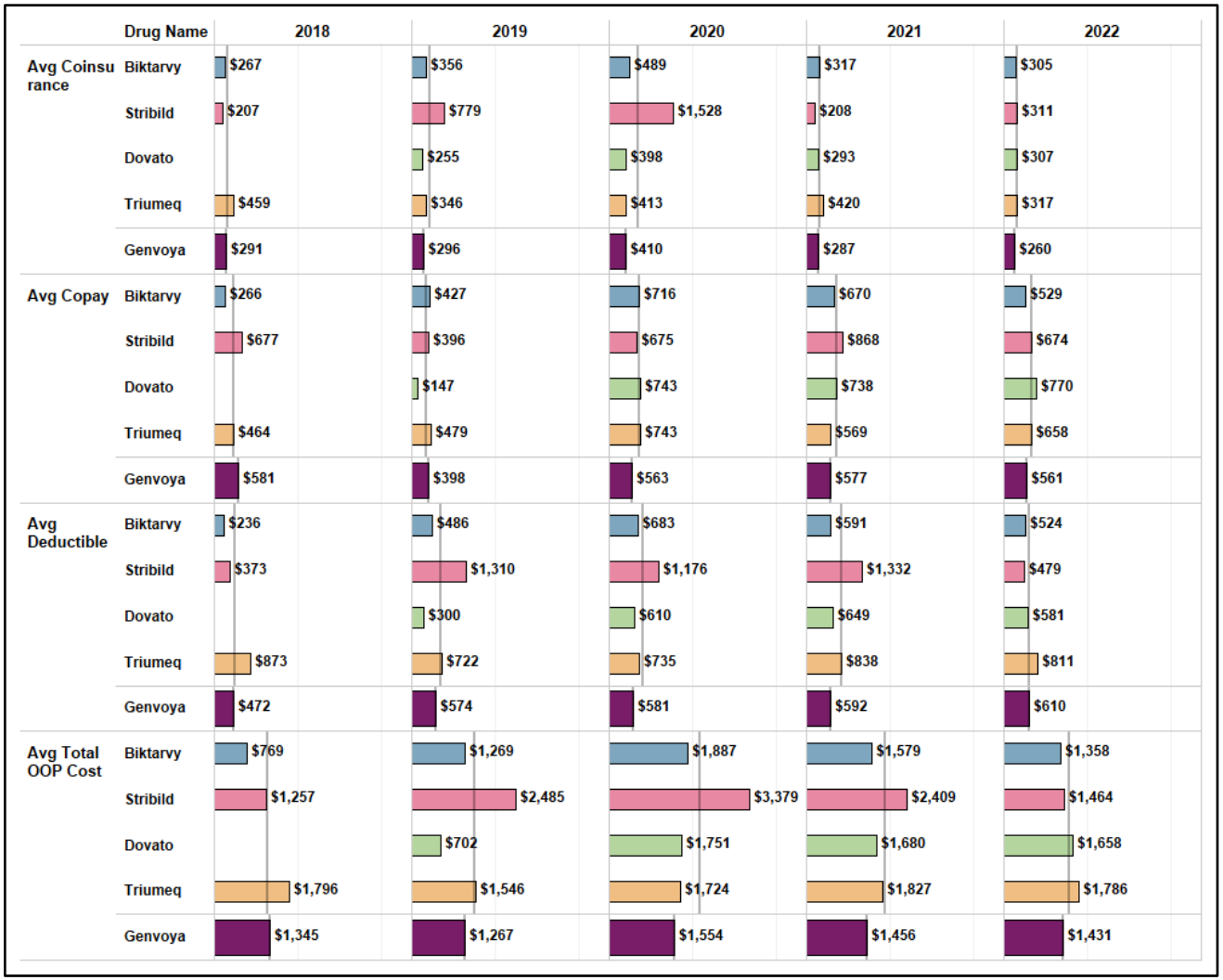


Figure E-2 shows each out-of-pocket cost type for commercially insured individuals with Genvoya in dark purple and identified therapeutic alternatives by year. A light gray line shows the average of identified therapeutic alternatives as a comparison to determine if Genvoya is more or less expensive than the average of identified therapeutic alternatives. For example, the bottom right corner shows the average total out-of-pocket cost in 2022; Genvoya was $1,431, which is just below the average of the four 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 Payment Type	2018	2019	2020	2021	2022
Genvoya	**Average Copay**	$581	$398	$563	$577	$561
	Percent Difference		*-31.55%*	*41.61%*	*2.46%*	*-2.78%*
	Average Coinsurance	$291	$296	$410	$287	$260
	Percent Difference		*1.49%*	*38.64%*	*-30.09%*	*-9.19%*
	Average Deductible	$472	$574	$581	$592	$610
	Percent Difference		*21.56%*	*1.20%*	*1.99%*	*2.94%*
	Average Total OOP Cost	$1,345	$1,267	$1,554	$1,456	$1,431
	Percent Difference		*-5.75%*	*22.62%*	*-6.30%*	*-1.71%*
Biktarvy	**Average Copay**	$266	$427	$716	$670	$529
	Percent Difference		*60.26%*	*67.75%*	*-6.40%*	*-21.08%*
	Average Coinsurance	$267	$356	$489	$317	$305
	Percent Difference		*33.56%*	*37.13%*	*-35.09%*	*-3.99%*
	Average Deductible	$236	$486	$683	$591	$524
	Percent Difference		*105.59%*	*40.59%*	*-13.42%*	*-11.32%*
	Average Total OOP Cost	$769	$1,269	$1,887	$1,579	$1,358

Drug Name	Out of Pocket Payment Type	2018	2019	2020	2021	2022
	Percent Difference		*64.92%*	*48.75%*	*-16.37%*	*-13.99%*
Dovato	**Average Copay**		$147	$743	$738	$770
	Percent Difference			*403.63%*	*-0.63%*	*4.34%*
	Average Coinsurance		$255	$398	$293	$307
	Percent Difference			*56.25%*	*-26.40%*	*4.78%*
	Average Deductible		$300	$610	$649	$581
	Percent Difference			*103.28%*	*6.43%*	*-10.55%*
	Average Total OOP Cost		$702	$1,751	$1,680	$1,658
	Percent Difference			*149.29%*	*-4.02%*	*-1.34%*
Stribild	**Average Copay**	$677	$396	$675	$868	$674
	Percent Difference		*-41.49%*	*70.44%*	*28.59%*	*-22.43%*
	Average Coinsurance	$207	$779	$1,528	$208	$311
	Percent Difference		*277.22%*	*95.99%*	*-86.39%*	*49.42%*
	Average Deductible	$373	$1,310	$1,176	$1,332	$479
	Percent Difference		*251.06%*	*-10.22%*	*13.29%*	*-64.03%*
	Average Total OOP Cost	$1,257	$2,485	$3,379	$2,409	$1,464

Drug Name	Out of Pocket Payment Type	2018	2019	2020	2021	2022
	Percent Difference		*97.75%*	*35.95%*	*-28.72%*	*-39.23%*
Triumeq	**Average Copay**	$464	$479	$743	$569	$658
	Percent Difference		*3.16%*	*55.18%*	*-23.34%*	*15.58%*
	Average Coinsurance	$459	$346	$413	$420	$317
	Percent Difference		*-24.66%*	*19.44%*	*1.60%*	*-24.40%*
	Average Deductible	$873	$722	$735	$838	$811
	Percent Difference		*-17.31%*	*1.80%*	*14.01%*	*-3.22%*
	Average Total OOP Cost	$1,796	$1,546	$1,724	$1,827	$1,786
	Percent Difference		*-13.90%*	*11.48%*	*5.98%*	*-2.23%*

Table E-1 shows the average annual coinsurance, copayment, deductible, and total out-of-pocket amounts for Genvoya and identified therapeutic alternatives, as well as the year-over-year percent change across all commercial payers from January 2018 through December 2022. While there is large year-over-year variation in out-of-pocket payments, Genvoya remained largely consistent from 2018 to 2022 and is lower than three of the identified therapeutic alternatives. This is further illustrated in Figure E-3 below.

Figure E-3
Changes in Commercial Out-of-Pocket amounts by year and drug 2018-2022

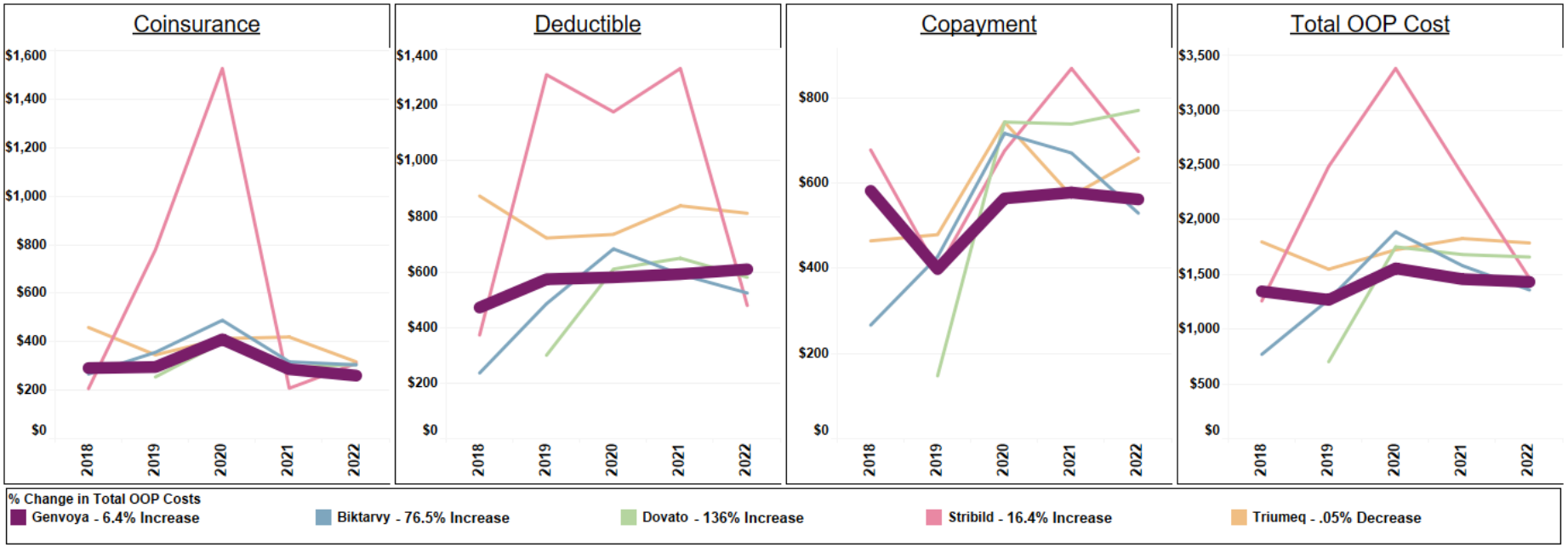


Figure E-3 shows the annual change in the annual average oop amounts for individuals with commercial coverage comparing Genvoya (dark purple) to identified therapeutic alternatives. Below the graph, the percent change in total out-of-pocket cost from January 2018 - December 2022 for each drug is indicated.

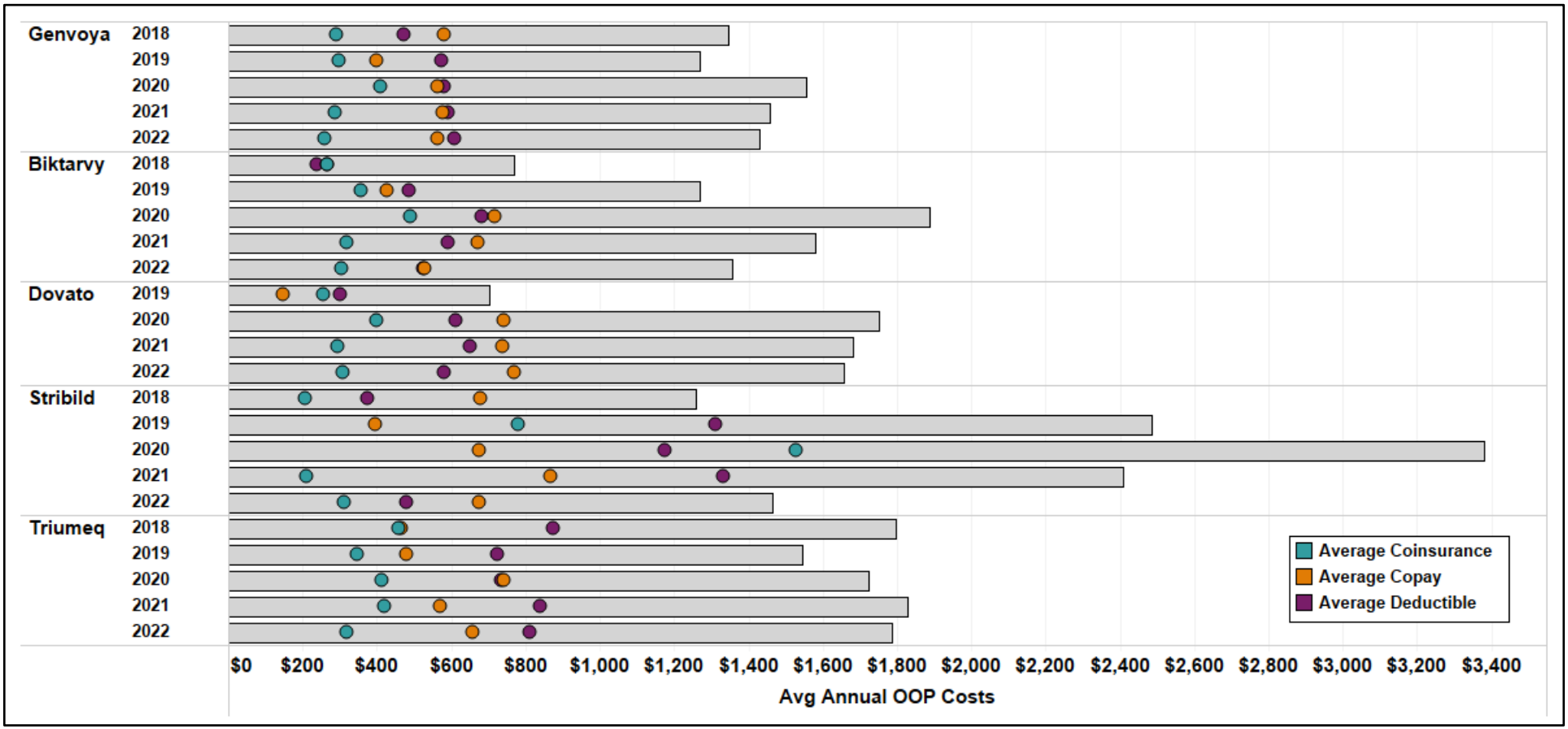
Table E-2
Average Monthly Commercial Out-of-Pocket Cost Information in 2022

	Genvoya	Biktarvy	Dovato	Stribild	Triumeq
Average Total OOP Cost	**$183**	$174	$207	$149	$205
Average Coinsurance Amount	**$33**	$38	$39	$30	$37

Average Copay Amount	**$75**	$68	$96	$72	$79
Average Deductible Amount	**$75**	$67	$72	$47	$89
Average Days Supply	**45.4**	42.1	39.4	43.4	41.9

Figure E-2 shows that in 2022, in an average month an individual with commercial insurance paid a total of $183, $75 went towards a patient's deductible, $33 was paid towards coinsurance, and $75 was paid via copayment. These payments were for an average of 45.4 days. Genvoya is higher than Biktarvy and Stribild in total out of pocket payments and is lower than Dovato and Triumeq.

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 average copay and average deductible for Genvoya. These increases are similar to those seen with Biktarvy, Dovato and Triumeq. Stribild has significant variation in average coinsurance and average deductible

Figure E-5

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

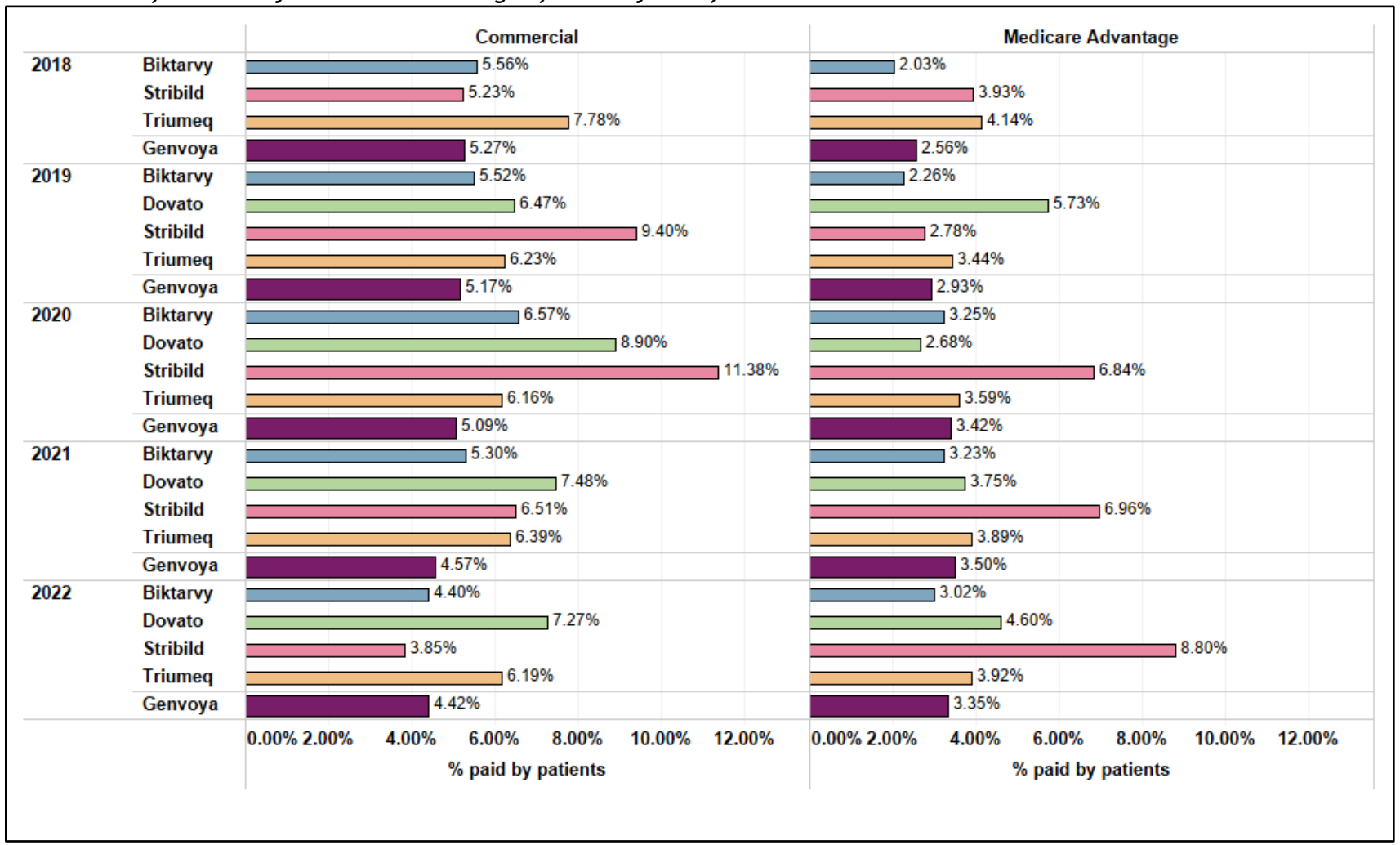


Figure E-5 provides context for what patients paid, as compared to their insurance plan, for Genvoya or identified therapeutic alternatives from 2018 through 2022. In 2022, commercial patients paid 4.42% of the total paid for Genvoya. Whereas patients with Medicare Advantage coverage paid 3.35% of the total paid amount for Genvoya.

Figure E-6

Total Out-of-Pocket Cost Histogram for Genvoya and Therapeutic Alternatives for 2022

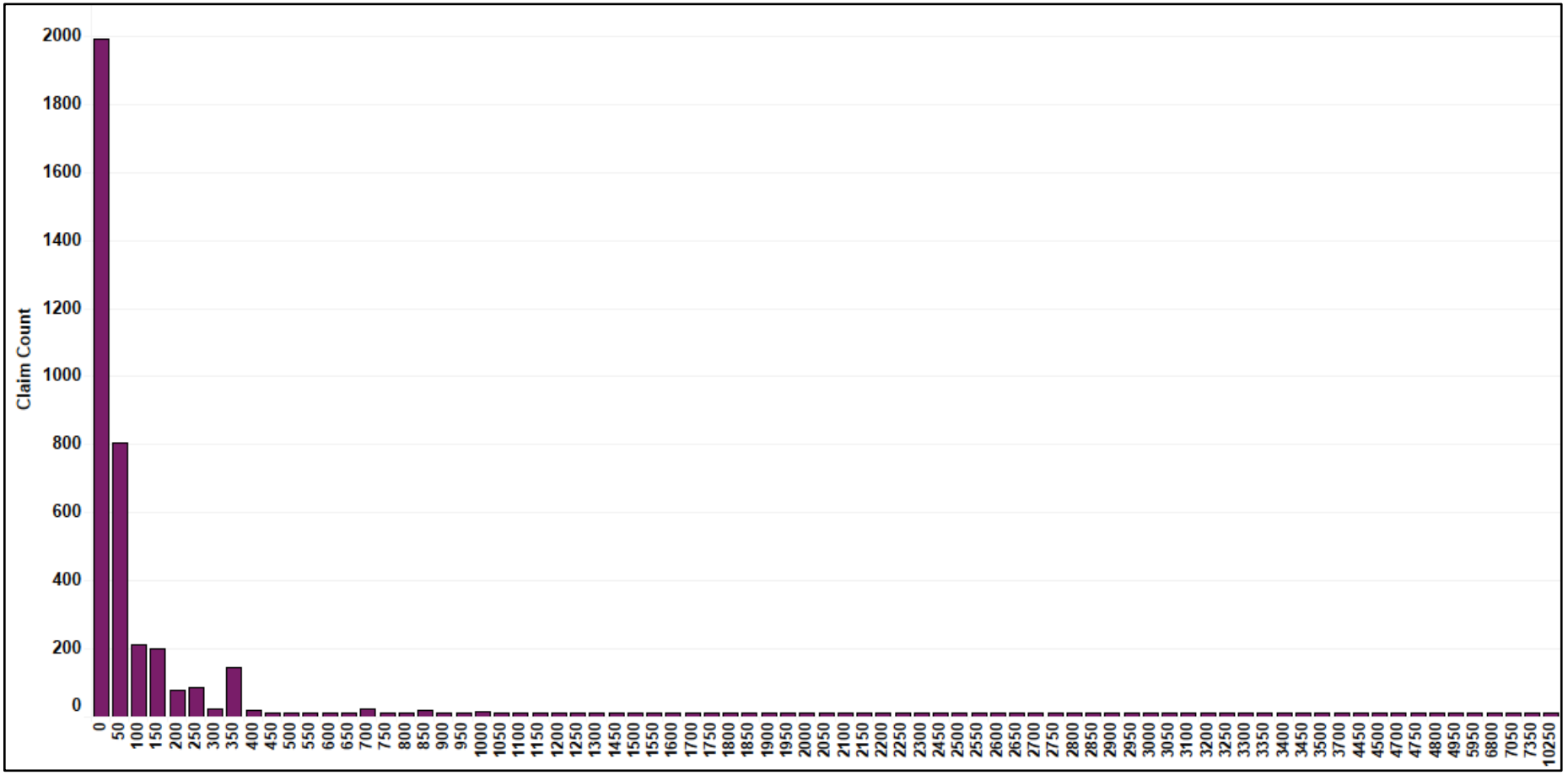


Figure E-6 shows a histogram of total out-of-pocket costs for individuals with commercial insurance in 2022 for utilizers of Genvoya. It shows the variation of the total out-of-pocket costs, where 45.24% of Genvoya utilizers paid between $0 and $50, though some individuals paid as much as $10,250 - $10,300.

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 Genvoya on commercial health plans were enrolled in high deductible health plans. In 2021 and 2022, fewer than 6% of patients using Genvoya 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
Genvoya	6.81%	6.17%	5.34%	3.92%	3.98%
Biktarvy	5.52%	5.38%	4.72%	3.89%	3.38%
Dovato			2.06%	1.06%	3.92%
Stribild			5.88%		
Triumeq	4.67%	2.96%	3.83%	4.02%	4.22%

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

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.

Out of the ten carriers in the market, all ten carriers cover this medication with unrestricted access, meaning there is no prior authorization or step therapy. The Total number of plans that provide coverage for Genvoya is 179 On Exchange (30 Small Group, 149 Individual) and 550 Off Exchange (341 Small Group, 209 Individual).

The carriers generally put Genvoya on a middle to lower tiers, meaning a lower portion of the drug is paid by patients than drugs on higher tiers, except for one carrier which has placed Genvoya on the highest tier.

Of the carriers that submitted filings, 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.

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

Table E-4
DOI-Regulated Plans Genvoya Out-of-Pocket Costs Overview

	Total Number of Plans	Minimum	Maximum	Average	Mode
% Coinsurance after Deductible	186	0%	50%	31.74%	50%
Copayment after Deductible	128	$0.00	$400.00	$173.79	$125.00
Copayment	415	$0.00	$785.00	$215.22	$125.00
Total Plans	**729**				

Table E-4 shows a summary of different types of cost sharing and their applicable ranges for DOI regulated plans for Genvoya. 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]

[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.

Appendix F

Genvoya: 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.

Genvoya: 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 percent), 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) in the 340B Drug Pricing Program are defined in statute and include HRSA-supported health centers, Ryan White clinics and State AIDS Drug Assistance

programs, Medicare/Medicaid Disproportionate Share Hospitals, children's hospitals, and other safety net providers.[1]

Ryan White HIV/AIDS Program

The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act was enacted by the Congress on August 18, 1990. This legislation created the Ryan White HIV/AIDS Program (RWHAP) to improve the quality and availability of HIV care and treatment for low-income people with HIV.[2] The Health Resources and Services Administration (HRSA) and RWHAP have led initiatives to address the needs of people with HIV to reduce stigma and to train providers to deliver culturally-appropriate HIV care and treatment. Nationally, the RWHAP provides HIV care and treatment services to more than half a million people with HIV, while working to ensure access to and retention in quality, integrated care, and treatment services for all people with HIV.[3]

The RWHAP is divided into several parts to meet the needs of different communities and populations, and includes support for an AIDS Drug Assistance Program (ADAP) for people who have limited or no health insurance.[4] Health centers provide high quality preventive and primary health care services, including HIV testing, PrEP, and medical care, to patients regardless of their ability to pay. Some people with HIV receive health care services directly at the health center itself, while others are referred to an HIV specialist in the community.

Providers who receive funding from RWHAP, sometimes referred to as Ryan White Clinics, are eligible to participate in the 340B program, as they receive funding under the Ryan White CARE Act, which provides support for entities that primarily render services to low-income, underinsured, or uninsured people living with HIV.[5] The comprehensive services that Ryan White clinics provide range from free or discounted medications to critical wrap-around support services for people living with HIV including case management, dental and behavioral health, and housing assistance. The 340B program enables Ryan White clinics to maximize their resources to support the full HIV/AIDS care continuum, from diagnosis, to linkage to care, to medication adherence and viral suppression.

The State Drug Assistance Program (SDAP), overseen by the Colorado Department of Public Health and Environment (CDPHE), provides funding to Ryan White Clinics for several services, including to help people living with HIV get access to medications, assistance with insurance premiums, and additional coverage of covered OOP medical costs.[6] SDAP is the payer of last resort and only accepts those with no other options.[7] The program is open to Colorado residents living with HIV with an income less than 500 percent of the Federal Poverty Level.[8] In 2024, income eligibility by household size is:

[1] https://www.hrsa.gov/opa.
[2] https://ryanwhite.hrsa.gov/livinghistory/.
[3] https://ryanwhite.hrsa.gov/livinghistory/.
[4] https://www.hiv.gov/hiv-basics/staying-in-hiv-care/hiv-treatment/paying-for-hiv-care-and-treatment/.
[5] https://rwc340b.org/wp-content/uploads/2023/10/RWC-340B-%E2%80%93-Who-We-Are-and-Our-Patient-Centric-Mission-Get-the-Facts.pdf.
[6] https://cdphe.colorado.gov/state-drug-assistance-program.
[7] https://cdphe.colorado.gov/sti-hiv-vh/living-with-hiv.
[8] https://drive.google.com/file/d/1RG5IcCOVqD62AttO0wdFOjsQ6jh31AaM/view.

Figure F-1
Colorado State Drug Assistance Program (SDAP) Income Eligibility Chart

Colorado State Drug Assistance Program (SDAP) Income Eligibility Chart						
2024 Federal Poverty Level Annual Income Chart						
Family Size	**100%**	**138%**	**250%**	**300%**	**400%**	**500%**
1	$ 15,060.00	$ 20,782.80	$ 37,650.00	$ 45,180.00	$ 60,240.00	$ 75,300.00
2	$ 20,440.00	$ 28,207.20	$ 51,100.00	$ 61,320.00	$ 81,760.00	$ 102,200.00
3	$ 25,820.00	$ 35,631.60	$ 64,550.00	$ 77,460.00	$ 103,280.00	$ 129,100.00
4	$ 31,200.00	$ 43,056.00	$ 78,000.00	$ 93,600.00	$ 124,800.00	$ 156,000.00
5	$ 36,580.00	$ 50,480.40	$ 91,450.00	$ 109,740.00	$ 146,320.00	$ 182,900.00
6	$ 41,960.00	$ 57,904.80	$ 104,900.00	$ 125,880.00	$ 167,840.00	$ 209,800.00
7	$ 47,340.00	$ 65,329.20	$ 118,350.00	$ 142,020.00	$ 189,360.00	$ 236,700.00
8	$ 52,720.00	$ 72,753.60	$ 131,800.00	$ 158,160.00	$ 210,880.00	$ 263,600.00
Under financial eligibility rules, any individual or family earning under 500% of FPL are eligible to receive services. ADAP will pay premium, prescription and medical copays for covered services and PHIP will cover medical costs associated with PrEP and limited medication assistance. Additionally, such individuals are eligible to receive Ryan White services funded by CDPHE.						

Figure F-1 shows the Colorado SDAP Income Eligibility Chart by family size and income as a percentage of the federal poverty level (FPL).[9]

Evidence

HRSA maintains a database of covered entities and contract pharmacies, including the number of unique covered entities and addresses by covered entity type.[10] 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[11]
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

[9] https://drive.google.com/file/d/1RG5IcCOVqD62AttO0wdFOjsQ6jh31AaM/view.

[10] https://340bopais.hrsa.gov/SearchLanding

[11] 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[11]
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
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 Genvoya.

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.[12]

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.

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

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.

Appendix G

Genvoya: 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.

Genvoya: 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 the 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

No records were found for Genvoya in the FDA orphan drug designations and approvals database.

[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

Appendix H

Genvoya: 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 Genvoya. 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 input from patients and caregivers for selected prescription drugs from the following sources:

- Results from public input sessions and surveys from 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.

Genvoya: 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 three patients and caregivers at a public meeting and three other patients in small group meetings. These meetings were structured to be a focus-group style meeting to gather information on the health and financial effects of Genvoya and largely followed the survey questions. In addition to input

gathered through public meetings, 22 patients and caregivers completed surveys regarding the health and financial effects of Genvoya[1].

At the initial time of survey release, the Board received 22 responses from patients and caregivers. 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 zero responses from Genvoya patients.

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 Genvoya, and financial effects of Genvoya. 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 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 22 responses from Genvoya patients, all of whom are Colorado residents. Three patients attended the public input sessions and two additional small group sessions were held. Themes from survey responses and public input sessions are summarized below.

All patients and caregivers who attended meetings or completed surveys were being treated for HIV. All survey respondents indicated that they are Colorado residents and are part of one or more priority populations as outlined in Policy.[2]

When asked about insurance status, those surveyed responded:

- Uninsured: 1
- Individual/private: 4
- Employer: 7
- Medicaid: 6
- Medicare: 3
- Ryan White: 1

[1] Board staff received 23 total survey responses from Genvoya patients and caregivers. One survey response indicated the patient used Genvoya to treat high cholesterol. As high cholesterol is not an approved indication for Genvoya, this survey response was excluded from this report.

[2] 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.

Health Effects of Genvoya

Some of the more common themes of the health effects of Genvoya are outlined below:

- 13 of 22 patients reported than Genvoya kept them undetectable.
- 5 of 22 said Genvoya did not work for them or gave them serious side effects.

When asked about side effects, survey respondents said:

- 8 of 22 had no side effects.
- 4 of 22 experienced nausea, upset stomach, or diarrhea.
- Other side effects mentioned include weight gain, fatty liver, sore joints, kidney issues, brain fog, elevated fasting blood pressure, fatigue, headaches, and cognitive decline.

- *"Side effects differ from person to person so having options when we talk about HIV medications is really important. We fight to hold onto every single one of them to keep them accessible because we know that side effects impact people differently based on whichever medication they're on, and some people are resistant to medications."* Public input session attendee.

When asked about health outcomes of Genvoya, the majority of patients said their treatment goal was to remain undetectable and to achieve overall physical health. Meeting attendees spoke to the importance of whole-person wellness in addition to medical outcomes when treating patients with HIV. Additionally, meeting attendees discussed the differences in Genvoya and the other drugs under review, namely that Genvoya treats a communicable disease and interruptions in treatment could lead to worries of a broader public health issue.

Therapeutic Alternatives

Survey respondents reported trying the following other treatments: Biktarvy, Sribild, Atripla, Descovy, Symtuza, AZT, Isentress, Truvada, Juluca, Abacavir, and Tivicay. Some patients had tried more treatments than they could remember.

Meeting attendees discussed the importance of patient choice and the critical need for access to multiple medications due to drug resistance.

- *"We thought we'd be able to take medication after medication until we really understood about drug resistance and the impact these medications have on people's bodies. Now we are in a much different place, where we have really good options that are multiple drug combinations into one pill that makes it so much easier to take medications, and these are so critical."* Public input session attendee.

Meeting attendees also discussed the stigma surrounding HIV and the importance for the community to have trust, self-determination, and to share in clinical decision making.

- *"It's not uncommon to hear from folks that we serve with HIV that having a single tablet versus the multiple tablet is not only less of a pill burden, but also it's less of that reminder of the stigma of HIV."* Public input session attendee.

One meeting attendee further discussed the importance of health equity and self-determination for people living with HIV, citing the Denver Principles, which outline rights and responsibilities for people living with HIV and provide recommendations to healthcare professionals, family, and friends.

Financial Effects of Genvoya

Patients and caregivers were asked three types of questions related to the financial effects of Genvoya. Some survey questions and meeting discussions focused on better understanding patient out-of-pocket (OOP) costs for Genvoya, while other survey questions and meeting discussions focused on better understanding the relative financial effects of Genvoya 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 which may contain information on 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 their monthly out-of-pocket cost for Genvoya and if the cost of Genvoya has ever affected their access. Of the 22 patients surveyed, no one reported paying over $100 per month for Genvoya.

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

Out-of-Pocket Cost per Month	Patient Response	Cost Affects Access
$0 - $50	20 of 22	12 of 20 said cost does not affect access. 7 of 20 said cost affects access.
$50 - 100	2 of 22	1 of 2 said cost does not affect access. 1 of 2 said cost does affect access.

- *"The cost of Genvoya and other HIV medications can be prohibitive, but we in Colorado are fortunate to have a really good state drug assistance program that helps people living with HIV access medications."* Public input session attendee.

Table H-2
Patient Responses: How does Genvoya impact each patient or their family?[3]

Survey Prompt	Patient Responses
This medication reduces the amount of time and money going to the doctor.	13 of 22
This medication reduces the amount of time and money spent going to the hospital or needing surgery.	4 of 22
This medication allows me to work and support my family.	10 of 22
Due to the cost of this medication, I have had to cut costs in other areas of my life.	4 of 22
Out-of-pocket costs have caused me to accrue medical debt.	0 of 22

Table H-3
Responses: Has the cost of Genvoya ever affected your adherence to it?[4]

Survey Prompt	Patient Responses
No	3 of 22

[3] 3 of 22 survey participants did not answer regarding the impact Genvoya has on the patient or their family.

[4] 12 out of 22 survey responses were blank or not applicable regarding if the cost of Genvoya has affected their adherence to it.

I have skipped doses of the drug in order to save money	3 of 22
I have reduced the dose of the drug in order to save money.	1 of 22
I have stretched time between doses of the drug in order to save money.	0 of 22
I have changed prescription drugs to treat my condition due to cost.	3 of 22

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 22 patients surveyed, 20 used an assistance program, and only 1 patient reported having trouble affording Genvoya despite assistance programs.

- *"HIV is unique in that is has a program specifically paid for by federal dollars that allows for assistance to be paid for up to 500% of the federal poverty level."*
- *"There are negotiated costs through the AIDS Crisis Task Force and from manufacturers of HIV medications that allow for not only very discounted prices for anybody living with HIV that is uninsured, but rebates that are available to the state to help reimburse the cost of insurance premiums and copays, but any other Ryan White funded service."*
- *"If someone is told they don't qualify for one of the state programs, they are given links to patient assistance programs that are available for various medications."*

Utilization Management Requirements

Table H-4
Patient responses when asked if they agree with any of the following statements regarding utilization management.[5]

Survey Prompt	Patient Responses
I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	3
My insurance plan has dropped or switched my drug coverage after the plan year started.	0
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.	3
My insurance plan requires prior approval to fill the prescription.	6
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.	10
I worry that the cost of my prescription will raise my insurance premium.	5

[5] 5 of 22 survey participants did not answer regarding utilization management of Genvoya.

Additional Financial Effects

Patients and caregivers were asked in public meetings and in surveys to share any additional information about how Genvoya affects them financially.

Survey respondents said:

- “None. Personally, I have been very lucky and blessed to have all the resources that I have.”
- “I have to pick expensive health ins to cover this.”
- Other survey respondents noted transportation costs, frustrating logistics, and not seeing through care because of challenges.

Audio from Public Patient and Caregiver Meetings

The audio from the September 20, 2023 public Zoom meeting is found via the following link: https://us06web.zoom.us/rec/play/z7vLOOpDi-7ZxdT3qsFgTo2J4D9MGX7RmQe_BrEXRm5s-xZ1xmKAOyDuFqegd60L7YBbEQqbRhCIpj8v.x73Ur6ftWKNOFriL

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 Genvoya, 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 is redacted.

Figure H-1
Patient and Caregiver Survey (begins on next page). Personal Information

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

Personal Information and Health Effects

ID#	Drug?	Colorado resident?	Insurance Type	Priority population	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	Genvoya	Yes	Insured through employer	People who have AIDs or HIV		Remain undetected	
2	Genvoya	Yes	Medicaid/Health First Colorado	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People who have AIDs or HIV	Minimal to negligible	Consistency with medication, access to treatment and medication, undetectable bloodwork.	Undetectable HIV status, but this is the function of the medication, and I have used other medications that have achieved the same effect. So, of course, the prescription drug was effective, but I do not know of any other beneficial health effects that I have not received from other medications of the same sort.
3	Genvoya	Yes	Insured through employer	People who have AIDs or HIV	It currently does not affect my daily life	Staying on therapy	Kept me undetectable
4	Genvoya	Yes	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People who have AIDs or HIV, Older adults	None	Overall physical health	Higher cd4

ID#	Drug?	Colorado resident?	Insurance Type	Priority population	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?
5	Genvoya	Yes	Medicare	People who have AIDs or HIV	NONE, I DONT LET HIV DEFINE ME	UNDETECTABLE VL AND HIGH T-CELL COUNT	BECAME UNDETECTABLE
6	Genvoya	Yes	Medicaid/Health First Colorado	People who have AIDs or HIV, Older adults	I pray a lot ! I have this for 30 years	My t cells rising	It makes me live
7	Genvoya	Yes	I do not have health insurance	People experiencing homelessness, People who are lesbian, gay, bisexual, transgender, queer, or questioning, People who have AIDs or HIV	It made me detectable again after being undetectable, made me depressed and made me not wanting to leave the house	To stay undetectable	None from Genyvoa
8	Genvoya	Yes	Individual (private) insurance	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People who have AIDs or HIV, Older adults	Not as long as I take medication	Well being vs death	Undetectable virus

ID#	Drug?	Colorado resident?	Insurance Type	Priority population	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?
9	Genvoya	Yes	Medicaid/Health First Colorado	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People who have AIDs or HIV, People with disabilities	All of the above	Stability	Lowered my detectable status
10	Genvoya	Yes	Medicaid/Health First Colorado	Black people, indigenous people, and people of color, People with disabilities	It gives me heavy night sweats. Also I've taken it 3 different times in different days and same results. Heavy slumpness. When I take the pill before of during work. I'm always feeling exhausted	Staying undeniable andnhealthy	My increase in appetite
11	Genvoya	Yes	Medicaid/Health First Colorado	People involved in the criminal justice system, People who are lesbian, gay, bisexual, transgender, queer, or questioning, People who have AIDs or HIV	Some depression	Staying undetectable and keeping my cd4 count above 600	Remained undetectable and had an average cd4 of 800

ID#	Drug?	Colorado resident?	Insurance Type	Priority population	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?
12	Genvoya	Yes	Individual (private) insurance	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People who have AIDs or HIV, Older adults	Affects my immune system making me prone to infections	Feeling healthier	continuing undetectable levels of HIV virus
13	Genvoya	Yes	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People who have AIDs or HIV, People with disabilities	I continued to work but depression has been horrific.	No or minimal side effects	High cd4 levels undetectable except for one 6 month period.
14	Genvoya	Yes	Individual (private) insurance	People who have AIDs or HIV	Achey joints	Keeping my T-cells up	Staying alive up to this point
15	Genvoya	Yes	Ryan White	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People who have AIDs or HIV	Was supposed to help me	Staying alive	Not applicable

ID#	Drug?	Colorado resident?	Insurance Type	Priority population	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	Genvoya	Yes	Individual (private) insurance	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People who have AIDs or HIV	Daily, depression, fatigue, tired of everything, low energy etc	Not gaining weight. And health general, positive behavior and energy gain.	Stop the virus from doing more harm however it makes gaining weight easy and that is not good.
17	Genvoya	Yes	Medicaid/Health First Colorado	People who have AIDs or HIV	hiv is not something i feel i can openly share ,that is all emcompassing	staying undetectable	staying undetectable
18	Genvoya	Yes	Insured through employer	Black people, indigenous people, and people of color, People who are lesbian, gay, bisexual, transgender, queer, or questioning, People who have AIDs or HIV	n/a	staying undetectable	none; being undetectable

ID#	Drug?	Colorado resident?	Insurance Type	Priority population	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	Genvoya	Yes	Medicare	Veteran, People who are lesbian, gay, bisexual, transgender, queer, or questioning, People who have AIDs or HIV, Older adults	NO	no Side effects	Genvoya caused me issues. I quit it.
20	Genvoya	Yes	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People who have AIDs or HIV	I used to have severe anxiety for having HIV. Finally after 20+ years I've gotten over it and I'm more open about being HIV+/undetectable.	Living a longer life.	None. I had serious side effects.
21	Genvoya	Yes	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People who have AIDs or HIV	I don't know	Keeps me undetectable and no side effects	It kept my numbers to be undetectable for my HIV

ID#	Drug?	Colorado resident?	Insurance Type	Priority population	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?
22	Genvoya	Yes	Medicare	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People who have AIDs or HIV, Older adults, People with disabilities	Yes	Survival	Undetectable viral load

Health Effects cont.

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		It's the drug my provider prescribed and it works for me.	None	
2	None that I am aware of.	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Tivicay - undetectable status, no other beneficial or adverse health effects Truvada - undetectable status, no other beneficial or adverse health effects Biktarvy - undetectable status, no other beneficial or adverse health effects Descovy - undetectable status, no other beneficial or adverse health effects

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?
3	None, had switched from Complera to Genvoya and had no SE when switching	It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	Biktarvy (what I am currently taking)
4	Diarrhea	It's the drug my provider prescribed and it works for me.	Yes, three other treatments.	Zito Udine, atripla,
5	NONE	BIKTARVY HAS 2 COMPONENTS WHILE GENVOYA HAD 3	Yes, one other treatment.	WAS ON STUDY 5202/5212? AT UNIVERSITY HOSPITAL
6	Non really except if I mixed it with a medication that does not mix correctly was very I'll from the mixture	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	It was way before Genvoya came out
7	Change my status from undetectable to detectable	It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	Stribuild and I'm currently using it and it works
8	None	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Azt, crixovan,d4t, sustiva, abacavir

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?
9	Upset stomach	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, one other treatment.	Triveda,
10	None	It's the drug my provider prescribed and it works for me.	None	Na
11	Moderate Weight gain	It's the drug my provider prescribed and it works for me.	Yes, three other treatments.	Biktarvy, symtuza, and now duvato. None have had any noticable changes.
12	I've developed a fatty liver which causes its own problems	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Norvir, can't remember the other names
13	Side effects with cholesterol medication.	It's the drug my provider prescribed and it works for me.	None	
14	Not much just sone sore joints	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	AZT, Crixivan, so many I can’t remember anymore

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?
15	Kidney disease	I'm no longer on this medication due to it causing me kidney disease	Yes, two other treatments.	Atripla, Stribild, Genvoya
16	Headaches, fatigue, and weight-gaining	Im not taking this midication any more I took it for 5 years.	Yes, one other treatment.	No other options I have. Just follow doctor instructiins.
17	none but my doctor thinks using less is better so she recently changed me to dovato w adverse effects,i have herpes complex that has been suppressed for decades,returned within 2 wks of stopping genvoya, i also tested detectable for 2 times . i am currently undetectable...	It's the drug my provider prescribed and it works for me., see above answer	Yes, more than three other treatments.	i have been on many hiv regimens i have had hiv long enough to have new drugs available
18	nausea at times	It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	same effect

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?
19	Brain fog, Insomnia, Elevated Fasting Blood Pressure, Loss of Cognitive skills	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Stribild, Atripla, and others
20	Constant diarrhea, headaches	It's the drug my provider prescribed and it works for me.	Unsure	Atripla, Biktarvy,
21		It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Issentress, Tuvada, Genvoya , Juluca
22	Kidney issues	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	

Financial Effects cont.

ID#	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.	Has the cost of this drug ever made it difficult for you to access it?	Has the cost of this drug ever affected your adherence to it? Select all that apply.	How does this drug impact you and/or your family? Select all statements that are true for you.	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?
1	$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
2	$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
3	$0-$50 per month	No			Yes
4	$0-$50 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.	Yes
5	$50 - $100 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.	Yes

ID#	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.	Has the cost of this drug ever made it difficult for you to access it?	Has the cost of this drug ever affected your adherence to it? Select all that apply.	How does this drug impact you and/or your family? Select all statements that are true for you.	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?
6	$0-$50 per month	No	This helped me I thank God for this drug !	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
7	$0-$50 per month	Yes		This medication allows me to work and help support my family.	Yes
8	$0-$50 per 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.	Yes
9	$0-$50 per month	No	Other's upset my stomach	This medication reduces the amount of time and money spent going to the doctor.	Yes
10	$50 - $100 per month	No			Yes
11	$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
12	$0-$50 per month	No	no		Yes

ID#	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.	Has the cost of this drug ever made it difficult for you to access it?	Has the cost of this drug ever affected your adherence to it? Select all that apply.	How does this drug impact you and/or your family? Select all statements that are true for you.	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?
13	$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.	Yes
14	$0-$50 per month	No	I have to pick expensive health ins to cover this	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
15	$0-$50 per month	No	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
16	$0-$50 per month	Yes	I have reduced the dose 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

ID#	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.	Has the cost of this drug ever made it difficult for you to access it?	Has the cost of this drug ever affected your adherence to it? Select all that apply.	How does this drug impact you and/or your family? Select all statements that are true for you.	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?
17	$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
18	$0-$50 per month	No	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
19	$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.	No
20	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes
21	$0-$50 per month	Yes	Was going to have to go on cobra insurance to keep meds covered but didn't have 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.	Yes
22	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money.	Out-of-pocket costs have caused me to accrue medical debt.	Yes

Financial Effects cont.

ID#	If you replied "yes" to the question above, how did you hear about the financial assistance?	Do you have difficulty affording the drug despite using a patient assistance program?	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	My provider	No	I worry that the cost of my prescription will raise my insurance premium.	
2	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 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. Personally, I have been very lucky and blessed to have all the resources that I have. Others do not. I hope that these necessary and life-saving prescription drugs will be made affordable (or free, preferably) and accessible to all who literally need them to live.
3	Work	No		No. I will say though that providers at work have prescribed Genvoya to pregnant people living with HIV. We are seeing lots of individuals who are uninsured, many new to the US, who have either no ARVs left or a very small supply. Having access to Gilead Advancing Access same day enrollment has allowed patients to stay on treatment without a treatment disruption. So if Genvoya is removed, I would just want to make sure there are regimens that we can get coverage the same day for individuals who are uninsured. And hopefully in a way that is fast and efficient.
4	My provider	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
5	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.	NONE

ID#	If you replied "yes" to the question above, how did you hear about the financial assistance?	Do you have difficulty affording the drug despite using a patient assistance program?	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.)?
6		No	My insurance plan requires prior approval to fill the prescription.	No
7	Non profit organization	No	My insurance plan requires prior approval to fill the prescription.	No
8	My provider	No		
9	ADAP	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.	Transportation costs
10	Internet search	No		
11	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

ID#	If you replied "yes" to the question above, how did you hear about the financial assistance?	Do you have difficulty affording the drug despite using a patient assistance program?	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	My provider		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, side affects tend to make me sicker on average
13	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.	
14	I did 25 yrs ago no assistance since then	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 worry that the cost of my prescription will raise my insurance premium.	No just cost of living sky high & I wish I could live in my own house
15	My provider	No		Not applicable

ID#	If you replied "yes" to the question above, how did you hear about the financial assistance?	Do you have difficulty affording the drug despite using a patient assistance program?	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	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.	Yes
17	My pharmacist	No		no
18	My provider	No	I worry that the cost of my prescription will raise my insurance premium.	frustrating logistics, and not seeing through care because of challenges
19		Yes	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	No
20	Prescription drug manufacturer	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.	N/A
21	My pharmacist	No	My insurance plan requires prior approval to fill the prescription.	

ID#	If you replied "yes" to the question above, how did you hear about the financial assistance?	Do you have difficulty affording the drug despite using a patient assistance program?	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.)?
22	My provider	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.	

Appendix I

Genvoya: 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 Genvoya 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 Genvoya. 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.

Genvoya: 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 20, 2023. In addition to input gathered through the public meeting, one individual completed surveys regarding the health and financial effects of Genvoya. Zero respondents both attended the public meeting and completed the survey. Additional input was gathered from two individuals with scientific or medical training via two additional small group meetings.

At the initial time of survey release, the Board received zero 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 one response from individuals with scientific or medical training.

To qualify to participate in meetings or surveys, respondents had to have scientific or medical experience with Genvoya. 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 Genvoya and financial effects of Genvoya. 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 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 both appendices when evaluating input from individuals with scientific and medical training.

Similarly, there is additional information in Appendix F which may contain additional input from individuals with scientific and medical training not captured in this appendix. The Board may want to weigh information from both appendices when evaluating impact to safety net providers.

Health Effects of Genvoya

Individuals with scientific or medical training stated in public meetings and in survey responses that HIV is an infectious disease that is highly transmissible but not curable. As viral load goes up, the patient's immune function goes down, putting the person living with HIV (PLHIV) at increased risk of morbidity as well as mortality. Many participants emphasized that medication adherence with HIV is critical to the health of PLHIV, as well as to public health due to the increased risk of transmission of HIV to other individuals.

Participants shared that regardless of whether an individual is on medication, PLHIV are still disproportionately experiencing negative impacts of social determinants of health as a whole, including stigma, poverty, homelessness, and high barriers to accessing care. One participant stated that roughly 940 people in Colorado on Genvoya, and that across Colorado, people that identify as Black, Latino, or Hispanic tend to be disproportionately impacted by HIV, along with people that are on the lower end of the socioeconomic spectrum.

When speaking about prescribing Genvoya, individuals with scientific or medical training stated in public meetings and in surveys that Genvoya is used to treat HIV per professional and medical guidelines, and that treatment is an individual choice with elaborate discussions occurring between patient and provider to

figure out what works best for the patient. One participant stated that Genvoya is not typically used in the first line, but it is good to have in the toolbox, especially for those clients that have been on it and stable for quite some time.

The ultimate goal is to make HIV the least burdensome for patients as possible, and Genvoya is a complete regimen that a patient can take one time per day. In addition to the health benefits mentioned above, the one tablet a day regimen of Genvoya minimizes the impact of HIV on people's lives, as they can take the medication in the privacy of their own home or wherever they feel comfortable. This minimizes the impact of stigma for PLHIV and they are more likely to adhere to the treatment due to its ease.

"Adherence and persistence of a medication is incredibly important and there are proven benefits of single tablet regimens for adherence.They're less likely to discontinue their therapy, there's actually proven benefits of greater viral suppression as well, because they're staying on their medications." Meeting participant

Individuals with scientific and medical training reported in public meetings and surveys that Genvoya provides the following beneficial health effects:

- High rates of virological suppression which prevents transmission
- Preserves the immune function of patients, both that are treatment naive and treatment experienced, including women, children, and older PLHIV
- Complete regimen, as it is a combination of four medications in one
- The one pill regimen is easy to take and adhere to
- No dosage adjustment needed for those with chronic hemodialysis
- Controls viremia in HIV positive individuals who take this medication daily to treat HIV infection
- Least weight gained as compared to therapeutic alternatives

Many participants emphasized the importance of PLHIV to be able to stick to an established regimen and maintain it unless there are clinical reasons for changing their regimen. It provides stability for those that have experienced trauma from being on many different regimens and considering many options. Participants discussed complications that come with disruptions in care including drug resistance and increased viral load which could lead to transmission of HIV.

Participants did not indicate any off-label usage for Genvoya.

Side Effects

One participant stated that the benefits of Genvoya outweigh the disadvantages. Participants also stated that if side effects are minimal or non-existent, and if patients are virally suppressed, there is usually not a reason to start them on a new drug.

Therapeutic Alternatives

Though the number of HIV medications may look vast, participants explained that they have different mechanisms of action, different ways that you need to take medicines, different drug to drug interactions, and some are not a complete regimen. Prescribers said they use their own clinical knowledge and discussions with their patients to pick a regimen from the recommended therapeutic alternatives in the guidelines.

"This [Genvoya] is a one pill once daily option that patients take and tolerate and should, in my opinion, be available as an antiretroviral option to HIV infected individuals. The best medication is the one the patient will take."

Financial Effects of Genvoya

Individuals with scientific and medical training were asked three types of questions related to the financial effects of Genvoya. Some survey questions and meeting discussions focused on better understanding patient

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

Patient Cost

When asked if patients raise concerns about the cost of the drug, some participants highlighted IQVIA lab data that shows approximately 85% of people on Genvoya have a co-pay of less than or equal to $5. Participants stated that most individuals on Medicaid can afford Genvoya, and affordability is more of an issue for people that are newly diagnosed. According to the Managed Markets Insights Technology, 99% of insured patients had Genvoya covered in 2023. More than half of patients use Medicaid or safety net providers. Additionally, Gilead Advancing Access copayment program is available.

One participant stated that the National Alliance of State and Territorial AIDS Directors developed the AIDS Crisis Task Force, which has successfully been able to negotiate drug pricing directly with manufacturers. The Ryan White CARE Act makes any participant in the AIDS Drug Assistance Program (ADAP) eligible for 340 B pricing. Participants stated that manufacturers have gone a long way to meet the cost concerns of state programs, saving billions of dollars over the years. More than half of funding for HIV/AIDs services in Colorado are funded by this rebate, and the amount of rebate dollars is more than the grant from the federal government: it is bringing in $15 - $25 million dollars of revenue into the state HIV/AIDS programs which they can spend not only on the ADAP program, but on any Ryan White funded service, including housing, dental, medical care, food banks, and other services, creating ancillary savings across the board.

Additionally, participants stated that ADAP in Colorado is much more robust than in other states, and offers wraparound coverage for people earning up to 500% of the federal poverty level. Several participants also stated how beneficial ADAP is for people that are undocumented and/or are refugees, who are ineligible for Medicaid but can still access Genvoya through ADAP. Fewer than 3% of the participants in ADAP are uninsured, including people who are undocumented.

Relative Financial Effects

The majority of individuals with scientific or medical training discussed the cost of not being on Genvoya or any other antiretroviral therapy. The impact of not being virally suppressed is dire to PLHIV, and because HIV is a highly transmissible disease, it is a risk to public health safety overall. From a public health perspective, one important aspect of ending the HIV epidemic is medication access. One participant stated that one new HIV infection can increase health care costs by approximately $850,000 over a lifetime.

“As expensive as Genvoya is, it's a lot less expensive than three weeks in intensive care. So anything we can do to keep people from hospitalizations is also cost savings and humane.” Participant response

Utilization Management

Participants stated that commercial insurance often requires step therapy and preferred tiers, and some patients end up with less expensive medications from the preferred list, which could be multiple pills a day. Participants also noted that accumulator plans are a barrier.

One participant shared that some ERISA plans are incredibly inexpensive for the employer, but skirt through state federal regulation and will not cover entire classes of medications. They stated there are payers that are navigating through the loopholes in the laws that allow for coverages to exist, for the better good of society and patients as a whole; but other payers are damaging the public welfare by maximizing profit to self.

Participants also share that when talking about cost to the system, they are less concerned about manufacturer profit, but rather the rebates a payer is keeping as revenue. Rebates are highly confidential, and participants stated that it is difficult to see how much the system is actually benefiting from rebates.

Going beyond rebates, providers discussed that they do not know how much they will be reimbursed, and they must charge more than they think they will be paid so they will be able to recoup the reimbursement.

"It's the nature of this sort of asymmetric information problem that we have within the healthcare system, where nothing is transparent. And I believe payers and manufacturers recoup the benefit of that secrecy to a considerable deficit of the providers and the patients" Participant response

Audio from Public Meetings with Individuals with Scientific or Medical Training

The audio from the September 20, 2023 public Zoom meeting is found via the following link: https://us06web.zoom.us/rec/play/SFvgjd57IVwJZBteZZtk9_lsoJeXmiAk669HcqsW5OM_IeubPkaOYhbacmRsScy5-FP0bGkaYjG83gSU.WAcREKxDcOdt7M3n

Individuals with Scientific or Medical Training Survey

The Scientific or Medical Training Survey was 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

ID#	Have you attended, or do you plan to attend, a public input session for individuals with scientific or medical training?	After you complete the survey, Board staff may have follow up questions for you. Do you consent to staff reaching out to you via email after you complete the survey?	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:	Which prescription drug are you providing comments on today?	Please list the conditions that are treated by the prescription drug for which you are providing expertise.	What is the impact of this condition(s) on your patients?
1	No	Yes	As a prescriber of this drug to patients.	In Colorado	Genvoya	HIV	Chronic condition IF antiretrovirals are taken and viral load suppressed. Can lead to death if not on appropriate antiretrovirals

ID#	From your experience, how is this drug used in standard medical practice?	From your experience, describe any off-label usage of this drug.	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.	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?
1	Used for HIV treatment	None that I know of	Controls viremia in HIV positive individuals who take this medication daily to treat HIV infection	Benefits outweigh disadvantages	Yes, multiple other antiretroviral therapies/combinations are available; however, this is a one pill once daily option that patients take and tolerate and should, in my opinion, be available as an antiretroviral option to HIV infected individuals. The best medication is the one the patient will take.	If a patient is taking this medication, has no side effects, watches drug interactions, and does not want to change therapy, I think it should be an option for the patient to take this therapy.	This medication cost is similar to alternatives.

ID#	Do you discuss this drug's expense with patients when prescribing?	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?	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	Someone else in my organization discusses financial effects with patients.	Another person in my office discusses with the patient	Yes	yes. On ADAP formulary	Yes	Again, I thing it should remain an option to those who tolerate it and would like to continue it.

Appendix J

Genvoya: 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.

Genvoya: 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 Genvoya for 60 days following selection of Genvoya for an affordability review.

Information from Manufacturer

Submissions from Gilead Sciences Inc.	Page #s
GENVOYA®'s Affordability Package submitted by Gilead Sciences as voluntary information	J3-J36

Information from Other Entities

Submissions from Other Entities	Pages #s
CORA: Drug Board Must Prioritize Patient Access When Shaping Policies to Lower Drug Prices	J37-J40
HealthHIV	J41-J44

Proprietary Information

Confidential Submissions	Page #s
None	Not applicable

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

Re: GENVOYA®'s Affordability Package submitted by Gilead Sciences as voluntary information

Dear Members of the Prescription Drug Affordability Review Board:

I am writing on behalf of Gilead Sciences, Inc. (Gilead) to submit voluntary information for the Colorado Prescription Drug Affordability Board's (the Board) affordability review of GENVOYA®. An index to our response to each of the affordability factors under consideration by the Board is provided in Appendix. Gilead also submitted a letter to the Board dated September 13, 2023, which supplements this affordability package and is also provided in Appendix. We urge the Board staff to consider the information below (as the Board is required to do under the statute), as it provides additional data, including Colorado-specific data that is not publicly available. Upon review of this information, we are confident that the Board will agree Genvoya is already affordable and accessible for Coloradans and therefore should not be considered for an upper payment limit (UPL).

1. Genvoya is already an affordable and accessible treatment for Coloradans living with Human Immunodeficiency Virus (HIV). The affordability of Genvoya is reflected in its low patient out-of-pocket (OOP) cost levels, with the vast majority of patients paying $5 or less monthly for the medicine across all payer types[1]. Furthermore, price is not a barrier to patient access as Genvoya is broadly accessible to patients in Colorado, with 99% of insured people having insurance coverage[2] and half of the drug's utilization covered by Medicaid and other safety-net providers that serve marginalized and lower income communities[3].

2. Despite advances in treatment and national and state commitments to end the HIV epidemic, HIV continues to be a major public health concern with wide-reaching medical and societal impacts. Because HIV is a unique disease that disproportionately affects underserved populations, open access to affordable HIV medicine, including Genvoya, is paramount to enable patient and provider choice and avoid disruptions that lead to worse outcomes and costly consequences.

3. Because Genvoya is already affordable and accessible to Coloradans living with HIV, imposing a UPL for Genvoya will address patient affordability in a very limited way. Instead, a UPL is likely to lead to disruptions in patient access to a valuable treatment option. Genvoya is recommended by the US Department of Health and Human Services (DHHS) treatment guidelines to treat a broad range of patients living with HIV[4]. Its potent viral suppression, safety profile, and high adherence and persistence make it a necessary option to support patient/provider treatment choice. Imposing a UPL threatens to undermine open-access initiatives and Colorado's goals to eliminate the HIV epidemic, harming underserved individuals and populations in Colorado.

1. Genvoya is already affordable and accessible for Coloradans with HIV

Open access to affordable treatment options for HIV is crucial to ensuring that people living with HIV (PLWH) start and stay on the treatment that is most appropriate for them. Genvoya is an important treatment option for patients that is both affordable and widely accessible across all payer types for Coloradans living with HIV today.

APCD data overestimates Genvoya OOP costs by ~4 times

As an initial matter, the Board should be aware that the All-Payer Claims Database (APCD), which the Board relied on in selecting drugs for affordability review, significantly overestimates final patient OOP costs. In particular, as the Board has acknowledged, the APCD does not take accurate account of secondary benefits, such as manufacturer cost-sharing assistance, Medicare payments for dual-eligible patients, and AIDS Drug Assistance Programs (ADAP) that offset a portion of the patient's costs. As a result of the Board's reliance on the APCD, the Board's dashboard overestimates the patient OOP costs for Genvoya by approximately 4 times when compared to IQVIA's Longitudinal Access and Adjudication Data (LAAD)[1]. Continuing to rely on the APCD in making affordability determinations would be a profound mistake, resulting in erroneous determinations.

In the sections that follow, Gilead is providing the final patient OOP cost levels as reflected in the 2022 IQVIA LAAD to address recognized gaps in the APCD and provide the Board staff with the most accurate and up-to-date picture of Genvoya affordability for patients in Colorado. The

data provided in this part of the affordability package reflect the final cost for patients after all secondary benefits, which is one of the affordability criteria listed in the statute and is of interest for the Board members as expressed during past Board meetings. Indeed, the Colorado legislature has emphasized that costs to patients is the key focus of the statute and should be a principal focus of the Board's affordability determination.

Genvoya is already affordable for Coloradans across payer types, with ~85% of claims having $5 or less final patient OOP cost

Genvoya is affordable to Coloradans with HIV across all payer types. The data below further demonstrates Genvoya's affordability to Colorado patients by insurance type as of 2022:

- Commercial and Affordable Care Act Health Insurance Exchange (HIX) represent 40% and 5% of claims for Genvoya in Colorado, respectively. Within Commercial and HIX segments, ~80% of claims have a ≤$5 final patient OOP cost for a 30-day supply after secondary benefits based on Colorado-level IQVIA's LAAD in 2022[1].
- Medicaid (Fee-for-service and Managed) represents 22%[1] of claims for Genvoya. Patients in this segment have a $0 copayment in Colorado thanks to SB 23-222, which removed the copayment requirement for certain Medicaid services and appropriated additional funds to the Colorado Department of Health Care Policy and Financing.
- Medicare represents 24% of claims for Genvoya[1]. It is estimated that ~74% of HIV Medicare patients are low-income subsidy (LIS)-eligible[5] and have ≤$10 copayment[6].

Moreover, under the federal Ryan White HIV/ AIDS Program Part B, the AIDS Drug Assistance Program (ADAP) provides FDA-approved medications at little or no cost to low-income people with HIV, who may have limited or no health insurance. Grant recipients can also use the ADAP funds to buy health insurance for eligible clients and provide services that improve access to, adherence to, and monitoring of drug treatments[7]. The eligibility criteria in the State of Colorado to qualify for ADAP support are (1) Colorado residency, (2) an HIV/AIDS diagnosis verifiable by the Colorado Department of Public Health & Environment or from a doctor or testing facility, and (3) an income at or below 500% of the Federal Poverty Level[8].

Genvoya is especially affordable when compared to other specialty classes

Comparison with other therapies further supports the affordability of Genvoya. The Board's own dashboard shows that more than half of the eligible drugs had higher patient OOP costs than Genvoya, with Genvoya having the lowest patient OOP costs of the five drugs selected for

affordability review in August 2023[9]. Indeed, based on IQVIA's LAAD in 2022, Genvoya patient OOP costs were 43% lower when compared with other specialty* prescription drug classes[1].

The affordability of Genvoya is further underscored by its low abandonment rates. Patient abandonment may be an indication of patient affordability issues[10]. The abandonment rate for Genvoya is 54% lower than abandonment rates seen across other specialty* drug classes in 2022 (6% vs. 13%, respectively) per Colorado-specific data sourced from IQVIA's LAAD[1]. IQVIA defined abandonment rates as the proportion of claims that are approved by the payer but are not picked up or filled within 14 days.

Gilead supports Genvoya affordability and accessibility for patients through patient support programs

Where cost is a barrier for patients, Gilead works to reduce affordability challenges for Genvoya through Advancing Access, a patient support program that helps eligible people on Gilead HIV treatment medications explore potential coverage options that may be right for them, whether they have insurance or not. One such support option is the Gilead co-pay coupon card, which helps eligible commercially insured individuals lower their out-of-pocket costs. Additionally, eligible uninsured individuals may qualify for medication free of charge through Gilead's Advancing Access Patient Assistance Program. Furthermore, our program is committed to providing information to help patients address insurance and coverage issues should they arise through benefit investigation, prior authorization information, and other resources to support patients' ability to access their Gilead medication.

Gilead supports Genvoya affordability and access for the healthcare system through discounts

Apart from affordability to patients, the Board has acknowledged in its review criteria and discussions the importance of affordability to the healthcare system as a whole and the impact of a UPL could have on safety-net providers, given the important role they play in ensuring access to treatment for underserved populations. Gilead pays substantial voluntary discounts and rebates on Genvoya, in addition to offering the drug to 340B covered entities at the 340B ceiling price as required by federal law to support access for low-income individuals and medically underserved patients. 340B covered entities represent a larger share of sales for HIV than for other therapeutic areas, underscoring the importance of these entities' ability to purchase HIV medications at the 340B ceiling price to enable access to HIV treatment for PLWH. IQVIA reported that in 2019, 25% of antiviral sales were at the 340B ceiling price, compared to

* Specialty prescription drug classes, as defined by IQVIA and used in its publicly available industry reports, include medicines that treat chronic, complex, or rare diseases, and possess additional distribution, care delivery, and / or cost characteristics that require specialty management by stakeholders.

11% of the entire US pharmaceutical market[11]. In 2022, 34% of utilization for Genvoya in Colorado was through 340B covered entity providers, further illustrating the importance of continued access to Genvoya for these institutions[3].

Genvoya has generated significant cost savings for patients and the state of Colorado through medical cost offsets

The affordability of Genvoya is also realized at the healthcare system level through offsets to medical costs for the state of Colorado. HIV treatment offsets other medical costs by reducing HIV transmission. Avoiding just one new infection results in an average of $850,557 in lifetime healthcare cost savings[12]. Non-adherence to HIV medication contributes substantially to HIV-related healthcare resource use and costs, with added costs for non-adherent patients attributed to increased morbidity, frequent hospital visits, ambulatory care, nursing home services, and laboratory tests, in addition to indirect costs of non-adherence (e.g., loss of productivity, caregiver burden, welfare). The consequences of non-adherence can result in direct healthcare costs up to $30,068 per non-adherent individual with HIV per year in the US[13]. Treatment with tenofovir alafenamide (TAF)-based single-tablet regimens (STRs), including Genvoya, can create additional medical cost offsets compared to other regimens by reducing:

- Rates of patients switching treatment due to virological failure
- Cases of chronic kidney disease (saving ~$6k - $16k increase in annual costs per CKD patient)[14]
- Cases of cardiovascular disease (saving ~$6k - $9k in monthly expenditures per CVD patient)[15]
- Incidence of fracture events (saving ~$1k - $2k in monthly expenditures for patients who experienced any fracture or osteoporosis)[16]

Genvoya is accessible to Colorado patients living with HIV

The extent to which insurers offer coverage for Genvoya in Colorado further confirms that current pricing is not a barrier to access. Formulary coverage data provided by Managed Markets Insight & Technology, LLC (MMIT)—which fills gaps in the Board's patient access and utilization-management data—shows that 99% of insured Coloradans have coverage for Genvoya. For 92% of these patients, the health plan does not require utilization management to dispense the drug, supporting the affordability of Genvoya[2]. Additionally, access through Medicaid and safety net providers is especially important due to the disproportionate impact of HIV on underserved populations. These channels play a critical role in reducing health disparities within HIV for medically underserved patients and impoverished communities, with half of Genvoya utilization in Colorado represented by Medicaid or safety net providers[3].

2. Despite significant advances, HIV continues to be a major public health concern, underscoring the need for continued access to medications

Although HIV diagnoses nationwide have decreased, diagnoses have increased in Colorado

Ending the HIV epidemic remains an important global public health goal, with efforts driven by initiatives such as the Joint United Nations Program on HIV/ AIDS (UNAIDS) fast track targets of 95-95-95. By 2030, the UNAIDS fast track targets aim for 95% of PLWH to know their HIV status, 95% of those who know their status to be receiving antiretroviral therapy, and 95% of those on antiretroviral therapy to be virologically suppressed[17]. In addition to this global initiative, the U.S. has established its own National HIV/ Acquired Immunodeficiency Syndrome (AIDS) Strategy (NHAS) and Federal Implementation Plan, including the Ending the HIV Epidemic (EHE) Initiative. These efforts share a common goal of reducing new HIV infections in the US by 75% in 2025 and 90% by 2030[18-21]. Overall, NHAS and EHE articulate goals, objectives, and strategies to prevent new HIV infections, treat PLWH to improve health outcomes, reduce HIV-related disparities, and better integrate and coordinate the efforts of all partners to achieve these bold targets for ending the epidemic.

At the state level, Colorado has identified HIV as a priority in the Department of Public Health and Environment (DPHE) strategic plan. Despite this prioritization, however, Colorado has experienced a rise in the number and rate of new HIV diagnoses[22]. From 2015 to 2021, HIV diagnoses in Colorado rose nearly 9%, while diagnoses declined more than 10% nationwide[23]. The disparity between national and Colorado HIV trends, as seen in the rising number and rate of diagnoses within Colorado, underscores the need for open access to treatment within Colorado. This requires concentrated effort across all stakeholders to reduce stigma surrounding HIV, remove barriers to accessing treatment, and provide support for PLWH throughout their treatment journey.

HIV disproportionately impacts underserved communities in Colorado

Access to HIV treatment is especially important to reduce health disparities experienced by socially marginalized and disenfranchised populations, particularly sexual minorities and communities of color, who are disproportionately impacted by HIV:

- Gay, bisexual, and other men who have sex with men (MSM) constitute the population most affected in the US, accounting for 69% of all new HIV diagnoses in 2019[24] at national level.
- Hispanic / LatinX individuals, who make up 22.3% of the Colorado population, are disproportionately impacted by new HIV diagnoses (32%) as shown by the AIDSVu Colorado data[25].

- Black individuals, who make up 4.1% of the Colorado population, are disproportionately represented in both new HIV diagnoses (16.7%) and statewide HIV prevalence (15.2%)[25].

Continued access to treatment is paramount to improve health outcomes and reduce health disparities in these populations.

Disruptions in HIV care may exacerbate current challenges in PLWH receiving treatment

The ability of all PLWH to receive care is further complicated by the stigma and discrimination associated with HIV. PLWH may suffer from misconceptions and judgment around HIV transmission, and as a result, feel negatively about their HIV status[26]. These feelings can then deter them from seeking or staying in care and on treatment, leading to worse patient outcomes and limiting progress toward public health goals. Given these challenges in initiating and maintaining treatment for HIV, it is critically important to limit barriers to treatment access and ensure patients' ability to remain on treatment, such as Genvoya, so that patients feel empowered and supported in their treatment journey.

Open access in HIV is critical for provider and patient choice

HIV treatment is complex, and there is longstanding recognition of the importance of open-access policies that protect patients' access to HIV treatment medication. For example, the State of Colorado recognizes the importance of open access to HIV treatments through SB 23-189, which requires health plans that cover health services related to sexually transmitted infections to include coverage of HIV prevention drugs and cover HIV treatment without step therapy or prior authorization requirements. Similarly, at the national level, HIV is a protected class within the Medicare Part D program. These and other open-access policies enable PLWH to start treatment quickly and remain engaged in care, which in turn improves health outcomes, lowers the risk of transmitting HIV to sexual partners, and reduces healthcare costs[12]. Policymakers at the state and national level recognize that disruptions or delays in access to appropriate HIV treatments can have serious consequences for PLWH and the broader community. Imposing a UPL threatens to undermine the intent of these policies and SB 21-175 by creating access hurdles driven by non-clinical decisions.

HIV is a lifelong disease and continued open access to effective and tolerable treatment options is critical for patient and provider choice to support individuals from early childhood through older age. Currently, there are more than 30 antiretroviral (ARV) drugs that are approved by the US Food and Drug Administration (FDA) for treatment of HIV. Despite the availability of many treatment options, patient retention in HIV care continues to be challenging. HIV medicines are distinct from each other and, according to DHHS guidelines, treatment selection must be an individualized choice[4]. As such, patients, in consultation with their healthcare provider, should be able to start, stay on, or switch to the HIV treatment deemed most appropriate for them. In Colorado, patients taking Genvoya have been on the medicine for 29 months on average, 53%

longer than the average for all HIV patients in the State of Colorado (19 months)[27]. Allowing these PLWH to continue their treatment with Genvoya without the disruption a UPL threatens to cause is critical for achieving high rates of virologic suppression, which requires high levels of adherence. It is estimated that only ~66% of PLWH are virally suppressed due to poor adherence to HIV care and treatment[28]. Reducing patients' ability to remain virally suppressed by disrupting access to their HIV treatment of choice could result in worse health outcomes, including greater risk of virologic failure, characterized by increased viral replication and viral load, and in turn, onward transmission of HIV[4]. As such, keeping patients on treatment is an important avenue to reduce new HIV diagnoses in Colorado and improve progress toward ending the HIV epidemic. For these reasons, the consequences of a UPL could only further increase the rise of new HIV cases in Colorado and undermine efforts to reduce HIV infections by 2030.

Ensuring that patients are able to initiate and remain on the HIV treatment that is best suited for their needs will help support patient satisfaction and adherence to their treatment. The Board has highlighted patient satisfaction information as a key data gap. Genvoya patient satisfaction has been demonstrated by high rates of adherence and persistence compared to other STRs included in a real-world study (Stribild, Triumeq, Odefsey, Complera, Atripla)[29]. We urge the Board to consider these data elements as important indicators of the need to protect open access to HIV medications and to ensure that treatment selection will continue to be an individualized choice of patients in consultation with their healthcare providers in Colorado without any impact from a UPL.

3. Genvoya is already affordable to Coloradans living with HIV, and imposing a UPL threatens to create unnecessary barriers to patient access to valuable HIV treatment

<u>Imposing a UPL would put patient access to critical medications at risk with limited impact on affordability</u>

As stated in the policies, procedures, and public meetings of the Board, the purpose of SB 21-175 and the potential implementation of UPLs is to protect Colorado residents from excessive prescription drug costs and ensure patient affordability. A critical part of the Board's decision-making, however, should be consideration of the resulting implications of a UPL on patient access. Key stakeholders have raised concrete and serious concerns regarding the potential for UPLs to reduce patient access to medications. As stated in comment letters from the Colorado Pharmacist Society and the Colorado Hospital Association[30], patient access to medications subject to UPLs will likely be limited if pharmacies and health systems cannot supply these medications in a financially viable manner. UPLs will lead to lower reimbursement rates from payers to pharmacies and providers and thus impact the supply-chain economics, leaving

pharmacies and providers to have to choose between taking a loss on the purchase of a UPL drug or discontinuing patient treatment by ceasing to stock or prescribe the medication. This impact to pharmacies and providers places patient access to treatments at risk and opens the possibility of disruptions in care and open-access initiatives. Respectfully, it would be unreasonable and contrary to the Board's mission to proceed with price setting that does not account for these serious access concerns.

UPL implementation risks limiting the value Genvoya brings to Coloradans living with HIV

As previously stated, HIV treatment is complex and requires patients to have access to the full scope of HIV treatment options. While implementing a UPL for Genvoya is unlikely to impact affordability, its disruptive impact on access threatens to undermine the many benefits that Genvoya brings to Coloradans living with HIV.

Genvoya is a single-tablet regimen (STR) that provides differentiated value for patients with HIV, having demonstrated high rates of virologic success in dedicated studies conducted in treatment-naïve and -experienced populations, including a wide variety of PLWH; e.g. virologically suppressed PLWH, women, children and adolescents with HIV, older PLWH, HIV/hepatitis B virus (HBV) co-infected PLWH[31-40]. The broad utility of Genvoya is recognized in DHHS HIV treatment guidelines, which support its use in both treatment-naïve and treatment experienced patients and recommend it as an initial ARV regimen in certain clinical situations, such as for patients with CrCl < 30 mL/min and on chronic hemodialysis[4]. Genvoya provides potent, durable, noninferior efficacy through Week 96 with a low rate of resistance (1%) in antiretroviral therapy (ART)-naïve adults from 2 parallel head-to-head clinical trials (Studies 104 and 111) against Stribild[41]. In addition to efficacy in ART-naïve patients, switching to Genvoya was associated with superior efficacy at Week 48 compared to continuation of emtricitabine / tenofovir disoproxil (FTC/TDF)-based regimens in virologically suppressed adults (97% vs 93%, respectively; P<0.001) (Study 109)[39]. Furthermore, in clinical trials, patients using Genvoya demonstrated favorable renal and bone laboratory parameters compared to those treated with other HIV treatments containing TDF (e.g., Stribild) and no associated cardiac risks, which have been associated with treatments containing abacavir [4,39,41-43].

While the high number of Coloradans taking Genvoya (940 in 2021) was one of the main drivers for the Board's selection of Genvoya for affordability review[9], it also demonstrates the value Genvoya brings to Colorado in improving and lengthening the life of Coloradans living with HIV, delivering cost offsets to the state's health system, and achieving state treatment targets to end the HIV epidemic. Respectfully, it would be a mistake to treat the high patient count as a driving consideration in the affordability analysis when instead it is better understood as a measure of the many benefits Genvoya brings to patients and the healthcare system.

Imposing a UPL threatens to harm socially vulnerable populations in Colorado

Finally, the Board should carefully consider the impact of UPL implementation on access to Genvoya for minority individuals and populations in Colorado, as it has the potential to increase health and social inequities experienced by underserved communities. The Board should recognize that setting a UPL can disproportionately impact care for disadvantaged individuals who are most likely to suffer from disruptions in care.

One representative of the Colorado Pharmacist Society raised this potential reality, highlighting the risk of "additional access issues for patients, especially in rural and underserved areas"[30]. Disruptions in patient access caused by the channel dynamics affecting hospitals, pharmacies, and health systems may lead to exacerbations in health disparities. These concerns are especially relevant in light of current HIV trends in Colorado, with new HIV diagnoses disproportionately impacting disadvantaged communities, such as the Hispanic / LatinX, Black, and sexual minority (e.g., trans women and MSM) communities[44].

In summary, Genvoya is already affordable and accessible for Coloradans living with HIV. Introducing a UPL will have limited impact on patient affordability yet is likely to create significant barriers to accessing and adhering to HIV treatment for socially vulnerable populations within Colorado, increase health and social inequities, harm patient outcomes, and damage efforts toward eliminating the HIV epidemic. We strongly believe the information provided in this affordability package demonstrates why Genvoya is already affordable and should not be subjected to a UPL. In addition, Gilead is concerned that some of the Board's actions are unlawful, as explained further in Appendix B. If you have any questions or wish to notify Gilead about future Board actions, please do not hesitate to contact me at kristie.banks@gilead.com.

***

Sincerely,

DocuSigned by:
Kristie Banks
3B4BECBA5AB74F3...

Kristie Banks
Vice President, Managed Markets
Gilead Sciences, Inc

References

1. Longitudinal Access and Adjudication Data (LAAD). United States: IQVIA. Published 2022.
2. Data provided by MMIT data (accessed August 2023).
3. Gilead internal data from Medicaid submitted claims and Chargeback data, 2022
4. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv (accessed August 2023).
5. Kaiser Family Foundation. Medicare and People with HIV. Available at https://www.kff.org/hivaids/issue-brief/medicare-and-people-with-hiv/ (published March 2023).
6. Centers for Medicare and Medicaid Services. 2023 Medicare Part D Low-Income Subsidy (LIS) Income and Resource Standards. Available at https://www.cms.gov/files/document/2023medicarepartdlowincomesubsidylisincomeandresourcestandardsg.pdf (published February 2023).
7. https://ryanwhite.hrsa.gov/about/parts-and-initiatives/part-b-adap (accessed September 2023)
8. https://www.kff.org/hivaids/state-indicator/adap-financial-eligibility-as-a-percent-of-the-federal-poverty-level/?currentTimeframe=0&selectedRows=%7B%22states%22:%7B%22colorado%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (accessed September 2023)
9. Colorado PDAB 2024 Eligible Drug Dashboard. Colorado: Colorado Division of Insurance. Updated July 25, 2023. Accessed August 2, 2023.
10. Medicine spending and affordability in the US, IQVIA 2020. Available at https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us (accessed September 2023).
11. IQVIA White Paper "The 340B Drug Discount Program: Complexity, Challenges, and Change", 2020 accessible at: https://www.iqvia.com/locations/united-states/library/white-papers/the-340b-drug-discount-program
12. Cohen JP, Beaubrun A, et al. Estimation of the Incremental Cumulative Cost of HIV Compared with a Non-HIV Population. PharmacoEconomics Open. (2020).
13. Abdulrahman SA, Ganasegeran K, Rampal L, Martins OF. HIV Treatment Adherence - A Shared Burden for Patients, Health-Care Providers, and Other Stakeholders. AIDS Rev. 2019;21(1):28-39. doi:10.24875/AIDSRev.19000037
14. McComsey G, Meyer N, Song X, Winston J. A longitudinal analysis of chronic kidney disease and related comorbidities among human immunodeficiency virus (HIV) patients [TH-PO528]. Presented at: Kidney Week 2015; November 3-8, 2015; San Diego, California.
15. Hsue P, Meyer N, Song X, Winston J. A longitudinal analysis of cardiovascular conditions and related comorbidities among human immunodeficiency virus (HIV) patients in the USA [Poster 1645]. Presented at: IDWeekTM; October 7-11, 2015; San Diego, California.
16. Meyer N, DeJesus E, Song X. A longitudinal analysis of fractures among human immunodeficiency virus (HIV) patients in the USA [Poster 1663]. Presented at IDWeek™; October 7-11, 2015b; San Diego, California.

17. UNAIDS. 95-95-95: Understanding Fast Track. Available at: www.unaids.org/sites/default/files/media_asset/201506_JC2743_Understanding_FastTrack_en.pdf (accessed September 2023).
18. HIV.gov. National HIV/AIDS Strategy (2022-2025). Available at https://www.hiv.gov/federal-response/national-hiv-aids-strategy/national-hiv-aids-strategy-2022-2025/ (accessed September 2023).
19. HIV.gov. Implementing the National HIV/AIDS Strategy. Available at https://www.hiv.gov/federal-response/national-hiv-aids-strategy/implementing-national-hiv-aids-strategy/ (accessed September 2023).
20. HIV.gov. Ending the HIV Epidemic Overview. Available at https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview/ (accessed September 2023).
21. America's HIV Epidemic Analysis Dashboard (AHEAD). The Six EHE Indicators. Available at https://ahead.hiv.gov/data (accessed July 2023).
22. Colorado HIV & AIDS prevention, care, and treatment 2022-2026 strategic plan. Denver, US: Colorado Department of Public Health & Environment; 2022.
23. CDC.gov. Atlas Plus Charts. Available at https://gis.cdc.gov/grasp/nchhstpatlas/charts.html (accessed September 2023).
24. Centers for Disease Control and Prevention. Diagnoses of HIV Infection in the United States and Dependent Areas 2019: Special Focus Profiles. Available at https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-32/content/special-focus-profiles.html#:~:text=In%202019%2C%20MSM%20accounted%20for,unaware%20of%20their%20HIV%20infection (accessed August 2023).
25. AIDSVu.org. Local Data: Colorado. Available at https://aidsvu.org/local-data/united-states/west/colorado/#demographics-2021 (accessed September 2023).
26. Centers for Disease Control and Prevention. HIV Stigma and Discrimination. Available at https://www.cdc.gov/hiv/basics/hiv-stigma/index.html (accessed August 2023).
27. IQVIA analysis for Gilead
28. HIV.gov. Limitations to Treatment Safety and Efficacy: Adherence to the Continuum of Care. Available at https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/adherence-continuum-care (updated March 2023).
29. Sutton SS, Hardin JW, Bramley TJ, D'Souza AO, Bennett CL. Single- Versus Multiple-Tablet HIV Regimens: Adherence and Hospitalization Risk. Am J Manag Care. 2016;22(4):242-248.
30. Colorado Department of Regulatory Agencies. Colorado Prescription Drug Affordability Review Board & Advisory Council. Written Testimony – Part 4: Upper Payment Limit Methodology. Available at: https://drive.google.com/drive/folders/1iyh5kEElajLvjlXdfi2FzFQ9Q12QJPCv.
31. Gaur A, et al. CROI 2016. Boston, MA. #817.
32. Hodder S, et al. CROI 2017. Seattle, WA. Poster #443
33. Perez-Valero I, et al. AIDS 2018. Amsterdam, NL. Poster TUAB0104.
34. Eron J, et al. ID Week 2019. Washington, DC. 2489.
35. Maggiolo F, et al. HIV Glasgow 2018, Poster 146.
36. Maggiolo F, et al. HIV Drug Therapy 2018. Glasgow, UK. Poster 145.
37. Gallant J, Brunetta J, Crofoot G, et al. Brief Report: Efficacy and Safety of Switching to a Single-Tablet Regimen of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide in HIV-1/Hepatitis B-Coinfected Adults. J Acquir Immune Defic Syndr 2016;73:294-298.

38. Huhn G, Tebas P, Gallant J, et al. A Randomized, Open-Label Trial to Evaluate Switching to Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide Plus Darunavir in Treatment-Experienced HIV-1-Infected Adults. J Acquir Immune Defic Syndr 2017;74:193-200.
39. Mills A, Arribas J, Andrade-Villanueva J, et al. Switching from tenofovir disoproxil fumarate to tenofovir alafenamide in antiretroviral regimens for virologically suppressed adults with HIV-1 infection: a randomised, active-controlled, multicentre, open-label, phase 3, non-inferiority study. Lancet Infec Dis 2016;16:43-52.
40. Post F, Tebas P, Clarke A, et al. Switching to Tenofovir Alafenamide, Coformulated With Elvitegravir, Cobicistat, and Emtricitabine, in HIV-Infected Adults With Renal Impairment: 96-Week Results From a Single-Arm, Multicenter, Open-Label Phase 3 Study. J Acquir Immune Defic Syndr 2017;74:180-184.
41. Sax PE, Wohl D, Yin MT, et al. Tenofovir alafenamide versus tenofovir disoproxil fumarate, coformulated with elvitegravir, cobicistat, and emtricitabine, for initial treatment of HIV-1 infection: two randomised, double-blind, phase 3, non-inferiority trials. Lancet. 2015a; 385(9987):2606-2615.
42. Pozniak A, Arribas J, Gupta SK, et al. Safety of tenofovir alafenamide in renal impairment [795]. Presented at: the 22nd Conference on Retroviruses and Opportunistic Infections; February 23-26, 2015; Seattle, Washington.
43. Gupta SK, Pozniak A, Arribas J, et al. Patients with renal impairment switching from tenofovir disoproxil fumarate to tenofovir alafenamide: week 48 renal and bone safety [1646]. Presented at 8th IAS Conference on HIV Pathogenesis, Treatment & Prevention; July 19-22, 2015a; Vancouver, Canada.
44. 2020 priority settings & research allocation data booklet. Colorado, US: STI / HIV & Viral Hepatitis Branch, Colorado Department of Public Health & Environment; 2020.
45. Richard Kane. PhRMA. New global analysis shows patient access challenges around the world. April 12, 2023. Available at: https://phrma.org/en/Blog/New-global-analysis-shows-patient-access-challenges-around-the-worldplaceholder (accessed August 2023)
46. Fuhr J, Sigaud L, Pociask S. How International Reference Pricing for Prescription Drugs Would Hurt American Consumers. The American Consumer. 2019 Jun. Available at: https://www.theamericanconsumer.org/wp-content/uploads/2019/06/IPI-Final-Study.pdf (Accessed August 2023)
47. Colo. Rev. Stat. Ann. § 10-16-1403(1)(a)-(b) (emphasis added).
48. *Id.* § 10-16-1406(2)(d); *see also id.* § 10-16-1406(4)(c) (in conducting affordability review, Board must consider the "effect of the price on Colorado's consumers' access to the prescription drug").
49. *See, e.g.*, S.B. 21-175 Preamble § 1(2) ("The general assembly therefore declares … it is imperative that Colorado take measures to reduce excessive prescription drug costs for Coloradans who cannot afford prescription drugs[.]"); Hearing of Colo. S. Comm. Health and Human Services, Mar. 17, 2021, 6:00 PM MT ("You know that rising drug prices impede the ability of Coloradans to actually afford to take the medications they need, and that the affordability challenge is a driver of healthcare disparities.") (Testimony of Kim Bimestefer), https://sg001-harmony.sliq.net/00327/Harmony/en/PowerBrowser/PowerBrowserV2/20210317/-1/11018#info .
50. Colo. Rev. Stat. Ann. § 24-4-106(7)(b)(IV).
51. Martinez v. Colorado Dep't of Hum. Servs., 97 P.3d 152, 157 (Colo. App. 2003).
52. Colo. Rev. Stat. Ann. § 24-4-106(7)(b)(I); s*ee Van DeVegt v. Board of Cty. Comm'rs of Larimer Cty.*, 55 P.2d 703, 705 (Colo. 1936) (agency action is arbitrary and capricious if agency "neglect[s] or refus[es]

to use reasonable diligence and care to procure such evidence as it is by law authorized to consider in exercising the discretion vested in it).

53. *See* Colo. Rev. Stat. Ann. § 24-4-106(7)(b)(V) (requiring vacatur of agency action that is "[n]ot in accord with the procedures or procedural limitations of [the APA] or as otherwise required by law").
54. *See Independent Petroleum Ass'n of Am. v. Babbitt*, 92 F.3d 1248, 1260 (D.C. Cir. 1996) ("It is the very meaning of the arbitrary and capricious standard" that "[t]he treatment of cases A and B, where the two cases are functionally indistinguishable, must be consistent.").

Appendix A: Index of Gilead's response to each of the affordability factors under consideration by the Board on Genvoya

Affordability criteria as provided by the Board	Summary of relevant information in this document and elsewhere
Current WAC & change in WAC	Genvoya is priced to value and cost-effectiveness reflecting patient clinical needs and access considerations and using standard well accepted methodologies. Genvoya's WAC change over the years assessed reflects an appropriate level required to support ongoing R&D investments, innovation, and ingredient costs, which rose commensurate with inflation.
Cost and availability of therapeutic alternatives available in CO	Gilead strongly believes that there are no therapeutic alternatives for HIV treatments. HIV drugs are unique, and each drug has specific qualities related to safety and tolerability, drug-drug interactions, dosing, and drug resistance that should be considered when selecting the best HIV treatment regimen for a patient. If, despite this concern, Colorado chooses to compare Genvoya to other medicines used to treat HIV, the state should rely on the DHHS guidelines to identify comparators. See also: Section 2: Genvoya's adherence and persistence vs other STRs; Section 3: Genvoya clinical differentiation.
Price effect on consumer access	Section 1: Genvoya current insurance coverage within Colorado from MMIT data
Relative financial effects of the drug on health, medical, or social services	Section 1: Economic value realized by availability of Genvoya
Patient co-payment and other cost-sharing information	Section 1: Genvoya patient co-payment levels across payer channels
Impact on safety net providers	Section 1: Genvoya utilization in CO represented by 340B covered entities and safety net providers
Orphan drug status	Genvoya does not have orphan drug designation
Input from patients and caregivers	Gilead appreciates the input provided by patients and caregivers during the Board's September 20, 2023 stakeholders meeting addressing Genvoya

	and encourages the Board to contact Gilead with questions stemming from this input.
Input from individuals with scientific or medical training	Gilead appreciates the input provided by individuals with scientific or medical training during the Board's September 20, 2023 stakeholders meeting addressing Genvoya and encourages the Board to contact Gilead with questions stemming from this input.
Information voluntarily submitted from manufacturers, PBMs, carriers, and other entities	This document serves as part of the Gilead voluntary submission for Genvoya
Rebates, discounts, and price concessions	Section 1: Gilead supports Genvoya affordability and access for the healthcare system through discounts
Health equity impact	Section 1: Genvoya patient co-payment levels for Medicaid; Genvoya utilization in CO represented by 340B covered entities and safety net providers Section 2: Impact of HIV on underserved communities Section 3: Impact of UPL implementation on health equity disparities within HIV
Information from the Colorado Department of Health Care Policy and Financing (HCPF)	Gilead understands that the Board may consider certain information from HCPF that relates to Genvoya. Gilead requests that the Board or Board staff provide Gilead with an opportunity to review and comment on any information provided by HCPF prior to the finalization of the Board Staff's Genvoya affordability report.
Non-adherence and utilization management information	Section 1: Genvoya utilization management in CO; Genvoya's abandonment rate Section 2: Genvoya's adherence data
Pricing Information	Gilead recognizes that the State may consider pricing information from other countries as it considers the affordability of Genvoya. We encourage the state to also consider that there are fewer medicines available in other countries than in the US. For example, on average, patients in other countries in the Organization for Economic Co-operation and Development that rely on various forms of pharmaceutical price-

	setting, have access to only 29% of new medicines, while patients in the United States have access to 85%[45]. In addition, international reference pricing can discourage future R&D investments[46].

Appendix B: The Board should address concerns with the lawfulness of its selection and affordability review before determining Genvoya's affordability

In this section, Gilead sets forth its preliminary, but significant, concerns regarding the lawfulness of the Board's actions thus far. As explained in more detail below, the Board's interpretation of SB 21-175—the law that established the Board and governs its conduct—contravenes the statutory text and the General Assembly's purpose in enacting SB 21-175. In addition, the Board has repeatedly failed to engage in reasoned decision-making in its selection of drugs for affordability review, its reliance on flawed data, its failure to promulgate a predictable and clear affordability metric, and its failure to establish basic procedural safeguards for manufacturers.

The discussion below is not an exhaustive survey of unlawful agency actions by the Board, nor does this submission discuss the grave constitutional flaws in SB 21-175 itself, which Gilead briefly discussed in its public comment letter, attached hereto as Appendix C. Gilead reserves the right to supplement its submission concerning the legal defects in the Board's actions, including by identifying future unlawful actions by the Board during affordability review and any adoption of a UPL. However, Gilead respectfully submits that these initial legal concerns should inform Board's actions going forward, including its affordability review.

First, the Board's initial selection of drugs for affordability review defied the statute because it was based entirely on identifying drugs with the highest total paid amount statewide, without regard to those drugs' affordability for individual patients. SB 21-175 clearly provides that the Board "shall … [c]ollect and evaluate information concerning the cost of prescription drugs sold to Colorado consumers [and] [p]erform affordability reviews of prescription drugs" for the purpose of "*protect[ing] Colorado consumers from excessive prescription drug costs*"[47]. After the Board identifies drugs eligible for affordability review, the statute directs the Board to select the drugs it will review by "[c]onsidering the average patient's out-of-pocket cost for the prescription drug[s]"[48]. SB 21-175's legislative history underscores the General Assembly's focus on ensuring affordability for Colorado patients, rather than overall cost savings for payers[49].

Despite these statutory commands, the Board's process for selecting drugs for affordability review did not consider individual patient affordability. Instead, after identifying 604 drugs as eligible for affordability review, the Board created a "Prioritized Summary and Ranked and Weighted List" that sorted drugs based entirely on the total amount paid for each drug in Colorado[9]. The Board's prioritization gave no consideration to individual patients' out-of-pocket cost. Indeed, although Genvoya has an annual patient out-of-pocket cost of only $1,293 even using the Board's flawed APCD data—which ranks in the third quartile of all 604 eligible drugs—it was ranked *sixth* out of 604 on the Board's prioritized list, because of the relatively high aggregate amount spent to dispense the drug to Colorado patients. The Board then relied on that prioritized list in selecting five drugs for affordability review, and it selected Genvoya after a higher-ranked drug was eliminated because it was soon coming off-patent. The sole basis for Genvoya's selection was its *aggregate* cost, which is relatively high not because it is costly, but

because of sheer patient count. In essence, the Board punished Gilead for its success in developing a drug that treats more Coloradans than most other drugs. This was not only arbitrary and capricious, but it disregarded the statute, which asks whether a drug is affordable to patients, not how much is spent on a drug in the aggregate in Colorado.

The Colorado Administrative Procedure Act prohibits agency action, like the Board's selection process, that is "[i]n excess of statutory jurisdiction, authority, purposes, or limitations"[50]. Colorado law requires "[a]n administrative agency … [to] comply strictly with its enabling statutes, and it has no authority to set aside or circumvent legislative mandates"[51]. Given the Board's failure to adhere to the statute's terms, the Board should vacate its selection of Genvoya and reselect drugs from the existing list of eligible drugs based on out-of-pocket cost, as the legislature intended.

Second, the Board's reliance on flawed and incomplete APCD data as part of its selection of drugs for affordability review – and any future reliance on that data in making determinations concerning affordability – is arbitrary and capricious[52]. As explained above, the APCD data generally does not include secondary benefits that may significantly reduce patients' cost-sharing, which in Genvoya's case means that the APCD overestimates patient out-of-pocket costs by *378%*[1,9].

Third, the Board has offered only a confusing 14-point rubric to govern its affordability review, but it has offered little guidance concerning how it will weigh those more than a dozen factors, much less has it provided objective standards concerning what rate of patient out-of-pocket expenditure it considers unaffordable. The Board's failure to provide any metric for determining whether a drug is affordable creates the risk of arbitrary decision-making. This also raises serious due process concerns because the lack of meaningful guidance makes it impossible for manufacturers, such as Gilead, to prepare full and robust submissions explaining why their drug is affordable. This harm is exacerbated by the legislature's unrestrained grant of authority to the Board to make freewheeling "affordability" determinations without providing sufficient standards and safeguards to protect against unreasonable determinations. The Board should suspend its affordability review, promulgate clear and predicable guidance concerning affordability, and restart its selection and affordability review under the revised guidance.

Finally, the Board's refusal to provide manufacturers such as Gilead with a meaningful opportunity to be heard before the Board makes an affordability determination is arbitrary and capricious and denies Gilead basic procedural safeguards required under federal and Colorado law[53]. The Board's affordability review procedures are deficient in multiple ways. Below is a non-exhaustive list of examples of Gilead's concerns about the procedures that apply to the Board's affordability review.

- The Board precludes manufacturers like Gilead from submitting written evidence after October 3, 2023, which is the same deadline for voluntary submissions by other stakeholders, including carriers, pharmacy benefit managers, and other entities. That

requirement deprives Gilead of any opportunity to respond on the record to those other stakeholders' statements concerning the affordability of Genvoya and threatens to leave the Board with incomplete information and unresolved questions concerning the affordability of Genvoya.

- Similarly, the Board has indicated that Gilead will have no opportunity to review and respond to the Board staff's draft affordability report concerning Genvoya, which will incorporate information from other stakeholders as well as other sources of information that Gilead has not had an opportunity to review. The draft report will form the basis of the Board's determination. Under the Board's procedures, the Board will not review this written submission directly.
- The Board has not instituted any process for Gilead to be heard at Board meetings—or even at the Genvoya-specific stakeholder hearings concerning Genvoya's affordability, apart from an ability to have a Gilead medical expert speak at one stakeholder meeting that was not attended by any Board members. Indeed, although there is an opportunity for public comment at Board meetings, Board staff have limited such comments to two minutes and expressly forbidden commenters from addressing the affordability of specific drugs under review. Moreover, Board staff have been inconsistent about whether manufacturers will be able to meet with Board members individually; staff apparently allowed one manufacturer to meet with the Board chair, but have indicated that other manufacturers would likely not be permitted to have such meetings. Such ad hoc decision-making and inconsistent treatment of similarly situated parties is the height of arbitrary and capricious agency action[54].
- The Board and Board staff have indicated that the Board plans to deliberate concerning the affordability of Genvoya, including by considering other stakeholders' comments about Genvoya, at its next two meetings on October 27, 2023 and December 9, 2023. Because the written submission process is the only opportunity that was made available to Gilead to submit information and argument concerning Genvoya, and the window to make a written submission will have closed long before those two meetings, Gilead will have no way to respond to any concerns or questions that Board members raise in those meetings or to correct incomplete or inaccurate comments made at those meetings.

Appendix C: Comment letter sent by Gilead on Sep 13th, 2023

See next page for the comment letter sent on Sept 13th, 2023.

GILEAD
Creating Possible

September 13, 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

Re: September 15 Prescription Drug Affordability Review Board Meeting

Dear Members of the Prescription Drug Affordability Review Board:

I am writing on behalf of Gilead Sciences, Inc. ("Gilead"), in response to the PDAB's recent selection of Genvoya® for an affordability review. Genvoya is affordable and accessible to HIV positive individuals in Colorado as shown by the fact that approximately 85% of Genvoya claims were less than $5 in Colorado in 2022[1] and 99% of insured patients had coverage for Genvoya in 2023.[2] HIV is a unique disease because it is both infectious and currently not curable, therefore it is critical to avoid treatment disruptions which could temporarily increase the risk of transmission. We are deeply concerned regarding the implications that a potential Upper Payment Limit ("UPL") applied to Genvoya may have on access to HIV therapy, clinical outcomes in those living with HIV, and public health in Colorado.

Gilead is a research-based biopharmaceutical company that discovers, develops, and commercializes innovative medicines for people with life-threatening diseases in areas of unmet medical need. Gilead's therapeutic areas of focus include HIV/AIDS, liver diseases, oncology, COVID-19, as well as certain cardiovascular and respiratory diseases. For more than 30 years, Gilead has been a leading innovator in the field of HIV, driving advances in treatment, prevention, testing, linkage to care, and cure research. Gilead is actively pursuing innovative cures and long-term viral suppression strategies while seeking to optimize antiretroviral regimens and prevention therapies for all individuals impacted by HIV.

Genvoya is a single-tablet regimen that provides unique value for patients with HIV. Genvoya has demonstrated high rates of virologic suppression in dedicated studies conducted in treatment-

[1] IQVIA's Longitudinal Access and Adjudication Data. Data on file with Gilead.
[2] MMIT data, August 2023.

naïve[3] and -experienced[4] populations, including a wide variety of people living with HIV, e.g., individuals who are virologically suppressed, women, children and adolescents with HIV, older people living with HIV, or people who have a HIV/hepatitis B virus co-infection. The Department of Health and Human Services' HIV treatment guidelines support Genvoya use in both treatment-naïve and treatment experienced patients. Genvoya is recommended as an initial antiretroviral[5] regimen in certain clinical situations, such as patients with a creatinine clearance level of 30-59 mL/min and requires no dosage adjustment for patients on chronic hemodialysis.[6]

As we have shared in previous comments to the State, we strongly oppose the use of UPLs to set drug prices. We also support the comments made by our trade associations PhRMA and BIO about the law and stand with the many patient and provider advocates who have voiced concerns with how Colorado's actions would not meaningfully improve patient affordability but would instead negatively impact patient access to critical therapies. This is particularly concerning for people living with HIV and their partners. Below we briefly summarize why the Board should recognize that Genvoya is affordable and decline to impose a UPL.

- Genvoya is already affordable and accessible for Coloradans with HIV.
- Imposing a UPL on Genvoya could have an adverse impact on patient access and affordability.
- Disruptions in HIV treatment will lead to worse clinical outcomes and unnecessary costly healthcare resource utilization, disproportionately affecting vulnerable populations.
- Treatment interruptions lead to detectable HIV virus and may be associated with a greater likelihood of HIV transmission to other Coloradans.
- Genvoya provides clinical, economic, and societal value to the State of Colorado.
- Setting a UPL for Genvoya would create disincentives for future investment in HIV research.
- Implementing a UPL in Colorado would raise legal concerns.
- Gilead should have opportunity to participate meaningfully in the affordability review and respond to the staff report about Genvoya.

Our detailed comments are provided below.

[3] A treatment-naïve person has never taken antiretroviral drugs. (Note: All definitions are from clinicalinfo.hiv.gov.)
[4] A treatment-experienced person is currently taking or has previously taken antiretroviral drugs.
[5] An antiretroviral is a drug used to prevent a retrovirus, such as HIV, from replicating. The term primarily refers to antiretroviral HIV drugs.
[6] https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/table-7-antiretroviral-regimen?view=full

I. Genvoya is already affordable and accessible for Coloradans with HIV

Genvoya is widely accessible to people living with HIV ("PLWH") across all payer types and is an affordable option for Coloradans with HIV. The Colorado PDAB's own dashboard shows that more than half of included drugs had higher out-of-pocket costs than Genvoya in 2021.

In addition, Colorado's All-Payer Claims Database ("APCD"), which was used to assess patient out-of-pocket costs in the PDAB dashboard, underestimates the affordability of HIV treatments like Genvoya because the data have limited ability to account for reimbursement provided by secondary payers. These payers often reimburse a portion of the patient's cost-sharing established by their health plan and include manufacturer cost sharing assistance, Medicare payments for dual-eligible patients, and AIDS Drug Assistance Programs, among others. As a result, the dashboard dramatically overestimates out-of-pocket costs for Genvoya by approximately four times when compared to IQVIA's Longitudinal Access and Adjudication Data ("LAAD"), which accounts for these types of secondary payers and is an industry-standard claims dataset.

When accounting for secondary payers, Genvoya and HIV drugs overall are very affordable. IQVIA's LAAD shows that approximately 85% of Genvoya claims were less than $5 in Colorado in 2022. This is consistent with other single-tablet regimens ("STRs") within the HIV class. In fact, IQVIA found that patients' annual out-of-pocket costs for the branded HIV STR class are consistently 40% lower than costs for all other branded specialty products. Gilead pays substantial discounts and rebates on Genvoya which help to support this affordability for patients.

When cost may be a barrier, Gilead works to help ensure patients can afford Genvoya and our other medicines through initiatives like our Advancing Access® Patient Support Program. Advancing Access offers support to patients through a co-pay coupon program, which provides copay support for eligible commercially insured individuals on HIV treatment who need help paying for their out-of-pocket medicine costs. Advancing Access also offers a patient assistance program, which provides Gilead medicines at no cost for qualified individuals who meet the program's eligibility criteria, and other patient offerings to support accessing medicines across our therapeutic areas.[7]

Lastly, patient access to Genvoya is robust. The latest formulary coverage data across all payer types show that 99% of Coloradans with insurance have coverage for Genvoya. In addition, 92% of those individuals are not required to go through utilization management before obtaining

[7] For more information about Advancing Access, please see Gilead's website: https://www.gilead.com/purpose/medication-access/us-patient-access.

Genvoya.[8] This is important because utilization management includes techniques such as prior authorization[9] – and step therapy[10] – can limit patients' ability to obtain the medicine they and their doctor determined was best for them.

II. Imposing a UPL on Genvoya could have an adverse impact on patient access and affordability

The PDAB legislation's intended purpose is to ensure that Coloradans can afford and take the medicines in they need.[11] Genvoya, however, is already widely accessible and affordable to PLWH enrolled in all types of coverage in Colorado, as previously discussed. Establishing a UPL for Genvoya would run counter to the PDAB's intent by making it harder to access a drug that is already accessible and affordable.

UPLs establish a limit on the amount that payers can reimburse pharmacies and providers for a given drug. Insufficient reimbursement rates create financial challenges for pharmacies and providers; clinics and hospitals may be forced to decide on either taking a loss on the purchase and provision of UPL drugs or discontinuing administration of the medication altogether. The former is financially unsustainable, and the latter would restrict access to a critical medication, lead to interruptions in care, and force clinicians and patients to consider inferior medications. Written comments submitted by the Colorado Hospital Association and Colorado Pharmacist Society warn that patient access to medications subject to a UPL may be limited if health systems and pharmacies cannot supply these medications in a financially viable manner.[12] In particular, the Colorado Pharmacists Society notes that providers and pharmacists may leave the market, exacerbating patient access issues and leading to interruptions in care, especially in underserved areas.

Evidence from other countries in the Organization for Economic Co-operation and Development (OECD) provides evidence that government price-setting policies do in fact reduce patients' ability to access to new medicines. On average, patients in other OECD countries that rely on various forms of pharmaceutical price-setting, have access to only 29% of new medicines, while patients in the United States have access to 85%.[13]

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[8] MMIT data, August 2023
[9] Prior authorization is a requirement imposed by an insurer under which a patient must demonstrate that they need the medicine prior to the insurer providing coverage.
[10] Step therapy is a requirement imposed by an insurer whereby a patient must try another drug before they can obtain coverage for the medicine their doctor prescribed.
[11] See, e.g., Colo. Rev. Stat. Ann. 10-16-1406(2)(d), (4)(c); https://www.kktv.com/2021/06/16/polis-signs-colorado-option-healthcare-bills-into-law/
[12] Letters are available at: https://drive.google.com/drive/folders/1iyh5kEElajLvjlXdfi2FzFQ9Q12QJPCv
[13] Richard Kane. PhRMA. New global analysis shows patient access challenges around the world. April 12, 2023. https://phrma.org/en/Blog/New-global-analysis-shows-patient-access-challenges-around-the-world.

State actions disrupting patient access to Genvoya in Colorado would be particularly concerning because it is a treatment for HIV that is currently being used by hundreds of patients in the state. As discussed below, HIV is an infectious disease and requires adherence to avoid spreading the disease or development of resistant forms of the virus. Avoiding care disruptions is critical to the health of both the individuals on Genvoya, their partners, and Colorado's goals of ending the HIV epidemic.

III. Disruptions in HIV treatment will lead to worse clinical outcomes and unnecessary costly healthcare resource utilization, disproportionately affecting vulnerable populations

Subjecting Genvoya to UPL would negatively impact many of the more than 13,000 people living with HIV in Colorado.[14] This is particularly concerning given that Colorado has seen a rise in both the number and rate of new HIV diagnoses, while the rest of the nation as a whole has experienced declines in annual new HIV diagnoses.[15] From 2015 to 2021, HIV diagnoses in Colorado rose nearly 9%, while diagnoses declined more than 10% nationwide.[16] In addition, in 2021 only 60.6% of individuals diagnosed with HIV in Colorado had achieved viral suppression, and 17.7% of HIV diagnoses were "late," which is defined as having an AIDS diagnosis within three months of initial HIV diagnosis.[17] This suggests that there remains a significant need to improve diagnosis and treatment of HIV in the state.

The complexity of treatment for HIV and the infectious nature of the disease mean that patient and provider choice are essential to driving positive health outcomes and ending the HIV epidemic. There is longstanding recognition amongst providers, guideline committees, and the HIV community that patients need access to the HIV medication that best fits their clinical circumstances as decided by the patient and their health care provider because one HIV product cannot simply stand in for another. For example, the U.S. Department of Health and Human Services' ("DHHS") guidelines on HIV treatment state that "selection of a regimen should be individualized" to the patient based on factors such as virologic efficacy, potential adverse effects, pill burden, drug–drug interaction potential, and comorbid conditions."[18] To fully benefit from advances in HIV treatment, patients, in consultation with their healthcare provider, should be able to start, continue, or switch to the HIV treatment regimen most appropriate for their clinical and life circumstances. Individualized treatment allows for maximization of clinical benefits, increasing the likelihood of adherence, which can improve the opportunity for viral

[14] https://aidsvu.org/local-data/united-states/west/colorado/
[15] Colorado HIV & AIDS Prevention, Care and Treatment 2022-2026 Strategic Plan.
[16] Gilead analysis based on data from CDC's Atlas Plus. Source data available at: https://gis.cdc.gov/grasp/nchhstpatlas/charts.html.
[17] https://aidsvu.org/local-data/united-states/west/colorado/
[18] HHS, Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV, G-4 (Mar. 23, 2023), https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv.

suppression, leading to better control of HIV, significantly decreased rates of hospitalization and lower healthcare costs,[19] reduced risk of treatment discontinuation, and avoidance of adverse consequences such as drug resistance and transmission of HIV.[20]

For these reasons – as well as the significant health disparities often faced by people living with HIV– it is critical to limit barriers to receiving effective treatment. Colorado's legislature has consistently over many years recognized the importance of protecting access to HIV therapies, most recently by passing legislation that restricts the use of prior authorization and step therapy requirements before HIV treatments can be prescribed or dispensed,[21] which Governor Polis signed into law in April.[22]

HIV disproportionately impacts socially marginalized and disenfranchised populations, particularly sexual minorities, and communities of color.[23] Therefore, state actions disrupting care for HIV would disproportionately harm some of the most vulnerable groups in Colorado who face many barriers that can limit their ability to access and adhere to treatment. As an example, Black people represent only 4.1% of Colorado's population but accounted for 15.2% of all people living with HIV in the state and 16.7% of new HIV diagnoses in 2021.[24] And Black Americans are less likely to be virally suppressed, with only 61% of Black Americans diagnosed with HIV virally suppressed in 2019, compared to 71% of white Americans.[25] As a result of these types of disparities, PLWH disproportionately experience the negative impacts of social determinants of health, such as stigma, poverty, and homelessness, that lead to higher barriers in accessing HIV care and attaining favorable treatment outcomes.[26] The PDAB should recognize that setting a UPL risks disproportionately impacting care for disadvantaged PLWH, as those individuals are most likely to suffer from disruptions in care.

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[19] Sutton S, et al., Impact of Pill Burden on Adherence, Risk of Hospitalization, and Viral Suppression in Patients with HIV Infection and AIDS Receiving Antiretroviral Therapy, 36 *Pharmacotherapy* 385-401 (2016); Sutton S, et al., Single- versus multiple-tablet HIV regimens: adherence and hospitalization risks, 22 American Journal of Managed Care 242-48 (2016).

[20] Yager J, et al., Relationship Between Single Tablet Antiretroviral Regimen and Adherence to Antiretroviral and Non-Antiretroviral Medications Among Veterans' Affairs Patients with Human Immunodeficiency Virus, 31 *AIDS Patient Care and STDs* 370-76 (2017); Cohen C, et al.; Association of Partial Adherence (PA) To Antiretroviral Therapy With Hospitalizations and Healthcare Costs in an HIV Population, 15 Journal of the International AIDS Society 18060 (2012); Bangsberg DR, et al., Adherence-Resistance Relationships For Protease And Non-Nucleoside Reverse Transcriptase Inhibitors Explained By Virological Fitness, 20 *AIDS* 223-32 (2006).

[21] https://leg.colorado.gov/sites/default/files/documents/2023A/bills/2023a_189_enr.pdf

[22] https://legiscan.com/CO/bill/SB189/2023.

[23] Pellowski J., Kalichman S., Matthews K., et. al., (2013). A pandemic of the poor: social disadvantage and the U.S. HIV epidemic. *The American psychologist*, *68*(4), 197–209. doi.org/10.1037/a0032694

[24] AIDSVu.org. Local Data: United States. Accessed from https://aidsvu.org/local-data/united-states/.

[25] Ibid.

[26] CDC. Behavioral and Clinical Characteristics of Persons with Diagnosed HIV Infection—Medical Monitoring Project, United States 2020 Cycle (June 2020–May 2021). https://www.cdc.gov/hiv/library/reports/hiv-surveillance-special-reports/no-29/index.html.

Identifying, successfully preventing, and treating HIV requires a comprehensive set of services, beyond medicines. For example, HIV testing and linkage to antiretroviral treatments ("ART") within traditional clinical settings is the bedrock of many HIV programs and is a key aspect of preventing and ending HIV within the U.S.[27,28] In addition, providing critical support services – like housing, food, transportation assistance, and patient navigation – is essential to keeping PLWH in ongoing care and crucial to their well-being and survival.[29,30] Evidence shows that comprehensive, integrated models of HIV care – inclusive of case management, HIV health care, mental and substance use screening and treatment, treatment adherence counseling, and social support services (transportation, emergency food assistance, housing, and legal assistance) – can lead to increased rates of retention in care, ART adherence, and viral suppression.[31] Patient navigation is often found to be positively associated with viral suppression.[32] For these reasons, policy changes like UPLs that can cause disruptions for HIV providers, particularly those who serve underserved communities, could lead to lower rates of adherence and worse outcomes for patients. For example, over half of Genvoya utilization in Colorado is by Medicaid or safety net providers.[33]

IV. Treatment interruptions lead to detectable HIV virus and may be associated with a greater likelihood of HIV transmission to other Coloradans

Patient and provider choice of therapy for HIV is critical because adherence to effective treatment of HIV can reduce the amount of HIV in the body to an undetectable level, which not only improves that patient's individual health and well-being but also has the added public health benefit of preventing sexual transmission of the virus. Researchers at the National Institutes of Health found that maintaining an undetectable viral load for at least six months results in people with HIV having no risk of sexually transmitting HIV to partners.[34] In contrast, delays in initiating HIV treatment, gaps that might occur as a patient switches from one regimen to another, or relegating a person living with HIV to a suboptimal treatment regimen can negatively

[27] Bunda BA, Bassett IV. Reaching the second 90: the strategies for linkage to care and antiretroviral therapy initiation. Accessed from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6798739/.
[28] HIV.gov. *Key Ending the Epidemic (EHE) Strategies*. Accessed from: https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/key-strategies/.
[29] U.S. Centers for Disease Control & Prevention (CDC). Issue Brief: Status Neutral HIV Care & Service Delivery. Accessed from: https://www.cdc.gov/hiv/policies/data/status-neutral-issue-brief.html.
[30] UNAIDS. *HIV Care & Support: HIV Care & Support Taking Into Account the 2016 WHO Consolidated Guidelines. Accessed from: https://www.unaids.org/sites/default/files/media_asset/JC2741_HIV-care-and-support_en.pdf*.
[31] Melvin SC, Gipson J. The Open Arms Healthcare Center's Integrated HIV Care Services Model. Prev Chronic Dis 2019;16:180633. DOI: http://dx.doi.org/10.5888/pcd16.180633
[32] Mizuno Y, Fagan J, Tie Y, Padilla M. Is Patient Navigation Used by People with HIV Who Need It? An Assessment from the Medical Monitoring Project, 2015 - 2017. Accessed from: https://pubmed.ncbi.nlm.nih.gov/32945692/.
[33] Gilead internal data from Medicaid submitted claims and Chargeback data, 2022
[34] Eisinger RW, Dieffenbach CW, Fauci AS. HIV Viral Load and Transmissibility of HIV Infection: Undetectable Equals Untransmittable. *JAMA*. 2019 Feb 5;321(5):451-452.

impact their ability to adhere to the treatment regimen and remain virally suppressed, which not only could result in worse health outcomes, treatment failure and higher healthcare costs, but also an increased risk of HIV transmission for people that are not virally suppressed to other Coloradans.[35,36] Any public policy decision that limits access to HIV medicines or interrupts care for patients currently on therapy and virally suppressed could result in new HIV infections because people living with HIV who are not virally suppressed can transmit HIV to their partners. Increased transmission would not only be horrendous for those newly infected with HIV; it would also drive up costs for Colorado.

Drug resistance is another important public health concern associated with treatment disruptions. Partial adherence to treatment regimens, where a patient takes some of their HIV medications but not all, can occur when PLWH are switched off a treatment regimen that is working to one that might be more complex or less appealing for that patient. Partial adherence poses a significant public health threat and can lead directly to the development of resistant forms of the virus.[37] Drug resistance is a serious consequence that can lead to treatment failure and may eliminate any further treatment from the class of drugs that the resistance impacts, thus requiring patients to switch to alternative treatment regimens that may be more limited and costlier, both in poor outcomes for the patient as well as in regards to increase health resource utilization. In addition, the drug-resistant form of the virus can then be spread to and infect other patients, which further undermines efforts to end the HIV epidemic.[38] The cost of this spread is substantial. Avoiding just one new HIV infection can reduce lifetime healthcare costs – which for many patients may be borne partly or entirely by Medicaid – by $850,557 on average. Additionally, average annual and cumulative healthcare costs were up to seven times higher for people living with HIV compared to those without HIV.[39]

V. Genvoya provides clinical, economic, and societal value to the State of Colorado

According to Colorado's APCD, Genvoya helped 940 Coloradans living with HIV in 2021. While the high patient count number was one of the main drivers for Genvoya's PDAB selection for affordability review, it also demonstrates the value Genvoya brings to Colorado in improving and lengthening the life of Coloradans living with HIV, delivering cost offsets to the state's health system. Disrupting the care of the Coloradans living with HIV who have been stable on

[35] Von Wyl V, Klimkait T, Yerly S, et al. Adherence as a predictor of the development of class-specific resistance mutations: the Swiss HIV Cohort Study. *PLoS One*. 2013;8(10):e77691. Published 2013 Oct 16. doi:10.1371/journal.pone.0077691

[36] Bangsberg DR, Acosta EP, Gupta R, et al. Adherence-resistance relationships for protease and non-nucleoside reverse transcriptase inhibitors explained by virological fitness. *AIDS*. 2006;20(2):223-231. doi:10.1097/01.aids.0000199825.34241.49

[37] Von Wyl V, Klimkait T, Yerly S, Nicca D, Furrer H, et al., Adherence as a Predictor of the Development of Class-Specific Resistance Mutations: the Swiss HIV Cohort Study, 8 *PLoS ONE* e77691 (2013).

[38] Guyer B, et al., AMCP NEXUS, Abstract #17 (2010).

[39] Cohen JP, Beaubrun A, Ding Y, Wade RL, Hines DM. Estimation of the Incremental Cumulative Cost of HIV Compared with a Non-HIV Population. *Pharmacoecon Open*. 2020;4(4):687-696.

Genvoya for years could lead to discontinuation of treatment for these patients, creating gaps in care which can lead to resistance, increased transmission, and higher healthcare costs. Colorado patients on Genvoya have been on the medicine for 29 months on average. This is 53% higher than the average for all HIV patients, which 19 months.[40] In contrast, maintaining robust access to Genvoya can help Colorado achieve state treatment targets to end the HIV epidemic.

There is a large body of evidence demonstrating why STRs, like Genvoya, provide value to patients compared to multi-tablet regimens ("MTRs", regimens of two or more pills per day) for PLWH. STRs can be taken once daily, avoiding complex dosing regimens that were required with MTRs.[41] This can increase patient adherence to their medicine, thereby reducing the risk of developing viral resistance and its associated complications, including poor patient health outcomes, possible transmission of resistant virus, and reduction in future treatment options.[42,43,44,45,46,47] As noted previously, improved adherence leads to better viral suppression, reduces hospitalization rates and overall healthcare costs, while lessening the risk of treatment discontinuation, and adverse consequences such as drug resistance and transmission of HIV.

Genvoya also provides economic and societal value to the State of Colorado. Treatment with HIV leads to reduced medical costs. Viral suppression with Genvoya reduces the risk of HIV transmission, which avoids substantial costs. As noted previously, one new HIV infection can increase healthcare costs by more than $850,000 over a lifetime.[48] Continued access to Genvoya for patients who are currently virally suppressed also supports the state's efforts to end the HIV epidemic, by avoiding disruptions in care that can result in disease transmission.[49]

VI. Setting a UPL for Genvoya would create disincentives for future investment in HIV research

By capping the prices for medicines, UPLs would fundamentally alter current economic and regulatory incentives that have led to tremendous innovation in HIV over the past four decades. Since 1987, over 3,000 clinical trials have been completed for potential treatments for HIV, with

[40] IQVIA analysis for Gilead.
[41] Astuti N. and Maggiolo F., Single-Tablet Regimens in HIV Therapy, 3 *Infectious Diseases and Therapy* 1-17 (2014); Sebaaly JC, Kelley D., Single-Tablet Regimens for the Treatment of HIV-1 Infection, 4 *Annals of Pharmacotherapy* 332-344 (2016).
[42] Charpentier C, et al., Conference on Retroviruses and Opportunistic Infections, Abstract #726 (2012).
[43] Clay et al. AIDS Res Ther (2018) 15:17.
[44] Cohen et al. AIDS Res Ther. 2020;17(1):12.
[45] Hanna, D.B., et al., Increase in STR Use and Associated Improvements in Adherence-Related Outcomes in HIV-Infected Women, 65 *J. Acquired Immune Deficiency Syndrome* 587-96 (2014).
[46] Sutton SS, et. Al., Odds of Viral Suppression by Single-Tablet Regimens, Multiple-Tablet Regimens, and Adherence Level in HIV/AIDS Patients Receiving Antiretroviral Therapy, 37 *Pharmacotherapy* 2014-13 (2017).
[47] Blanco JL, et al. AIDS. 2014; 28:2531-2539.
[48] Guyer B, et al., AMCP NEXUS, Abstract #17 (2010).
[49] Colorado HIV & AIDS Prevention, Care and Treatment 2022-2026 Strategic Plan.

the number of HIV clinical trials completed increasing each decade, from under 200 in the 1990s to over 1,600 in the 2010s. As a result of these substantial investments in HIV pharmaceutical research and development, the FDA has approved drugs for HIV that have transformed the care trajectory and prognosis for acquisition of HIV. When the first highly effective ART were approved in 1996, a recently infected 20-year-old was expected to live another 10 years, at most.[50] With modern treatments, people who are living with HIV and those who are HIV negative now have lifespans that are almost comparable.[51] Ongoing research into and development of HIV treatments has allowed for more effective treatments with fewer side effects/greater tolerability and improved patient quality of life.

Looking forwards, there remains a need for development of new treatments that can further improve patient outcomes, cure the disease, and support the eventual end of the HIV epidemic. Currently, there are with many HIV drugs in the pipeline, including programs aiming to cure HIV.[52] Setting a UPL would cause severe reductions in revenue and related cash flows, leading to corresponding reductions in research and development ("R&D") investments.

Even a UPL like Colorado's that purports to apply only to one state's patients would likely have national implications for the economics of developing new medicines: UPL-priced drugs could be diverted to other states, UPL-priced drugs could impact pricing metrics that affect drug sales nationwide, or additional states could decide to mimic Colorado. Expectations of revenue drive investors' interest in high-risk investment such as pharmaceutical research, where failure is substantially more common than success. When revenue expectations decline, so does investment in R&D. Indeed, academic literature estimates that a 1% reduction in future drug revenue corresponds to a 1.5% reduction in R&D.[53]

Specific to HIV, an economic study by Charles River Associates projects that a nationwide price setting policy for HIV medicines would lead to a 21.6% to 22.0% decline in R&D investment and 537 to 551 fewer HIV/AIDS clinical trials between 2021-2035. The reduction in the number of clinical trials is significant, since this ultimately impacts the likelihood of new treatments

[50] Siddiqi, A. et al. Population-Based Estimates of Life Expectancy After HIV Diagnosis. United States 2008-2011. J Acuir Immune Defic Syndr. 2016 June 1; 72(2): 230-236.
[51] Marcus, JL, et al. Comparison of overall and comorbidity-free life expectancy between insured adults with and without HIV infection, 200-2016. JAMA Netw Open. 2020, Jun; 3(6).
[52] Charles River Associates (2021) Assessing the implications of centralized drug price setting to investment in clinical development for HIV treatments. https://www.crai.com/insights-events/publications/assessing-the-implications-of-centralized-drug-price-setting-to-investment-in-clinical-development-for-hiv-treatments/
[53] Philipson, T. J., & Durie, T. (2021, September 14). (Working Paper). The Evidence Base on the Impact of Price Controls on Medical Innovation. Retrieved from https://bfi.uchicago.edu/working-paper/the-evidence-base-on-the-impact-of-price-controls-on-medical-innovation/.

coming to market, the prospect of a cure, and the development of vaccines or other transformational therapies for HIV.[54]

Similarly, researchers at the University of Chicago estimate that a national price setting policy will lead to a $165 billion reduction in R&D spending on antivirals, 23.1% reduction in antiviral innovation, 21 to 43 fewer new antivirals coming to market, specifically 4 to 9 fewer HIV drugs, and a 6-year delay for new drugs that would have become available earlier without the price setting policy.[55] While not directly national in scope, any UPL established for Colorado will likely have similar negative impacts on HIV drug discovery and innovation. Therefore, the PDAB should not risk changing the existing economic model that has resulted in the continued discovery and development of more advanced and effective HIV medicines.

VII. Implementing a UPL in Colorado would raise legal concerns

In addition to harm to Coloradans' access to Genvoya that would result from imposition of a UPL, the PDAB's actions so far, and the Colorado law that established the PDAB ("SB 21-175"), raise significant constitutional concerns.

Setting a UPL for Genvoya would conflict with federal patent law (including the Constitution's Patent and Copyright Clause) and more targeted federal laws that encourage the development of specific types of new medicines, in violation of the Constitution's Supremacy Clause. These laws all establish a comprehensive framework that encourages companies such as Gilead to develop innovative therapies like Genvoya, by rewarding them with limited periods during which they will hold the exclusive right to market their medicines. In calibrating those rights and balancing them against the interest in patient access and competition, Congress has sought to ensure a sufficient return not only on the investments made directly in the therapies that make it to market, but also on the necessary investments made in broader pharmaceutical research, recognizing that the majority of drug candidates do not ultimately come to market. And beyond Congress's efforts to spur innovation through patent and pharmaceutical-specific regulatory exclusivity periods, Congress has further balanced innovation with access on a national scale through its policies that guide purchasing for veterans, military personnel, certain hospitals, and pharmacies, and through other federal programs that ensure drug access. Setting a UPL that eliminates or reduces the risk-reward that Congress intended to provide would impermissibly second-guess Congress's determination, with unforeseeable effects on future investment – significantly undercutting Congress' goals.

[54] Charles River Associates (2021) Assessing the implications of centralized drug price setting to investment in clinical development for HIV treatments. https://www.crai.com/insights-events/publications/assessing-the-implications-of-centralized-drug-price-setting-to-investment-in-clinical-development-for-hiv-treatments/

[55] Philipson, T. J., & Durie, T. (2021, September 14). (Working Paper). The Evidence Base on the Impact of Price Controls on Medical Innovation. Retrieved from https://bfi.uchicago.edu/working-paper/the-evidence-base-on-the-impact-of-price-controls-on-medical-innovation/.

By setting a UPL for Genvoya, the PDAB would also be inserting itself into a complicated national drug market without regard to the mechanisms by which manufacturers, wholesalers, payers, and providers make drugs accessible. Prescription drugs are distributed on a nationwide or regional basis and are not packaged differently for specific state markets. Most prescription drugs are manufactured outside of Colorado. Most wholesalers, many pharmacies and pharmacy benefit managers, are based outside Colorado as well. Thus, the PDAB is poised, through its regulation of the price of prescription drugs dispensed or administered in Colorado, to reach outside of the state and regulate entirely out-of-state transactions, contravening the Constitution's Commerce Clause. The PDAB has so far failed to address the ripple effects and workability issues that will arise from its effort to leverage in-state sales to force pricing changes outside Colorado.

The PDAB has also failed to implement statutory language properly or make rational decisions. For instance, the PDAB's selection of drugs for affordability review focused almost entirely on the overall cost to drug purchasers, without regard to the actual out-of-pocket cost patients pay – which, in Genvoya's case, is lower than hundreds of other drugs that were eligible for affordability review. This failure to prioritize patient access and affordability disregards the statutory text and purpose. Similarly, PDAB staff acknowledged errors in the dashboard weighting system, but failed to correct those errors before PDAB members voted to select drugs for review based on a prioritized list the PDAB acknowledged was limited or flawed.

VIII. Gilead should have opportunity to participate meaningfully in the affordability review and respond to the staff report about Genvoya

Gilead has a unique ability to offer the PDAB an important perspective to share about Genvoya and the likely impact of a UPL. Moreover, Gilead stands to be directly and significantly affected by the PDAB's Genvoya pricing decisions. Yet so far, the Board has failed to afford manufacturers a meaningful opportunity to participate in its decision-making process. The PDAB has decided to exclude manufacturers from the statutorily mandated public stakeholder meetings and to categorically prohibit them from engaging with PDAB members directly. Instead, the PDAB has limited manufacturers to a written submission that will be reviewed by staff for incorporation into a report to PDAB members. There is no opportunity to engage in any sort of dialogue regarding the complicated, confidential information submitted, no opportunity to appear before the PDAB directly, and no opportunity to respond to the staff's draft report or other stakeholders' comments or submissions about Genvoya. We support providing an opportunity for patients, caregivers, and medical and scientific experts to share their perspectives. But by failing to provide manufacturers with the same opportunity as other stakeholders for a public hearing, and by denying manufacturers an opportunity to respond to other stakeholders' comments about their medicines, the PDAB risks making a rash decision finding drugs

unaffordable and setting UPLs without the full picture of all the relevant information and potential consequences. Those procedures flout the PDAB's obligation to engage in rational, reasoned decision-making, deprive manufacturers of a fair hearing, and aggravate the statute's interference with Congress's careful national balance of pharmaceutical innovation and patient access. The PDAB should therefore revise its process to give Gilead and other manufacturers an opportunity to meaningly participate in their drugs' affordability reviews.

***

In conclusion, Genvoya is currently affordable in Colorado, and it is important that the PDAB not subject it to a UPL. A UPL would inherently come between patients and their physicians, disrupting treatment for people currently suppressing their HIV virus with Genvoya, harming patient and public health. If you have any questions or wish to notify Gilead about future PDAB actions, please do not hesitate to contact me at kristie.banks@gilead.com.

Sincerely,

DocuSigned by:
Kristie Banks
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Kristie Banks
Vice President, Managed Markets
Gilead Sciences, Inc

CORA
Colorado Organizations and Individuals Responding to HIV/AIDS

September 20, 2023
Colorado Prescription Drug Affordability Board
Colorado Division of Insurance
1560 Broadway, Suite 850
Denver, CO 80202

Re: Drug Board Must Prioritize Patient Access When Shaping Policies to Lower Drug Prices

Dear Madam Chair and Honorable Members of the Colorado Prescription Drug Affordability Board:

We, the undersigned individuals and organizations, collectively represent people in Colorado and around the country who are living with and vulnerable to acquiring HIV and the communities that serve them. We write to you today to urge the Colorado Prescription Drug Affordability Board (PDAB) to avoid taking any action that could impede access to HIV treatment.

In August, the PDAB selected GENVOYA® among the five drugs that were chosen for a formal affordability review, a decision that threatens treatment access for the 940 Coloradoans taking GENVOYA® and has implications for the more than 13,000 Coloradoans living with HIV today. People living with HIV depend on consistent access to HIV medications like GENVOYA® to manage their health and well-being. But the PDAB is considering policies that could upend the ability of patients with HIV and other complex conditions to access and adhere to their treatments, without meaningfully engaging people living with HIV and other stakeholders. To be clear, 21 days to collect feedback and a survey tailored to only assess "affordability" from the payor perspective is *not* meaningful engagement. To date, no direct outreach has been made to any of our organizations from DOI - we write of our own volition and out of deep concern for the following, unaddressed issues:

Public Health Goals are Threatened: To successfully combat the HIV epidemic and defeat other chronic conditions, patients must have uninterrupted access to the most effective medicines recommended by their doctors.

- People living with HIV represent some of the most marginalized groups in the US and face many barriers that can limit their ability to access and adhere to treatment.
- The complexity of treatment for HIV, side effects of medications, and the nature of the disease mean that patient and provider choice are essential to driving positive health outcomes.
- There is longstanding recognition that patients need access to the HIV medication that was prescribed for them, and that one HIV product cannot simply stand in for another. To fully benefit from advances in HIV treatment, patients, in consultation with their healthcare provider, should be able to start, stay, or switch to the HIV treatment regimen deemed most appropriate for them.

- Any decision that limits access to these medicines, disrupts treatment for patients who are stable on critical therapies, or creates incentives to steer patients away from the therapy deemed most appropriate for them in consultation with their provider could have negative impacts on medication viral persistence, and patient quality of life, and health outcomes.

Undermining Recently Added Patient Protections: Colorado currently has strong access protections for HIV, and GENVOYA® is already affordable for most Coloradoans living with HIV

- Just this year, Colorado lawmakers recognized the importance of protecting access to HIV therapies and advanced first-of-its-kind legislation to protect access to medication for HIV prevention and treatment.
- 99% of insured patients in Colorado had coverage for GENVOYA® in 2021, and, according to IQVIA data, approximately 85% of claims show that patients have less than a $5 copayment across all payer segments.
- Selection of Genvoya or any anti-retroviral medication for cost control measures necessarily creates incentives for one medication over another, without regard for patient experience, the patient-provider relationship, or the unique and individual needs of a patient.

Upper Payment Limits Threaten Public Health Funding Mechanisms: Rather than improve patient affordability or remove treatment access barriers, a UPL would negatively impact patient access to critical HIV therapies and support services.

- When UPLs are set, reimbursement rates are lowered for hospitals or clinics giving them less incentive to purchase specific drugs even though it may be the most effective medication to help a patient manage a chronic condition. When reimbursement rates are lowered through a UPL, it can also lead to barriers to biopharmaceutical companies supplying new innovative medicines to health facilities, making it difficult for doctors to prescribe treatments they think are best suited for their patients. While well intentioned, patients often bear the brunt of the challenges with such policies.
- The impacts of the UPL process are only compounded when we consider the potential impact on the 340B Drug Pricing Program, a federal safety-net program that helps health facilities stretch scarce federal resources to better serve low-income and uninsured patients. Under the program, qualified clinics and other covered entities buy treatments at a discount and are statutorily required to reinvest the difference between the reimbursement rate and the discount price into providing medications and comprehensive wrap-around services to the vulnerable communities they serve. This ultimately allows patients to access essential care they might not otherwise be able to afford.
- Under a UPL, health facilities such as hospitals or clinics will receive lower reimbursements for prescribed treatments and therefore generate fewer dollars to support patients and the care we need to live and thrive. If the PDAB sets restrictive UPLs for drugs for chronic conditions like HIV, health facilities and the health professionals tasked with providing care will be faced with the decision to potentially stop

prescribing these medicines and face having to cut support services that patients have come to rely on.

Instituting UPLs and other short-sighted “fixes” threatens to have severe consequences on Colorado’s progress addressing HIV epidemic and only views “affordability” from the perspective of payors, rather than patients. Setting a UPL only shifts costs burdens from payors to patients and the providers serving them. From issues of pharmacy deserts, patient steering, incentivizing practices that amount to prior authorizations and step-therapy by any other mechanism, patient cost of care is comprised of far more influential factors than a manufacturer’s list price or manufacturer patient assistance programs. The board must pause and meaningfully integrate these metrics of patient cost of care and experience in assessing “affordability” and access. Colorado is the first state to review drug affordability and we have grave concerns about the unintended consequences for people living with HIV.

On behalf of the people living with HIV in Colorado, our healthcare providers, and our community-based partners, we strongly urge the Board to put the needs of patients first when considering policies that work under the auspices of addressing patient cost of care.

Sincerely,

Barb Cardell

CORA Legislative Chair and the undersigned

<u>Individual</u>

- Dr. Thomas J. Bogdan
- Bob Bongiovanni
- Judith Cardell
- Philip Doyle
- Cidney Fisk
- Calvin Lavan Gipson
- Kari Hartel
- Toi Hughes
- Jamey Johnston
- Jen Laws
- Brandon M. Macsata
- Mary Jane Maestas
- Karen Middleton
- Deja Moore
- Dr S.N. Nyecks
- Frank O’Cana
- Laurie
- Shannon
- Matt Pagnotti
- Jessica Rosero
- Sarah Rowan, MD

- Michael Ruppal
- Nancy Steinfurth

Organizations

- 5280 Fast Track Cities Initiative
- The AIDS Institute
- AIDS United
- ADAP Advocacy
- Boulder County AIDS Project
- COBALT
- Community Access National Network
- HIV Health
- Positive Women's Network Colorado
- Positive Women's Network USA
- US People Living with HIV Caucus
- Vivent Health
- Vivent Health Pharmacy

HealthHIV appreciates the opportunity to actively engage in discussions regarding affordability review. We understand the importance and necessity of this process, and we support its intentions. However, our organization has significant reservations concerning the approach and criteria currently being utilized.

We value the PDAB's stakeholder engagement initiative for its aim to foster inclusivity. However, its current structure is wanting in the meaningful involvement of public health professionals, especially those well-versed with the intricacies of the 340B Drug Pricing Program and supplemental rebates.

The decision to spotlight Genvoya, an essential antiretroviral treatment for those Person living with HIV (PWH), appears weighted by the understanding that less costly therapeutic equivalents drives the discussions.

As a PWH on Genvoya and former Coloradan that wasn't why we spent years vying for access.

This decision primarily emphasizes the vantage point of payers, sidelining the authentic experiences and challenges faced by patients. Except for the "out-of-pocket cost" metric, which draws from data given by payors, the criteria don't mirror the realities patients grapple with, realities that are predominantly intensified by pharmacy benefit managers (PBMs) and their policies.

Such policies, including practices like step-therapy or "fail-first", prior authorizations, pharmacy steering, mandatory mail-order systems, and unequal reimbursement policies aimed at independent pharmacies, critically limit patients' access to essential care. This is felt most acutely by marginalized communities, yet the criteria for "affordability" and the surveys from PDAB fail to capture these concerns.

I… we commend Colorado for its forward-thinking stance in legislation, highlighting the harm these PBM practices inflict on public health. It is disconcerting, however, to observe how the selection of Genvoya might potentially negate the benefits of these legislative efforts.

Stakeholder engagement, in its current form, appears rushed and not thorough. For context, comprehensive stakeholder interactions, like those within the Ryan White Program (RWP), span months. In stark contrast, the proposed 21-day timeframe for this pivotal feedback raises concerns.

Moreover, the potential repercussions on Colorado's State Drug Assistance Program (SDAP) seem to have been overlooked. SDAP, functioning as the state's ADAP, is indispensable and primarily funded by the Ryan White HIV/AIDS Program. Notably, ADAPs operate based on rebate revenues and stand out as the sole non-provider entity within the 340B Discount Drug Program. The majority of healthcare providers for HIV, in tandem with Ryan White services, derive their support from these programs, ensuring a gamut of crucial services for patients.

The PDAB is also making crucial decisions based on claims data that represents fewer than 70% of Colorado's residents and under 75% of its insured population. This incomplete data doesn't give a comprehensive outlook.

The data utilized by the PDAB also seem to factor in the effects of insurance benefit structures on individual out-of-pocket expenses. Critical details, like whether a patient has a high-deductible plan or coinsurance, are absent. Such omissions distort the complete scenario, especially considering that insurers and pharmacy benefit managers are gradually burdening patients with increasing costs via higher deductibles and coinsurance.

Moreover, the current database doesn't reflect the rebates, discounts, or other price reductions that health services like Medicaid and private insurers obtain from pharmaceutical firms. As a result, the PDAB's drug review decisions may not reflect the actual costs incurred by Medicaid or health insurance providers.

Colorado's rich history of innovation and patient-centric focus is more than just laudable. Our state gave birth to the Denver Principles, which outlined rights and responsibilities for people living with HIV and provided recommendations to healthcare professionals, family, and friends. The current operations of this Board seem to diverge from these foundational principles. For that alone, we strongly urge a recalibration, one that centers patient experiences, to genuinely foster medication access for patients.

Patients, especially those with complex diseases, trust their medication plans. The Board's strategy to decrease costs might inadvertently make critical medications unattainable. This stance goes against Medicare's six protected classes (6 PC's), which are set to assure those with chronic conditions have uninterrupted access to their treatments.

And because of that, Upper Payment Limits (UPL) Threaten Public Health Funding Mechanisms and those lasting Denver Principles:

The very premise of an UPL suggests improved affordability but with reduced access barriers for FDA approved HHS guideline treatments. But in reality, the application of UPLs has the potential to undercut patient access to pivotal HIV therapies and the essential support services that accompany them.

As a PWH myself in the early days of Colorado's struggles with an untreatable epidemic, I remember the light those Principles brought to bear for me. And for me timely, uninterrupted access was everything! And it remains that for any lifelong condition.

Yet undermining those Principles for cost containment means more than bringing the hammer down on drug inflation.

Without more structured Community engagement, it means:

1. **Unintended Consequences on Patients:** While UPL policies are typically implemented with noble intentions—aimed at cost-saving and increased access—the real-world

implications often place an undue burden on patients. Reduced access to preferred treatments, potential therapy switches, and the constant worry of whether their essential medications will continue to be available all contribute to heightened anxiety and potential health setbacks for patients.

2. **Dilemmas for Healthcare Providers:** The ramifications of restrictive UPLs on drugs for chronic conditions like HIV could push healthcare facilities into untenable positions. Faced with tightened budgets and financial constraints, these institutions might be compelled to discontinue prescribing certain medications. This is not a mere inconvenience; it translates to the potential disruption of treatment regimens, increased health risks, and the heart-wrenching task of possibly discontinuing support services that have been lifelines for countless patients.

3. **Implications for the 340B Drug Pricing Program:** The 340B program stands as a beacon of hope for numerous low-income and uninsured patients, offering discounted medications through qualifying clinics and entities. These institutions purchase treatments at a reduced rate and retain the difference between the actual price and reimbursement rate, effectively funneling those funds back into patient care and other critical services. UPLs jeopardize this structure. Reduced reimbursements mean fewer resources are cycled back into the system, which can cripple the capacity of these entities to offer indispensable services.

4. **Decreased Incentives for Hospitals and Clinics:** The establishment of UPLs often results in reduced reimbursement rates for hospitals and clinics. This diminished rate reduces the financial incentive for these institutions to procure specific drugs, even if they are the most potent and effective for managing conditions like HIV. As a consequence, patients may find themselves prescribed alternative, potentially less effective medications based solely on economic constraints.
5. **Potential Impacts:** One real-world consideration that I have as an advocate and long-term survivor, is the true fear (not perceived, but actual!) that my disease may outlive advancements (that may never come). And without more consideration, UPLs, might influence decisions when supplying novel medications to health facilities. If the financial landscape becomes less predictable or offers reduced returns, it could potentially slow the enthusiasm for developing and distributing breakthrough therapies. Such a scenario might limit healthcare professionals in recommending the latest treatments that they believe are optimal for their patients**.**

Please seek out more input… more information before making this precedent-setting move. 21-days of stakeholdering compared to our collective 41 year wait for a cure (or my 33 wait for better treatments) is too little time for this Board to make.

In fact, during deliberations that guided the drug selection process, some doubts emerged about the veracity of the data on how many Colorado patients were using certain medications. Still,

patient numbers remained a pivotal criterion in the drug affordability review process; and the Board had to reassess its approach to determining the cost of a treatment course. And that question alone subsequently impacted its primary judgments on qualifying drugs. The Colorado law doesn't impose a fixed deadline for choosing drugs for affordability evaluations.

In light of these extensive implications, it becomes imperative to re-evaluate the broader consequences of UPLs, particularly as they intersect with chronic conditions and their respective treatments.

Thank you for your time and consideration. We anticipate a collaborative dialogue and a refined approach that serves the interests of all stakeholders, especially patients.

Appendix K

Genvoya: 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 Genvoya, 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 Genvoya 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.

Genvoya: 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 is provided first, followed by manufacturer financial assistance programs.

[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
Genvoya Net Sales and Gross-to-Net Estimates

Figure K-1 shows the net sales and gross-to-net estimates for Genvoya since it first launched in 2015. The total gross-to-net estimate in October 2015 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	Genvoya	Biktarvy	Dovato	Stribild	Triumeq
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 (reflect 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 Genvoya should actually exceed those provided to non-Medicaid entities.

[4] 42 CFR § 447.509 Medicaid drug rebates (MDR)

Table K-2

Figure K-2 shows the total gross-to-net sales estimate for Genvoya and identified therapeutic alternatives. The gross-to-net sales estimate for Genvoya has increased to [redacted] in the third quarter of 2023, [redacted]

Table K-2
Gross-to-net Estimate Total for Genvoya and Therapeutic Alternatives

Quarter and Year	Genvoya	Biktarvy	Dovato	Stribild	Triumeq
October 2015	[redacted]			[redacted]	[redacted]
January 2016	[redacted]			[redacted]	[redacted]
April 2016	[redacted]			[redacted]	[redacted]
July 2016	[redacted]			[redacted]	[redacted]
October 2016	[redacted]			[redacted]	[redacted]
January 2017	[redacted]			[redacted]	[redacted]
April 2017	[redacted]			[redacted]	[redacted]
July 2017	[redacted]			[redacted]	[redacted]
October 2017	[redacted]			[redacted]	[redacted]
January 2018	[redacted]	[redacted]		[redacted]	[redacted]
April 2018	[redacted]	[redacted]		[redacted]	[redacted]
July 2018	[redacted]	[redacted]		[redacted]	[redacted]
October 2018	[redacted]	[redacted]		[redacted]	[redacted]
January 2019	[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]
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 for Genvoya and identified therapeutic alternatives from October 2015 to July 2023.

Figure K-3
Genvoya Net Sales as a percent of Gilead Total Net Sales

Figure K-3 shows Genvoya net sales (in purple) as a percent of Gilead total net sales from the first quarter of 2018 through the third quarter of 2023. In the third quarter of 2023, Genvoya accounted for an estimated [redacted] of Gilead's total net sales.

Table K-4
Quarterly Net Sales by drug

Year	Quarter	Genvoya	Biktarvy	Dovato	Stribild	Triumeq
2015	Q4	[redacted]			[redacted]	[redacted]
2016	Q1	[redacted]			[redacted]	[redacted]
2016	Q2	[redacted]			[redacted]	[redacted]
2016	Q3	[redacted]			[redacted]	[redacted]
2016	Q4	[redacted]			[redacted]	[redacted]

Year	Quarter	Genvoya	Biktarvy	Dovato	Stribild	Triumeq
2017	Q1	[redacted]			[redacted]	[redacted]
2017	Q2	[redacted]			[redacted]	[redacted]
2017	Q3	[redacted]			[redacted]	[redacted]
2017	Q4	[redacted]			[redacted]	[redacted]
2018	Q1	[redacted]	[redacted]		[redacted]	[redacted]
2018	Q2	[redacted]	[redacted]		[redacted]	[redacted]
2018	Q3	[redacted]	[redacted]		[redacted]	[redacted]
2018	Q4	[redacted]	[redacted]		[redacted]	[redacted]
2019	Q1	[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]
2021	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Year	Quarter	Genvoya	Biktarvy	Dovato	Stribild	Triumeq
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-4 lists the quarterly estimates of net sales for Genvoya and identified therapeutic alternatives from October 2019 to July 2023. These amounts are reflected in Figure K-1 above.

Manufacturer Financial Assistance Programs

As part of voluntarily submitted information from Gilead Sciences, Inc., the Vice President of Managed Markets submitted the following statement regarding patient assistance: “Where cost is a barrier for patients, Gilead works to reduce affordability challenges for Genvoya through Advancing Access, a patient support program that helps eligible people on Gilead HIV treatment medications explore potential coverage options that may be right for them, whether they have insurance or not. One such support option is the Gilead co-pay coupon card, which helps eligible commercially insured individuals lower their out-of-pocket costs. Additionally, eligible uninsured individuals may qualify for medication free of charge through Gilead’s Advancing Access Patient Assistance Program. Furthermore, our program is committed to providing information to help patients address insurance and coverage issues should they arise through benefit investigation, prior authorization information, and other resources to support patients’ ability to access their Gilead medication.”[5] In terms of medical cost offsets for patients, Gilead said the following: “The affordability of Genvoya is also realized at the healthcare system level through offsets to medical costs for the state of Colorado. HIV treatment offsets other medical costs by reducing HIV transmission. Avoiding just

[5] https://drive.google.com/file/d/13q4cyzhUudWEhOQUymh94JlrCLHvw8mQ/view?usp=drive_link

one new infection results in an average of $850,557 in lifetime healthcare cost savings. Non-adherence to HIV medication contributes substantially to HIV-related healthcare resource use and costs, with added costs for non-adherent patients attributed to increased morbidity, frequent hospital visits, ambulatory care, nursing home services, and laboratory tests, in addition to indirect costs of non-adherence (e.g., loss of productivity, caregiver burden, welfare)."[6] Additionally, Gilead made the following statement regarding Medicaid: "Additionally, access through Medicaid and safety net providers is especially important due to the disproportionate impact of HIV on underserved populations. These channels play a critical role in reducing health disparities within HIV for medically underserved patients and impoverished communities, with half of Genvoya utilization in Colorado represented by Medicaid or safety net providers."[7]

Board staff gathered further information on the Advancing Access Co-Pay Program via their public website.[8] The Gilead Co-pay Coupon ("Coupon") can be used only by eligible residents of the US, Puerto Rico, or US territories at participating eligible pharmacies in the US, Puerto Rico, or US territories. The Coupon covers a set amount in co-pays per year, depending on the Gilead product. The program covers up to $7,200 in co-pays per year with no monthly limit for Genvoya. The Coupon is only valid for patients with commercial insurance; Medicare and Medicaid patients aren't eligible for participation. Additionally, The Coupon will not reimburse any payments made by Flexible Spending Account (FSA), Health Savings Account (HSA), Health Reimbursement Account (HRA), or any other payor or discount/co-pay program.[9]

See Appendices H, I, and J for more information on both manufacturer financial assistance programs and other patient assistance programs.

[6] https://drive.google.com/file/d/13q4cyzhUudWEhOQUymh94JlrCLHvw8mQ/view?usp=drive_link

[7] https://drive.google.com/file/d/13q4cyzhUudWEhOQUymh94JlrCLHvw8mQ/view?usp=drive_link

[8] https://www.gileadadvancingaccess.com/financial-support/gilead-copay-card

[9] https://www.gileadadvancingaccess.com/financial-support/gilead-copay-card

Appendix L

Genvoya: 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 Genvoya 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 Genvoya 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.

Genvoya: Health Equity Factors Evidence

Social Vulnerability Index (SVI) Information

Board staff calculated SVI scores for patients who utilized Genvoya 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 Genvoya 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 Genvoya in 2022 who resided in Colorado counties with SVI scores above the statewide average.

Following the methodology outlined above, staff calculated that 60.07% of patients who filled a prescription for Genvoya lived in a county with an SVI score above the statewide average of 49.95%, meaning that 60.07% of Genvoya patients lived in a county with higher social vulnerability. This could indicate that patients who utilize Genvoya 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 Genvoya

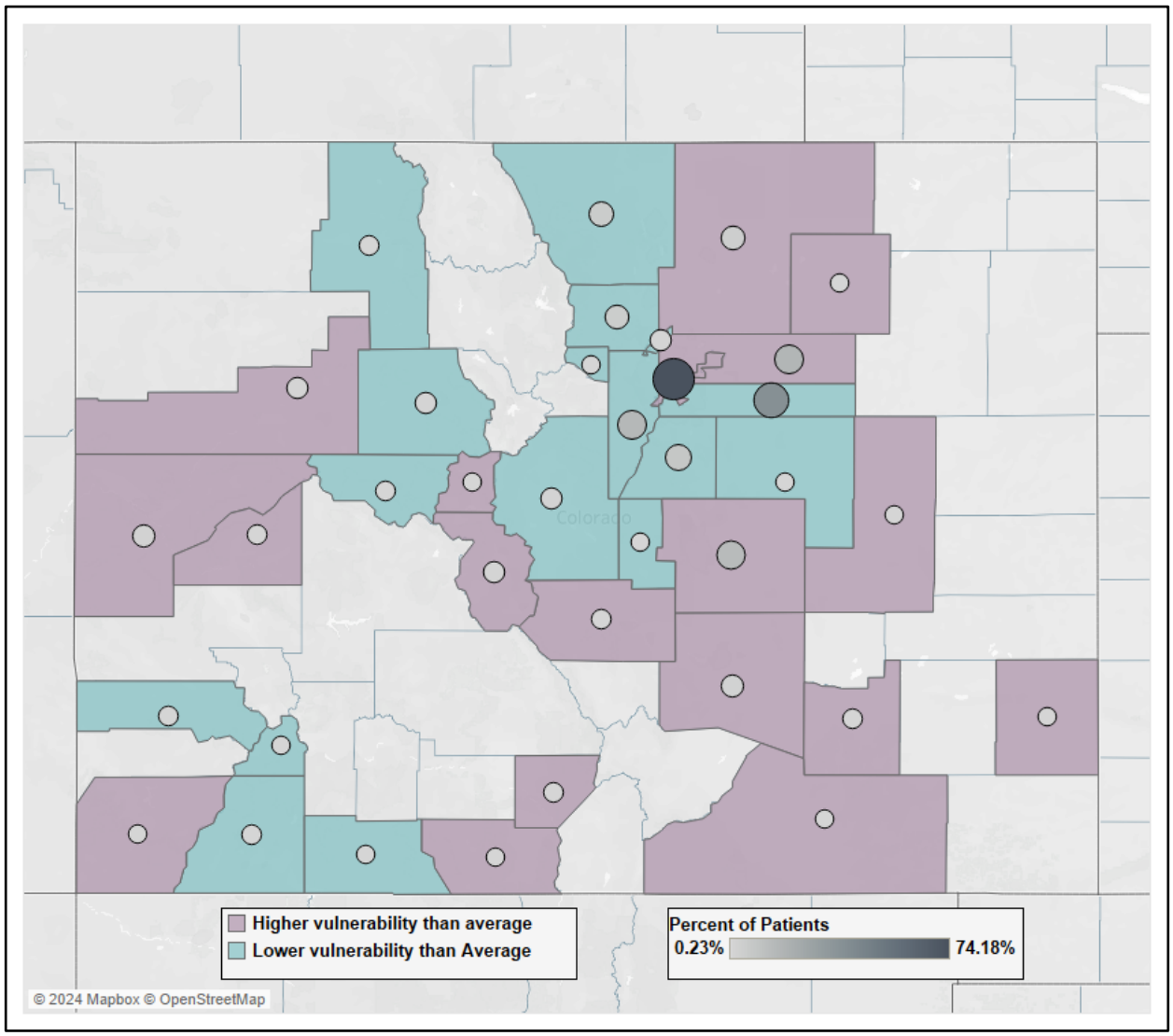

Figure L-1 shows the State of Colorado by county, where purple counties indicate higher than average SVI scores and teal counties indicate a lower than average SVI score, and counties without color did not have any patients who used Genvoya in 2022 residing in them. The dots on each county show the percent of patients who used Genvoya 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 Using Genvoya and Therapeutic Alternatives by County

	County	County SVI Score	Genvoya	Biktarvy	Dovato	Stribild	Triumeq
Counties with Higher Vulnerability Than Average	ADAMS	80.95%	8.53%	8.87%	7.29%	10.00%	7.86%
	ALAMOSA	100.00%	0.23%	0.26%	0.20%		0.14%
	BACA	52.38%		0.02%			
	BENT	82.54%		0.02%			
	CHAFFEE	63.49%	0.46%	0.19%	0.20%		
	CONEJOS	93.65%	0.11%				
	COSTILLA	95.24%		0.10%			
	CROWLEY	77.78%		0.10%			
	DELTA	79.37%	0.34%	0.38%	0.40%		0.41%
	DENVER	73.02%	37.09%	32.92%	36.64%	20.00%	34.28%
	EL PASO	53.97%	7.17%	9.08%	8.10%	15.00%	13.41%
	FREMONT	60.32%	0.34%	0.60%			0.41%
	GARFIELD	61.90%	0.57%	0.50%	0.61%		0.81%
	KIT CARSON	69.84%		0.05%			
	LAKE	57.14%	0.11%	0.05%			
	LAS ANIMAS	85.71%	0.11%	0.17%			0.41%
	LINCOLN	55.56%	0.11%	0.05%	0.20%		
	LOGAN	71.43%		0.24%			0.27%
	MESA	74.60%	1.02%	1.72%	1.62%		1.90%
	MOFFAT	90.48%		0.05%			0.14%

	MONTEZUMA	58.73%	0.11%	0.29%	0.20%		0.14%
	MONTROSE	68.25%		0.26%			0.41%
	MORGAN	92.06%	0.11%	0.36%	0.40%		0.27%
	OTERO	87.30%	0.23%	0.24%			0.41%
	PHILLIPS	50.79%		0.02%	0.20%		
	PROWERS	98.41%	0.11%	0.02%			0.14%
	PUEBLO	84.13%	1.14%	2.53%	1.21%		2.30%
	RIO GRANDE	96.83%		0.19%			
	SAGUACHE	88.89%		0.05%	0.20%		
	WELD	66.67%	2.16%	3.47%	1.82%	5.00%	1.90%
	YUMA	65.08%		0.05%	0.20%		
	Total		***60.07%***	***62.85%***	***59.51%***	***50.00%***	***65.58%***
Counties with Lower Vulnerability Than Average	ARAPAHOE	49.21%	19.34%	16.59%	16.40%	20.00%	17.34%
	ARCHULETA	41.27%	0.11%	0.14%			
	BOULDER	39.68%	2.62%	3.61%	6.48%		1.90%
	BROOMFIELD	9.52%	0.57%	0.93%	1.01%		0.41%
	CHEYENNE	14.29%			0.20%		
	CLEAR CREEK	19.05%		0.22%			0.41%
	CUSTER	6.35%					0.14%
	DOLORES	12.70%		0.05%			
	DOUGLAS	1.59%	4.21%	1.94%	2.02%	5.00%	2.03%
	EAGLE	44.44%	0.57%	0.41%	0.20%		0.27%
	ELBERT	0.00%	0.11%	0.14%	0.20%		0.14%

	GILPIN	4.76%	0.11%				
	GRAND	28.57%		0.12%	0.20%		0.27%
	HINSDALE	38.10%					0.14%
	HUERFANO	42.86%		0.14%			
	JEFFERSON	20.63%	7.85%	8.25%	9.31%	5.00%	7.18%
	KIOWA	23.81%		0.02%			
	LA PLATA	36.51%	0.34%	0.67%	0.40%		
	LARIMER	33.33%	2.84%	3.49%	3.44%	20.00%	2.30%
	OURAY	6.35%		0.02%			
	PARK	3.17%	0.68%	0.26%			0.14%
	PITKIN	15.87%	0.23%	0.07%			0.27%
	RIO BLANCO	47.62%		0.02%			
	ROUTT	11.11%	0.23%	0.17%	0.20%		0.14%
	SAN JUAN	44.44%	0.11%	0.02%			
	SAN MIGUEL	26.98%	0.23%	0.02%			
	SUMMIT	30.16%		0.22%	0.20%		0.68%
	TELLER	17.46%	0.11%	0.19%	0.61%		0.54%
	WASHINGTON	34.92%					0.14%
	Total		***40.27%***	***37.72%***	***40.89%***	***50.00%***	***34.42%***

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 Genvoya 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 Genvoya and Therapeutic Alternatives

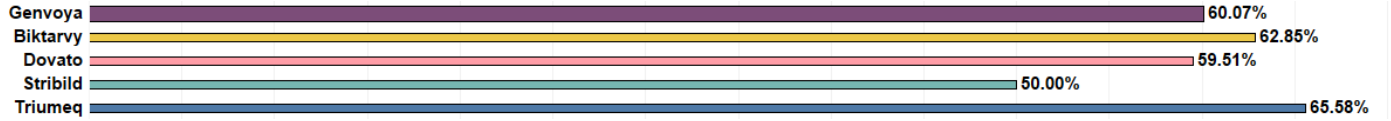

Figure L-2 shows the percent of utilizers of Genvoya and identified therapeutic alternatives that lived in a county with a higher social vulnerability index score than the statewide average.

Health Equity Literature Review

A literature review was conducted for Genvoya's indication of HIV and is meant to provide a broad overview of potential health equity impacts related to the condition. Citations are provided for more information regarding the specific study populations, locations, and time frames being studied.

HIV disproportionately impacts priority populations, particularly sexual minorities, and communities of color.[3] In 2021, Black individuals aged 13 and older represented approximately 12% of the US population, but accounted for 40% of people with HIV. Hispanic/Latino persons aged 13 and older represented 18% of the population but accounted for 25% of people with HIV in the US.[4] AIDSVu Colorado data shows that Hispanic/Latino individuals who make up 22.3% of the Colorado population, are disproportionately impacted by new HIV diagnoses (32%), and Black individuals, who make up 4.1% of the Colorado population, are disproportionately represented in both new HIV diagnoses (16.7%) and statewide HIV prevalence (15.2%).[5]

The United States Center for Disease Control (CDC), reports that gay, bisexual and other men who have sex with men (MSM) are disproportionately affected by HIV in the US. In 2021, this population accounted for 69% of the estimated 32,100 new diagnoses in 2021, even though they made up only 2% of the overall population.[6]

HIV.gov reports that in 2021, adult and adolescent transgender people and people of additional gender identity were 2.5% (912) of new HIV diagnoses in the United States, despite being approximately 1% of the total US population.[7] There is a particular concern for the high prevalence of HIV infections among transgender women: CDC's National HIV Behavioral Surveillance survey in 7 major US cities found that 42% of all transgender female respondents and 62% of all African American transgender female respondents tested positive for HIV.[8]

HIV disparities persist in the number of new HIV diagnoses, linkage to care and treatment, and retention in care.[9] The causes of these disparities are complex and interrelated and can be attributed to myriad social and structural factors such as HIV stigma, homophobia, discrimination, poverty, and limited access to high-quality health care.[10] Stigma, homophobia, and discrimination make MSM of all races/ethnicities susceptible to multiple physical and mental health problems and can affect whether they seek and receive high-quality health services, including HIV testing, treatment, and other prevention services.[11]

Increasing awareness of HIV status through HIV testing is essential for reducing the risk of transmission and for addressing disparities. Individuals who were HIV infected but unaware of their status accounted for 30%

[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3700367/

[4] https://www.hiv.gov/hiv-basics/overview/data-and-trends/impact-on-racial-and-ethnic-minorities/.

[5] https://aidsvu.org/local-data/united-states/west/colorado/#demographics-2021

[6] https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-32/content/special-focus-profiles.html#:~:text=In%202019%2C%20MSM%20accounted%20for,unaware%20of%20their%20HIV%20infection

[7] https://www.hiv.gov/hiv-basics/overview/data-and-trends/impact-on-racial-and-ethnic-minorities/.

[8] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8579984/

[9] https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/resources/october-2021-careaction-newsletter.pdf

[10] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4937112/#B3

[11] https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-32/content/special-focus-profiles.html#:~:text=In%202019%2C%20MSM%20accounted%20for,unaware%20of%20their%20HIV%20infection

of HIV transmissions in 2009.[12] CDC recommends that everyone 13 to 64 years of age get tested for HIV at least once as part of routine health care; however, they recommend people at higher risk for HIV should get tested each year, with sexually active gay and bisexual men benefitting from testing every 3 to 6 months.[13] Lack of awareness of HIV status may be due to recent infection, not getting tested due to underestimation of personal risk, or fewer opportunities to get tested, and individuals who do not know they have HIV can unknowingly infect others.[14]

Differences in antiretroviral therapy (ART) use by race/ethnicity are documented frequently in the literature, with results showing that use of ART is lower for African Americans than for white people and Hispanics/Latinos.[15] Black and Hispanics/Latino individuals are also less likely to be aware of their HIV status and less likely to be retained in care than white people. These differences may explain the lower rates of viral suppression among African Americans and Hispanics/Latinos compared with white people.[16]

HIV viral suppression is critical to improve health, prevent sexual transmission, and reduce perinatal transmission.[17] CDC defines viral suppression as having less than 200 copies of HIV per milliliter of blood, keeping the immune system working and preventing illness.[18] Compared to the overall viral suppression rate of 88.1%, the viral suppression rates are lower for Black/African American people, transgender people, and youth.[19] Only 61% of Black Americans diagnosed with HIV virally suppressed in 2019, compared to 71% of white Americans.[20]

The U.S. Department of Health and Human Services' Minority HIV/AIDS Fund is helping improve HIV prevention, care, and treatment for communities of color by bringing federal, state, and community organizations together to design and test innovative solutions that address critical emerging needs and by working to improve the efficiency, effectiveness, and impact of federal investments in HIV programs and services for racial and ethnic minorities.[21]

The Health Resources and Services Administration's (HRSA) Ryan White HIV/AIDS Program (RWHAP) provides a comprehensive system of HIV primary medical care, medications, and essential support services for low-income people with HIV who are uninsured and underserved (See Appendix F for more information).[22] Currently, more than 73 percent of RWHAP clients are from racial/ethnic minority populations disproportionately affected by HIV and HIV disparities, including 46.6 percent Black/African American clients and 23.3 percent Hispanic/Latino clients. In addition, 60.7 percent of RWHAP clients live below 100 percent of the Federal Poverty Level and 46.8 percent are aged 50 years or older.[23] In 2022, nearly 90% of RWHAP clients receiving HIV medical care were virally suppressed, exceeding the national viral suppression average of 66% among all people with diagnosed HIV.

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12 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4937112/#B41

13 https://hivinfo.nih.gov/understanding-hiv/fact-sheets/hiv-testing

14 https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-32/content/special-focus-profiles.html#:~:text=In%202019%2C%20MSM%20accounted%20for,unaware%20of%20their%20HIV%20infection

15 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4937112/#B28

16 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4937112/

17 https://www.who.int/publications/i/item/9789240055179

18 https://www.cdc.gov/hiv/risk/art/index.html#:~:text=Getting%20and%20keeping%20an%20undetectable,pregnancy%2C%20birth%2C%20and%20breastfeeding.

19 https://www.hiv.gov/hiv-basics/overview/data-and-trends/impact-on-racial-and-ethnic-minorities/

20 AIDSVu.org. Local Data: United States. Accessed from https://aidsvu.org/local-data/united-states/.

21 https://www.hiv.gov/hiv-basics/overview/data-and-trends/impact-on-racial-and-ethnic-minorities/

22 https://www.hiv.gov/hiv-basics/overview/data-and-trends/impact-on-racial-and-ethnic-minorities/

23 https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/resources/october-2021-careaction-newsletter.pdf

In addition to the information contained above, Appendix H, Appendix I, and Appendix J 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 impacts of Genvoya.

Appendix M

Genvoya: 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 identified 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.

Genvoya: 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 Genvoya from HCPF.

In accordance with Colorado Senate Bill 19-005, HCPF is developing a Canadian prescription drug importation program and in December 2022 submitted a Section 804 Importation Program (SIP) application to the FDA for approval.[1] HCPF has stated the agency will submit an updated application in early 2024 addressing the FDA's feedback, with the FDA suggesting a six month SIP review timeline, and with HCPF estimating the Colorado Importation Program could be operational by late 2024 at the earliest.

In HCPF's SIP application[2] and appendices[3], Genvoya is listed as a prescription drug for potential importation, with the following information provided:

[1] https://hcpf.colorado.gov/drug-importation.

[2] https://hcpf.colorado.gov/sites/hcpf/files/Colorado%27s%20Drug%20Importation%20Program%202022%20Formal%20SIP.pdf.

[3] https://hcpf.colorado.gov/sites/hcpf/files/Colorado%20SIP%20Appendix.pdf.

Table M-1
Section 804 Importation Program Drug List December 5th, 2022 - Genvoya

Drug Name	Genvoya
Strength	150-150- 200-10mg
Brand or Generic	Brand
Drug Category	HIV
Colorado Unit Price	$101.78
Canadian Unit Price with 50% Markup[(9)]	$49.28
APDC Units	136220
Self Funded Units[(8)]	72002
Total Units	208222
Annual Colorado Commercial Cost	$21,193,696.37
Annual Importation Cost	$10,260,209.32
Total Annual Savings	$10,933,487.04
Percent Savings	52%

The following prescription drugs under the "Drug Category: HIV" were also listed for potential importation:

Table M-2
Section 804 Importation Program Drug List December 5th, 2022 - Drug Category: HIV

Drug Name	Total Annual Savings	Percent Savings
Biktarvy	$25,774,143.00	58%
Cabenuva (2mL)	$169,536.43	63%
Cabenuva (3mL)	$40,927.65	51%
Descovy	$6,619,878.40	41%
Edurant	$118,221.02	63%
Genvoya	$10,933,487.04	52%
Odefsey	$118,221.02	52%

Drug Name	Total Annual Savings	Percent Savings
Symtuza	$1,004,133.88	51%
Tivicay	$4,576,941.62	59%
Triumeq	$5,512,559.79	51%

Additionally, 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.[4] These lists are developed with recommendations from HCPF's Drug Utilization Review Board.[5]

HCPF's PDL outlines the following information effective as of January 1, 2024:[6]

- For human immunodeficiency virus treatments, oral: Genvoya is a preferred agent with no prior authorization required. No HIV treatment, oral requires a prior authorization, including identified therapeutic alternatives.

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/pharmacy-resources.
[5] https://hcpf.colorado.gov/drug-utilization-review-board.
[6] https://hcpf.colorado.gov/sites/hcpf/files/01-01-24%20PDL-V8.1.pdf.

Appendix N

Genvoya: 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 will attempt 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 Genvoya 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.

Genvoya: Non-Adherence and Utilization Management Evidence

Utilization management may include practices like step therapy or prior authorization requirements. Colorado Senate Bill 23-189 requires Medicaid and state-regulated commercial plans that cover health services related to sexually transmitted infections include coverage of HIV prevention drugs or cover HIV treatment, like Genvoya, without step therapy or prior authorization requirements.[1] At the federal level, Medicare requires Part D plan sponsors to include on their formulary all drugs in six categories, including antiretrovirals, like Genvoya, and antiretrovirals may not be subject to prior authorizations or step therapy requirements.[2]

[1] https://leg.colorado.gov/bills/sb23-189
[2] https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-and-part-d-drug-pricing-final-rule-cms-4180-f

Stakeholder Input

Patients and caregivers submitting voluntary information and in meetings did not disclose information about non-adherence of Genvoya due to cost. Of the 22 patients and caregivers surveyed:

- Eight participants indicated that cost impacted their access to Genvoya and three respondents indicated that they skipped or stretched doses of the drug to save money. Thirteen participants indicated that cost had not impacted their access to Genvoya.
- Six said their insurance plan requires prior approval to fill the prescription, ten said their insurance plan limits the supply of the drug, five worried that the cost of the prescription will raise their premium, and three said their insurance required them to try a medication they had previously failed.

See Appendix H for more information.

Individuals with scientific or medical training largely said that they had not encountered issues with utilization management. See Appendix I for more information.

Voluntarily Submitted Information

Gilead Sciences, Inc. voluntarily submitted information that Colorado "patients taking Genvoya have been on the medicine for 29 months on average, 53% longer than the average for all HIV patients in" the state, citing an IQVIA analysis for Gilead that was not disclosed. Additionally information was provided that "Genvoya patient satisfaction has been demonstrated by high rates of adherence and persistence compared to other STRs included in a real-world study (Stribild, Triumeq, Odefsey, Complera, Atripla)", citing Sutton SS, Hardin JW, Bramley TJ, D'Souza AO, Bennett CL. Single- Versus Multiple-Tablet HIV Regimens: Adherence and Hospitalization Risk. Am J Manag Care. 2016;22(4):242-248. See Appendix J for more information.

Appendix O

Genvoya: 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 Genvoya's price - See Appendix A for more information.

Genvoya: 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 Genvoya and Gilead Sciences, Inc., specifically introductory prices and weighted average costs for multiple strengths and dosage forms of Genvoya as reported by the manufacturer in 2021 and 2022.
- Patent Exclusivity Report - Information regarding Gilead Sciences, Inc., but not Genvoya, is contained in this report.
- WAC Increases - Information regarding Gilead Sciences, Inc., but not Genvoya, is contained in this report.
- Research and Development Costs - Information regarding Gilead Sciences, Inc. is contained in this report, specifically that Gilead Sciences, Inc.'s 2022 research and development costs were $5.363 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 8 expected reports from Gilead Sciences, Inc. with 8 reports received.[4] No information regarding Gilead Sciences, Inc., nor Genvoya, was contained in the Price Increase - Five Year Price Analysis Dashboard or Comparative Price Change Analysis Dashboard.

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.[5] While information regarding other prescription drugs manufactured by Gilead Sciences, Inc. was contained in this report, no information regarding Genvoya was found.

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[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://mhdo.maine.gov/RxReferenceRates.htm.

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).[6]

Information is provided for three state fiscal years, which run from July 1 through June 30. In the most recent report (July 1, 2021 through June 30, 2022), Genvoya does not appear on any of the lists overall, nor does it appear in the detailed lists 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.[7] Drug Price Transparency Program Reports are available from 2019-2022.[8] The 2022 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 copayments and coinsurance. Genvoya does not appear on the list (p. 50).[9] The report also contains information regarding drugs with greatest increases in year-over-year health plan spending, as well as the amount of that increase. Genvoya does not appear on the list (p. 51).[10]

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.[11] 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), Gilead Sciences, Inc. submitted information in 2020 and 2021, but nothing related to Genvoya.

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[6] https://mhdo.maine.gov/tableau/prescriptionReports.cshtml.

[7] https://dfr.oregon.gov/drugtransparency/Pages/index.aspx.

[8] https://dfr.oregon.gov/drugtransparency/Pages/annual-reports.aspx.

[9] https://dfr.oregon.gov/drugtransparency/Documents/Prescription-Drug-Price-Transparency-Annual-Report-2022.pdf.

[10] https://dfr.oregon.gov/drugtransparency/Documents/Prescription-Drug-Price-Transparency-Annual-Report-2022.pdf.

[11] https://data.chhs.ca.gov/dataset/prescription-drugs-introduced-to-market.

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.[12] Genvoya Sciences, Inc. reported NDCs associated with Genvoya.

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.[13] Gilead Sciences, Inc. did not report WAC information to HHSC in 2020, 2021, 2022 or 2023 and did not report any qualifying price increases in 2021, 2022, or 2023 for any drugs, including Genvoya.

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.[14]

Figure O-1
Payer Rank of Genvoya Impact on Premiums in 2022

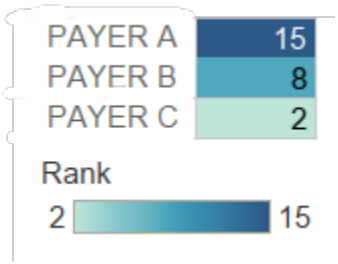

Figure O-1 shows the rank that each payer submitted indicating that Genvoya was a drug in the top 15 prescription drugs that increased premiums. For example, Payer C indicated that Genvoya was the second highest drug responsible for increases to premiums. The box represented shows the rank number and lighter boxes indicate a lower rank, meaning a larger increase in premiums than a lower rank and darker box.

[12] https://data.chhs.ca.gov/dataset/prescription-drug-wholesale-acquisition-cost-wac-increases.
[13] https://www.dshs.texas.gov/prescription-drug-price-disclosure-program/about.
[14] 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.

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 Genvoya 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 Genvoya'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.

Manufacturer Pricing Information

The SEC requires all public companies to file a Form 10-K each year, and a Form 10-Q each quarter.[15] These forms provide a financial snapshot of the company's revenues, assets, and liabilities for the previous year. Gilead Sciences, Inc.'s 2022 10-K details that Genvoya's international Product Revenue decreased from approximately $2.879 billion in 2021 to $2.404 billion in 2022 (p.60).

[15] 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, Gilead Sciences, Inc.,: https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/data/882095/000088209523000007/gild-20221231.htm

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 claims from January 2018 through December 2022, which were paid through May 2023, were used for analyses. Medical claims were not examined in this affordability review, since Genvoya is only reimbursed on pharmacy claims. Drugs are identified on pharmacy claims with their National Drug Code (NDC). Genvoya has one NDC code found in the APCD and utilized in these analyses. APCD claims are categorized by the submitting payer and are categorized as Medicaid, Medicare Advantage, and all other submitters are commercial.

Genvoya and identified therapeutic alternatives NDC codes found in the APCD and utilized in these analyses were:

Drug Name	NDC
Genvoya	61958-1901-01
Biktarvy	50090-6247-00, 61958-2501-01, 61958-2501-03, 61958-2505-01
Dovato	49702-0246-13
Stribild	61958-1201-01
Triumeq	49702-0231-13, 49702-0258-37, 49702-0272-59

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.

First DataBank AnalySource

AnalySource provides WAC and other pricing benchmarks for all NDCs at current rates and historic levels. The Genvoya NDC code found in AnalySource was 61958-1901-01.

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. It is noted when these are included.

SSR Health

- Board staff contracted with SSR Health[1] 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.[2] 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.

[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