

From: Pickle, Devona
Subject: Revised Versions
To: cmizener@lslog.com
Sent: April 13, 2023 1:35 PM (UTC-04:00)
Attached: SIP RFI Responses to FDA_2023-04-XX.docx, SIP Proposal - 04-XX-2023.docx, Agency SIP Methodology and Data for Cost Analysis.docx, Florida_SIP_Response_Ltr_FINAL_2023-04-13.docx

Chris – These versions have been updated following a thorough review by our outside counsel.

D.D. Pickle

Health Care Policy

(office) 850-412-4646

(mobile) 850-895-7894

Due to the competitive procurements of the Prescription Drug Direct Purchasing Program and the Statewide Medicaid Managed Care Program, we are in a statutorily imposed “Blackout Period” until 72 hours after the award and cannot provide interpretation or additional information not included in the solicitation documents.

**AGENCY FOR HEALTH CARE ADMINISTRATION
SECTION 804 IMPORTATION PROGRAM PROPOSAL
METHODOLOGY AND DATA FOR COST ANALYSIS**

Table 1, Estimated Total Florida Medicaid Reimbursement for Selected Drugs, provides the gross Medicaid reimbursement for each prescription drug to be imported. The dollar amounts are calculated from the total reimbursement for the Rate Year (RY) 21/22 for Florida's Statewide Medicaid Managed Care (SMMC) program scaled to the overall Florida Medicaid population. This is used for projecting the utilization for both the Baseline and Plan Scenarios. Drugs with multiple strength or dosage forms include only include data on those strengths/dosage forms selected for importation as well as any bioequivalent dosage forms.

TABLE 1 ESTIMATED TOTAL FLORIDA MEDICAID REIMBURSEMENT FOR SELECTED DRUGS		
Product Name	Therapeutic Class	RY 21/22
XTANDI	Specialty - Cancer - Non-chemotherapy	\$5,563,861
RAVICTI	Specialty - Endocrine and Metabolic Agents	\$10,050,548
ELIQUIS	Traditional - Anticoagulants	\$41,980,441
REXULTI	Traditional - Antipsychotic	\$8,628,317
VRAYLAR	Traditional - Antipsychotic	\$30,315,332
ENTRESTO	Traditional - Cardiovascular	\$20,902,845
BIKTARVY	Traditional - HIV	\$187,793,887
DESCOVY	Traditional - HIV	\$31,883,475
DOVATO	Traditional - HIV	\$18,567,857
GENVOYA	Traditional - HIV	\$35,535,449
JULUCA	Traditional - HIV	\$11,213,363
ODEFSEY	Traditional - HIV	\$15,905,591
PREZCOBIX	Traditional - HIV	\$12,446,067
PREZISTA	Traditional - HIV	\$5,583,545
SYMTUZA	Traditional - HIV	\$37,434,540
TIVICAY	Traditional - HIV	\$30,009,358
EUCRISA	Traditional - Other	\$8,982,171
Totals		\$512,796,648

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

Table 2, Rebate for Selected Drugs by NDC, provides the total rebates received by Florida Medicaid for prescription drugs provided through the SMMC program for RY21/22. For the selected NDCs, each row represents the total rebates received by the Agency, including all federal and supplemental rebates. Due to confidentiality laws, this information, as well as any information that can be used to calculate specific rebates, is redacted.

TABLE 2 REBATE FOR SELECTED DRUGS BY NDC			
NDC	Product Name	Therapeutic Class	Rebate RY 21/22
61958250101	BIKTARVY	Traditional - HIV	[REDACTED]
61958250103	BIKTARVY	Traditional - HIV	[REDACTED]
61958200201	DESCOVY	Traditional - HIV	[REDACTED]
61958200202	DESCOVY	Traditional - HIV	[REDACTED]
49702024613	DOVATO	Traditional - HIV	[REDACTED]
00003089321	ELIQUIS	Traditional - Anticoagulants	[REDACTED]
00003089331	ELIQUIS	Traditional - Anticoagulants	[REDACTED]
00003089421	ELIQUIS	Traditional - Anticoagulants	[REDACTED]
00003089431	ELIQUIS	Traditional - Anticoagulants	[REDACTED]
00003089470	ELIQUIS	Traditional - Anticoagulants	[REDACTED]
00078065920	ENTRESTO	Traditional - Cardiovascular	[REDACTED]
00078065967	ENTRESTO	Traditional - Cardiovascular	[REDACTED]
00078069620	ENTRESTO	Traditional - Cardiovascular	[REDACTED]
00078069667	ENTRESTO	Traditional - Cardiovascular	[REDACTED]
00078077720	ENTRESTO	Traditional - Cardiovascular	[REDACTED]
00078077767	ENTRESTO	Traditional - Cardiovascular	[REDACTED]
55724021111	EUCRISA	Traditional - Other	[REDACTED]
55724021121	EUCRISA	Traditional - Other	[REDACTED]
61958190101	GENVOYA	Traditional - HIV	[REDACTED]
49702024213	JULUCA	Traditional - HIV	[REDACTED]
61958210101	ODEFSEY	Traditional - HIV	[REDACTED]
59676057530	PREZCOBIX	Traditional - HIV	[REDACTED]
59676056201	PREZISTA	Traditional - HIV	[REDACTED]
59676056630	PREZISTA	Traditional - HIV	[REDACTED]
75987005006	RAVICTI	Specialty - Endocrine and Metabolic Agents	[REDACTED]
59148003513	REXULTI	Traditional - Antipsychotic	[REDACTED]
59148003613	REXULTI	Traditional - Antipsychotic	[REDACTED]
59148003713	REXULTI	Traditional - Antipsychotic	[REDACTED]
59148003813	REXULTI	Traditional - Antipsychotic	[REDACTED]
59148003913	REXULTI	Traditional - Antipsychotic	[REDACTED]
59148004013	REXULTI	Traditional - Antipsychotic	[REDACTED]
59676080030	SYMTUZA	Traditional - HIV	[REDACTED]
49702022813	TIVICAY	Traditional - HIV	[REDACTED]
61874011511	VRAYLAR	Traditional - Antipsychotic	[REDACTED]
61874011520	VRAYLAR	Traditional - Antipsychotic	[REDACTED]
61874011530	VRAYLAR	Traditional - Antipsychotic	[REDACTED]
61874013011	VRAYLAR	Traditional - Antipsychotic	[REDACTED]
61874013020	VRAYLAR	Traditional - Antipsychotic	[REDACTED]
61874013030	VRAYLAR	Traditional - Antipsychotic	[REDACTED]

TABLE 2 REBATE FOR SELECTED DRUGS BY NDC			
NDC	Product Name	Therapeutic Class	Rebate RY 21/22
61874014530	VRAYLAR	Traditional - Antipsychotic	██████████
61874016030	VRAYLAR	Traditional - Antipsychotic	██████████
00469012599	XTANDI	Specialty - Cancer - Non-chemotherapy	██████████
00469062599	XTANDI	Specialty - Cancer - Non-chemotherapy	██████████
	TOTAL		██████████

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

Table 3, Estimated Total Net Cost for Florida Medicaid, provides the net cost for each drug calculated by subtracting the estimated total rebate from the estimated total reimbursement. The estimated total rebate is calculated by adjusting the actual rebates received through the SMMC Program for RY21/22 to represent the entire Florida Medicaid population in the same manner as **Table 1**.

TABLE 3 ESTIMATED TOTAL NET COST FOR FLORIDA MEDICAID		
Product Name	Therapeutic Class	RY 21/22
XTANDI	Specialty - Cancer - Non-chemotherapy	
RAVICTI	Specialty - Endocrine and Metabolic Agents	
ELIQUIS	Traditional - Anticoagulants	
REXULTI	Traditional - Antipsychotic	
VRAYLAR	Traditional - Antipsychotic	
ENTRESTO	Traditional - Cardiovascular	
BIKTARVY	Traditional - HIV	
DESCOVY	Traditional - HIV	
DOVATO	Traditional - HIV	
GENVOYA	Traditional - HIV	
JULUCA	Traditional - HIV	
ODEFSEY	Traditional - HIV	
PREZCOBIX	Traditional - HIV	
PREZISTA	Traditional - HIV	
SYMTUZA	Traditional - HIV	
TIVICAY	Traditional - HIV	
EUCRISA	Traditional - Other	
Totals		

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

Table 4, Projected Two-Year Baseline Scenario, provides projections into RY 23-24 and RY 24-25 that were created by trending utilization rate and unit cost. Future utilization rate was trended using the aggregate statewide growth rate used in capitation rate development for the MMA rate certification for managed care entities. Drug cost projection was created using Historical Wholesale Acquisition Cost (WAC) increases by NDC from the Medi-Span database in addition to BioMed Tracker and Datamonitor Health which includes individual drug product sales forecasts and disease state sales forecasts. Due to the ending of the Public Health Emergency (PHE), Florida Medicaid will see a significant decrease in the number of recipients. As such, both projected years in the Baseline Scenario will be scaled by multiplying by projected number of recipients after the unwinding process and divided by the number of recipients receiving services at the end of RY 21/22.

TABLE 4 PROJECTED TWO-YEAR BASELINE SCENARIO			
Product Name	Therapeutic Class	RY 23/24	RY 24/25
XTANDI	Specialty - Cancer - Non-chemotherapy		
RAVICTI	Specialty - Endocrine and Metabolic Agents		
ELIQUIS	Traditional - Anticoagulants		
REXULTI	Traditional - Antipsychotic		
VRAYLAR	Traditional - Antipsychotic		
ENTRESTO	Traditional - Cardiovascular		
BIKTARVY	Traditional - HIV		
DESCOVY	Traditional - HIV		
DOVATO	Traditional - HIV		
GENVOYA	Traditional - HIV		
JULUCA	Traditional - HIV		
ODEFSEY	Traditional - HIV		
PREZCOBIX	Traditional - HIV		
PREZISTA	Traditional - HIV		
SYMTUZA	Traditional - HIV		
TIVICAY	Traditional - HIV		
EUCRISA	Traditional - Other		
Totals		\$314,839,019.87	\$333,549,830.38

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

Table 5, Estimated Total Imported Drug Cost for RY 21/22, provides calculations using utilization rates in RY 21/22 multiplied by Canadian unit prices for each imported drug. The Canadian prices were found on the official websites of the provinces or Ontario and Quebec. For drugs not listed on their formulary or website, the Importer requested direct prices from the Foreign Seller. These prices represent the cost to the Importer. A 7.0% Importer fee and a \$10.25 professional dispensing fee was used.

TABLE 5 ESTIMATED TOTAL IMPORTED DRUG COST FOR RY 21/22		
Product Name	Therapeutic Class	RY 21/22
XTANDI	Specialty - Cancer - Non-chemotherapy	\$1,317,627.58
RAVICTI	Specialty - Endocrine and Metabolic Agents	\$1,665,810.67
ELIQUIS	Traditional - Anticoagulants	\$7,374,011.15
REXULTI	Traditional - Antipsychotic	\$666,510.57
VRAYLAR	Traditional - Antipsychotic	\$3,297,488.76
ENTRESTO	Traditional - Cardiovascular	\$6,572,406.79
BIKTARVY	Traditional - HIV	\$52,637,322.11
DESCOVY	Traditional - HIV	\$13,300,297.05
DOVATO	Traditional - HIV	\$5,705,729.41
GENVOYA	Traditional - HIV	\$11,458,525.16
JULUCA	Traditional - HIV	\$3,335,118.68
ODEFSEY	Traditional - HIV	\$5,311,953.91
PREZCOBIX	Traditional - HIV	\$3,592,802.98
PREZISTA	Traditional - HIV	\$1,892,462.52
SYM TUZA	Traditional - HIV	\$12,049,679.85
TIVICAY	Traditional - HIV	\$8,087,179.68
EUCRISA	Traditional - Other	\$1,802,015.18
Totals		\$140,066,942.05

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

Table 6, Projected Two-Year Plan Scenario (100%), provides a projected Plan Scenario for a 100% uptake rate. The Medicaid Program will reimburse for these drugs at a 7.0% upcharge in the first RY of the Plan Scenario and 6.5% in the second RY. In addition, there will be a \$10.25 professional dispensing fee paid to the dispensing pharmacy. Canadian law currently limits medication price increases to 5.1% per year. It is assumed in the analysis that all drug prices will increase to the maximum amount permitted each year. The utilization trends as well as the population adjustment due to the end of the PHE will be calculated in the same way as the Baseline Scenario. The Plan Scenario will include operation fees. There is a flat cost of \$14,496,000.00 per year in accordance with the contract between the Agency and the Importer.

TABLE 6 PROJECTED TWO-YEAR PLAN SCENARIO (100%)			
Product Name	Therapeutic Class	RY 23/24	RY 24/25
XTANDI	Specialty - Cancer - Non-chemotherapy		
RAVICTI	Specialty - Endocrine and Metabolic Agents		
ELIQUIS	Traditional - Anticoagulants		
REXULTI	Traditional - Antipsychotic		
VRAYLAR	Traditional - Antipsychotic		
ENTRESTO	Traditional - Cardiovascular		
BIKTARVY	Traditional - HIV		
DESCOVY	Traditional - HIV		
DOVATO	Traditional - HIV		
GENVOYA	Traditional - HIV		
JULUCA	Traditional - HIV		
ODEFSEY	Traditional - HIV		
PREZCOBIX	Traditional - HIV		
PREZISTA	Traditional - HIV		
SYMTUZA	Traditional - HIV		
TIVICAY	Traditional - HIV		
EUCRISA	Traditional - Other		
Product Totals		\$120,996,498.94	\$126,591,617.29
Operation Cost		\$14,496,000.00	\$14,496,000.00
Totals		\$135,492,498.94	\$141,087,617.29

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

Table 7, Projected Plan Scenario (75%), provides a projected Plan Scenario for a 75% Uptake Rate. This uses the methodology as previous projections, assuming 75% of the utilization is from the drug costs in the Plan Scenario and 25% from the Baseline Scenario. However, the full amount of the operation fees would still apply. Due to the unpredictable nature of supplemental rebates, this analysis does not quantize the effect of this program on future Medicaid rebates.

TABLE 7 PROJECTED PLAN SCENARIO (75%)			
Product Name	Therapeutic Class	RY 23/24	RY 24/25
XTANDI	Specialty - Cancer - Non-chemotherapy		
RAVICTI	Specialty - Endocrine and Metabolic Agents		
ELIQUIS	Traditional - Anticoagulants		
REXULTI	Traditional - Antipsychotic		
VRAYLAR	Traditional - Antipsychotic		
ENTRESTO	Traditional - Cardiovascular		
BIKTARVY	Traditional - HIV		
DESCOVY	Traditional - HIV		
DOVATO	Traditional - HIV		
GENVOYA	Traditional - HIV		
JULUCA	Traditional - HIV		
ODEFSEY	Traditional - HIV		
PREZCOBIX	Traditional - HIV		
PREZISTA	Traditional - HIV		
SYMTUZA	Traditional - HIV		
TIVICAY	Traditional - HIV		
EUCRISA	Traditional - Other		
Product Totals		\$169,457,129.1	\$178,331,170.56
Operation Cost		\$14,496,000.00	\$14,496,000.00
Totals		\$183,953,129.17	\$192,827,170.56

Table 8, Projected Program Cost Savings, provides the final projected cost savings. Each row represents the projected savings generated between Plan Scenario and the Baseline Scenario for 100% uptake of imported drugs and for 75% uptake.

TABLE 8 PROJECTED PROGRAM COST SAVINGS			
Uptake Rate	RY 2023-24	RY 2024-25	Total
100% Uptake	\$ 179,346,520.93	\$ 192,462,213.09	\$371,808,734.03
75% Uptake	\$ 130,885,890.70	\$ 140,722,659.82	\$271,608,550.52

Note: Final projected program cost savings for 100% uptake is the difference between the totals in **Table 4, Two-Year Projected Baseline Scenario,** and **Table 6, Projected Two-Year Plan Scenario (100%).** Final projected program cost savings for 75% uptake is the difference between the totals in **Table 4, Two-Year Projected Baseline Scenario,** and **Table 7, Projected Plan Scenario (75%).**

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK