

Attachment E: Cost Savings

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

The following document explains the methodology and provides data on the cost savings calculations. Cost information is based on Rate Years (RY), which corresponds to federal fiscal years. Price increases are projected using Calendar Years (CY). The following dataset calculates savings based on outpatient prescription drug spending in Florida Medicaid, including claims from both fee-for-service recipients and enrollees in State Medicaid Managed Care (SMMC) health plans. Due to the confidentiality requirements of 42 U.S.C. 1396r-8 (b)(3)(d), individual rebates, as well as any information that can be used to calculate individual rebates, are redacted.

In response to the FDA's third Request for Information on August 14 and meeting on September 29, 2023, the Agency added Tables 16 – 20 to provide break-even analyses. In addition, Milliman provided utilization and price trends for the original analyses. This information is provided in Tables 2, 3, 8, and 11. Because Milliman considers the data and methodology used to calculate these numbers to be propriety, they are not provided.

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Table 1: The Proposed Importation List specifies medications that the Sponsor has identified as importable prescription drugs that can generate cost savings to American consumers. This table lists the Product Name (trade name), therapeutic class, and the active ingredients (generic name). For more information on which dosage and dosage forms are included for each medication, please see Attachment D.

TABLE 1 PROPOSED IMPORTATION LIST		
Product Name	Therapeutic Class	Active Ingredients
XTANDI	Specialty - Cancer - Non-chemotherapy	Enzalutamide
RAVICTI	Specialty - Endocrine and Metabolic Agents	Glycerol phenylbutyrate
REXULTI	Traditional - Antipsychotic	Brexipiprazole
VRAYLAR	Traditional - Antipsychotic	Cariprazine
BIKTARVY	Traditional - HIV	Bictegravir, emtricitabine, tenofovir alafenamide
DESCOVY	Traditional - HIV	Emtricitabine / tenofovir alafenamide
DOVATO	Traditional - HIV	Dolutegravir, lamivudine
GENVOYA	Traditional - HIV	Elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide
JULUCA	Traditional - HIV	Dolutegravir, rilpivirine
ODEFSEY	Traditional - HIV	Rilpivirine, emtricitabine, tenofovir alafenamide
PREZCOBIX	Traditional - HIV	Darunavir, cobicistat
PREZISTA	Traditional - HIV	Darunavir
SYMTUZA	Traditional - HIV	Darunavir, cobicistat, emtricitabine, tenofovir alafenamide
TIVICAY	Traditional - HIV	Dolutegravir

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Table 2: The Projected Total Utilization for Selected Drugs by Number of Prescriptions table provides information on the number of projected prescriptions for the selected drugs for RY 23/24 and RY 24/25. The projections are calculated from RY 21/22 estimates, which were obtained through Medicaid.gov for RY 21/22 for SMMC claims and adjusted to represent all Florida Medicaid recipients (SMMC and FFS). This estimate is based upon the assumption that the capitated utilization rates for SMMC and FFS do not differ significantly and one can be used to estimate the other. The rate of utilization change is represented in table 3. All utilizations for different doses intended for importation have been combined into a single row under the assumption that the relative utilization does not change with time.

TABLE 2 PROJECTED TOTAL UTILIZATION FOR SELECTED DRUGS BY NUMBER OF PRESCRIPTIONS			
Product Name	RY 21/22	RY 23/24	RY 23/24
XTANDI	483.2	456.5	457.0
RAVICTI	194.0	183.3	183.5
REXULTI	6,732.0	6,360.0	6,366.4
VRAYLAR	24,325.4	22,981.4	23,004.4
BIKTARVY	53,304.9	50,359.8	50,410.2
DESCOVY	16,064.2	15,176.6	15,191.8
DOVATO	7,105.7	6,713.1	6,719.8
GENVOYA	9,963.8	9,413.3	9,422.7
JULUCA	3,594.9	3,396.2	3,399.6
ODEFSEY	4,963.5	4,689.3	4,694.0
PREZCOBIX	5,705.5	5,390.2	5,395.6
PREZISTA	3,024.7	2,857.6	2,860.4
SYMTUZA	8,931.4	8,437.9	8,446.4
TIVICAY	14,394.5	13,599.2	13,612.8
Totals	158,787.6	150,014.6	150,164.6

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Table 3: The Projected Annual Utilization Change for Selected Drugs table provides the annual projected change in the number of prescriptions per year. The changes are year-over-year and compounded for future change. Due to the Medicaid Redeterminations following the expiring of the COVID-19 Public Health Emergency (PHE) executive order, an adjustment was made to represent a decrease of Florida Medicaid recipients. The decrease of 5.443% was obtained using the ratio of Milliman projected number of member months for RY 23/24 (34,459,004) to the actual SMMC member-months for RY 21/22 (36,474,197). Rate years projected are not to be affected by the PHE and are assumed to grow at 0.100%. All utilizations for different doses intended for importation have been combined into a single row under the assumption that the relative utilization does not change with time.

TABLE 3 PROJECTED ANNUAL UTILIZATION CHANGE FOR SELECTED DRUGS				
Product Name	RY 21/22	RY 22/23	RY 23/24	RY 24/25
XTANDI	BASELINE	0.000%	-5.443%	0.100%
RAVICTI	BASELINE	0.000%	-5.443%	0.100%
REXULTI	BASELINE	0.000%	-5.443%	0.100%
VRAYLAR	BASELINE	0.000%	-5.443%	0.100%
BIKTARVY	BASELINE	0.000%	-5.443%	0.100%
DESCOVY	BASELINE	0.000%	-5.443%	0.100%
DOVATO	BASELINE	0.000%	-5.443%	0.100%
GENVOYA	BASELINE	0.000%	-5.443%	0.100%
JULUCA	BASELINE	0.000%	-5.443%	0.100%
ODEFSEY	BASELINE	0.000%	-5.443%	0.100%
PREZCOBIX	BASELINE	0.000%	-5.443%	0.100%
PREZISTA	BASELINE	0.000%	-5.443%	0.100%
SYMTUZA	BASELINE	0.000%	-5.443%	0.100%
TIVICAY	BASELINE	0.000%	-5.443%	0.100%

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Table 4: The Estimated Total Florida Medicaid Reimbursement for Selected Drugs for RY 21/22 table provides the gross total Medicaid reimbursement for each prescription drug to be imported. The dollar amounts are calculated from the total reimbursement for the RY 21/22 for SMMC and scaled to the overall Florida Medicaid population using the same method for estimating utilization in Table 2. The Per-Claim Cost was calculated by dividing the Total Cost by the Total Utilization for each drug. The raw data for total cost was obtained from data.medicaid.gov and includes all professional dispensing fees. Prices for different doses intended for importation have been summed into a single row under the assumption that ratio of prices of one dose does not change with time with respect to another dose.

TABLE 4 ESTIMATED TOTAL FLORIDA MEDICAID REIMBURSEMENT FOR SELECTED DRUGS FOR RY 21/22		
Product Name	Total Cost	Per-Claim Cost
XTANDI	\$5,563,861.34	\$11,513.54
RAVICTI	\$10,050,548.00	\$51,806.95
REXULTI	\$8,628,316.64	\$1,281.69
VRAYLAR	\$30,315,332.31	\$1,246.24
BIKTARVY	\$187,793,887.39	\$3,523.01
DESCOVY	\$31,883,474.51	\$1,984.76
DOVATO	\$18,567,857.49	\$2,613.10
GENVOYA	\$35,535,448.56	\$3,566.44
JULUCA	\$11,213,362.57	\$3,119.28
ODEFSEY	\$15,905,591.08	\$3,204.50
PREZCOBIX	\$12,446,067.49	\$2,181.43
PREZISTA	\$5,583,544.65	\$1,846.00
SYMTUZA	\$37,434,539.56	\$4,191.35
TIVICAY	\$30,009,358.08	\$2,084.78
TOTAL	\$440,931,189.68	N/A

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Table 5: The Medicaid Rebates for Selected Drugs by NDC table provides the total rebates received by Florida Medicaid for prescription drugs provided through the SMMC program for RY 21/22. For the selected NDCs, each row represents the total rebates received by the Agency, including all federal and supplemental rebates. The Per-Claim column is calculated by dividing the Total Rebate by Total Utilization found in Table 2. In accordance with section 1927(b)(3)(d) of the Social Security Act, this information, as well as any information that can be used to calculate specific rebates, is redacted.

TABLE 5 MEDICAID REBATES FOR SELECTED DRUGS BY NDC			
Product Name	NDCs	Total Rebate	Per Claim Rebate
BIKTARVY	61958250101, 61958250103	[REDACTED]	[REDACTED]
DESCOVY	61958200201, 61958200202	[REDACTED]	[REDACTED]
DOVATO	49702024613	[REDACTED]	[REDACTED]
GENVOYA	61958190101	[REDACTED]	[REDACTED]
JULUCA	49702024213	[REDACTED]	[REDACTED]
ODEFSEY	61958210101	[REDACTED]	[REDACTED]
PREZCOBIX	59676057530	[REDACTED]	[REDACTED]
PREZISTA	59676056201, 59676056630	[REDACTED]	[REDACTED]
RAVICTI	75987005006	[REDACTED]	[REDACTED]
REXULTI	59148003513, 59148003613, 59148003713, 59148003813, 59148003913, 59148004013	[REDACTED]	[REDACTED]
SYM TUZA	59676080030	[REDACTED]	[REDACTED]
TIVICAY	49702022813	[REDACTED]	[REDACTED]
VRAYLAR	61874011511, 61874011520, 61874011530, 61874013011, 61874013020, 61874013030, 61874014530, 61874016030	[REDACTED]	[REDACTED]
XTANDI	00469012599, 00469062599	[REDACTED]	[REDACTED]

Exempt from disclosure pursuant to 1927(b)(4)(D) of the Social Security Act, section VII(b) of the National Drug Rebate Agreement, and 119.0715, F.S.

Table 6: The Estimated US Net Cost for US Products During RY 21/22 table provides net prices for the selected drugs under Florida Medicaid after applying rebates for RY 21/22. The estimates are calculated by extending SMMC net prices to all Florida Medicaid prescription drug claims in the same period for the selected drugs. The values also include professional dispensing fees. In accordance with section 1927(b)(3)(d) of the Social Security Act, this information is redacted because it can be utilized to calculate individual rebates.

TABLE 6 ESTIMATED US NET COST FOR SELECTED DRUGS DURING RY 21/22		
Product Name	Total Cost	Per-Claim Cost
XTANDI		
RAVICTI		
REXULTI		
VRAYLAR		
BIKTARVY		
DESCOVY		
DOVATO		
GENVOYA		
JULUCA		
ODEFSEY		
PREZCOBIX		
PREZISTA		
SYMTUZA		
TIVICAY		
TOTAL	\$308,792,049.71	N/A

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Exempt from disclosure pursuant to 1927(b)(4)(D) of the Social Security Act, section VII(b) of the National Drug Rebate Agreement, and 119.0715, F.S.

Table 7: The Projected Future Annual US Cost for Selected Drugs table provides projected net prices for the selected prescription drugs under Florida Medicaid for RY 23/24 and RY 24/25. For each rate year, the total net cost and per-claim cost are listed under separate columns for each prescription drug. The total cost is the product of the Per-Claim Cost multiplied by the projected number of prescriptions for the matching Rate Year. The Per-Claim costs are projected using RY 21/22 net prices multiplied by projected annual US price changes as shown in Table 8. In accordance with section 1927(b)(3)(d) of the Social Security Act, this information is redacted because it can be used to calculate individual rebates.

TABLE 7 PROJECTED FUTURE NET ANNUAL US COST FOR SELECTED DRUGS				
Product Name	RY 23/24		RY 24/25	
	Total Cost	Per Claim Cost	Total Cost	Per Claim Cost
XTANDI				
RAVICTI				
REXULTI				
VRAYLAR				
BIKTARVY				
DESCOVY				
DOVATO				
GENVOYA				
JULUCA				
ODEFSEY				
PREZCOBIX				
PREZISTA				
SYMTUZA				
TIVICAY				
TOTAL	\$317,861,499.42	N/A	\$336,570,069.89	N/A

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Exempt from disclosure pursuant to 1927(b)(4)(D) of the Social Security Act, section VII(b) of the National Drug Rebate Agreement, and 119.0715, F.S.

Table 8: The Projected Annual US Price Change for Selected Drugs table provides projected net price changes for the selected prescription drugs under Florida Medicaid for CY 2022 through CY 2025. The base prices are from Table 6, Estimated US Net Cost for US Products During RY 21/22. Milliman conducted the price analysis using RY 21/22 prices and historical data from rate estimates. All price increases begin on January 1st and are compounded from the previous calendar year.

TABLE 8 PROJECTED ANNUAL US PRICE CHANGE FOR SELECTED DRUGS				
Product Name	CY2022	CY2023	CY2024	CY2025
XTANDI	4.77%	4.77%	4.77%	4.77%
RAVICTI	2.89%	2.89%	2.89%	2.89%
REXULTI	5.71%	5.71%	5.71%	5.71%
VRAYLAR	1.79%	1.79%	1.79%	1.79%
BIKTARVY	6.54%	6.54%	6.54%	6.54%
DESCOVY	5.20%	5.20%	5.20%	5.20%
DOVATO	5.27%	5.27%	5.27%	5.27%
GENVOYA	5.20%	5.20%	5.20%	5.20%
JULUCA	5.15%	5.15%	5.15%	5.15%
ODEFSEY	5.20%	5.20%	5.20%	5.20%
PREZCOBIX	6.50%	6.50%	6.50%	6.50%
PREZISTA	6.50%	6.50%	6.50%	6.50%
SYMTUZA	5.37%	5.37%	5.37%	5.37%
TIVICAY	5.15%	5.15%	5.15%	5.15%

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Table 9: The Estimated Canadian Cost for Selected Drugs During RY 21/22 table provides prices for the selected drugs for RY 21/22. The per-unit and per-container prices were collected from Health Canada’s website during February and March of 2023. For approved products not listed on the formulary, the prices were reported directly from the Foreign Seller. To compare Canadian prices from 2023 to US prices from RY 21/22, all raw ingredient costs were adjusted down by 1.25 years (multiplying 2023 prices by $1.051^{-1.25} = 0.9397$). Per-Claim Cost is the Total Cost divided by the estimated number of prescriptions for RY 21/22, as provided in Table 2. All amounts are shown in US Dollars with a constant exchange rate of 1.3805 CAD/USD. The cost of importation is 7% of the raw ingredient price as specified between the Agency and Importer. The values also include professional dispensing fees (\$10.25 per claim for both SMMC and FFS). The Total Combined Cost is the combination of the ingredient cost, importation cost, and dispensing fees. The per-claim price is provided in the last column and is the quotient of Total Combined Cost and the 21/22 utilization found in Table 2.

TABLE 9 ESTIMATED CANADIAN COST FOR SELECTED DRUGS DURING RY 21/22					
Product Name	Total Ingredient Cost	Total Importation Cost	Total Dispensing Fees	Total Combined Cost	Per-Claim Combined Cost
XTANDI	\$1,152,842.07	\$80,698.95	\$4,953.26	\$1,238,494.28	\$2,562.87
RAVICTI	\$1,461,233.88	\$102,286.37	\$1,988.50	\$1,565,508.76	\$8,069.63
REXULTI	\$524,754.95	\$36,732.85	\$69,002.58	\$630,490.38	\$93.66
VRAYLAR	\$2,677,007.76	\$187,390.54	\$249,335.48	\$3,113,733.78	\$128.00
BIKTARVY	\$45,748,312.51	\$3,202,381.88	\$546,375.24	\$49,497,069.62	\$928.57
DESCOVY	\$11,536,233.69	\$807,536.36	\$164,657.65	\$12,508,427.70	\$778.65
DOVATO	\$4,947,030.21	\$346,292.11	\$72,833.38	\$5,366,155.70	\$755.19
GENVOYA	\$9,973,632.21	\$698,154.25	\$102,129.32	\$10,773,915.79	\$1,081.30
JULUCA	\$2,896,671.35	\$202,766.99	\$36,847.22	\$3,136,285.56	\$872.44
ODEFSEY	\$4,620,484.94	\$323,433.95	\$50,876.01	\$4,994,794.90	\$1,006.30
PREZCOBIX	\$3,103,980.18	\$217,278.61	\$58,480.99	\$3,379,739.78	\$592.37
PREZISTA	\$1,634,806.78	\$114,436.47	\$31,002.97	\$1,780,246.22	\$588.57
SYMTUZA	\$10,502,101.50	\$735,147.11	\$91,546.73	\$11,328,795.33	\$1,268.42
TIVICAY	\$6,972,899.70	\$488,102.98	\$147,543.70	\$7,608,546.38	\$528.57
TOTAL	\$107,751,991.73	\$7,542,639.42	\$1,627,573.04	\$116,922,204.19	N/A

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Table 10: The Projected Annual Canadian Cost for Selected Drugs table provides projected prices for the selected drugs for Medicaid RY 23/24 and RY 24/25 if the prescription drugs were imported from Canada. For each rate year, the total cost and per-claim cost are listed under separate columns for each prescription drug. The total cost is the product of the Per-Claim Cost multiplied by the projected number of prescriptions in Table 2 for the matching Rate Year. The Per-Claim costs are projected using RY 21/22 net prices multiplied by annual US price changes as shown in Table 11. All numbers below include professional dispensing fees of \$10.25 per claim and the corresponding importation fee (7% for the first year and 6.5% for the second year).

TABLE 10 PROJECTED ANNUAL CANADIAN COST FOR SELECTED DRUGS				
Product Name	RY 23/24		RY 24/25	
	Total	Per Claim	Total	Per Claim
XTANDI	\$1,276,059.46	\$2,795.03	\$1,335,990.47	\$2,923.38
RAVICTI	\$1,613,359.85	\$8,802.63	\$1,689,318.69	\$9,207.86
REXULTI	\$643,901.62	\$101.24	\$671,244.30	\$105.44
VRAYLAR	\$3,187,823.40	\$138.71	\$3,327,213.54	\$144.63
BIKTARVY	\$50,968,444.12	\$1,012.09	\$53,347,021.03	\$1,058.26
DESCOVY	\$12,877,975.31	\$848.54	\$13,477,800.30	\$887.18
DOVATO	\$5,524,504.24	\$822.94	\$5,781,726.54	\$860.40
GENVOYA	\$11,095,630.01	\$1,178.71	\$11,614,169.73	\$1,232.57
JULUCA	\$3,229,324.97	\$950.85	\$3,379,932.78	\$994.21
ODEFSEY	\$5,143,638.63	\$1,096.89	\$5,383,865.91	\$1,146.98
PREZCOBIX	\$3,478,388.27	\$645.31	\$3,639,792.72	\$674.58
PREZISTA	\$1,832,191.32	\$641.17	\$1,917,200.13	\$670.25
SYMTUZA	\$11,668,439.78	\$1,382.86	\$12,214,440.07	\$1,446.12
TIVICAY	\$7,829,260.73	\$575.71	\$8,191,861.12	\$601.78
TOTAL	\$120,368,941.73	N/A	\$125,971,577.32	N/A

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Table 11: The Projected Annual Canadian Price Change for Selected Drugs table provides projected net price changes for the selected drugs under Florida Medicaid for CY 2022 through CY 2025 (Refer to Table 9 for base prices). All prescription drug prices are assumed to increase by 5.1% year-over-year, the maximum allowed under Canadian law and occur on Jan 1st of each calendar year.

TABLE 11 PROJECTED ANNUAL CANADIAN PRICE CHANGE FOR SELECTED DRUGS					
Product Name	CY2022	CY2023	CY2024	CY2025	
XTANDI	5.10%	5.10%	5.10%	5.10%	5.10%
RAVICTI	5.10%	5.10%	5.10%	5.10%	5.10%
REXULTI	5.10%	5.10%	5.10%	5.10%	5.10%
VRAYLAR	5.10%	5.10%	5.10%	5.10%	5.10%
BIKTARVY	5.10%	5.10%	5.10%	5.10%	5.10%
DESCOVY	5.10%	5.10%	5.10%	5.10%	5.10%
DOVATO	5.10%	5.10%	5.10%	5.10%	5.10%
GENVOYA	5.10%	5.10%	5.10%	5.10%	5.10%
JULUCA	5.10%	5.10%	5.10%	5.10%	5.10%
ODEFSEY	5.10%	5.10%	5.10%	5.10%	5.10%
PREZCOBIX	5.10%	5.10%	5.10%	5.10%	5.10%
PREZISTA	5.10%	5.10%	5.10%	5.10%	5.10%
SYMTUZA	5.10%	5.10%	5.10%	5.10%	5.10%
TIVICAY	5.10%	5.10%	5.10%	5.10%	5.10%

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Table 12: The Projected Base Scenario table presents the two-year projected cost of the selected drugs for Florida Medicaid if importation does not occur. The cost includes dispensing fees and rebates.

TABLE 12 PROJECTED BASELINE SCENARIO			
	RY 23/24	RY 24/25	TOTAL
DRUG COST	\$317,861,499.42	\$336,570,069.89	\$654,431,569.32
PROGRAM COST	\$0.00	\$0.00	\$0.00
TOTAL	\$317,861,499.42	\$336,570,069.89	\$654,431,569.32

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Table 13: The Projected Plan Scenario (100% Uptake) table presents the two-year projected cost for Florida Medicaid if Canadian supplies were utilized for all selected drugs. The cost includes dispensing fees and all administrative expenses as specified in the contract between the Agency and the Importer.

Table 14: The Projected Plan Scenario (75% Uptake) table provides information on the Plan Scenario if only 75% of the dispensed drugs consist of imports from Canada while the other 25% use the same US supply as the Base Scenario. The same program administrative costs would occur as Table 13.

TABLE 13 PROJECTED PLAN SCENARIO (100% UPTAKE)			
	RY 23/24	RY 24/25	TOTAL
DRUG COST	\$120,368,941.73	\$125,971,577.32	\$246,340,519.05
PROGRAM COST	\$14,496,000.00	\$14,496,000.00	\$28,992,000.00
TOTAL	\$134,864,941.73	\$140,467,577.32	\$275,332,519.05

TABLE 14 PROJECTED PLAN SCENARIO (75% UPTAKE)			
	RY 23/24	RY 24/25	TOTAL
DRUG COST	\$169,742,081.15	\$178,621,200.47	\$348,363,281.62
PROGRAM COST	\$14,496,000.00	\$14,496,000.00	\$28,992,000.00
TOTAL	\$184,238,081.15	\$193,117,200.47	\$377,355,281.62

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Table 15, Projected Savings, provides the projected total savings for Plan Scenarios with 100% and 75% Uptake, separated by Risk Years. Both savings projections are differences between the Baseline Scenario and the corresponding year.

TABLE 15 PROJECTED SAVINGS			
	RY 23/24	RY 24/25	TOTAL
100% UPTAKE	\$182,996,557.70	\$196,102,492.57	\$379,099,050.27
75% UPTAKE	\$133,623,418.27	\$143,452,869.43	\$277,076,287.70

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Table 16, Itemized Break-Even Analysis Information for Projected Gross US Prices (RY 23/24), provides information on pre-rebate Medicaid prices projected into RY 23/24. Prices increases are calculated using Table 4 for baseline prices and table 8 for annual rates of change. The projected average gross unit price is calculated by dividing the subtotal by the projected total units. The Projected Subtotal was calculated using the RY 21/22 estimated subtotals, the two-year utilization change, and the two-year projected pricing changes. Units Per Claim is the weighted average number of defined units per claim from RY21/22 (not previously provided). The Agency assumes the average units per claim do not change over time. Because these numbers are calculated using point-of-sale reimbursement, no further fees or administrative costs need to be added.

TABLE 16 ITEMIZED BREAK-EVEN ANALYSIS FOR PROJECTED GROSS US PRICES (RY 23/24)						
Product Name	Unit Size	Proj. Average Gross Unit Price	Projected Total Units	Projected Number of Claims	Units Per Claim	Projected Subtotal
XTANDI	Capsule or Tablet	\$218.05	26,461.64	456.5	57.96	\$5,769,962.05
RAVICTI	Milliliter	\$365.57	27,497.90	183.3	150.03	\$10,052,418.12
REXULTI	Tablet	\$126.98	71,730.64	6,360.0	11.28	\$9,108,144.09
VRAYLAR	Capsule	\$136.80	216,901.25	22,981.4	9.44	\$29,672,368.52
BIKTARVY	Tablet	\$97.14	2,073,105.50	50,359.8	41.17	\$201,380,410.41
DESCOVY	Tablet	\$52.22	638,297.03	15,176.6	42.06	\$33,334,253.21
DOVATO	Tablet	\$69.67	279,030.82	6,713.1	41.57	\$19,439,944.06
GENVOYA	Tablet	\$97.83	379,751.90	9,413.3	40.34	\$37,152,993.56
JULUCA	Tablet	\$86.57	135,308.51	3,396.2	39.84	\$11,713,121.26
ODEFSEY	Tablet	\$90.41	183,933.51	4,689.3	39.22	\$16,629,559.61
PREZCOBIX	Tablet	\$63.00	211,687.91	5,390.2	39.27	\$13,336,010.70
PREZISTA	Tablet	\$53.37	112,097.78	2,857.6	39.23	\$5,982,955.28
SYMTUZA	Tablet	\$111.65	351,700.05	8,437.9	41.68	\$39,266,255.92
TIVICAY	Tablet	\$57.26	547,459.29	13,599.2	40.26	\$31,346,479.34
TOTAL		N/A	5,254,963.72	150,014.6	N/A	\$464,184,876.15

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Table 17, Itemized Break-Even Analysis Information for Projected Gross US Prices (RY 24/25), provides information on pre-rebate Medicaid prices projected into RY 24/25. Prices increases are calculated using Table 4 for baseline prices and table 8 for annual rates of change. The projected average gross unit price is calculated by dividing the subtotal by the projected total units. The Projected Subtotal was calculated using the RY 21/22 estimated subtotals, cumulative three-year utilization change, and cumulative projected pricing changes. Units Per Claim is the weighted average number of defined units per claim from RY21/22. The Agency assumes the average units per claim do not change over time. Because these numbers are calculated using point-of-sale reimbursement, no further fees or administrative costs need to be added.

TABLE 17 ITEMIZED BREAK-EVEN ANALYSIS INFORMATION FOR PROJECTED GROSS US PRICES (RY 24/25)						
Product Name	Unit Size	Proj. Average Gross Unit Price	Projected Total Units	Projected Number of Claims	Units Per Claim	Subtotal
XTANDI	Capsule or Tablet	\$228.45	26,488.1	457.0	57.96	\$6,051,275.88
RAVICTI	Milliliter	\$376.14	27,525.4	183.5	150.03	\$10,353,484.54
REXULTI	Tablet	\$134.22	71,802.4	6,366.4	11.28	\$9,637,366.78
VRAYLAR	Capsule	\$139.24	217,118.2	23,004.4	9.44	\$30,232,415.87
BIKTARVY	Tablet	\$103.49	2,075,178.6	50,410.2	41.17	\$214,763,840.26
DESCOVY	Tablet	\$54.94	638,935.3	15,191.8	42.06	\$35,101,801.28
DOVATO	Tablet	\$73.34	279,309.8	6,719.8	41.57	\$20,485,078.33
GENVOYA	Tablet	\$102.92	380,131.7	9,422.7	40.34	\$39,123,320.41
JULUCA	Tablet	\$91.02	135,443.8	3,399.6	39.84	\$12,328,690.58
ODEFSEY	Tablet	\$95.11	184,117.4	4,694.0	39.22	\$17,511,451.23
PREZCOBIX	Tablet	\$67.09	211,899.6	5,395.6	39.27	\$14,216,711.84
PREZISTA	Tablet	\$56.84	112,209.9	2,860.4	39.23	\$6,378,155.57
SYMTUZA	Tablet	\$117.64	352,051.7	8,446.4	41.68	\$41,416,066.69
TIVICAY	Tablet	\$60.21	548,006.7	13,612.8	40.26	\$32,993,690.59
TOTAL		N/A	5,260,218.69	150,164.6	N/A	\$490,593,349.85

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Table 18, Itemized Break-Even Analysis Information for Projected Canadian Prices (RY 23/24), provides information on Canadian prices projected into RY 23/24. Unit Prices are quantized per smallest unit as described in Tables 16 and 17. Unit Ingredient Cost is calculated using the projected total Canadian ingredient price for RY 23/24 divided by the projected number of units. The unit importation fee is the per-unit amount the Importer charges (7%) for each imported drug. The wholesale unit price is the sum of the previous two columns. The whole Dispensing fee is charged once per claim. The subtotal is the sum of the total dispensing fees and wholesale prices. Total dispensing fees are the product of the dispensing fee and the number of claims.

TABLE 18 ITEMIZED BREAK-EVEN ANALYSIS INFORMATION FOR PROJECTED CANADIAN PRICES (RY 23/24)							
Product Name	Unit Ingredient Cost	Unit Importation Fee	Wholesale unit price	Total Units	Dispensing Fee	Number of Claims	Subtotal
XTANDI	\$44.90	\$3.14	\$48.05	26,461.6	\$10.25	456.5	\$1,276,059.46
RAVICTI	\$54.77	\$3.83	\$58.60	27,497.9	\$10.25	183.3	\$1,613,359.85
REXULTI	\$7.54	\$0.53	\$8.07	71,730.6	\$10.25	6,360.0	\$643,901.62
VRAYLAR	\$12.72	\$0.89	\$13.61	216,901.3	\$10.25	22,981.4	\$3,187,823.40
BIKTARVY	\$22.74	\$1.59	\$24.34	2,073,105.5	\$10.25	50,359.8	\$50,968,444.12
DESCOVY	\$18.63	\$1.30	\$19.93	638,297.0	\$10.25	15,176.6	\$12,877,975.31
DOVATO	\$18.27	\$1.28	\$19.55	279,030.8	\$10.25	6,713.1	\$5,524,504.24
GENVOYA	\$27.07	\$1.89	\$28.96	379,751.9	\$10.25	9,413.3	\$11,095,630.01
JULUCA	\$22.06	\$1.54	\$23.61	135,308.5	\$10.25	3,396.2	\$3,229,324.97
ODEFSEY	\$25.89	\$1.81	\$27.70	183,933.5	\$10.25	4,689.3	\$5,143,638.63
PREZCOBIX	\$15.11	\$1.06	\$16.17	211,687.9	\$10.25	5,390.2	\$3,478,388.27
PREZISTA	\$15.03	\$1.05	\$16.08	112,097.8	\$10.25	2,857.6	\$1,832,191.32
SYMTUZA	\$30.78	\$2.15	\$32.93	351,700.0	\$10.25	8,437.9	\$11,668,439.78
TIVICAY	\$13.13	\$0.92	\$14.05	547,459.3	\$10.25	13,599.2	\$7,829,260.73
Subtotal	N/A	N/A	N/A	5,254,963.7	N/A	150,014.6	\$120,368,941.73
Program Cost	N/A	N/A	N/A	N/A	N/A	N/A	\$14,496,000.00
TOTAL	N/A	N/A	N/A	5,254,963.72	N/A	150,014.6	\$134,864,941.73

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Table 19, Itemized Break-Even Analysis Information for Projected Canadian Prices (RY 24/25), provides information on Canadian prices projected into RY 24/25. Unit Prices are quantized per smallest unit as described in Tables 16 and 17. Unit Ingredient Cost is calculated using the projected total Canadian ingredient price for RY 24/25 divided by the projected number of units. The unit importation fee is the per-unit amount the Importer charges (6.5%) for each imported drug. The wholesale unit price is the sum of the previous two columns. The whole Dispensing fee is charged once per claim. The subtotal is the sum of the total dispensing fees and wholesale prices. Total dispensing fees are the product of the dispensing fee and the number of claims.

TABLE 19 ITEMIZED BREAK-EVEN ANALYSIS INFORMATION FOR PROJECTED CANADIAN (RY 24/25)							
Product Name	Unit Ingredient Cost	Unit Importation Fee	Wholesale unit price	Total Units	Dispensing Fee	Number of Claims	Total Cost
XTANDI	\$47.19	\$2.36	\$49.55	26,488.1	\$10.25	457.0	\$1,335,990.47
RAVICTI	\$57.56	\$2.88	\$60.44	27,525.4	\$10.25	183.5	\$1,689,318.69
REXULTI	\$7.92	\$0.40	\$8.32	71,802.4	\$10.25	6,366.4	\$671,244.30
VRAYLAR	\$13.37	\$0.67	\$14.04	217,118.2	\$10.25	23,004.4	\$3,327,213.54
BIKTARVY	\$23.90	\$1.20	\$25.10	2,075,178.6	\$10.25	50,410.2	\$53,347,021.03
DESCOVY	\$19.58	\$0.98	\$20.56	638,935.3	\$10.25	15,191.8	\$13,477,800.30
DOVATO	\$19.21	\$0.96	\$20.17	279,309.8	\$10.25	6,719.8	\$5,781,726.54
GENVOYA	\$28.45	\$1.42	\$29.87	380,131.7	\$10.25	9,422.7	\$11,614,169.73
JULUCA	\$23.19	\$1.16	\$24.35	135,443.8	\$10.25	3,399.6	\$3,379,932.78
ODEFSEY	\$27.21	\$1.36	\$28.57	184,117.4	\$10.25	4,694.0	\$5,383,865.91
PREZCOBIX	\$15.88	\$0.79	\$16.68	211,899.6	\$10.25	5,395.6	\$3,639,792.72
PREZISTA	\$15.80	\$0.79	\$16.59	112,209.9	\$10.25	2,860.4	\$1,917,200.13
SYMTUZA	\$32.35	\$1.62	\$33.96	352,051.7	\$10.25	8,446.4	\$12,214,440.07
TIVICAY	\$13.80	\$0.69	\$14.49	548,006.7	\$10.25	13,612.8	\$8,191,861.12
Subtotal	N/A	N/A	N/A	5,260,218.7	N/A	150,164.6	\$125,971,577.32
Program Cost	N/A	N/A	N/A	N/A	N/A	N/A	\$14,496,000.00
TOTAL	N/A	N/A	N/A	5,260,218.7	N/A	150,014.6	\$140,467,577.32

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Table 20, Break-Even Analysis, provides information on the threshold of whether this program would produce cost-savings. Percentage Cost is the ratio of the cost of importing selected prescription drugs from Canada to the analogous drugs in the United States. The complement is the Break-Even Percentage, or the maximum amount of rebate Florida Medicaid can receive while generating cost-savings.

TABLE 20 PROJECTED SAVINGS				
Year	US Gross Total Cost	Canadian Total Cost	Percentage Cost	Break-Even Percentage
RY 23/24	\$464,184,876.15	\$134,864,941.73	29.05%	70.95%
RY 24/25	\$490,593,349.85	\$140,467,577.32	28.63%	71.37%

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April 14, 2023

Matt Cooper
Assistant Deputy Secretary
Bureau of Medicaid Data Analytics
Agency for Health Care Administration
2727 Mahan Drive
Tallahassee, FL 32308-5407
Sent via email: matthew.cooper@ahca.myflorida.com

Re: Analysis of the Canadian Drug Importation Program

Dear Matt:

The Florida's Agency of Health Care Administration (Agency) engaged Milliman to analyze the potential gross cost change to projected October 2023 through September 2024 (RY 23/24) and RY 24/25 pharmacy costs for select drugs covered under the Statewide Medicaid Managed Care (SMMC) program assuming the Canadian Drug Importation Program (Program) is approved by the Federal Drug Administration (FDA). Our understanding is that the Agency will combine our results along with additional analysis regarding the change in rebate costs, projected membership changes, and any other adjustments necessary to arrive at projected pharmacy costs as part of their submission to the FDA.

We provide two exhibits with this letter to facilitate the Agency in their analysis of the projected net cost savings associated with these drugs:

- **Exhibit 1: Net Projected Savings for the Program** – This exhibit calculates the net projected savings for the program under various scenarios (25%, 50%, 75%, and 100% of utilization shifting from the current process to coverage under the Program). Please Note, these projected savings exclude any other adjustments other than the rebates that may need to be made to arrive at the true savings.
- **Exhibit 2: Rebate / Dispensing Fee Inputs** – This exhibit allows the Agency to input the RY 21/22 rebate assumptions for managed care plans during RY 21/22 along with any changes in the dispensing fee assumptions. Note, the Agency's pharmacy benefit manager (PBM) considers the rebate assumptions proprietary and confidential. Therefore, Milliman is unable to review this information for completeness or reasonability.

Note, the following items were not considered in this modeling and may result in actual RY 23/24 and RY 24/25 savings that vary significantly from our calculations:

- Unwinding of the Public Health Emergency, resulting in a disenrollment of a significant portion of the Medicaid members, changes in utilization across the mix of drugs, and a reduction of overall projected costs
- Changes in the Preferred Drug List (PDL) covered under the Florida Medicaid program
- Unforeseen changes to newly launched drugs or major list price changes to US or Canadian drugs
- Changes in contracting as a result of the implementation of this Program
- Canada's willingness to participate in the Program
- Changes in utilization trends over time due to various items that may impact actual uptake of Canadian drug utilization
- Any other unforeseen circumstances impacting the Program, such as additional COVID-19 outbreaks impacting utilization

This analysis or results from this analysis is not intended to imply that this program is allowed or feasible by law. It is very important to note, that this analysis does not include prescription drug rebates under the Medicaid Drug Rebate Program (MDRP), and that the impact of those rebates could fully offset the projected "savings" attributable to this program.

METHODOLOGY

This section details the methodology that the model uses to calculate the projected costs under the current program and the proposed Program.

Data Sources

Data used for this analysis relied on encounter claims data from October 2021 through September 2022 (RY 21/22) for members enrolled in Florida's Statewide Medicaid Managed Care (SMMC) Managed Medical Assistance (MMA) program, as well as data provided by the Agency for purposes of data validation. The Agency provided Milliman a scope of drugs that would be included in the Program for both United States' (US) drug products and the corresponding Canadian drug products. The US drug products were provided at the National Drug Code (NDC) level and the Canadian products were provided at the Drug Identification Number (DIN) level. In addition, the Agency provided Canadian drug acquisition prices converted to US dollars as of March 2023, which were used for the Canadian re-priced drug amounts.

Since a significant portion of the pharmacy costs are paid by managed care plans, we first calculated the total pharmacy costs for members enrolled in an MMA plan. We then applied a factor to these costs to account for members in the Fee for Service (FFS) program based on the distribution of utilization between managed care and FFS in the State Drug Utilization Data (SDUD) for Calendar Year 2021.

We summarized the base data using the actual amount paid on claims. Each NDC was then converted to the Canadian DIN equivalent and re-priced based on the information provided by the Agency to estimate the costs under the new Program. The actual paid amounts and the re-priced amounts were trended forward using separate trends to the RY 23/24 and RY 24/25 periods at the NDC and DIN level. The next section provides more detail regarding how we developed the trends.

Trend Assumptions

We used the following information to develop the trends applied to the RY 21/22 data.

- **US unit cost trends:** These were developed using the following sources:
 - Historical Wholesale Acquisition Cost (WAC) increases by NDC from the Medi-Span database
 - BioMed Tracker and Datamonitor Health, which includes individual drug product sales forecasts and disease state sales forecasts
- **Canadian unit cost trends:** These were developed using drug trends for patented Canadian products, which are set at a capped rate of 5.1%. This is the inflationary cap for the 12-month period ending December 2023, according to the Canadian Government website.¹
- **Utilization trends:** Utilization trends were set to the aggregate statewide growth rate used in capitation rate development for the MMA rate certification for managed care entities.

US Drug Cost Buildup

The MCO encounter data received includes the total paid amount, which is inclusive of the ingredient cost and dispensing fee. To trend the drug cost, we backed out an assumed \$0.70 dispensing fee per encounter to get to the gross drug ingredient cost. This dispensing fee is based on average dispensing fees from MCOs in a study conducted by Milliman for the SMMC program utilizing 2018 data.² We then trended the ingredient cost dispensing fee using the

¹ <https://www.canada.ca/en/patented-medicine-prices-review/services/are-you-patentee/cpi-adjustment-factors/2023-cpi-adjustment-factors.html>

² <https://www.floridapharmacy.org/wp-content/uploads/2023/02/Report-template-with-corporate-brand-colors-styles-and-formatting-US-letter.pdf>

utilization and unit cost methodology outlined above for each year from RY 21/22 to RY 24/25. The encounter data was then scaled by a factor, as outlined above, to include the FFS utilization which is inclusive of the difference in the \$10.25 FFS dispensing fee.

The Agency was not allowed to provide us with any Federal rebate drug information for contractual reasons. Because of this, our model only accounts for the gross drug cost on the US side and does not factor in Federal rebates gained through the Medicaid Drug Rebate Program (MDRP). We provide placeholder fields for the Agency to insert actual collected rebates for RY 21/22 by individual drug. This placeholder feeds into the model buildup and trends RY 21/22 rebates proportional to the ingredient cost of the drugs. After trending, the net US drug cost is comprised of three final components:

1. The drug ingredient cost.
2. The per claim dispensing fee of \$0.70.
3. The offsetting rebate amount that the Agency collected.

Canadian Drug Cost Buildup

Utilizing the Canadian drug pricing to US Dollar conversion provided by the Agency, we calculated a base cost for Canadian drug pricing by multiplying the unit acquisition costs to the dispensed drug units on the encounter claims. We then trended the utilization and unit cost with the methodology outlined above for each year from RY 21/22 to RY 24/25 based on the Canadian drug cost trends. With guidance from the Agency, we provide a placeholder input for dispensing fees for imported drugs, which can be set at the contracted amount by the Agency. The net Canadian drug cost is comprised of three components:

1. The drug ingredient cost.
2. The per claim dispensing fee of \$10.25.
3. The drug importation fee of 7.0% of the Canadian drug acquisition price in the first year and 6.5% in the second year onward. This assumption is based on information provided by the Agency.

Scenario Modeling

Exhibit 1 provides the results of the methodology above under four scenarios: 100%, 75%, 50%, and 25% conversion of US drug utilization to Canadian drug utilization. Milliman did not attempt to estimate what shifting may actually occur if this Program is implemented.

We assume no impact to member access in our utilization trends. Therefore, our aggregate utilization within each scenario trends are identical. However, there are some possible outcomes that could impact member uptake of Canadian drugs, including but not limited to:

1. Pharmacy supply chain, stocking, and dispensing to eligible population.
2. Sufficient supply of Canadian drugs to meet demand.
3. Member perception of imported drugs.

NEXT STEPS

We request that the Agency review this letter and the model and provide feedback prior to finalizing this analysis. Additionally, we request the Agency provide the documentation that it intends to submit to the FDA prior to submission to ensure that the information contained in the report is consistent with the analysis being provided.

CAVEATS AND LIMITATIONS ON USE

This analysis does not account for unforeseen marketplace conditions, including but not limited to Preferred Drug List (PDL) changes to newly launched generic products or major list price changes to US or Canadian drugs. These results are based on projected cost and utilization of RY 21/22 cost and drug mix.

Policy changes that would impact Florida's Medicaid program are also not considered in this analysis. This could include the unwinding of the Public Health Emergency and disenrollment of members, Canada's participation in the program, State mandated price changes impacting gross drug costs or other benefit design changes. This analysis or results from this analysis is not intended to imply that this program is allowed or feasible by law.

Milliman designed this analysis to consider only the gross cost of US and Canadian drug pricing trended forward to projection years RY 23/24 and RY 24/25. The model is being provided to the Agency to input Federal rebate information which corresponds to the base data period in RY 21/22. Rebate data is not and will not be audited or attested to by Milliman for completeness or reasonability.

The information in this file is intended for the Agency for the purpose of projecting a range of possible outcomes for the Canadian Drug Importation program. Milliman recognizes that materials it delivers to the Agency may be public records subject to disclosure to third parties; however, Milliman does not intend to benefit, and assumes no duty or liability to, parties other than the Agency who receive this work. Do not distribute this information outside of the Agency without Milliman's written permission. We grant permission to share this information with independent counsel, if necessary. This material should only be distributed and reviewed in its entirety. In any event, this information is not intended to benefit any third parties.

The exhibits provided reflect Florida Medicaid's encounter data and Canadian drug pricing provided by the Agency. We accepted this information without audit. To the extent the data and information is not accurate, or is not complete, the values provided in this analysis may likewise be inaccurate or incomplete. This analysis is subject to the terms and conditions of the October 12, 2021 contract between the Agency and Milliman.

In preparing this letter and attachments, we relied on contracts provided by the Agency, information from SMMC plans, financial data summaries, publicly available data, and industry expertise. We did not audit any of this information, but we did assess the information for reasonableness. If the information used is inadequate or incomplete, this letter and attachments may be likewise inadequate or incomplete.

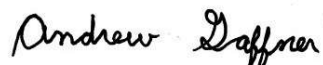
The differences between the administrative cost assumptions and actual experience will depend on the extent to which future experience conforms to these estimates. It is certain that actual experience will not conform exactly to this information.

This letter and attachments are intended solely for the use and benefit of the Agency, and are only to be relied upon by the Agency. Milliman recognizes that materials it delivers to the Agency may be public records subject to disclosure to third parties; however, Milliman does not intend to benefit, and assumes no duty or liability to parties other than the Agency who receive this work. We understand this material will be shared with the capitated plans, including CMS Plan. This material should only be distributed and reviewed in its entirety.

Guidelines issued by the American Academy of Actuaries require actuaries to include their professional qualifications in all actuarial communications. I, Andrew L. Gaffner, am a principal and consulting actuary at Milliman and a member of the American Academy of Actuaries, and I meet the Qualifications Standards of the Academy to render the actuarial communication contained herein. To the best of my knowledge and belief, this communication is complete and accurate and has been prepared in accordance with generally recognized and accepted actuarial principles and practices.

This letter and exhibit are subject to the terms and conditions of the October 12, 2021 contract between the Agency and Milliman.

Sincerely,

A handwritten signature in black ink that reads 'Andrew L. Gaffner'.

Andrew L. Gaffner, FSA, MAAA
Principal and Consulting Actuary

ALG/jm

Attachments (Provided in Excel only)