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International Referenced Rate Pricing for Prescription Drugs

Public Law 2021, Chapter 606 (LD 1636), *An Act To Determine Potential Savings in Prescription Drug Costs by Using International Pricing*, 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 in the State of Maine to a referenced rate as defined in the law. **This is MHDO's first annual report.**

Definitions for Terminology Used in this Report

Brand Drug – a prescription drug, having a unique NDC, marketed under a proprietary name or registered trademark name, including a biological product, and approved under a New Drug Application or Biologics License Application.

Drug Identification Number (DIN) – a computer-generated eight-digit number assigned by Health Canada to a drug product prior to being marketed in Canada. A DIN uniquely identifies the following product characteristics: manufacturer; product name; active ingredient(s); strength(s) of active ingredient(s); pharmaceutical form; route of administration.

Generic Drug – a prescription drug, having a unique NDC, whether identified by its chemical, proprietary or nonproprietary name, that is not a brand drug, is therapeutically equivalent to a brand drug in dosage, strength, method of consumption, performance and intended use, and approved under an Abbreviated New Drug Application. Generic Drug includes a biosimilar product.

Multi-Source Drug – a brand drug or generic drug that is available from more than one manufacturer.

National Drug Code (NDC) – a code maintained by the US Food and Drug Administration that is uniquely assigned by manufacturer, product, and packaging.

Pharmaceutically Equivalent Drug Products - brand drugs and/or generic drugs that are identical in active ingredient(s), dosage form, route of administration, and strength or concentration

Prices on Canadian Provincial Formularies - represent amounts paid by payers in the province

Single Source Drug – a brand drug or generic drug that is only available from one manufacturer.

Wholesale Acquisition Cost (WAC) – a manufacturer’s published list price for sale of a prescription drug product with a unique NDC to a wholesale drug distributor or other entity that purchases a prescription drug directly from the manufacturer, not including any price concessions. WAC represents the price paid in the US to manufacturers by drug wholesalers and almost never reflects actual amounts paid by payers in the US.

Reference Rates Determined

The following provisions in statute govern the determination of referenced rates of prescription drugs.

Part I

§8741, 2. A. Identify the 100 most costly prescription drugs and the 100 most frequently prescribed prescription drugs in the State of Maine, the Manufacturers of these drugs and the average wholesale acquisition cost for each drug for the most current 12-month period.

- MHDO identified the 100 most costly generic drugs and brand drugs and the 100 most frequently prescribed generic drugs and brand drugs in the State of Maine, the manufacturers of these drugs and the average wholesale acquisition costs for the most recent 12-month period, which is January 1, 2022 – December 31, 2022. These prescription drugs are identified by their National Drug Code (NDC).
- The total number of distinct NDC’s identified in both categories of costliest and most frequently prescribed for both generic drugs and brand name drugs is 286.
- The data below is a snapshot of the complete data set that is available in the Excel File here.

Top 100 Most Costly and Most Prescribed Prescription Drugs										
Top 100 List	Manufacturer Name	NDC	Item Description	Therapeutic Class	US Source Type	Average WAC	Manufacturer Product Available in Canada	Manufacturer Product Priced on Provincial Formulary	Other Manufacturer Product(s) Available in Canada	Manufacturer Product(s) Priced on Provincial Formulary
Brand Most Prescribed	ABBOTT DIABETES CARE	57599000101	Continuous Blood Glucose System Sensor Miscellaneous 1.000 EA UU	Medical Devices And Supplies	Single Source	\$60.74				
Brand Most Prescribed	ABBOTT DIABETES CARE	57599000200	Continuous Blood Glucose System Sensor Miscellaneous 1.000 EA UU	Medical Devices And Supplies	Single Source	\$80.74				
Brand Most Costly	ABBVIE	00074024302	Adalimumab 40 MG/0.4ML Prefilled Syringe Kit 1.000 EA UU	Analgesics - Anti-Inflammatory	Single Source	\$6,394.10			X	X
Brand Most Costly	ABBVIE	00074433902	Adalimumab 40 MG/0.8ML Pen-injector Kit 1.000 EA UU	Analgesics - Anti-Inflammatory	Single Source	\$6,394.10			X	X
Brand Most Costly	ABBVIE	00074379902	Adalimumab 40 MG/0.8ML Prefilled Syringe Kit 1.000 EA UU	Analgesics - Anti-Inflammatory	Single Source	\$6,394.10			X	X
Brand Most Costly	ABBVIE	00074262528	Glecaprevir-Fibrentasvir 100-40 MG Tablet 84.000 EA UU	Anti-Infective Agents - Antivirals	Single Source	\$13,200.00	X	X		
Brand Most Costly	ABBVIE	00074210001	Risankizumab-rzaa 150 MG/ML Solution Auto-injector 1.000 ML UD	Dermatologicals	Single Source	\$18,227.95				
Brand Most Costly	ABBVIE	00074230630	Upadacitinib 15 MG Tablet Extended Release 24 Hour 30.000 EA UU	Analgesics - Anti-Inflammatory	Single Source	\$5,657.34	X	X		
Generic Most Prescribed	ACCORD HEALTHCARE	16729000617	Simvastatin 40 MG Tablet 1000.000 EA	Cardiovascular Agents - Antihyperlipidemics	Multi-Source	\$102.49			X	X
Generic Most Costly	ACORDA THERAPEUTICS	10144042760	Dalfampidine 10 MG Tablet Extended Release 12 Hour 60.000 EA	Psychotherapeutic and Neurological Agents - Miscellaneous - Misc	Multi-Source	\$3,518.11			X	X
Generic Most Costly	ACTAVIS PHARMA	00591352530	Lidocaine 5 % Patch 30.000 EA UU	Dermatologicals	Multi-Source	\$89.86				
Generic Most Prescribed	ACTAVIS PHARMA	00591544305	Prednisone 20 MG Tablet 500.000 EA	Endocrine and Metabolic Agents - Corticosteroids	Multi-Source	\$102.56				
Generic Most Costly	AJANTA PHARMA LIMITED	27241009990	Duloxetine HCl 60 MG Capsule Delayed Release Particles 1000.000	Central Nervous System Agents - Antidepressants	Multi-Source	\$300.00			X	X
Generic Most Prescribed	AKORN	50383070216	Fluticasone Propionate (Nasal) 50 MCG/ACT Suspension 16.000 GM	Antihistamines/Nasal Agents/Cough & Cold/Respiratory/Misc - Nasal Agents	Multi-Source	\$13.04			X	X
Generic Most Costly	ALVOGEN	47781035703	Buprenorphine HCl-Naloxone HCl Dihydrate 8-2 MG Film 30.000 EA	Analgesics - Opioid	Multi-Source	\$190.00			X	
Generic Most Costly	ALVOGEN	47781010444	Estradiol Vaginal O.1 MG/GM Cream 42.500 GM UU	Vaginal And Related Products	Multi-Source	\$167.25				

Part II

§8741 2. B. To the extent possible, determine the referenced rate for each drug identified in paragraph 2.A. (Part 1) by comparing the wholesale acquisition cost to the cost in official publications of the governments of the Canadian provinces of Ontario, Quebec, British Columbia, and Alberta. **The referenced rate for each prescription drug must be calculated as the lowest cost among the resources described in this paragraph and the wholesale acquisition cost for the most recent 12-month period.** If a specific drug identified in paragraph A is not included within the resources described in this paragraph, MHDO shall use for the purpose of determining the referenced rate the ceiling price for drugs as reported in other official publications of the government of Canada.

- For 193 of the 286 NDCs identified in Part I of this report (which represents 67.5% of the total), there is not a corresponding Drug Identification Number (DIN) on a provincial formulary in Canada.
 - When comparing NDCs in the US to the equivalent DINs in Canada there are not as many prescription drug products available in Canada.
 - In Canada, multi-source brand drugs (brand drugs that are also available from generic manufacturers) are often excluded from provincial formularies and are instead replaced by lower cost generic equivalents.
- A reference rate as defined above (the lowest cost option when looking at the WAC and the costs in the Canadian provinces) has been determined for 93 of the 286 NDCs identified in Part I of this report (which represents 32.5% of the total).

- o The reference rate for 21 of the 93 NDCs is based on the WAC as that is the lowest cost option; 19 of these 21 NDCs are for generic drugs and 2 NDCs are for brand drugs.
- o The reference rate for 72 of the 93 NDCs is based on the lowest cost option identified in the Canadian provinces; 16 of these 72 NDCs are for generic drugs and 56 NDCs are for brand drugs.
- The data below is a snapshot of the complete data set that is available in the Excel File here.

Reference Rate

§8741 2. B. To the extent possible, determine the referenced rate for each drug identified in paragraph 2.A. (Part 1) by comparing the wholesale acquisition cost to the cost in official publications of the governments of the Canadian provinces of Ontario, Quebec, British Columbia, and Alberta. The referenced rate for each prescription drug must be calculated as the lowest cost among the resources described in this paragraph and the wholesale acquisition cost for the most recent 12-month period.

Top 100 List	Manufacturer Name	NDC	Item Description	Average WAC Per Unit	Province Paid Per Unit				Reference Rate
					Ontario	British Columbia	Alberta	Lowest Value	
Brand Most Prescribed	ABBOTT DIABETES CARE	57599080000	Continuous Blood Glucose System Sensor Miscellaneous 1.000 EA	\$60.7429	N/A	N/A	N/A	N/A	\$60.7429
Brand Most Prescribed	ABBOTT DIABETES CARE	57599000101	Continuous Blood Glucose System Sensor Miscellaneous 1.000 EA	\$60.7429	N/A	N/A	N/A	N/A	\$60.7429
Brand Most Costly	ABBVIE	00074024902	Adalimumab 40 MG/0.4ML Prefilled Syringe Kit 1.000 EA UU	\$3,197.0500	N/A	N/A	N/A	N/A	\$3,197.0500
Brand Most Costly	ABBVIE	00074433902	Adalimumab 40 MG/0.8ML Pen-injector Kit 1.000 EA UU	\$3,197.0500	N/A	N/A	N/A	N/A	\$3,197.0500
Brand Most Costly	ABBVIE	00074379902	Adalimumab 40 MG/0.8ML Prefilled Syringe Kit 1.000 EA UU	\$3,197.0500	N/A	N/A	N/A	N/A	\$3,197.0500
Brand Most Costly	ABBVIE	00074262528	Glecaprevir-Pibrentasvir 100-40 MG Tablet 84.000 EA UU	\$157.1429	\$178.2950	\$181.8609	\$178.2950	\$178.2950	\$157.1429
Brand Most Costly	ABBVIE	00074210001	Risankizumab-rzaa 150 MG/ML Solution Auto-injector 1.000 ML UD	\$18,227.9481	N/A	N/A	N/A	N/A	\$18,227.9481
Brand Most Costly	ABBVIE	00074230630	Upadacitinib 15 MG Tablet Extended Release 24 Hour 30.000 EA UU	\$188.5780	\$36.8579	N/A	\$36.8579	\$36.8579	\$36.8579
Generic Most Prescribed	ACCORD HEALTHCARE	16729000617	Simvastatin 40 MG Tablet 1000.000 EA	\$0.1024	N/A	N/A	N/A	N/A	\$0.1024
Generic Most Costly	ACORDA THERAPEUTICS	10144042760	Dalfampridine 10 MG Tablet Extended Release 12 Hour 60.000 EA	\$58.6352	N/A	N/A	N/A	N/A	\$58.6352
Generic Most Costly	ACTAVIS PHARMA	00591352530	Lidocaine 5 % Patch 30.000 EA UU	\$2.9953	N/A	N/A	N/A	N/A	\$2.9953
Generic Most Prescribed	ACTAVIS PHARMA	00591544305	Prednisone 20 MG Tablet 500.000 EA	\$0.2051	N/A	N/A	N/A	N/A	\$0.2051
Generic Most Costly	AJANTA PHARMA LIMITED	27241009900	Duloxetine HCl 60 MG Capsule Delayed Release Particles 1000.000	\$0.3000	N/A	N/A	N/A	N/A	\$0.3000
Generic Most Prescribed	AKORN	50383070016	Fluticasone Propionate (Nasal) 50 MCG/ACT Suspension 16.000 GM	\$0.8150	N/A	N/A	N/A	N/A	\$0.8150
Generic Most Costly	ALVOGEN	47781095703	Buprenorphine HCl-Naloxone HCl Dihydrate 8-2 MG Film 30.000 EA	\$6.3333	N/A	N/A	N/A	N/A	\$6.3333
Generic Most Costly	ALVOGEN	47781010444	Estradiol Vaginal 0.1 MG/GM Cream 42.500 GM UU	\$3.9353	N/A	N/A	N/A	N/A	\$3.9353

Part III

§8741 2. C. For each drug identified in paragraph A, the organization shall determine the potential savings that could be achieved by subjecting those drugs to the referenced rate as calculated pursuant to paragraph B. The savings must be determined based on the payments reported in the organization's claims database for the most current 12- month period.

- A reference rate was calculated for the 93 NDCs as identified above.
- The potential savings calculation for the 72 drugs with a reference rate based on the lowest cost option identified in the Canadian provinces is \$146.7M; of which 1.4% of the potential saving is for generic drugs and 98.6% is for brand drugs. (**Note:** potential savings calculations do not consider the impact of rebates to net prices in the US market as rebate data at the NDC level is not available in the MHDO claims data).
- The data below is a snapshot of the complete data set that is available in the Excel File here

Potential Savings

§8741 2. C. For each drug identified in paragraph A, the organization shall determine the potential savings that could be achieved by subjecting those drugs to the referenced rate as calculated pursuant to paragraph B. The savings must be determined based on the payments reported in the organization's claims database for the most current 12- month period.

Top 100 List	Manufacturer Name	NDC	Item Description	Average WAC Per Unit	Reference Rate	Annual Cost @ Average WAC Per Unit	Annual Cost @ Reference Rate Per Unit	Potential Savings
Brand Most Costly	JANSSEN BIOTECH	57894006103	Ustekinumab 90 MG/ML Solution Prefilled Syringe 1.000 ML UD	\$25,432.8997	\$3,344.0018	\$42,857,096	\$5,632,408	\$37,204,688
Brand Most Costly, Brand Most Prescribed	B-M SQUIBB U.S. (PRIMARY CARE)	00003089421	Apixaban 5 MG Tablet 60.000 EA	\$8.8168	\$1.2239	\$11,770,430	\$1,633,106	\$10,137,324
Brand Most Costly, Brand Most Prescribed	LILLY	00022751001	Insulin Lispro 100 UNIT/ML Solution 10.000 ML UU	\$27.4700	\$2.3544	\$5,999,565	\$514,211	\$5,485,354
Brand Most Costly	GILEAD SCIENCES	61958250101	Bimegestrol-Emtricitabine-Tenofovir Alafenamide Fumarate 50-200-25 MG Tablet	\$19.4600	\$29.3715	\$7,124,180	\$1,751,615	\$5,372,565
Brand Most Costly	PFIZER U.S.	00689050130	Tofacitinib Citrate 11 MG Tablet Extended Release 24 Hour 30.000 EA UU	\$173.3890	\$35.8827	\$6,280,565	\$1,299,758	\$4,980,807
Brand Most Costly	VERTEX PHARMACEUTICALS, INC.	51167033101	Elexacaftor-Tezacaftor-ivacaftor 100-50-75 & 150 MG Tablet Therapy Pack 84.000 EA	\$298.4171	\$209.6750	\$15,681,600	\$11,018,268	\$4,663,332
Brand Most Costly, Brand Most Prescribed	BOEHRINGER INGELHEIM	00597015330	Empagliflozin 25 MG Tablet 30.000 EA	\$18.9979	\$2.0650	\$5,221,925	\$567,604	\$4,654,321
Brand Most Costly, Brand Most Prescribed	BOEHRINGER INGELHEIM	00597015230	Empagliflozin 10 MG Tablet 30.000 EA	\$18.9979	\$2.0650	\$4,215,522	\$458,212	\$3,757,310
Generic Most Costly, Generic Most Prescribed	TEVA PHARMACEUTICALS USA	00093317431	Albuterol Sulfate 108 (90 Base) MCG/ACT Aerosol Solution 8.500 GM UU	\$4.2329	\$0.0243	\$647,490	\$3,718	\$643,772
Generic Most Costly	MYLAN	00378932132	Fluticasone-Salmeterol 250-50 MCG/ACT Aerosol Powder Breath Activated 60.000 EA	\$1.9407	\$0.6335	\$832,470	\$271,742	\$560,728
Generic Most Costly	MYLAN	00378932032	Fluticasone-Salmeterol 100-50 MCG/ACT Aerosol Powder Breath Activated 60.000 EA	\$1.5618	\$0.5292	\$321,170	\$108,825	\$212,345
Generic Most Costly	MYLAN	00378932232	Fluticasone-Salmeterol 500-50 MCG/ACT Aerosol Powder Breath Activated 60.000 EA	\$2.5523	\$0.8994	\$317,178	\$111,982	\$205,196
Generic Most Costly	SANDOZ	61314063705	Prednisolone Acetate (Ophth) 1 % Suspension 5.000 ML UU	\$8.8500	\$1.4527	\$89,158	\$14,635	\$74,523
Generic Most Costly	SANDOZ	00781618556	Travoprost 0.004 % Solution 2.500 ML UU	\$66.1920	\$6.4610	\$66,286	\$6,471	\$59,815
Generic Most Costly, Generic Most Prescribed	MYLAN	00378932005	Atorvastatin Calcium 40 MG Tablet 500.000 EA	\$0.2752	\$0.1754	\$146,856	\$93,599	\$53,257
Generic Most Costly, Generic Most Prescribed	MYLAN	00378935105	Atorvastatin Calcium 20 MG Tablet 500.000 EA	\$0.2752	\$0.1632	\$121,289	\$71,928	\$49,361

Key Findings Preparing This Report

- When comparing NDCs in the US to pharmaceutically equivalent DINs in Canada there are not as many prescription drug products available in Canada.
- Many drugs currently patented in the US are not under patent in Canada. This allows for generic competition in Canada while brand drugs remain the only products available in the US.
 - o In Canada, multi-source brand drugs (brand drugs that are also available from generic manufacturers) are often excluded from provincial formularies and are almost always replaced by lower cost generic equivalents.
- Prices on Canadian provincial formularies represent amounts paid by payers in the province. In contrast, WAC represents the price paid to manufacturers by drug wholesalers and almost never reflects actual amounts paid by payers in the US.
 - o Many generic drugs show no Reference Rate savings resulting from the comparison of Canadian paid amounts to the US WAC amounts.

Data Sources and Methodology

Under contract with MHDO, Ten2Eleven Business Solutions provided MHDO technical support in the preparation of this report.

MHDO performed its analysis using descriptive drug product, pharmaceutical equivalency, and historical pricing information compiled from Wolters Kluwer's Medi-Span MedFile v2 (MediSpan) and Canadian Drug File data files, and pharmaceutical claims data submitted to the MHDO All Payer Claims Database as required by 90-590 Rule Chapter 243, Uniform Reporting System for Health Care Claims Data Sets, for the most recent 12-month period (April 1, 2021-March 31, 2022).

Manufacturers are incorporated as different corporate entities in the US and Canada. To compare country to country pricing between products by manufacturer, MHDO developed a crosswalk of US and Canadian manufacturers. Where possible, manufacturers were mapped by associating similar corporate names; when no match was found, MHDO performed internet research to determine corporate relationships between US manufacturers of NDCs on the Top 100 List and manufacturers of pharmaceutically equivalent products in Canada.

The MediSpan and Canadian Drug Files share a common proprietary data element that is maintained by Wolters Kluwer to denote pharmaceutically equivalent drug products. This Generic Product Identifier (GPI) was used together with the manufacturer crosswalk to map products that are identical with respect to active ingredient(s), dosage form, route of administration, and strength or concentration but without considering the presence of inactive ingredients.

Where US NDCs could be mapped to a Canadian DIN, and were priced on at least one provincial formulary, MHDO determined a Reference Rate for the NDC as described in §8741 2. B. Province pricing was evaluated based on amounts published as applicable for December 31, 2022, adjusted for the US / Canadian exchange rate of 1.3554 posted by the Wall Street Journal as of the close of the market on Friday, December 30, 2022 . Reference Rate values were calculated per NDC unit of measure.

MHDO next calculated potential savings that could be achieved by subjecting NDCs on the Top 100 List to the Reference Rate. MHDO first determined the total quantity dispensed (by NDC unit of measure) and average percent markup above/below WAC for commercial claims during the claim review period (April 1, 2021 – March 31, 2022). The average rate of markup above/below WAC was then applied to both the average WAC per NDC unit of measure and the Reference Rate, and both metrics were multiplied by the dispensed quantity. Finally, resultant values were compared to determine total potential savings for each NDC.

MHDO received one time funding from an external source to cover the annual data acquisition cost for the Canadian Drug File. Funding is needed to continue MHDO's subscription to the data file on an annual basis.

Footnotes:

¹ Wall Street Journal Website. Markets. Accessed January 9, 2022 at <https://www.wsj.com/market-data/quotes/fx/USDCAD/historical-prices>

² Average WAC per NDC unit of measure was calculated by summing the mathematical product(s) of the number of days during the most recent 12-month period (January 1, 2022 – December 31, 2022) that a drug product was priced at a unique WAC per unit value multiplied by the unique WAC per unit value and dividing the sum of all mathematical products by the number of days in the 12-month period. $((\$a \times 31 \text{ days}) + (\$b \times 150 \text{ days}) + (\$c \times 184 \text{ days})) / 365 \text{ days}$