NATIONAL AND PROVINCIAL
OVERVIEW

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NOTEWORTHY NATIONAL DEVELOPMENTS

UPDATE ON PATENTED MEDICINE PRICES REVIEW BOARD (PMPRB) REFORM

In 2017, the Government of Canada proposed changes that would modernize the framework of the Patented Medicine Regulations, reflecting the evolution of the pharma sector and making prescription drugs more affordable for Canadians.

The new guidelines are expected to take a risk-based approach to price regulation that considers value and affordability, in addition to list prices in comparable countries.

Within this framework, all new drugs will have a maximum list price (MLP) based on the median of the 12 comparator countries chosen. Drugs will be classified as Category 1 (first-in-class or providing a substantial improvement over existing therapies) or Category 2 (all other drugs). Pharmacoeconomics, market size and gross domestic product factors will be applied, depending on the classification, to determine the list price. The MLP will apply for three years or until the drug is sold in seven countries, when it will be "frozen". Only if a new treatment indication is approved, sales exceed market size, new evidence of cost-effectiveness is shown, or significant changes in international pricing occur will MLPs be re-evaluated.

The finalized guidelines are expected later in 2019. The PMPRB reform will provide more transparency in drug pricing in Canada and eventually lower costs. These changes will benefit public and private plans as well as Canadians who pay for all or part of their prescriptions out-of-pocket.

CANNABIS LEGALIZATION

The Cannabis Act, which provides a strict legal framework for controlling the production, distribution, sale and possession of cannabis across Canada, came into force in October 2018. Since then, Canadians 18 years of age or older may legally possess up to 30 grams of cannabis (dried or equivalent) and may buy dried or fresh cannabis from provincially licensed retailers. The sale of cannabis edibles and concentrates is expected to become legal later in 2019.

Retail models fall under provincial jurisdiction. Some provinces decided to adopt a public model (such as Quebec and all Atlantic provinces); others decided on a private model (Ontario, Manitoba, Saskatchewan, Alberta); British Columbia adopted a mixed model.

Although legalization of recreational cannabis does not affect the current regulations around medical cannabis, it appreciably raised public interest. Increased demand for medical cannabis is therefore likely, prompting questions regarding the type of coverage plan sponsors will provide. The indications for which medical cannabis has demonstrated efficacy are very narrow (pain management in palliative care, cancer and multiple sclerosis) and there are currently no guidelines in terms of dosing. There is therefore a pressing need to develop solutions that will optimize medical cannabis coverage and ensure it is used in accordance with the most comprehensive data available. Express Scripts Canada is working closely with its clients to develop these solutions.

NATIONAL PHARMACARE

Discussions are still underway in regard to the implementation of a National Pharmacare plan. The main goal is improving access to medications for Canadians who cannot afford them despite coverage by public and/or private plans. The Advisory Council on the Implementation of National Pharmacare issued an interim report in March 2019 that laid out the core principles and foundational elements for successful implementation.

Among those recommendations is the creation of a national drug agency that would manage the program and provide guidance and advice to governments. The agency would consolidate many of the prescription drug-related functions currently managed by various levels of government. The council also recommended the development of a comprehensive, evidence-based national formulary to harmonize coverage across the country. Special considerations would be given to treatment for rare diseases.

The question of which national pharmacare model will be recommended has not yet been addressed but is expected in the council's final report, along with the architecture and implementation plan.

Discussions include models focused on expensive drugs, including those for rare diseases; a "fill in the gaps'' approach targeting the most vulnerable Canadians; and a single-payer public model with coverage ranging from essential medicines to a more comprehensive formulary. The many possible options would all have different consequences on patient outcomes, access to medicines, public and private cost and the budget required to implement. The final report from the Advisory Council is expected in June 2019. It will evaluate the different options in regard to the model and implementation of pharmacare throughout Canada.

National pharmacare is looking large in the 2019 Federal Budget. It focuses on three key issues supporting the initial interim recommendations from the Advisory Council:

- The creation of a Canadian Drug Agency with a mission to negotiate drug prices.
- The creation of a new National Drug Formulary, intended to provide additional consistency in drug coverage in the country.
- The creation of a National Strategy for Drugs for Rare Diseases, an investment of up to $1B over two years to help Canadians suffering from rare diseases to access the drugs they need through a national strategy for high-cost drugs.

With federal elections coming in October 2019, national pharmacare has officially become an election issue. As the anticipated impact on plan sponsors will be significant, Express Scripts Canada continues to monitor these developments closely.

USMCA

On September 30, 2018, the United States, Mexican and Canadian governments announced they had reached an agreement on the modernized United States-Mexico-Canada Agreement (USMCA), intended to replace the North American Free Trade Agreement (NAFTA) currently in force. The new agreement, which will come into effect after each country's ratification, will change data protection for biologic drugs in Canada. Currently, data protection protects innovative drugs, biologic and non-biologic, from generic competition for a period of eight years. With USMCA, Canada agreed to extend the term for biologic drugs data protection to ten years. This extension could potentially have a substantial impact on the cost of drugs here by delaying access to biosimilars and could result in additional spending for plan sponsors.

OPIOID CRISIS

The opioid crisis continues in Canada, with a reported 3,996 deaths related to opioid poisoning in 2017, as compared to 2,946 in 2016. While campaigns continue to raise awareness among the medical community as well as the public, Health Canada has proposed reclassification of the opioid painkiller tramadol as a Schedule I narcotic under the Controlled Drug and Substances Act. This would place new restrictions on how it is prescribed and dispensed as a way of reducing abuse and dependence.

The Government of Canada also removed the requirement that physicians obtain an exemption to prescribe or administer methadone, an opioid agonist treatment. This change, which came into effect in May 2018, is intended to increase access to opioid addiction treatment.

PAN-CANADIAN PHARMACEUTICAL ALLIANCE (PCPA)

The pan-Canadian Pharmaceutical Alliance, or pCPA, conducts joint provincial and territorial negotiations for generics, biosimilars and brand name drugs. All brand name drugs submitted for funding through the national review process – Common Drug Review (CDR) or the pan-Canadian Oncology Drug Review (pCODR) – are considered for negotiation through the pCPA.

One of the results of these negotiations was the generic price initiative implemented in April 2018, a five-year agreement in which generic versions of nearly 70 of the most commonly prescribed drugs are now priced at 10% or 18% of the equivalent brand-name product, representing a discount of up to 90%.

The pCPA negotiations continue with the goal of achieving greater drug value for patients and plan sponsors.

SECTION 3 – NATIONAL AND PROVINCIAL OVERVIEW

PROVINCIAL OVERVIEW

BRITISH COLUMBIA

Private Drug Trend

The overall drug trend for private plans in British Columbia was 3.3% for 2018, higher than the national average of 0.9%. Both the cost per prescription (1.8%) and utilization (1.5%) contributed to the overall increase.

Noteworthy Developments Within the Provincial Public Drug Benefit Program

Smoking cessation. Coverage of smoking cessation products was limited to a single continuous course of treatment, lasting up to 12 weeks, and using one eligible smoking product each calendar year. As of June 2018, limits to ensure compliance with coverage maximums were introduced. If a person has already received coverage for their 12-week course of treatment in a calendar year, PharmaNet will refuse PharmaCare payment of any additional smoking cessation product costs. This means that claims may be submitted for private coverage, especially for patients who require combination therapies or treatment lasting longer than 12 weeks.

Hepatitis C treatment coverage extension. In March 2018, British Columbia expanded the clinical eligibility criteria to provide coverage to more patients living with hepatitis C. Treatment is now covered regardless of the type (genotype) or severity of the disease (fibrosis stage, presence of decompensated cirrhosis). This may reduce private plan spending.

Biosimilars. Since August 2018, BC PharmaCare covers Basaglar™ (biosimilar to Lantus®) for all patients who have received Special Authorization coverage for insulin glargine. Lantus will no longer be covered for new patients starting insulin glargine, but coverage will be maintained for patients already taking Lantus.

ALBERTA

Private Drug Trend

In 2018, the cost per prescription increased by 0.5% and utilization by 0.8%, which resulted in an overall trend of 1.3% for the province. It remains relatively similar to the national average.

Noteworthy Developments Within the Provincial Public Drug Benefit Program

There were no noteworthy legislative or pharmacy practice changes identified in 2018.

SASKATCHEWAN

Private Drug Trend

The cost per prescription increased by 0.7% and utilization was up 1% for 2018, for an overall trend of 1.7%.

Noteworthy Developments Within the Provincial Public Drug Benefit Program

Hepatitis C treatment coverage extension. As of April 2018, Exceptional Drug Status (EDS) criteria for existing hepatitis C drugs have been updated. Hepatitis C patients may now qualify for EDS regardless of the disease severity or prognosis factors, and a reduction in private plan claims is anticipated.

Minor Ailment Program. In November, the Drug Plan and Extended Benefits Branch (DPEBB) and the Pharmacy Association of Saskatchewan reached a one-year agreement that expands the Minor Ailment Program. The list of conditions for which pharmacists can prescribe drugs has been extended, with the addition of nine minor ailments and self-care conditions, including shingles and uncomplicated urinary tract infection in women. Smoking cessation has also been added to the program as of January 2019.

Pharmacists in the province are now remunerated for the administration of medroxyprogesterone (Depo-Provera® and generics) by injection to eligible Saskatchewan residents.

Finally, the dispensing fee increased from $11.40 to $11.60 as of November 2018.