CANADA

Recent and planned developments in pharmaceutical policies 2019

Special topic: patient-based reimbursement decisions

CHANGES IN PRICING

On January 16, 2019, the Patented Medicine Prices Review Board issued a Notice of Hearing for allegations of excessive pricing of cysteamine bitartrate, sold under the trade name “Procysbi” by the patentee Horizon Therapeutics Canada.

In the spring of 2019, the Federal Government plans to approve regulation that will modernize the way patented drug prices are reviewed in Canada, including considering a revised list of countries used in external price referencing and by allowing the value for money and affordability to be taken into consideration. The new regulations are forthcoming and are not expected to come into force until summer 2020.

As of April 30, 2019, a total of 286 negotiations for new brand name drugs and indications has been completed by the pCPA, the pan-Canadian alliance that negotiates prices on behalf of Canada’s federal, provincial and territorial governments.

CHANGES IN REIMBURSEMENT

Effective January 1, 2019, British Columbia reduced or eliminated deductibles and co-payments for all low-income earners with household net incomes below $45,000.

Effective April 1, 2019, the Ontario provincial government changed the eligibility requirements for patients 25 years old and under that were covered under the OHIP+ plan in 2018, limiting it to those without private coverage.

OTHERS CHANGES

The Federal Government announced in the 2019 Budget its intention to work with its partners to move forward on three foundational elements of national pharmacare.

- Create **the Canadian Drug Agency** that would assess the effectiveness of new prescription drugs and negotiate drug prices on behalf of Canadians. Negotiating better prices could help lower the cost of prescription drugs for Canadians by up to $3 billion per year in the long term.
- Take steps toward the development of a **national formulary—**a comprehensive, evidence-based list of prescribed drugs, to be developed as part of the Canadian Drug Agency. This would provide the basis for a consistent approach to formulary listing and patient access across the country.
- Establish **a national strategy for high-cost drugs for rare diseases—**to help Canadians with rare diseases access the drugs they need, Budget 2019 proposes to invest up to $1 billion over two years, starting in 2022–23, with up to $500 million per year ongoing. This would include the creation of a national strategy for high-cost drugs for rare diseases, to gather and evaluate evidence on high-cost drugs for rare diseases, improve the consistency of decision-making and access across the country, negotiate prices with drug manufacturers, and ensure that effective treatments reach the patients who need them.

The Advisory Council on National Pharmacare is expected to deliver its final report in the spring of 2019 and will include options and recommendations as to what measures the federal government should take towards the implementation of an affordable national pharmacare for Canadians and their families, employers and governments.

Health Canada's Regulatory Review of Drugs and Devices (R2D2) initiative aims to provide more timely access to medicines for Canadians. Under this initiative, greater collaboration is being sought between organizations that play a role in drug access, including Health Canada and the health technology assessment (HTA) organizations in Canada.

In November 2018, CADTH embarked upon external stakeholder consultations to develop a new supplemental process for reviewing Highly Specialized / Complex Drugs. These drugs pose a number a challenges for the HTA process given the lack of robust evidence to support efficacy, safety and cost-effectiveness evaluations, their high-cost and the perceived role in addressing unmet needs. The primary objective of the proposal is to implement a proactive, consistent, fair and transparent process to assess complex/specialized drugs for the purpose of making responsive funding decisions.

SPECIAL TOPIC: patient-based reimbursement decisions

Canada does not have a special reimbursement procedure for patients who need medicines that are not included in the reimbursement system, or which do not have a market authorisation, however hospitals, public and private drug plans may provide reimbursement on a case-by-case basis.

OUT-PATIENT

Public reimbursement lists are managed independently by each of the Canadian provinces and territories, reflecting the needs of their citizens and jurisdictional priorities. The majority of drug products on these lists are reimbursed at full benefit, however, the public plans maintain as part of their formularies a list of drugs that will be reimbursed on a limited or restricted basis.

Public plans require special authorization before reimbursing these drugs. In most cases, the prescribing physician is required to make the request in writing to the drug plan, justifying the use of the drug requested. In some cases, this includes providing the rationale for why formulary-listed drugs are not suitable and addressing the clinical circumstances for which the drug is required. Typically, the length of time for which coverage is granted and the frequency of renewal depends on the drug and treatment for which the request is being made.

Drugs without market authorization can be made available through Health Canada’s Special Access Programme (SAP). Health Canada encourages patients to apply for clinical trials for the drug, if any are available. While there is no requirement for manufacturers to provide drugs released via the SAP free of charge, many do. A number of jurisdictions have compassionate coverage programs available that could be used to reimburse the cost of SAP drugs that are not available for free. These programs are not designed specifically to cover SAP drugs, however requests are reviewed on a case-by-case basis.

IN-PATIENT

In Canada, hospital-based Pharmacy and Therapeutics Committees function at either the individual hospital level, district or regional health authority level, or provincial level. Pharmacy and Therapeutics Committees are the organizations responsible for managing drug-related issues for the organization represented by the committee. As with the out-patient environment, the prescribing physician is required to make the request in writing to the Pharmacy and Therapeutics Committee to justify the use of the drug requested. Typically, the length of time for which coverage is granted and the frequency of renewal depends on the drug and treatment for which the request is being made.