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REGULATORY FOCUS

Drug Reimbursement in Canada

By George Wyatt, MBA

This article provides a high-level overview of the elements of prescription drug reimbursement in Canada and discusses the costs, processes and reimbursement plans associated with a number of federal health agencies and payers and describes some of the variety of drug plans in place.

The Regulatory–Reimbursement Interface

Community (out-patient) drug reimbursement is usually considered after a drug has received regulatory approval from Health Canada. Regulatory processes in Canada are managed by Health Canada, which is responsible for determining efficacy, safety and quality. While Health Canada makes no pronouncement of value upon acceptance, the agency's interest in lifecycle management could influence the value equation in ensuing years. The drug in question may become "more valuable" if useful data and/or indications are added. Conversely, a drug may become "less valuable" if real-world monitoring reveals more adverse events than anticipated, especially if these are serious adverse events.

Drug reimbursement goes beyond the regulatory process and focuses on value. Does this drug give me more value than other drugs or therapies?" And, it is worth noting that drugs are sometimes reimbursed "off-label" if payers perceive there is a value in doing so. An example is found in the treatment of Wet AMD. Governments set up clinics to treat Wet AMD, but they did not give the clinics enough money to fund every patient for treatment with Lucentis (ranibizumab injection) because there was discussion that Avastin (bevacizumab) could work at a fraction of the price.{1}

Medicare

Recently, there has been much discussion about single-payer systems in light of the ongoing healthcare debate in the US where many people do not have health insurance

or are under-insured. While most G20 countries have single payer systems, the systems have significant differences. For example, Canada's single-payer Medicare system does not cover all healthcare costs. The Canadian Medicare system generally covers costs for patients in hospital and covers their visits to medical doctors. Each province decides what is medically necessary, and there is reasonable conformity across the country despite exceptions, some of which are notable.

Drugs administered in the hospital are paid through the Medicare system. The province provides funding to the hospitals and each hospital decides how the money should be spent. Each hospital also decides which drugs are on its formulary. And, hospitals try to save money on medications by asking patients to bring their own.

Drug Pricing

Drug pricing is regulated in Canada at the "top end." There are three types of prices and the discussion of drug pricing involves many elements, so only the highlights appear below.

The Patented Medicine Prices Review Board (PMPRB), a federal agency, determines the maximum price at which a drug can be sold in Canada. This price must not be "excessive."{2} The non-excessive price is determined through several mechanisms and by comparing the prices in Canada with those in certain other nations. There are remedies for drugs priced higher than the maximum allowable price. For example, the PMPRB may say that the ceiling price is $2.00 per tablet. If the company sells the drug at $3.00 per tablet, they will have to pay a fine of $1.00 multiplied by the number of tablets sold at that price.

The PMPRB also reports on R&D spending by pharmaceutical companies in Canada. PMPRB has indicated in recent years that the pharmaceutical industry is not living up to its commitment.{3} The industry trade association says the industry is doing so, but that PMPRB's methodology does not recognize some of the money spent on R&D.{4}

List prices are those published by drug companies. Net prices are those negotiated by payers with pharmaceutical companies through what is referred to as Product Listing Agreements (PLAs), which are similar to patient access schemes in the UK or managed care contracts in the US. The net price is calculated depending on the type of tender or negotiated arrangement in play, e.g., rebate, cap, etc. There is interest in pay-for-performance types of contracts, but these are in the early stages in Canada.

For example, a company may decide that the list price of a drug will be $1.50 per tablet, which is lower than the ceiling price set by PMPRB in the previous example. However, a payer may say that there is not enough value if the price is $1.50 per tablet, but there would be enough value at $1.00 per tablet. The company could potentially set up a rebate agreement with the payer for $0.50 per tablet multiplied by the number of tablets sold at that price. The product would likely be reimbursed and this information would probably be kept confidential so as not to damage revenue from other payers.

Drug Coverage

There is currently no national drug coverage system in Canada, although there is an active debate on National Pharmacare, the parameters of which have yet to be defined. There is a mix of public and private coverage. It may be easy for people to remember 40/40/20. Governments pay 40 percent of the costs. Forty percent of the costs are paid by private insurance, which is usually arranged through the employee benefit plans. Individuals pay 20 percent of the costs, which is usually made up of premiums, deductibles and co-pays that go toward public and private coverage.

The cash market for prescriptions drugs is relatively small in Canada. However the out-of-pocket impact is not insignificant when patients have high dollar value contributions. For example, patients may have 80 percent coverage for a drug under a plan. But if the drug is a high-cost biologic, or a drug for a rare disease, the co-pay could be a significant burden for the patient. Biosimilars are now entering Canadian marketplace and may reduce out-of-pocket drug costs for some patients.

Health Technology Assessment (HTA) Processes

There are two main publicly-funded HTA bodies in Canada, the Canadian Agency for Drugs and Technologies in Health (CADTH) and the Institut National d'Excellence en Santé et en Services Sociaux (INESSS).{5} INESSS advises Québec decision-makers and CADTH supports public healthcare services in the rest of Canada. CADTH is also active in organizations such as Health Technology Assessment International (HTAi) and often provides advice to other countries on how to set up and manage their HTA systems. Canada will host the HTAi conference in Vancouver in June 2018.

CADTH has a number of programs and services to provide advice to drug plan decision-makers. When it comes to public drug plan coverage, two main CADTH HTA programs apply: the Common Drug Review (CDR){6} and the pan-Canadian Oncology Drug Review (pCODR).{7} CDR provides recommendations to public drug plans for all medicines except active cancer treatments, which are handled by pCODR. The recommendations and other information are made public on their websites, which allows anyone to take advantage of their expertise. These recommendations play a significant role in whether public drug plan reimbursement can be achieved. The recommendations provide detailed information on the clinical and economic evidence about the drug. The recommendations also discuss if and how the drug should be funded, i.e., the clinical criteria and/or the economic conditions that could apply to the funding decisions. These recommendations also are playing an increasingly important role for private drug plans, even if the perspective of private drug plans is different.

Common Drug Review (CDR)

The Common Drug Review has served all public drug plans in Canada - except Québec - since 2002. CDR reviews a drug to see if it is cost-effective from a health systems (see Medicare) perspective, including the public drug plan. Since its inception, CDR has issued more than 400 recommendations with a positive recommendation rate of approximately 62 percent. The positivity rate has increased to nearly 80 percent since late 2012 when CDR implemented an approach focused more on criteria and conditions, including the prices and costs of drugs under review.

Pan-Canadian Oncology Drug Review (pCODR)

The pan-Canadian Oncology Drug Review was formally established in 2010 to assess drugs for active cancer treatment only. These drugs were originally part of the mandate of the CDR, but it was felt the perspective and methods at CDR did not suit active cancer treatment. Early in 2007, the Joint Oncology Drug Review (JODR) was created to conduct reviews of these drugs and update methods. This became an interim process, i.e., iJODR, when it was determined that pCODR needed to be formed.

pCODR uses a deliberative framework{8} that considers four main areas:

- overall clinical benefit
- alignment with patient values
- cost-effectiveness
- feasibility of adoption into the health system

The pCODR recommendations are largely positive and focus on a place in therapy approach for the treatment of the type of cancer. There is more interaction with the pharmaceutical company than is the case with CDR, and the reviews can start earlier – up to 12 months prior to the issuance of the Notice of Compliance (NOC) from Health Canada.

Institut National d'Excellence en Santé et en Services Sociaux (INESSS)

INESSS is an HTA body like CADTH and serves the interests of Québec. One of the functions of INESSS is to advise the Québec government regarding the drugs that should be reimbursed by the public drug plan. INESSS differs from CDR in that it takes a societal perspective when evaluating a drug. There is an attempt to quantify elements such as caretaker time, as part of the INESSS process. For example, some patients need to make

multiple visits to HCPs, but are unable to make these visits on their own. They must be accompanied by a caregiver, who may have to take time off work to do so. INESSS tries to account for these and other similar issues when making assessments.

For many years, the positivity rate for INESSS recommendations was higher than that of CDR. This was detailed in a poster presented at the ISPOR meeting in Montreal in May 2014.{9} However, since CDR changed their approach in 2012, the positivity rate at INESSS is slightly lower than that found at CDR.

Pan-Canadian Pharmaceutical Alliance (pCPA)

The pCPA is the office responsible for facilitating the value negotiations between the public drug plans and the pharmaceutical companies.{10} It acts in a secretariat fashion. All public drug plans in Canada, including Québec now participate.

On the brand name drug side, once a recommendation is ready from an HTA body, such as CDR, the provinces determine if a negotiation should take place and which province will voluntarily lead the negotiation. If negotiations come to a successful conclusion, a Letter of Intent (LOI) is issued and forms the basis for contracts executed by each jurisdiction under that jurisdiction's legislation, regulations and contract language, following which reimbursement is put in place. As of 31 July 2017, 163 negotiations have been completed under this process.

The pCPA also oversees the implementation of the value price initiative for generic drugs. This sets reimbursement prices for high volume generic drugs for drug plans. For example, the prices for 12 multi-source drugs have been set at 18 percent of the brand name list price while six multi-source drugs have been set at 15 percent of the brand name list price.

Canadian governments are quite pleased with this initiative. "As of 31 March 2017, the pCPA's efforts have led to a $1.28 billion a year in estimated combined jurisdictional savings."{11}

Public Drug Plans

Under Canada's constitution, delivery of health services is the responsibility of the provinces. This means every province has its own way of providing drug benefits. Accordingly, each province has multiple drug programs, some being administered out of provincial offices while others are administered out of hospitals. Some programs are in place for just one class of drugs, while other programs list thousands of drugs. In addition, the federal government provides drug benefits to specific groups, such as its employees, native Canadians, and the Canadian forces. This means there are hundreds of public drug plans across Canada.

Eligibility for these public plans is also diverse. Some provinces have main plans that focus on seniors and those on social assistance. Other provinces provide drug coverage for all eligible residents of a province; these are the so-called "universal plans." Most of these types of plans come with a combination of premiums, deductibles and co-pays. Yet other plans may provide first dollar coverage for certain types of drugs and/or medical conditions. New specialists, called "reimbursement navigators," are now in place at several public and private institutions to sort out these obstacles for patients.

Private Drug Plans

Employers often sponsor private drug plans as part of benefit plans. This is a tax-efficient means of providing benefits to employees as the employees usually receive the benefits tax-free and they are a full deduction for the employer.

A few large insurance companies play a very prominent role in the private drug plan market, especially after a series of acquisitions a number of years ago. Other smaller insurance companies have carved out niche markets. Pharmacy Benefit Managers (PBMs) also play a key role in the evaluation of products for private drug plans, including the large insurance companies.

The perspective for private drug plans focuses more on productivity. This is a challenge to measure and is usually not included in the design of drug trials. This perspective differs from those of the HTA applied to the public drugs plans. For example, Quebec's

INESSS takes a societal approach, which takes a more holistic approach of the patient experience. CADTH, on the other hand, takes a health system perspective in that it wants to know if a drug is going to reduce hospitalization or physician visits. The pan-Canadian Pharmaceutical Alliance is more focused on the overall budget impact and compares the drug's cost versus other drug therapies.

Rules and Exceptions

Typically, criteria are applied before reimbursement is granted for a new drug in order to manage drug expenditures. These criteria can be applied in several ways, e.g., step therapy (patient must fail or not tolerate Drug A before Drug B can be reimbursed); clinical (patient must have a particular condition or meet certain clinical criteria like disease severity for the drug to be reimbursed); maximum cost (drug plan will only pay a maximum price for any drug in the category or class), etc.

There are always exceptions to the rules. Sometimes drugs can be reimbursed on a case by case basis. There are also several cases where drugs are reimbursed by various public and private drug plans if they are accepted under Health Canada's Special Access Program rather than waiting for Health Canada approval. This is especially the case for life-sustaining drugs.

Summary and Outlook

Drug reimbursement in Canada is complicated. Benefits for patients can be available depending on location of residence, age, income, condition, etc. Challenges for payers continue because the data they require to make good decisions is often unavailable at the time a drug receives regulatory approval. Pharmaceutical companies face almost impossible tasks of trying to provide the answers to payers when they have to deal with multiple perspectives around the world. Organizations like EUnetHTA are working to meet some of these challenges.{12} CADTH is an observer at this organization. Real World Evidence (RWE) has the potential to provide answers, but there are challenges associated with RWE as well.

The pace of change is only accelerating. Stay tuned.

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