Canadian Journal of Health Technologies

CADTH

May 2021 Volume 1 Issue 5

CADTH Health Technology Review

Overview of Formulary Management Practices of Publicly Funded Provincial and Territorial Drug Plans

Environmental Scan

CADTH

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ISSN: 2563-6596

About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

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Abbreviations

ACDR	Atlantic Common Drug Review
AEAC	Atlantic Expert Advisory Committee
CDEC	CADTH Canadian Drug Expert Committee
CDR	CADTH Common Drug Review
CED	Committee to Evaluate Drugs (Ontario)
CSEMI	Le Comité scientifique de l'évaluation de médicaments aux fins d'inscription (INESSS)
DACS	Drug Advisory Committee of Saskatchewan
DBC	Drug Benefit Council (British Columbia)
DTAC	Drugs and Therapeutics Advisory Committee (NIHB)
ECDET	Expert Committee on Drug Evaluation and Therapeutics (Alberta)
ES	Environmental Scan
FPT	federal, provincial, and territorial governments
HTA	health technology assessment
INESSS	Institut national d'excellence en santé et en services sociaux
MBSTC	Manitoba Drug Standards and Therapeutics Committee
NIHB	Non-Insured Health Benefits
pCODR	CADTH pan-Canadian Oncology Drug Review
pCPA	pan-Canadian Pharmaceutical Alliance
pERC	CADTH pCODR Expert Review Committee
PT	provincial and territorial
RAMQ	Régie de l'assurance maladie du Québec

Context

In Canada, provincial and territorial (PT) public drug plans generally provide prescription drug (hereafter *drugs*) coverage for specific segments of the population such as seniors (persons aged 65 years of age or older), individuals with low income, or those with high drug costs relative to their income; therefore, public coverage determined based on predefined eligibility criteria. Additionally, federal public drug plans provide coverage for veterans, First Nations and Inuit peoples, federally incarcerated offenders, the Royal Canadian Mounted Police, and the military. Each public drug plan maintains its own formulary — a list of medications that the drug plan reimburses for the eligible population — and any criteria that the eligible population must meet to obtain access. Drug plans have an established decision-making framework to determine if a drug should be listed in its drug plans' formulary. Although these decisions are largely based on evidence of comparative safety and effectiveness, drug plans also must consider the cost of the drug and its potential budgetary impact and the drug plans' mandate. Since provinces and territories have different eligible populations, different budgetary considerations, and different mandates, there is variation in drug coverage across public drug plans in Canada. Such variation may affect total pharmaceutical costs to the health system, access to treatment for certain medical conditions, the degree of therapeutic choice available to prescribers, and potential health outcomes at both the patient and population level.[1] Hence, the Government of Canada has been exploring policies to address this issue of variations in access to medications. One such policy option is a national, universal pharmacare program and steps to achieve this system, including the development of a national formulary.[2]

In Canada, there are centralized processes for regulatory review for market authorization and for health technology assessments (HTAs) of drugs to inform which drugs should be listed in a drug plan's formulary. All prescription drugs are reviewed by Health Canada for their safety, efficacy, and quality before being authorized for sale (i.e., market authorization).[3] Once a drug receives market authorization from Health Canada, and should the drug sponsor decide to seek public payer reimbursement for the drug, it must undergo HTA by Institut national d'excellence en santé et en services sociaux (INESSS) for the province of Quebec and CADTH for the rest of Canada. These agencies evaluate the clinical and economic evidence on the drugs and input from relevant stakeholders, such as patients and clinicians, and make non-binding, reimbursement recommendations and advice to federal, provincial, and territorial public drug plans. Unlike a regulatory review, HTA review seeks to elucidate relative clinical efficacy and relative economic value over existing alternative treatments. Each public drug plan then makes its own reimbursement decisions — through its own jurisdictional drug review process — based on evidence-based recommendations while also considering the drug plans' mandates, priorities, and resources. Not all prescription drugs fall under CADTH's mandate, including generic drugs or biosimilars; prophylactic vaccines; drugs funded only by a hospital payer; drugs used only for diagnostic purposes; non-prescription drugs; natural health products; drugs indicated for parenteral nutrition, fluid, or electrolyte imbalance; and drugs eligible for review as a new brand within an already approved category on the Canadian Blood Services formulary. These drug products, if eligible for public payer reimbursement, are reviewed directly by the public drug plans.[4-6]

Formulary management has become increasingly important in recent years. Not only has there been a considerable number of new drug submissions in Canada (78 in Canada in 2018),[7] but there has also been a shift toward higher-cost medications. For example, the average annual treatment costs for the 20 top-selling patented medicines grew 10-fold from 2006 to 2018, up to $18,414 per patient. The share of total sales of patented medicines that

represent high-cost medicines saw a sharp increase from 5% in 2006 to 42% in 2018, despite less than 1% of the population using these medicines.[8] These trends have reaffirmed the need for prudent analysis of formulary decisions. However, there is still room for improvement. For example, despite discussion in HTA in disinvestment, payers have been hesitant to de-list medications and no formal processes for de-listing exists across the country.

Sustainability of a national, universal pharmacare program requires the development of effective national formulary management principles and processes. Hence, it would be important to understand the similarities and differences between the public drug plans' current formulary management principles and reimbursement-related decision-making frameworks and processes to explore opportunities to harmonize existing practices and to subsequently develop and maintain a robust national formulary.

Objectives

The key objective of this Environmental Scan (ES) is to identify and compare formulary management practices, including drug review processes, decision-making principles and frameworks, and committee structures, of the PT public drug plans in Canada.

This ES only includes information on Canadian PT public drug plans and does not include information about Canadian federal public drug plans (except the Non-Insured Health Benefits [NIHB] program), private payers, or any international jurisdictions. The output of this ES is this report; a future version may be published on the CADTH website.

Methods

The findings of this ES are based on information obtained from the Canadian public drug plan formulary websites. Official websites of the Canadian public drug plans were searched between November 10, 2020, and December 15, 2020. A supplemental literature search for background information was conducted in PubMed, as well as a focused internet search.

Table 1 presents information on the components of the information presented in this ES: a list of the publicly funded PT drug plans (10 provincial and 1 territorial) and the type of information gathered. Publicly reimbursed medications for residents of Nunavut and the Northwest Territories follow the coverage category and reimbursement criteria of the NIHB program.[9,10] Hence, information on NIHB formulary management practices is provided even though other federal drug plans are excluded from this ES.

Research Questions

This following research question was addressed:

- What are the similarities and differences between the formulary management practices at Canadian publicly funded PT drug plans?

Synthesis Approach

A qualitative comparison using a systematic approach was adopted to identify the similarities and differences between the formulary management practices across PT drug plans. Only an overview of the national-level and regional-level drug review process is provided to give a holistic view of factors that influence reimbursement decisions. Details of formulary management practices by PT drug plans are presented in this ES.

The focus of this ES is on the PT drug plans' decision-making processes for drugs reviewed by CADTH Common Drug Review (CDR) or CADTH pan-Canadian Oncology Drug Review (pCODR). Brief information on the PT drug plans' decision-making processes for drugs outside the mandate of CDR and pCDOR is also presented. Given that Quebec has its own reimbursement review process and does not participate in the CDR or pCODR process, brief information on INESSS and Régie de l'assurance maladie du Québec (RAMQ) are presented separately.

Findings

The findings presented are based on information obtained from the Canadian public drug plan formulary websites, collected as of December 15, 2020.The following section presents a summary of the findings relating to formulary management practices by the PT public

Table 1: Components for Information Gathering

Topic	Details
PT public drug plan formulary	• Alberta: Drug Benefit List • British Columbia: PharmaCare Formulary • Manitoba: Manitoba Drug Formulary • New Brunswick: New Brunswick Drug Plans Formulary • Newfoundland and Labrador: Prescription Drug Program Formulary • Nova Scotia: Nova Scotia Pharmacare Formulary • Ontario: Ontario Drug Benefit Formulary • Quebec: Régie de l'assurance maladie du Québec • Prince Edward Island: PEI Pharmacare Formulary • Saskatchewan: Saskatchewan Formulary • Yukon: Yukon Drug Formulary • Nunavut and Northwest Territories: NIHB
Types of information	The following aspects of the formulary management practices are presented: • Overview of national and regional drug review processes – HTA • PT drug plans decision-making process for drugs reviewed by CADTH and those that fall outside the CADTH mandate ◦ drug review committee structure and mandate ◦ drug review process, including timelines and priority reviews ◦ submission requirements

HTA = health technology assessment; NIHB = Non-Insured Health Benefits; PT = provincial and territorial.

drug plans. A public drug plan may have different drug programs under which an eligible population may be covered; for example, a chronic disease program, senior's program, and/or children's program. It should be noted that public drug plan formularies discussed subsequently may be applicable to more than 1 drug program for a given drug plan. Publicly reimbursed medications for residents of Nunavut and the Northwest Territories follow the coverage categories and reimbursement criteria of the NIHB program.[9,10] Hence, information on NIHB formulary management practices is provided even though other federal drug plans are excluded from this ES.

Overview of National and Regional Drug Review Processes

In Canada, there are some national-level processes to assess the therapeutic, economic, and societal values of a drug, which subsequently inform PT plans' reimbursement-related decisions. These processes include HTA reviews of the drugs and collective negotiations with the drug sponsor.

Once a drug receives market authorization from Health Canada, and should the sponsor decide to seek public payer reimbursement for the drug, most drugs undergo the reimbursement review process at the 2 major HTA agencies in Canada: CADTH and INESSS. These agencies evaluate the clinical and economic evidence on the drugs and input from patients and clinicians, and provide reimbursement recommendations and advice to federal, provincial, and territorial public drug plans.

CADTH Reimbursement Review: All Canadian public drug plans (except Quebec) participate in CADTH's drug review process. The purpose of CADTH's reimbursement review process is to reduce duplication across jurisdictions, maximize the use of limited resources, and enhance the consistency of drug reviews. Following the reimbursement review, CADTH issues non-binding reimbursement recommendations and/or review reports to federal, provincial, and territorial drug programs (except Quebec); cancer agencies; and Canadian Blood Services. Each drug program makes its own reimbursement decisions based on CADTH's recommendation and other factors, including the plan's mandate, jurisdictional priorities, and financial resources.[4] Appendix 1 provides information on drugs eligible for review by the CADTH reimbursement review process, CADTH Committees that make drug listing recommendations, and categories of recommendations.

Eligible drug products are reviewed by 1 of the following reimbursement review processes at CADTH:

- CADTH Process for Drugs with Expanded Health System Implications for novel products that are likely to pose substantial system-wide implementation challenges
- pCODR process for drugs used in the active treatment of cancer
- CADTH Interim Plasma Protein Product process for plasma protein products
- CDR process for all other eligible drug products.[4]

In some situations, CADTH may consult with drug programs to confirm the eligibility of a drug and make a decision on a case-by-case basis.[4] Information on the CADTH reimbursement review process is available on their website.[5] Information about INESSS is presented in the Drug Review and Decision-Making Processes in Quebec.

The majority of the new drugs that have been reviewed by, and have received a recommendation from, CADTH and/or INESSS go through a national, collective, expert-

informed negotiation process with the drug submission sponsor, through the pan-Canadian Pharmaceutical Alliance (pCPA). The mandate of pCPA is to increase access to clinically effective and cost-effective treatments, achieve consistent and lower drug costs, reduce duplications of effort, and improve consistency of decisions among participating jurisdictions. All PT drug plans are pCPA member jurisdictions. Additionally, 3 of the 6 federal drug plans, NIHB, Correctional Services Canada, and Veterans Affairs Canada also participate in the pCPA negotiation process. In addition to new drugs, the negotiation process through pCPA may also be initiated for existing drugs and line extensions. Through the pCPA negotiation process, public drug plans could achieve greater value for brand and generic drug products. Details on the pCPA negotiation process are available at on the pCPA website.[11,12] pCPA posts all decisions for all drugs for which the negotiations were unsuccessful and those that reached a negotiated price. The negotiated price is confidential and not published. Reaching a negotiated price is a critical component of a successful listing.

Drug Review Processes in the PT Drug Plans (Except Quebec)

This section discusses the decision-making processes of the PT drug plans, which have been divided into the following 2 groups:

- PT drug plans' drug review and decision-making process for drugs that are reviewed by CADTH (hereafter *CADTH-reviewed drugs*)
- PT drug plans' drug review and decision-making process for drugs that are not eligible for CADTH review.

Most drug plans have established expert committees with an advisory role that review the clinical and economic evidence on drugs and make listing recommendations for CADTH-reviewed drugs and/or drugs that fall outside the mandate of CADTH. An expert committee was identified for 7 (British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Nova Scotia, and Prince Edward Island) out of 9 public drug plans (except Quebec), and Yukon and NIHB. The number of expert committee members ranged from 6 to 16. These committees comprise mostly experts, such as physicians and pharmacists, and may also include public members to provide a lay person or patient perspective. British Columbia, Saskatchewan, and Ontario also have public members in their committees. These members are appointed and have an initial term ranging from 1 year to 3 years to ensure an adequate turnover of membership with a mix of new members and experienced members. Information on meeting schedules and/or quorum requirements (voting and decision-making) were only available for British Columbia, Saskatchewan, Ontario, and Yukon[13-21]:

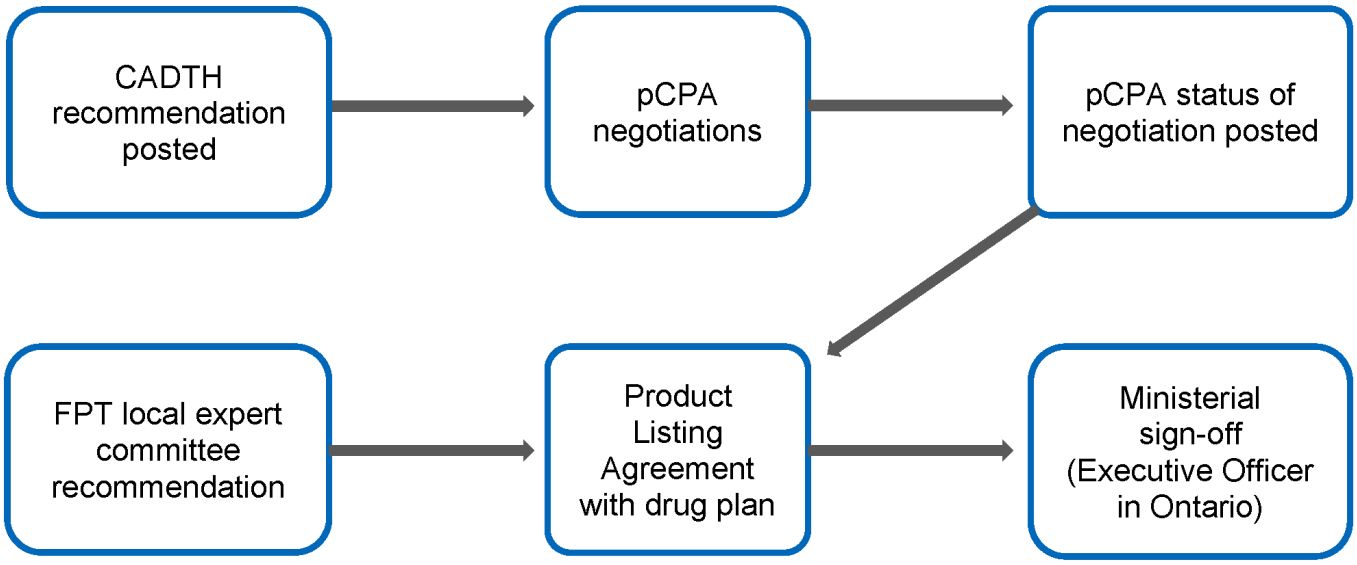
- The expert review committees in British Columbia, Alberta, Saskatchewan, Manitoba, and Yukon review and make drug listing recommendations on CADTH-reviewed drugs as well as drugs that are not eligible for CADTH review.[13,16,17,20,22]
- The expert committees in Ontario and NIHB only review and make listing recommendations on drugs not eligible for CADTH review. Ontario and NIHB rely on CADTH's review and recommendation to make listing decisions on CADTH-reviewed drugs. However, the public drug plan in Ontario may seek the expert committee's advice on drug products previously reviewed by CADTH on a case-by-case basis.[21,23,24]
- New Brunswick, Nova Scotia, Prince Edward Island, and Newfoundland and Labrador do not conduct their own review of CADTH-reviewed drugs and rely on CADTH's review and recommendation to make listing decisions on these drugs. The public drug plans in Atlantic Canada (New Brunswick, Nova Scotia, Newfoundland and Labrador and Prince Edward Island) also participate in the Atlantic CADTH Common Drug Review (ACDR)

process, which engages the Atlantic Expert Advisory Committee (AEAC), an expert review committee (there are no public members on the AEAC). ACDR only reviews and provides recommendations on drugs that are not eligible for CADTH review.[25] More details on ACDR is provided in PT Drug Plan Review Processes for Drugs Not Eligible for CADTH Review later section and in Appendix 1. The expert review committee in Nova Scotia only conducts the interchangeability review of drugs.[15] The expert review committee in Prince Edward Island makes the final decision on drug listing but does not conduct an expert review.[26]

Table 2 presents information on the structure of committees for public drug plans including their composition, appointment, term, meeting schedule, and quorum requirements (as available).

Figure 1 provides information on the formulary decision-making process framework at the drug plan level and the factors considered by the decision-maker in making the listing decision. Appendix 2 provides a list of departments within the relevant ministries that are responsible for formulary management. Note that the local expert review can occur in parallel with the CADTH and pCPA processes.

Figure 1: Formulary Decision-Making Process Framework



FPT = federal, provincial, and territorial; pCPA = pan-Canadian Pharmaceutical Alliance.
Source: Canadian public drug plan websites.[13,14,16,18,21,24,27-33]

Oncology Drugs

Drugs used in the active treatment of cancer can be administered intravenously (administered in a hospital setting) and orally (can be administered by the patient themselves at home). Drug listing decisions on IV cancer drugs administered in the hospital are generally made by the hospital payer (funded by the government) and fall outside the mandate of public drug plan formularies discussed in this ES. Ontario, an example of an exception, has established the New Drug Funding Program for Cancer Care for making listing decisions on most IV cancer drugs administered in hospitals. However, this program and the drug listing decision-making process is separate from Ontario's public drug plan discussed in this ES.[34] The drug

Table 2: Expert Review Committee Structure of Public Drug Plans

Drug plans	Name of committee	Total number of members	Expert members	Public members	Appointed by	Term	Meeting schedule	Quorum
BC	Drug Benefit Council	12 (including chair and vice-chair)	9 experts in critical appraisal of medical reports, medicine, ethics, pharmacy, and health economics	3	Minister of Health	1 to 6 years	10 meetings (and as needed)	8 voting members
AB	Expert Committee on Drug Evaluation and Therapeutics	9	9 members	0	Minister of Health	NA	NA	NA
SK	Drug Advisory Committee of Saskatchewan	14	12 HCP with expertise in family medicine, internal medicine, pharmacology, critical drug appraisal, health economics, medical ethics, community pharmacy practice, hospital pharmacy practice, and other disciplines	2	Minister of Health	3 years	Regular	Majority (50% plus 1)
MB	Manitoba Drug Standards and Therapeutics Committee	6	3 physicians and 3 pharmacists	Unknown	Minister of Health, Seniors and Active Living	NA	NA	NA
ON	Committee to Evaluate Drugs	Chair plus 16[a]	14 practising physicians, pharmacists, and an economist with expertise in a wide range of specialties, including geriatrics, infectious disease, family medicine, pharmacology, health economics, epidemiology, and other disciplines	2	Lieutenant Governor in Council	3 years	Monthly	NA
NS	Nova Scotia Drugs and Therapeutics Committee	NA	Representatives from the professions of medicine, dentistry, and pharmacy	0	NA	NA	NA	NA

Drug plans	Name of committee	Total number of members	Expert members	Public members	Appointed by	Term	Meeting schedule	Quorum
PE	Provincial Drugs and Therapeutics Committee	NA	NA	0	NA	NA	NA	NA
YT	Yukon Formulary Working Group	NA	A pharmacist, pharmaceutical program manager, program officer, and consultants as required	Unknown	Director of Insured Health Services	NA	Monthly	NA
NIHB (for NU and NT)	NIHB Drugs and Therapeutics Advisory Committee	8 to 12	First Nations or Inuit health professionals with at least 3 physicians and at least 3 pharmacists	0	NA	NA	NA	NA

AB = Alberta; BC = British Columbia; HCP = health care professional; MB = Manitoba; NA = not available; NIHB = Non-Insured Health Benefits; NS = Nova Scotia; NT = Northwest Territories; NU = Nunavut; ON = Ontario; PE = Prince Edward Island; SK = Saskatchewan; YT = Yukon.

Note: Committees were not identified for New Brunswick and Newfoundland and Labrador.

[a]The Director of the Drug Program Branch Policy and Strategy Branch is designated as the Executive Secretary and the Senior Manager, Drug Benefit Management unit of the Drug Program Policy and Strategy Branch is designated as the Senior Consultant.

Source: Canadian public drug plan websites.[13-21]

review process at Canadian PTs for all IV cancer drugs administered in the hospital is outside the scope of this scan.

All public drug plan formularies discussed in the scan are applicable to oral cancer drugs (administered at home) except for British Columbia, Alberta, and Saskatchewan. In these provinces, drug listing decisions for oral cancer drugs (administered at home) fall under the purview of provincial cancer agencies or other government drug benefit programs.[35-37] Similar to the public drug plans, these provincial cancer agencies or other government drug benefit programs also consider CADTH recommendations (through the pCODR drug review process) when making reimbursement decisions. However, further details on the drug review process for these provincial cancer agencies or other government drug benefit programs are outside the scope of this scan.

PT Drug Plan Decision-Making Processes for CADTH-Reviewed Drugs

Every participating public drug plan considers CADTH's recommendation when making drug listing decisions. However, CADTH's recommendations are non-binding and each public drug plan makes its own reimbursement decisions based on CADTH's recommendation as well as other factors, including the plan's mandate, jurisdictional priorities, and budgetary considerations.

For CADTH-reviewed drugs, none of the drug plans duplicate the review conducted by CADTH, but rather expand on them. Although the final listing decision of each drug plan is based on evidence-based recommendations from CADTH, some public drug plans have an expert review council or committee that also conducts an additional review. In their reviews, these drug plan–specific expert review committees consider CADTH's review and recommendation as well as other jurisdictional factors and make a recommendation to the final decision-maker about drug listing. Public drug plans in British Columbia, Alberta, Saskatchewan, Manitoba, and Yukon have review committees that review and make recommendations to the respective decision-maker in the jurisdiction about listing CADTH-reviewed drugs. An expert committee was not identified for New Brunswick, Nova Scotia, Newfoundland and Labrador, Prince Edward Island, Ontario, and NIHB, which review CADTH-reviewed drugs and make listing recommendations. The final decision-maker in these jurisdictions directly considers CADTH's recommendation as well as other jurisdictional factors and makes listing decisions for CADTH-reviewed drugs. Ontario, Nova Scotia, Prince Edward Island, and NIHB do have an expert review committee but they do not review CADTH-reviewed drugs. The public drug plan in Ontario may seek the expert committee's advice on drug products previously reviewed by the CADTH on a case-by-case basis.[13,14,16,18,21,24,27-33]

The CADTH recommendations and the clinical and economic reports are posted on the CADTH website. pCPA posts the status and decisions of negotiations. The individual drug plans post the list of newly reimbursed drugs.

Table 3 provides information on the review and/or advisory role of the PT drug committees for CADTH-reviewed drugs and the factors considered by the committee in making their recommendation.

Table 3: Review and Advisory Role of the Expert Committees for CADTH-Reviewed Drugs

Drug plan	Review and advisory role of the committee	Factors considered by the committee in making the recommendation (if available)
British Columbia	DBC: Screen drugs to determine if they are first in class[a] or similar[b] drugs as other PharmaCare drugs: • For first in class drugs: conducts full review[c] through DRRC[d,e] (most cases) and makes listing recommendation including criteria and condition • For similar drugs: advises PharmaCare to accept CADTH recommendation (most cases) Pharmacare internal review (without involving DBC): reviews the submission of a drug for which DBC decides not to conduct a full review and makes listing recommendation	For first in class drugs: • clinical effect of the drug and health outcomes (CADTH and/or DRRT clinical evidence review reports) • whether it is good value for British Columbians (based on CADTH and/or DRRT pharmacoeconomic review reports) • whether PharmaCare already covers any drugs that work as effectively as this 1 • CADTH reports (if available) • ethical considerations • CADTH-gathered patient input; drug sponsor responses to the CADTH Recommendation and Reasons for Recommendation • public input to PharmaCare's Your Voice web page For similar drug: CADTH recommendation (most cases) Pharmacare internal review (without involving DBC): CADTH recommendation
Alberta	ECDET conducts a review and makes listing recommendation	• Criteria for Listing Drug Products (Appendix 3); CADTH recommendations
Saskatchewan	DACS conducts a review and makes listing recommendation	• CADTH recommendation • Clinical evidence • Pharmacoeconomic analysis and Saskatchewan budget impact analysis • Other expert review information • Perspective of a health care program payer within a publicly funded health care system • Perspective of the public and/or patient and other jurisdictional factors
Manitoba	DSTC conducts a review and makes listing recommendation	• CADTH recommendation • Reviews of the scientific literature • Comparable drug therapies • Anticipated drug costs • Therapeutic benefits

Drug plan	Review and advisory role of the committee	Factors considered by the committee in making the recommendation (if available)
Ontario	CED does not conduct a routine review of CADTH-reviewed drugs; the Ontario Public Drug Programs may seek CED's advice on drug products previously reviewed by CADTH on a case-by-case basis	• CADTH recommendation • Considering current formulary listings • Need for clinical criteria • Population served by the ODB program
Atlantic	NA	• NA
Yukon	Yukon Formulary Working Group conducts a review and makes listing recommendation	• CADTH recommendation other jurisdictional factors

CDEC = CADTH Canadian Drug Expert Committee; CED = Committee to Evaluate Drugs, DACS = Drug Advisory Committee of Saskatchewan; DBC = Drug Benefit Council; DRRC = Drug Review Resource Committee; DRRT = Drug Review Resource Teams; ECDET = Expert Committee on Drug Evaluation and Therapeutics; MBSTC = Manitoba Drug Standards and Therapeutics Committee; NA = information not available; NIHB = Non-insured Health Benefit; ODB = Ontario Drug Benefit; pCODR = CADTH pan-Canadian Oncology Drug Review; pCPA = pan-Canadian Pharmaceutical Alliance; pERC = pCODR Expert Review committee.

Note: Expert review committees (if present) in New Brunswick, Nova Scotia, Newfoundland and Labrador, and NIHB do not conduct a review of CADTH-reviewed drugs. The final decision-maker at these drug plans (Table 3) directly considers the CADTH recommendation and other jurisdictional factors to make drug listing decisions for CADTH-reviewed drugs.

[a]First in class drug can be a new chemical entity that works a different way than drugs previously reviewed, a new combination of existing drugs (with significantly different ingredients), an existing drug that is now being used for a new indication, or a subsequent entry biologic.

[b]A similar drug is, for example, a drug that belongs to a previously reviewed group of drugs that work the same way and are used to treat the same indication as previously reviewed drugs.

[c]A full review by DBC entails consideration of input from the following when conducting the review: any British Columbia resident who has the illness or condition that a drug will be used to treat, their caregivers, British Columbia patient advocacy groups that represent British Columbia residents who have the illness or condition, practising British Columbia clinicians with specific expertise with the drug or the illness it is used to treat, and manufacturers/drug submission sponsors.

[d]The DRRC, a sub-committee of the DBC, establishes the review requirements, including the type of clinical reports and other inputs available and required for a review of each drug submission. The DRRC assigns expert review teams, called DRRTs, to complete the required reports for each submission.

[e]A standard review is 9 months and a complex review is 12 months. A review is complex if there is a need to develop clinical coverage criteria, create a Special Authority form, complete a Product Listing Agreement, or other such steps. For other patented drug submissions, including line extensions, coverage status, and blood glucose test strips, the review start date will be the date the complete submission is received by the Ministry. If CDR conducts a review, the Ministry's review generally follows an internal 9-month timeline. For non-CDR drug submissions, the Ministry's review generally follows a 12-month timeline.

Source: Canadian public drug plan websites.[13,14,16,18,21,24,27-33]

Review Process

Details of a full review process were identified only for British Columbia. Although it does not duplicate the review conducted by CADTH, British Columbia conducts a full review of select CADTH-reviewed drugs. These are drugs that that the expert review committee screens as a first in class drug. British Columbia defines a first in class drug as "(i) a new chemical entity that works a different way than drugs previously reviewed, (ii) a new combination of existing drugs (with significantly different ingredients), (iii) an existing drug that is now being used for a new indication, or (iv) a 'Subsequent Entry Biologics' (SEB)."[32] The review entails an expert team review (by a sub-committee and expert team of DBC). The drug plan has a formal process to gather input from relevant patient (groups), clinicians, and manufacturers to inform the full review.[32] Further details are provided in Table 3.

Submission Requirements

When making an application for a drug listing to CADTH, sponsors are required to make separate submissions to all the drug plans that they seek reimbursements from. All 9 provincial drug plans and NIHB require a sponsor to provide a jurisdiction-specific budget impact assessment before pCPA negotiations (before the CADTH expert committee meeting). In addition to the technical documentation required for CDR (clinical evidence and pharmacoeconomic analysis), sponsors may be required to provide pricing information and confirmation of their ability to supply and consent to submitting Periodic Safety Update Reports (submitted to Health Canada) to the drug plan and to unrestricted sharing of information regarding the drug review between public drug plans, CADTH, and other relevant government agencies.[14,16,21,22,27,29,33,38-40] Details of submission requirements were not available for Yukon.

Decision-Making Factors

In addition to CADTH and the PT drug plans' expert committee recommendations (as applicable), the final decision-maker at the Ministries of Health also considers other jurisdictional factors, such as the plan's mandate, priorities, and resources, when making listing decisions. Ontario, British Columbia, and NIHB explicitly outline these jurisdictional factors, which could include needs of the eligible population, existing drug plan policies about the class of drugs, which program within the drug plan should cover the drug, whether the drug plan has the resources to cover the cost of the drug (budget consideration and/or sustainability), and results of pCPA negotiation (if any) (Table 3).[21,24,32,33] In addition, criteria or policies for formulary listings were identified for Alberta and Saskatchewan, which also influence the listing decisions (Appendix 3). These criteria apply to both CDR and pCODR drugs and non-CDR and non-pCODR drugs.[22,29]

PT Drug Plan Review Processes for Drugs Not Eligible for CADTH Review

CADTH was given a specific mandate by the federal, provincial, and territorial governments (FPTs) and associated funding; therefore, not all prescription drugs are eligible for a CADTH review. Drugs that are not eligible for review by CADTH include line extensions, generics, biosimilars, and modifications to current coverage status.

- **Line extensions:** These are considered to be submissions for new strengths, delivery mechanisms, or dosage forms of a covered drug listed on the formulary.

- **Biosimilar**: A biosimilar (previously referred to as *subsequent entry biologic*) is a drug product demonstrated to be highly similar to a biologic drug that has previously been authorized for sale in Canada (reference biologic drug). Biosimilars are approved by Health Canada based on a thorough comparison to a reference biologic drug. A biosimilar and a reference biologic drug can be shown to be similar, but not identical.
- **Modification of current coverage status:** Drug sponsors may request to change the current coverage of a drug. Requests to modify the coverage status of a drug generally apply to drugs not eligible for a CADTH review when new and relevant clinical information has become available.[22]

Expert review committees in British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, and NIHB conduct a review of these types of drug submissions and make recommendations to the final decision-making body.[16,21,29,32,33,36] Provincially funded drug plans in Atlantic Canada (New Brunswick, Nova Scotia, Newfoundland and Labrador, and Prince Edward Island) participate in the ACDR process, which assesses the clinical effectiveness and cost-effectiveness of drugs that do not fall under the mandates of CADTH. Like CADTH, ACDR provides formulary listing recommendations to the provincially funded drug plans in Atlantic Canada. Additionally, ACDR also reviews and provides formulary listing recommendations, online extensions, resubmissions for products not previously reviewed by CDR, currently listed drugs, and drug classes.[25] Appendix 1 provides information on drugs eligible for review by the ACDR reimbursement review process and AEAC, ACDR's expert review committee that makes drug listing recommendations. Further details on the ACDR process is available at the ACDR website.[25] Information on Yukon was not available. The final decision-making body and the factors they consider for making listing decision for drugs not eligible for CADTH review are the same as that for CADTH-reviewed drugs.

Some drug plans (Alberta, Saskatchewan, Manitoba, Ontario, Newfoundland and Labrador, and Nova Scotia) conduct an interchangeability review.[16,24,29,33,36,41-43] Drug products designated as interchangeable (e.g., generics) are expected to be safe when switched with other drug products in the interchangeable grouping, and to have the same therapeutic effectiveness when administered to patients under the conditions specified in the labelling.[22] The decision of interchangeability of generic drugs largely falls under the FPT mandate (in some cases with pharmacists) and they have different rules across drug plans. The final decision-making body and the factors they consider for making listing decision for drugs not eligible for CADTH review are often the same as that for CADTH-reviewed drugs.

Table 4 provides information on the different categories of drugs reviewed by the drug plan that are not eligible for CADTH review (i.e., drugs that are outside the mandate of CADTH). Table 5 provides information on the review and/or advisory role of the drug committees for drugs not eligible for CADTH review including interchangeability reviews.

Each drug plan has specific submission requirements for the drugs not eligible for CADTH review. Appendix 4 provides links to the submission requirements and/or checklist. Most drug plans appear to review drug submissions on a first-come, first-served basis; submission deadlines were only identified for Alberta.[44]

Review Timelines and Priority Review

Review Timelines

Review timelines were not identified for the review conducted by expert committees of the drug plans except for British Columbia and Ontario. Local reviews may be done in parallel

Table 4: Drugs Reviewed by the Drug Plans That Are Not Eligible for CADTH Review

Drug plans	Drugs reviewed
British Columbia	• Biosimilars • Modification to current coverage • Line extensions • Generic products
Alberta	• New Chemical Entities or New Combination Products in which 1 or more of the active moieties have never been listed on the List, and other single source Drug Products that have never been listed on the List and are not eligible for review under the CDR Procedure • Changes to special authorization or restricted benefit status of listed single source drug products due to a new indication • Line extension drug products resubmission • Interchangeable drug products (expedited and full review) • Non-interchangeable old drug products[a] • Biosimilar drug products • Resubmissions
Saskatchewan	• Single source products that do not contain new chemical entities • Line extension products • Interchangeable product submissions • Drug products without a Canadian reference product
Manitoba	• All generic drug products, including pseudo-generics (including for interchangeability grouping) • Old drug products (including for interchangeability grouping) • Line extension products • **Changes to benefit status of listed single source drug products due to a new indication**

Drug plans	Drugs reviewed
Ontario	• Single source products that do not contain new chemical entities • Brand line extension products • Drug products without official product monograph • Pseudogeneric products • Interchangeable product • Over-the-counter drug products • Special drugs program products • Off-Formulary Interchangeability drug products.
ACDR (for NB, NS, NL, PE)	• New drug products that do not fall under the mandates of CDR or pCODR • Biosimilar (non-oncology indications only) • Line extensions • Resubmissions
Atlantic	• Interchangeability (for NS and NL only)
Yukon	• NA
NIHB (for NU and NT)	• Line extensions • Generics • All other submissions

ACDR = Atlantic CADTH Common Drug Review; CDR = CADTH Common Drug Review; NA = information not available; NB = New Brunswick; NIHB = Non-Insured Health Benefits; NL = Newfoundland and Labrador; NS = Nova Scotia; NT = Northwest Territories; NU = Nunavut; pCODR = CADTH pan-Canadian Oncology Drug Review; PE = Prince Edward Island.

[a]Non-Interchangeable Old Drug Products are drug products where the active moiety or moieties are designated as an "Old Drug" by Health Canada and evidence to support interchangeability CANNOT be provided. The Drug Product is approved on the basis of a Drug Identification Number application (i.e., a Notice of Compliance is not issued by Health Canada).

Source: Canadian public drug plan websites.[16,21,22,25,29,33,42,43,45,46]

Table 5: Review and Advisory Role of the Expert Committees for Drugs That Are Not Eligible for CADTH Review and Review for Interchangeability

Drug plans	Review and advisory role of the committee for drugs not eligible for CADTH Review	Review and advisory role of the committee for interchangeability
British Columbia	**Pharmacare:** reviews internally (without involving DBC), and make decisions on submissions for line extensions **DBC:** reviews the submissions for modifications to coverage criteria[a] and makes reimbursement-related recommendations Biosimilars: same process as for drugs reviewed through CDR or pCDOR	Does not fall under the purview of drug plan
Alberta	**ECDET**: reviews and provides recommendations on products not eligible for CDR review	**Alberta Blue Cross[b]:** screens submissions to determine if the drug should go though the Expedited Review or Full Review; products deemed eligible for Expedited Review are recommended directly to Alberta Health **ECDET**: reviews and provides recommendation on products not eligible for Interchangeable Expedited Review (i.e., those requiring Full Review)
Saskatchewan	**DACS**: reviews submissions and makes listing recommendations	**Executive Director of drug plan:** makes final decision on interchangeable generic drugs (for majority of the drugs) **DACS**: reviews and makes listing recommendation on complex interchangeable drug submissions
Manitoba	**MDSTC:** reviews and makes listing recommendation	**MDSTC:** reviews and makes listing recommendation
Ontario	**CED:** Reviews and makes listing recommendation	**CED**: reviews and makes listing recommendation
New Brunswick	Participates in ACDR process (recommendation from AEAC)	Does not fall under the purview of drug plan, but rests with pharmacists
Nova Scotia	Participates in ACDR process (recommendation from AEAC)	**Nova Scotia Drugs and Therapeutics Committee:** reviews and makes listing recommendation
Newfoundland and Labrador	Participates in ACDR process (recommendation from AEAC)	A professional committee, appointed by the Minister of Health and Community Services in consultation with the Newfoundland and Labrador Medical Association and the Pharmacist's Association of Newfoundland and Labrador, advises the Minister on matters relating to the Newfoundland and Labrador Interchangeable Drug Products Formulary
Prince Edward Island	Participates in ACDR process (recommendation from AEAC)	Does not fall under the purview of drug plan

Drug plans	Review and advisory role of the committee for drugs not eligible for CADTH Review	Review and advisory role of the committee for interchangeability
Yukon	NA	Health Canada's Notice of Compliance and Declaration of Equivalence are reviewed for designation of interchangeability
NIHB (for NU and NT)	**NIHB's DTAC:** reviews and makes listing recommendation (may also be reviewed internally by NIHB without involving DTAC)	Interchangeability is determined as per provincial or territorial drug plan formularies

ACDR = Atlantic CADTH Common Drug Review: AEAC = Atlantic Expert Advisory Committee; CDR = CADTH Common Drug Review; CED = Committee to Evaluate Drugs; DACS = Drug Advisory Committee of Saskatchewan; DTAC = Drugs and Therapeutics Advisory Committee; DBC = Drug Benefit Council; ECDET = Expert Committee on Drug Evaluation and Therapeutics; MBSTC = Manitoba Drug Standards and Therapeutics Committee; NA = information not available; NIHB = Non-insured Health Benefit; NT = Northwest Territories; NU = Nunavut; pCODR = CADTH pan-Canadian Oncology Drug Review.

[a]If a drug has already been reviewed by CDR, then CDR would need to review any changes to drug coverage before PharmaCare would initiate a review.

[b]Alberta Blue Cross is the body which adjudicates drug claims on behalf of Alberta Health and who acts as secretariate for drug submissions from sponsors.

Source: Canadian public drug plan websites.[13,14,16,18,21,24,25,27-33]

with CADTH's review, pCPA's negotiation, or during the product listing agreement with the manufacturer. For CADTH-reviewed drugs, the review timeline in British Columbia was 9 to 12 months (for full review).[32] In Ontario, for drugs not eligible for CADTH review, the timeline for review and recommendation ranged from 2 months to 4 months after a complete submission, and may be longer for complex submission.[33]

Priority Review

A process for a priority review of drug submissions was identified for British Columbia and Alberta. In British Columbia, a drug submission may be given priority status if it meets a significant clinical need or if it shows major therapeutic benefit or shows substantial economic benefit. The timeline for such priority drug reviews is 6 months for standard submissions or 9 months for complex submissions.[47] In Alberta, products not eligible for review under CDR procedures may, at the sole discretion of Alberta Health and/or the Minister, be considered for priority review and possible addition to the formulary list if the product submission is otherwise complete and the product has been granted Priority Review status by Health Canada.[22]

Drug Review and Decision-Making Processes in Quebec

INESSS evaluates new therapies (drugs and technologies) from a scientific, economic, organizational, ethical, and societal perspective, and makes recommendations to the Minister of Health and Social Services for the purpose of updates to the List of Medications.[6] The List of Medications is a regulatory list of the medications covered by Quebec's basic prescription drug insurance plan.[48] Based on the recommendation, the Minister determines whether the drug — for which a sponsor has made a request — should be listed (and any appropriate terms and conditions) or not. This decisions result in updates of the List of Medications of the public plan, which is published and administered by RAMQ.[6] Appendix 1 provides information on the drugs eligible for review by INESSS's reimbursement review process, and the Comité scientifique de l'évaluation de médicaments aux fins d'inscription (CSEMI),

INESSS's expert review committee that makes drug listing recommendations and categories of recommendations.

INESSS carries out its drug evaluation mandate based on 5 parameters: therapeutic value, reasonableness of the price charged, cost-effectiveness ratio of the medication, impact of adding the medication to the list on the health of the population and on the other components of the health and social services system, and advisability of adding the medication to the list with regard to the purpose of the public plan. The purpose of the basic plan is to ensure that all persons in Quebec have reasonable and fair access to the medication required by their state of health. For the purpose of making its recommendations, INESSS's 6 criteria that enable it to take into account all 5 parameters are identification of the unmet health need in the intended patient population and the determination of the level of this need, the drug's ability to confer a clinical benefit, the drug's efficiency, the level of impact of the medical condition and on the health of the general population, the drug's level of burden on the system's budget, and the system's organizational ability to offer the drug.[6] Further information on INESSS's reimbursement review process is available information on INESSS' reimbursement review can be found on their website.[6]

Limitations

Formulary management practices presented in this report are current up December 15, 2020 (i.e., the date of the final search of the drug plans' websites). These findings are relevant to the Canadian PT public drug plans and did not include information about Canadian federal public drug plans (except NIHB), private insurers, or any international jurisdictions.

There was a lack of information on review timelines for all drug plans. There was also limited information available about committee structure for some drug plans (Alberta, Manitoba, Nova Scotia, Prince Edward Island, Yukon, and NIHB). Expert review committees were not identified for Nova Scotia and Newfoundland and Labrador. It is unknown if such expert committees exist in these jurisdictions or if the information is not available publicly. There is also a lack of specifics on the jurisdictional factors (the plan's mandate, priorities, and resources) considered by decision-makers in New Brunswick, Nova Scotia, Newfoundland and Labrador, Prince Edward Island, and Yukon when making listing decisions. The public drug plan formularies in British Columbia, Alberta, and Saskatchewan discussed in this ES are not applicable to oral cancer drugs (administered at home).

Summary of the Evidence and Implications for Policy-Making

Public drug plans' reimbursement decisions regarding most new drugs are based on CADTH recommendations, which then advise pCPA negotiations and may also be subject to local reviews before a formulary listing decision is made. These local decision-making processes can be generalized into 2 schemes which appear to have a geographic divide (Western versus Eastern Canada):

1. Local expert committees review all new drug submissions (both within and outside the scope of CADTH). A full expert review of all drugs is conducted by British Columbia, Alberta, Saskatchewan, Manitoba, Quebec, and Yukon. These reviews can supersede a CADTH recommendation or can be used to suggest reimbursement criteria that reflect local clinical practice (e.g., Alberta, Saskatchewan), and Quebec does not participate in CADTH altogether. The timing of these reviews can run concurrently with ongoing CADTH and pCPA processes and may or may not be used in consideration of a final decision.
2. Local expert committees only review drug submissions that are out of scope for CADTH. For Ontario, NIHB, and the Atlantic provinces, expert committees are tasked with providing advice for drug submissions that fall outside the scope of CADTH, such as line extensions, pediatric submissions, and biosimilars.

The rationale for these 2 schemes of advising local formulary decision-making processes is likely a function of historical precedence. Most payers would have developed expert committees at or before the era when CADTH was used prominently for pan-Canadian decisions. Prior to CADTH and pCPA, there was limited collaboration among PTs regarding drug plans, which necessitated local processes. As CADTH has taken on more capacity to conduct reviews, some PTs have chosen to reallocate local resources, whereas some have preferred to maintain existing workflow. Moreover, CADTH once assessed different types of submissions (including biosimilars and line extensions), which later fell out of scope and has necessitated continued need for local expert committee advice for these decision-making processes.

The advantages of PTs maintaining local experts to advise decision-making is that there is greater autonomy and ability to apply the lens of local clinical practice and jurisdictional priorities. The disadvantage of such decentralization in expert advice is the increased probability that decisions are not harmonized across the country, potentially leading to different listing statuses or reimbursement criteria. There may also be redundancy in efforts between local expert committees and CADTH which may impact timelines for final decisions.

In the context of developing a framework for decision-making for a national pharmacare program, it would be prudent for all PTs to follow a consistent process to maximize formulary harmonization and reduce redundancies. There are 3 options for policy-makers (Table 6): align the country to the Western model (i.e., local expert committees review all drugs), align the country to the Eastern model (i.e., local expert committees review drugs out of scope for CADTH), or align the country to a centralized model in which the scope of CADTH is increased in lieu of local expert committees. Each of these policy choices have trade-offs between local autonomy and resource efficiency. Perhaps autonomy and efficiency could be maximized in a model in which PTs could input their local jurisdictional needs to a centralized process, which would maximize efficiency by requiring fewer overall resources. However, if efficiency is not a key driver, at least the prospect of greater harmonization in listing status and reimbursement criteria could be sufficient rationale for a centralized process.

Table 6: Summary of Policy Options for Decision-Makers in Aligning Local Decision-Making Processes

Policy option	Description	Pros	Cons
Western model (i.e., BC, AB, MB, SK, NIHB)	Individual provinces use expert committees to review all drug product submissions, both within and outside the scope of CADTH	• Opportunity to incorporate local clinical practice • Opportunity to review criteria based on local treatment options and alternatives • Efficiency due to higher scale of reviews • Greater autonomy for decisions	• Potential redundancy of work with CADTH • Misalignment of timelines with other pan-Canadian initiatives such as pCPA • Potential for misalignment in decisions across FPTs
Eastern model (i.e., ON, Atlantic Canada)	Individual provinces use expert committees to review drug product submissions out of scope for CADTH	• More efficiency vs. Western model in that committees focus on providing recommendations to decision-makers without CADTH guidance • Less autonomy in decisions for products in scope for CADTH • More alignment across FPTs	• Fewer submissions means less efficiency of scale for committees and reviews • Less autonomy for drug recommendations and potential for less local feedback
Centralized model (CADTH)	Increase scope of CADTH and have local expert committees provide more regional feedback	• Increased harmonization of decisions and timelines across FPTs • Alignment of best practices across expert committees (e.g., patient input processes)	• Increased demand of CADTH reviews will limit capacity without increased funding • Loss of autonomy for local reviews despite inclusion of feedback to CADTH process

AB = Alberta; BC = British Columbia; FPT = federal, provincial, and territorial governments; MB = Manitoba; NIHB = Non-insured Health Benefit; ON = Ontario; pCPA = pan-Canadian Pharmaceutical Alliance; SK = Saskatchewan.

References

1. Morgan SG, Daw JR, Greyson D, Shnier A, Holbrook A, Lexchin J. Variation in the prescription drugs covered by health systems across high-income countries: a review of and recommendations for the academic literature. *Health Policy.* 2020;124(3):231-238. PubMed
2. House of Commons Debates: 43rd Parliament, 2nd Session, Volume 150, No. 001. Ottawa (ON): Parliament of Canada; 2020 Sep 23: https://www.ourcommons.ca/DocumentViewer/en/43-2/house/sitting-1/hansard#Int-10932397 Accessed 2020 Dec 02.
3. How are drugs reviewed in Canada. Ottawa (ON): Health Canada; 2015: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fact-sheets/drugs-reviewed-canada.html. Accessed 2020 Dec 02.
4. Procedures for CADTH reimbursement reviews. Ottawa (ON): CADTH; 2020: https://cadth.ca/sites/default/files/Drug_Review_Process/CADTH_Drug_Reimbursement_Review_Procedures.pdf. Accessed 2020 Dec 14.
5. CADTH reimbursement reviews. Ottawa (ON): CADTH; 2020: https://cadth.ca/cadth-reimbursement-reviews. Accessed 2020 Dec 14.
6. Aubin M-C, Boulanger M, Brouard M-È, Hotte M. Evaluation of drugs for listing purposes: a change of approach. Montreal (QC): INESSS; 2018: https://www.inesss.qc.ca/fileadmin/doc/INESSS/Inscription_medicaments/Processus/Evaluation_of_drugs_a_change_of_approach.pdf. Accessed 2020 Dec 02.
7. Canada H. Drug and Medical Device Highlights 2018. 2019.
8. Board PMPR. Annual Report: 2018. 2018.
9. Extended Health Benefits for Specified Disease Conditions Program. Inuvik (NT): Government of Northwest Territories; 2020: https://www.hss.gov.nt.ca/en/services/supplementary-health-benefits/extended-health-benefits-specified-disease-conditions. Accessed 2020 Dec 02.
10. EHB Full Coverage Plan. Rankin Inlet (NU): Nunavut Department of Health; 2020: https://gov.nu.ca/health/information/ehb-full-coverage-plan. Accessed 2020 Dec 02.
11. The negotiation process. Toronto (ON): pan-Canadian Pharmaceutical Alliance (pCPA); 2020: https://www.pcpacanada.ca/negotiation-process. Accessed 2020 Dec 10.
12. About pCPA. Toronto (ON): pan-Canadian Pharmaceutical Alliance (pCPA); 2020: https://www.pcpacanada.ca/about. Accessed 2020 Dec 10.
13. Yukon Drug Formulary - preamble. Whitehorse (YT): Government of Yukon; 2020: https://ihs.gov.yk.ca/drugs/f?p=161:9000::PRINT_PREAMBLE:NO:::&cs=3etdc_nWifLhlYI99lzvbreG9CBY. Accessed 2020 Nov 14.
14. P.E.I. Pharmacare Formulary. Charlottetown (PE): Health PEI; 2020: https://www.princeedwardisland.ca/sites/default/files/publications/pei_pharmacare_formulary.pdf. Accessed 2020 Nov 14.
15. Nova Scotia Drugs and Therapeutics Committee. Halifax (NS): Government of Nova Scotia; 2020: https://novascotia.ca/dhw/pharmacare/nova-scotia-drug-therapeutic-committee.asp. Accessed 2020 Nov 14.
16. Manitoba Drug Formulary review process. *Manitoba Drug Benefits and Interchangeability Formulary*. Winnipeg (MB): Manitoba Health and Seniors Care; 2020: https://www.gov.mb.ca/health/mdbif/review.html. Accessed 2020 Nov 16.
17. Drug Advisory Committee of Saskatchewan: terms of reference. Regina (SK): Government of Saskatchewan; 2016: https://formulary.drugplan.ehealthsask.ca/PDFs/DACS_TOR_Apr_2016.pdf. Accessed 2020 Nov 14.
18. Alberta Drug Benefit List: submission for drug reviews. Edmonton (AB): Government of Alberta; 2020: https://www.ab.bluecross.ca/dbl/pdfs/dbl_sec1_drug.pdf. Accessed 2020 Nov 15.
19. Committee To Evaluate Drugs. Toronto (ON): Government of Ontario; 2020: https://www.pas.gov.on.ca/Home/Agency/262. Accessed 2020 Nov 18.
20. Drug Benefit Council - terms of reference. Victoria (BC): BC Ministry of Health; 2010: https://www2.gov.bc.ca/assets/gov/health/health-drug-coverage/pharmacare/dbc-termsofref.pdf. Accessed 2020 Nov 14.
21. Non-Insured Health Benefits: drug benefit list. Ottawa (ON): Indigenous Services Canada; 2020: https://www.sac-isc.gc.ca/DAM/DAM-ISC-SAC/DAM-HLTH/STAGING/texte-text/nihb_benefits-services_drugs_dbl-index_1573154657223_eng.pdf. Accessed 2020 Dec 24.
22. Alberta Drug Benefit List: introduction. Edmonton (AB): Government of Alberta; 2020: https://www.ab.bluecross.ca/dbl/pdfs/dbl_sec1_intro.pdf. Accessed 2020 Nov 15.
23. How drugs are considered: funding decisions. The Committee to Evaluate Drugs (CED). Toronto (ON): Ontario Ministry of Health and Ministry Long Term Care; 2013: https://www.health.gov.on.ca/en/pro/programs/drugs/how_drugs_approv/funding_ced.aspx. Accessed 2020 Nov 18.
24. Ontario Public Drug Programs. Ontario drug benefit: how drugs are considered. Toronto (ON): Ontario Ministry of Health and Ministry of Long Term Care; 2018: http://www.health.gov.on.ca/en/pro/programs/drugs/how_drugs_approv/how_drugs_approv.aspx#5 Accessed 2020 Nov 18.
25. Atlantic Common Drug Review. Halifax (NS): Government of Nova Scotia; 2020: https://novascotia.ca/dhw/pharmacare/atlantic-common-drug-review.asp. Accessed 2020 Nov 14.
26. PEI Pharmacare Formulary. Charlottetown (PE): Health PEI; 2020: https://www.princeedwardisland.ca/en/information/health-pei/pei-pharmacare-formulary?utm_source=redirect&utm_medium=url&utm_campaign=formulary. Accessed 2020 Nov 14.
27. NLPDP Provider Guide. Appendix C – Drug Benefit Review Process St. John's (NL): Health and Community Services, Government of Newfoundland and Labrador; 2020: https://www.gov.nl.ca/hcs/files/prescription-provider-guide-appendix-c.pdf. Accessed 2020 Nov 14.
28. New Brunswick Drug Plans drug review process. Fredericton (NB): Government of New Brunswick; 2020: https://www2.gnb.ca/content/gnb/en/departments/health/MedicarePrescriptionDrugPlan/NBDrugPlan/ForHealthCareProfessionals/DrugReviewProcess.html. Accessed 2020 Nov 14.

29. Saskatchewan Formulary: preface. Regina (SK): Government of Saskatchewan; 2017: https://formulary.drugplan.ehealthsask.ca/PDFs/PREFACE_Updated_March_1_2017.pdf. Accessed 2020 Nov 14.
30. The drug review process in B.C. - overview. Victoria (BC): BC Ministry of Health; 2020: https://www2.gov.bc.ca/assets/gov/health/health-drug-coverage/pharmacare/drugrevproc2.pdf. Accessed 2020 Nov 14.
31. Nova Scotia Pharmacare: benefits and reimbursement. Halifax (NS): Government of Nova Scotia; 2020: https://novascotia.ca/dhw/pharmacare/benefits-and-reimbursement.asp. Accessed 2020 Nov 14.
32. The drug review process in B.C. - detailed. Victoria (BC): BC Ministry of Health; 2020: https://www2.gov.bc.ca/assets/gov/health/health-drug-coverage/pharmacare/drugrevproc.pdf. Accessed 2020 Nov 14.
33. Drug submissions: Ontario guidelines for drug submission and evaluation Toronto (ON): Ontario Ministry of Health and Ministry of Long-Term Care; 2016: https://www.health.gov.on.ca/en/pro/programs/drugs/drug_submissions/guide_submission_evaluation.aspx. Accessed 2020 Nov 18.
34. Publicly Funded Drug Programs: New Drug Funding Program for Cancer Care. Toronto (ON): Ontario Ministry of Health and Ministry of Long-Term Care; 2019: http://www.health.gov.on.ca/en/pro/programs/drugs/funded_drug/fund_new_drug.aspx#:~:text=The%20New%20Drug%20Funding%20Program,cancer%20drugs%20administered%20in%20hospitals Accessed 2021 Jan 15.
35. Frequently Asked Questions. Regina (SK): Saskatchewan Cancer Agency; 2018: http://www.saskcancer.ca/health-professionals-article/frequently-asked-questions-health-professionals. Accessed 2021 Jan 15.
36. Drug benefit list and drug review process. Edmonton (AB): Government of Alberta; 2020: https://www.alberta.ca/drug-benefit-list-and-drug-review-process.aspx. Accessed 2020 Nov 15.
37. BC Cancer. Drug Funding. 2021; http://www.bccancer.bc.ca/health-professionals/clinical-resources/pharmacy/drug-funding. Accessed 2021 Jan 15.
38. Nova Scotia Pharmacare. Halifax (NS): Government of Nova Scotia; 2020: https://novascotia.ca/dhw/pharmacare/expert-committees.asp. Accessed 2020 Nov 14.
39. Patented Drugs submission checklist. Victoria (BC): BC Ministry of Health; 2019: https://www2.gov.bc.ca/assets/gov/health/practitioner-pro/patented_drugs_checklist.pdf. Accessed 2020 Nov 14.
40. Brand Drug submission requirements. Fredericton (NB): Government of New Brunswick; 2020: https://www2.gnb.ca/content/gnb/en/departments/health/MedicarePrescriptionDrugPlan/TheNewBrunswickPrescriptionDrugProgram/BrandDrugSubmissionRequirements.html. Accessed 2020 Nov 14.
41. Submission requirements. *Manitoba Drug Benefits and Interchangeability Formulary*. Winnipeg (MB): Manitoba Health and Seniors Care; 2020: https://www.gov.mb.ca/health/mdbif/sub.html. Accessed 2020 Nov 16.
42. Introduction to the Newfoundland and Labrador Interchangeable Drug Products Formulary (NIDPF). St. John's (NL): Health and Community Services, Government of Newfoundland and Labrador; 2020: https://www.gov.nl.ca/hcs/prescription/idf-intro/. Accessed 2020 Nov 14.
43. Nova Scotia Pharmacare: interchangeable products. Halifax (NS): Government of Nova Scotia; 2020: https://novascotia.ca/dhw/pharmacare/interchangeable-products.asp. Accessed 2020 Nov 14.
44. Drug manufacturer submission deadlines. Edmonton (AB): Government of Alberta; 2020: https://www.ab.bluecross.ca/dbl/submission-deadlines.php. Accessed 2020 Nov 15.
45. Submitting patented drugs and biosimilars. Victoria (BC): BC Ministry of Health; 2020: https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/health-industry-professionals/submitting-patented-drugs-biosimilars. Accessed 2020 Nov 14.
46. Submitting generic drug products. Victoria (BC): BC Ministry of Health; 2020: https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/health-industry-professionals/submitting-generic-drug-products. Accessed 2020 Nov 14.
47. 6.5 Drug review process. Victoria (BC): BC Ministry of Health; 2020: https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/pharmacare-publications/pharmacare-policy-manual-2012/understanding-pharmacare-benefit-status/drug-review-process Accessed 2020 Nov 14.
48. List of medications. Quebec (QC): Government of Quebec; 2020: https://www.ramq.gouv.qc.ca/en/about-us/list-medications. Accessed 2020 Dec 02.
49. CADTH Canadian Drug Expert Committee: terms of reference. Ottawa (ON): CADTH; 2020: https://www.cadth.ca/sites/default/files/corporate/corp_committees/CDEC%20TORs%20-%20%20June%2025%202020.pdf. Accessed 2020 Dec 14.
50. CADTH pan-Canadian Oncology Drug Review Expert Review Committee: terms of reference. Ottawa (ON): CADTH; 2020: https://www.cadth.ca/sites/default/files/pcodr/The%20pCODR%20Expert%20Review%20Committee%20%28pERC%29/pERC%20TOR%20-%20June%2025%202020.pdf. Accessed 2020 Dec 14.
51. Règles de fonctionnement du Comité scientifique de l'évaluation de médicaments aux fins d'inscription Montreal (QC): INESSS; 2018: https://www.inesss.qc.ca/fileadmin/doc/INESSS/DocuAdmin/Comites_scientifiques/Regles-CSEMI.pdf. Accessed 2020 Dec 02.
52. Atlantic Expert Advisory Committee: terms of reference. 2010. https://novascotia.ca/dhw/pharmacare/documents/ACDR_Terms_Reference.pdf Accessed 2020 Nov 14.
53. Extended health benefits for specified disease conditions program. Inuvik (NT): Government of the Northwest Territories; 2019: https://www.hss.gov.nt.ca/en/services/supplementary-health-benefits/extended-health-benefits-specified-disease-conditions. Accessed 2020 Oct 22.
54. PharmaCare for B.C. Residents - Contact Us. Victoria (BC): BC Ministry of Health; 2020: https://www2.gov.bc.ca/gov/content/health/health-drug-coverage/pharmacare-for-bc-residents/contact-us. Accessed 2020 Nov 14.

Appendix 1: Information on CADTH, ACDR, and INESSS Reimbursement Review Structures

Table 7: Participating Jurisdiction(s), Eligible Drugs, and Categories of Recommendation

National- or regional-level drug review process	Participating jurisdiction	Eligible drugs	Categories of recommendation
CADTH (CDR, pCODR)	FPT public drug programs (except Quebec)	• New drug • Drug with new indication • New combination product • New formulation of existing drug and subsequent entry products for nonbiological complex drugs	• Reimbursed • Reimbursed with conditions • Not be reimbursed
ACDR	Provincially funded drug plans in Atlantic Canada (New Brunswick, Nova Scotia, Newfoundland and Labrador, and Prince Edward Island)	• New drug products that do not fall under the mandates of the CDR and pCODR processes • Biosimilars (non-oncology indications only) • Line extensions • Natural health products • Resubmissions for products not previously reviewed by CDR • Currently listed drugs and drug classes	Including but not limited to: • list • not list • delist • restrict coverage of a drug to a specific indication, or • limit duration of therapy
INESSS	Quebec	• New drugs • New indications for already-listed drugs • Line extension products (new strengths and new dosage forms for already-listed drugs) • Biosimilars • Multisource drugs (generics and natural health products) • Diagnostic agents, dressings • Nutritional formulas	• Listing • Conditional listing • Refusal to list

ACDR = Atlantic CADTH Common Drug Review: CDR = CADTH Common Drug Review; FPT = federal, provincial, and territorial governments; INESSS = Institut national d'excellence en santé et en services sociaux; pCODR = CADTH pan-Canadian Oncology Drug Review.

Source: Relevant organization's websites.[4,6,25]

Table 8: Expert Committee Mandate, Membership, Appointment, Term, and Meeting Schedule

Committees	Mandate	Membership	Appointment, term, and meeting schedule
CADTH: CDEC	Provide reimbursement recommendation for drugs that are reviewed through CADTH's CDR process to participating jurisdiction	16 members including 1 chair, 3 patient representatives, 1 ethicist, and 11 expert members who hold qualification as physician, pharmacist, health economist, or other professional health designations and have expertise and experience in 1 or more of the following areas: health economics, health policy or administration, pharmacy, clinical pharmacology, general medical practice, internal medicine, and any other recognized medical specialty. Members are also expected to have experience and knowledge related to HTA, reimbursement policy, and/or epidemiology	Appointment: identified through a public call for nominations and appointed by CADTH President and CEO Term: 3 years Meeting schedule: once a month
CADTH: pERC	Provide reimbursement recommendation for oncology drugs that are reviewed through CADTH's pCODR process to participating jurisdictions	17 members including 1 chair, 3 patient representatives, 1 ethicist, and 12 expert members who hold qualification as physician, pharmacist, health economist, or other professional health designations and have expertise and experience in 1 or more of the following areas: HTA, health economics, health policy or administration, pharmacy, clinical pharmacology, epidemiology, general medical practice, internal medicine, and medical, surgical, or radiation oncology	Appointment: identified through a public call for nominations and appointed by CADTH President and CEO Term: 3 years Meeting schedule: once a month
ACDR: AEAC	Conducts the review of the clinical and pharmacoeconomic evidence for the drugs AEAC makes formulary listing recommendations to the Atlantic Ministers of Health (or delegate) through the Atlantic Pharmacare Review Committee, a committee of the Atlantic Drug Plan Managers	10 members (including a chair and vice-chair), including a physician, a pharmacist, an economist, or other professional designation with expertise in 1 or more areas such as, but not limited to, general practice, internal medicine, geriatric medicine, hospital or community pharmacy, clinical pharmacology, pharmacoeconomics, or clinical epidemiology	Appointment: nominated by the APRC Term: 2 years Meeting schedule: at least 4 times annually

Committees	Mandate	Membership	Appointment, term, and meeting schedule
INESSS: CSEMI	With the support of the Medicines Directorate, the Committee assesses the data, deliberates, and makes recommendations to the INESSS board of directors for requests relating to new innovative drugs, new indications for drugs already registered, certain diagnostic agents (other than blood glucose test strips), and any another request that requires their expertise	15 to 20 members who can provide the following perspectives: • Scientific perspective ◦ ≥ 1 member with expertise in clinical epidemiology and biostatistics ◦ ≥ 1 member with expertise in economic analysis • Clinical perspective ◦ ≥ 3 specialist clinicians ◦ ≥ 2 primary care clinicians ◦ ≥ 2 clinical pharmacists • Management perspective ◦ ≥ 1 manager member in the health network • Ethical perspective ◦ ≥ 1 member (with training or expertise in health issues and resource allocation) • Citizen perspective ◦ ≥ 2 members with interests in the health and well-being of the population of Quebec	• Appointment: appointed by the Chairman and CEO and the Director of the Medication Directorate and approved by INESSS Board of Directors • Term: 3 to 4 years • Meeting schedule: once a month

ACDR = Atlantic CADTH Common Drug Review: AEAC = Atlantic Expert Advisory Committee; CDR = CADTH Common Drug Review; CDEC = CADTH Canadian Drug Expert Committee; CSEMI = le Comité scientifique de l'évaluation de médicaments aux fins d'inscription; HTA = health technology assessment; INESSS = Institut national d'excellence en santé et en services sociaux; pCPA = pan-Canadian Pharmaceutical Alliance; pERC = CADTH pan-Canadian Oncology Drug Review (pCODR) Expert Review Committee; RAMQ = Régie de l'assurance maladie du Québec.

Source: Relevant organization's websites.[49-52]

Appendix 2: Departments Responsible for Formulary Management

Table 9: Departments Responsible for Formular Management

Drug plans	Department, division, and/or branch	Ministry
British Columbia	Pharmaceutical Services Division	Ministry of Health
Alberta	Pharmaceutical and Health Benefits Branch	Ministry of Health
Saskatchewan	Drug Plan and Extended Benefits Branch	Ministry of Health
Manitoba	Provincial Drug Programs	Manitoba Health, Seniors and Active Living
Ontario	Ontario Public Drug Programs,	Ministry of Health, Ministry of Long-Term Care
New Brunswick	Pharmaceutical Services Branch	Department of Health
Nova Scotia	Pharmaceutical Services Branch	Nova Scotia Department of Health and Wellness
Newfoundland and Labrador	Pharmaceutical Services Division	Ministry of Health and Community Services
Prince Edward Island	PEI Pharmacare, Health PEI	Ministry of Health and Wellness
Yukon	Insured Health Services	Department of Health and Social Services
Northwest Territories	Health Benefits Program, Health Services Administration	Department of Health and Social Services
Nunavut	Nunavut Health Insurance Programs Office	Department of Health

Source: Canadian PT ministries' and public drug plans' websites.[10,13,14,16,22,27-29,31,33,53,54]

Appendix 3: Criteria or Policy for Formulary Listing for Alberta and Saskatchewan

Alberta – Criteria for Listing Drug Products[22]

1. Clinical studies must have demonstrated the safety and efficacy of the product in appropriate populations.
2. The product must:
   - possess therapeutic advantage (as defined in No. 3) for the disease entity for which the product is indicated, or
   - be more cost-effective than presently accepted therapy.
3. Assessment of therapeutic advantage may include consideration of:
   - clinical efficacy;
   - risk/benefit ratio;
   - toxicity;
   - compliance;
   - clinical outcomes;
   - Health Canada or any other International Regulatory Agency issued warnings and advisories;
   - population health issues; or
   - any other factor which affects the therapeutic value of the product.
4. The Expert Committee, Alberta Health and/or the Minister may, in addition to all of the factors listed above, also consider any factors that they consider appropriate, including but not limited to any or all of the following:
   - the recommendations from the CDR review,
   - failure by a manufacturer to supply a sufficient quantity of Drug Product to meet the demand in Alberta (as determined by Alberta Health at its sole discretion, and based on any information it deems appropriate),
   - failure by a manufacturer to provide (A) a Price Confirmation, or (B) a Price Confirmation or Confirmed Price in accordance with the Price
   - failure by a manufacturer to comply with any APC Terms and Conditions;
   - type of drug, Drug Product, class or category and indications for use,
   - other available alternative products, treatments or therapies,
   - whether the product is interchangeable,
   - cost of the product and/or potential cost savings or impact on drug expenditures under the List,
   - volume of use and amounts paid out for similar products, classes or categories,
   - utilization patterns
   - expenditure management and resources,
   - patent issues,
   - coverage provided by other programs,
   - for interchangeable products, concerns that are related to or affect the interchangeability of the Drug Product,

- issues, concerns, objectives, goals and/or mandates related to any government policies, plans or programs, and
- patient care concerns related to factors external to the Drug Product.

5. Products not eligible for review under the CDR Procedure may, at the sole discretion of Alberta Health and/or the Minister, be considered for priority review and possible addition to the List if the product submission is otherwise complete, and the product has been granted Priority Review status by the TPD, Health Canada. A copy of documentation from the TPD granting Priority Review status is required.
6. The onus is on the Manufacturer to formally request, in writing, consideration on a priority review basis if, in the opinion of the manufacturer, the product meets any of the above priority review criteria. Request for priority review does not automatically mean that the submission will be considered on that basis. The decision whether to conduct a priority review will be made by Alberta Health and/or the Minister at their sole option and discretion.

Saskatchewan: Policy for Inclusion of Products in the Saskatchewan Formulary[29]

1. Only products produced by manufacturers approved by Health Canada will be considered.
2. Only drug products formulated and produced in accordance with sound manufacturing principles and found to comply with official standards will be considered.
3. Only drug products which are valid therapeutic agents, with proven clinical effectiveness, for the diagnosis, prevention or treatment of mental or physical disorders will be listed. The availability of suitable alternative agents, and potential for undesirable effects will be considered.

   The medical literature and clinical studies are reviewed and evaluated to determine if the drug product is therapeutically effective for the treatment of the conditions for which the drug is indicated.

   The clinical literature is also reviewed to determine the therapeutic advantages or disadvantages in relation to alternative agents, which may or may not be listed in the Saskatchewan Formulary.

   The rate and severity of potential undesirable effects are reviewed and compared with those for alternative products.

   In reviewing products for which suitable alternatives are listed in the Formulary, consideration will be given to the following additional criteria:

   - clinical documentation must clearly demonstrate therapeutic advantages such as:
     - more effective for treatment of the condition(s) for which the drug is intended;
     - increased safety as shown by reduced toxicity and reduced incidence of adverse reactions and/or side effects;
     - improved dosing schedule;
     - reduced potential for abuse or inappropriate use;

   OR

     - anticipated cost of a product of equivalent therapeutic effectiveness must offer a potential economic advantage over listed alternatives.

4. The cost of therapy relative to the clinical efficacy is reviewed and compared to the cost of therapy relative to the clinical efficacy of alternative agents.

   An increased cost may be justified if the drug product produces better clinical results in a significant portion of the patient population, demonstrates fewer or less severe undesirable effects, or has a dosage regime which improves patient compliance.

   The cost of oral combination products relative to the combined costs of the single entities, the cost of the various dosage strengths relative to therapeutic advantages, and the cost of additional dosage forms relative to the therapeutic advantages will be considered when reviewing such products.

5. Some drug products will not be listed as regular benefits, but may be made available on Exception Drug Status for treatment of approved clinical indications. (See Appendix A) for Exception Drug Status criteria.

6. Combination products are required to meet the following additional criteria:

   - each component must make a contribution to the claimed effect;
   - the dosage of each component (amount, frequency, duration of therapeutic effect) must be such that the combination is safe and effective for a significant patient population, requiring such concurrent therapy as defined in the labelling;
   - a component may be added to:
     - enhance safety or effectiveness of the principal active ingredient;
     - minimize the potential for abuse of the principal active ingredient.
   - combination fixed ratio must be "right" for:
     - significant portion of patients;
     - significant amount of natural history of disease.

7. Sustained, prolonged or delayed release dosage forms are required to meet the following additional criteria:

   - clinical studies have demonstrated the sustained, prolonged or delayed action of the active ingredient;
   - the dosage form possesses therapeutic advantages in the treatment of the disease entity for which the product is indicated.

8. The various strengths of 1 dosage form will be considered if they possess therapeutic advantages and meet the required standards for quality and cost.

9. The various dosage forms of a drug product will be evaluated individually.

10. Drug products not listed in the Schedules of the Food and Drugs Act, Narcotic Control Act or the Saskatchewan Pharmacy Act, but usually sold on prescription, will be considered for inclusion.

11. Products which contain the same amount of the same active ingredient in an equivalent dosage form and are of acceptable equivalent therapeutic effectiveness will be listed as interchangeable.

12. The following will not be listed:

    - fertility agents;
    - drugs used in erectile dysfunction;
    - certain over-the-counter preparations;
    - drugs used primarily in hospitals;

- antineoplastic agents (these are provided to patients through the Saskatchewan Cancer Agency);
- anti-tuberculosis drugs;
- blood derivatives – immune serum globulin for prophylaxis against infectious hepatitis or measles or for treatment of immune deficiency disease is available from the Health Offices;
- vaccines and sera – most immunological agents are available from the Health Offices;
- safety engineered syringes.

13. Drug products identified by trade names deemed to be inappropriate, confusing and/or misleading may not be listed. Some examples include:
    - products with similar or identical trade names but containing different active ingredients;
    - products with a different strength of ingredient, manufactured by the same supplier, but with a different trade name.

Appendix 4: Links to Submission Requirements for Drugs Reviewed by the Drug Plans That Are Not Eligible for CADTH Review

Table 10: Links to PT Submission Requirements for Drugs Not Eligible for CADTH Review

Drug plans	Drugs reviewed by drugs plans that are not eligible for CADTH review	Link to submission requirements
British Columbia	• Biosimilar • Modification to current coverage • Line extension • Generic products	• https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/health-industry-professionals/submitting-patented-drugs-biosimilars • https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/health-industry-professionals/submitting-generic-drug-products
Alberta	• New Chemical Entities or New Combination Products where 1 or more of the active moieties have never been listed on the List, and other single source Drug Products that have never been listed on the List and are not eligible for review under the CDR Procedure • Changes to special authorization or restricted benefit status of listed single source drug products due to a new indication • Line extension drug products resubmission • Interchangeable drug products (Expedited and Full Review) • Non-interchangeable old drug products[a] • Biosimilar drug products • Resubmissions	• https://www.ab.bluecross.ca/dbl/pdfs/dbl_sec1_drug.pdf
Saskatchewan	• Single Source Products That Do Not Contain New Chemical Entities • Line Extension Products • Interchangeable Product Submissions • Drug Products Without a Canadian Reference Product	• https://formulary.drugplan.ehealthsask.ca/PDFs/PREFACE_Updated_March_1_2017.pdf
Manitoba	• All Generic Drug Products, including pseudo-generics (including for interchangeability grouping) • Old Drug Products (including for interchangeability grouping) • Line Extension Products • **Changes to Benefit Status of listed Single Source Drug Products due to a new indication**	• https://www.gov.mb.ca/health/mdbif/sub.html

Drug plans	Drugs reviewed by drugs plans that are not eligible for CADTH review	Link to submission requirements
Ontario	• Single source products that do not contain new chemical entities • Requirements in specific cases (e.g., brand line extension products, drug products without official product monograph, pseudogeneric products) • Interchangeable product submissions • Over-the-counter drug products • Oncology drug products • Special drugs program products • Off-Formulary Interchangeability drug products	• https://www.health.gov.on.ca/en/pro/programs/drugs/dsguide/docs/dse_guide.pdf
ACDR (for NB, NS, NL, PE)	• New drug products that do not fall under the mandates of CDR or pCODR • Biosimilar submission requirements (non-oncology indications only) • Line extensions • Resubmissions • Interchangeability (for NS and NL only)	• https://novascotia.ca/dhw/pharmacare/atlantic-common-drug-review.asp#resubmit • NS Interchangeability: https://novascotia.ca/dhw/pharmacare/nova-scotia-drug-therapeutic-committee.asp • NL Interchangeability: https://www.gov.nl.ca/hcs/prescription/idf-intro/#4a
Yukon	• NA	
NIHB (for NU and NT)	• Line extensions • Generics • All other submissions	• https://www.sac-isc.gc.ca/eng/1572888328565/1572888420703#s3

ACDR = Atlantic CADTH Common Drug Review: CDR = CADTH Common Drug Review; NA = information not available; NB = New Brunswick; NIHB = Non-insured Health Benefit; NL = Newfoundland and Labrador; NS = Nova Scotia; NT = Northwest Territories; NU = Nunavut; pCODR = CADTH pan-Canadian Oncology Drug Review; PE = Prince Edward Island.

Source: Canadian Public drug plan websites.[16,21,22,25,29,33,42,43,45,46]