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Federal Policies and Public Reimbursement of Pediatric Medicines in Canada

Key Messages

- Most medicines are initially researched and developed primarily for adult indications.
- There are several challenges with researching and developing drugs for pediatric populations including but not limited to low disease prevalence, small patient populations, challenges with conducting long-term studies, short supply of pediatric investigators, and pediatric-specific physiological and behavioural considerations (appropriate facilities, protocols, and so forth).
- Therefore, most pediatric prescriptions have not received regulatory approval by Health Canada (i.e., off label) for pediatric populations nor are they available in pediatric-appropriate routes of administration or doses.
- In Canada, reimbursement of drugs for pediatric indications occurs through private coverage or a public drug plan through universal coverage programs or programs that exist based on need such as income, high-cost drugs, or specific diseases. Drugs not listed on public drug plan formularies may be funded through a restricted benefit (reimbursement limited by specific clinical criteria or to a defined patient subgroup).
- Drug reimbursement decisions, informed by health technology assessments, are also impacted by similar gaps in pediatric-specific clinical data.
- This Environmental Scan summarizes various initiatives by Health Canada that aim to improve access to pediatric medicines. In addition, policies of public drug programs regarding access to and reimbursement of pediatric medicines and formulations, including compounded and off-label medicine, are also summarized.

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Introduction

Pediatric populations face limited, restricted, and sometimes inequitable access to essential medicines. Medicines used within the pediatric population are often developed and tested in adults only.[1] In the absence of pediatric safety and efficacy data being generated or submitted to Health Canada for regulatory approval, off-label use of drugs in pediatric populations remains common in Canada.[2] Compared to adults, rapid growth and development from infancy through adolescence can alter the way patients absorb, distribute, and eliminate medicine.[1] As such, most of the medicines used in the pediatric population do not have sufficient information in their product monograph to guide the use of these medicines in neonates, children, or youth for clinicians.

Among 270 new drugs approved by Health Canada (January 1, 2007 to December 31, 2016), only 47.1% (127) had pediatric-specific information, and 27.8% (75) had pediatric-specific indication in the product label.[3] Of the 75 product monographs with pediatric-specific indication(s), 90.5% (68) had dosing information for the adolescent age group (12 to 17 years); only 8.0% (6) and 1.4% (1) of the product monographs had dosing information for term infants and preterm infants, respectively,[3] and only 41.3% (31) were formulated for oral use in pediatric populations. Of the 31 drugs formulated for oral use in pediatrics, approximately 50% (15) were indicated for children aged 6 years or younger, with only 9 of the 15 drugs being available in a child-friendly oral dosage form.[3] Child-friendly oral dosage forms are formulations designed for pediatric use such as oral liquids, granules, minitablets, dispersible tablets, or chewable tablets.[3] As such, children and youth rely heavily on compounded and off-label use of prescription drugs, as most pediatric prescriptions involve the use of medicine that are not approved by Health Canada (i.e., off label) for the pediatric population or are not available in pediatric-appropriate dosages, and/or routes of administration.[4-6]

Canada does not have pediatric-specific regulations that mandate pharmaceutical companies to conduct pediatric studies, although a 6-month extension on data protection for new drugs with pediatric-specific clinical trials data, as well as previous and current initiatives outlined in Table 2 encourage generation and submission of pediatric data to Health Canada.

There are challenges in research and development within the pediatric population including but not limited to:[7,8]

- low disease prevalence
- small study population
- ethical concerns (e.g., informed consent in long-term studies)
- physiological and behavioural considerations for appropriate facilities, protocols, and processes for conducting research
- implementing long-term studies in children
- short supply of trained pediatric investigators.

Drug reimbursement decisions informed by health technology assessments (HTAs) are also impacted by the gaps in pediatric-specific clinical data. HTA agencies that provide reimbursement recommendations like Canada's Drug Agency, may also face similar challenges, particularly when it comes to determining

the added benefit of pediatric formulations (safety, adherence, patient accessibility, and so forth).[9-11] Many existing health economic evaluation tools are designed to assess the cost-effectiveness of medicine in the adult population, but are limited in their application in pediatric populations.[11-13]

Most pediatric medicines for children in Canada are reimbursed through demographic, family-income, or disease-specific formularies offered by public drug plans across Canada or private insurance; however, the amount covered varies across jurisdictions in Canada. Only 3 jurisdictions (Quebec, Ontario, and the Non-Insured Health Benefits [NIHB]) provide universal coverage for all individuals aged younger than 25 years,[14] resulting in disparity for access to medicine in pediatric populations, which is further exacerbated by out-of-pocket costs, due to copayments or deductibles.[5,15]

Objectives

The objective of this Environmental Scan (ES) is to provide a summary of the regulatory and reimbursement landscape for medicines used in the pediatric population in Canada, including policies related to compounding.

The following research questions are addressed in the ES:

1. What are the Canadian regulatory policies, legislations, regulations, and incentives to industry (i.e., manufacturers) regarding access to pediatric medicines and formulations, including compounded medicine?
2. What are the Canadian public drug plans' policies regarding access to and reimbursement of pediatric medicines and formulations, including compounded and off-label medicine?

Methods

The components of the information presented in this ES are presented in Table 1.

Literature Search

An information specialist conducted a literature search on key resources including MEDLINE via Ovid, Embase via Ovid, the websites of health agencies in Canada, as well as a focused internet search. The search approach was customized to retrieve a limited set of results, balancing comprehensiveness with relevancy. The search strategy comprised both controlled vocabularies, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. Search concepts were developed based on the elements of the research questions and selection criteria. The main search concepts focused on drug formulation policies for pediatric patients in Canada. No filters were applied to limit the retrieval by study type. The search was completed on February 27, 2023, and updated searches were completed on July 5, 2024, and on August 6, 2025. Retrieval was not limited by publication date or by language.

A grey literature search was conducted on key resources, including the websites of Health Canada, Canada's Drug Agency, public drug plans in Canada, as well as relevant professional and regulatory pharmacy associations. No bibliographic literature searches were performed. The databases were searched on February 24, 2023; July 5, 2024; and August 6, 2025. Information on the components of the literature screening and information gathered is presented in Table 1.

Some information[16,17] presented in this report was not discovered in our literature search and was obtained through communication with the Pharmaceutical Advisory Committee Formulary Working Group (FWG)[8] and is publicly available.

Table 1: Components for Literature Screening and Information Gathering

Component	Description
Population	Children (< 18 years old)
Settings	**Federal regulatory body** • Health Canada **Professional and regulatory association** • National Association of Pharmacy Regulatory Authorities • Newfoundland and Labrador Pharmacy Board • Prince Edward Island College of Pharmacy • Nova Scotia College of Pharmacists • New Brunswick College of Pharmacists • Ordre des pharmaciens du Québec • Ontario College of Pharmacists • College of Pharmacists of Manitoba • Saskatchewan College of Pharmacy Professionals • Alberta College of Pharmacy • College of Pharmacists of British Columbia • Yukon Regulatory Authority • Northwest Territories Regulatory Authority **Canadian federal, provincial, and territorial publicly funded drug plan formularies** • Newfoundland and Labrador Prescription Drug Program Formulary • Prince Edward Island Pharmacare Formulary • Nova Scotia Formulary • New Brunswick Drug Plans Formulary • Régie de l'assurance maladie du Québec • Ontario Drug Benefit Formulary • Manitoba Pharmacare Drug Formulary • Saskatchewan Drug Plan Formulary • Alberta Drug Benefit List • British Columbia Pharmacare Formulary • Yukon Drug Program Formulary • Non-Insured Health Benefits Drug Benefit List (also applicable to Nunavut and the Northwest Territories[a]) [federal plan]

Component	Description
Types of Information	• Regulatory policies that mandate or encourage submission of pediatric-specific efficacy or safety data of commercially available drugs. • Policies related to compounding of medicine that may be relevant or have an impact on the pediatric population. • Public drug plan formularies and policies related to reimbursement of medicine used in children including any compounded products and drugs used off-label in children.

[a]Nunavut and the Northwest Territories follow the coverage category and criteria of the Non-Insured Health Benefits program.[19,20]

Findings

Federal Policies

The current regulatory framework does not require manufacturers to submit or update their product information when safety or efficacy data becomes available for pediatric use. Additionally, manufacturers are not obliged to seek pediatric indications or develop pediatric formulations for new drugs, even when pediatric use is anticipated.[21]

Six-Month Pediatric Extension for Data Protection

Section C.08.004.1 of the *Food and Drug Regulations* stipulates a guaranteed minimum 8-year period of market exclusivity for an innovative drug (i.e., a drug that contains a medicinal ingredient not previously approved in Canada).[22] In addition to this 8-year period of market exclusivity, there is a provision for a pediatric extension which allows an additional 6 months of market exclusivity when a manufacturer of an innovative drug submits results of clinical trials designed and conducted for a pediatric population for regulatory review.[22] This provision for a 6-month extension for data protection may encourage manufacturers to provide clinical data on pediatric medicines.[22] To qualify for the additional data protection, the new drug submission (NDS), or any supplemental new drug submission (SNDS) with pediatric-specific clinical trial data that must be filed within the first 5 years of the 8-year data protection period. The information from the pediatric studies may either result in a pediatric indication or demonstrate that the drug should not be used in pediatric populations, resulting in the addition of contraindications and/or other warning statements in the labelling.[22] In either case, the information may be deemed sufficient to grant the 6-month pediatric extension, based on a case-by-case review. Between 2006 (when the policy was introduced) and 2019, 320 innovative drugs received market approval from Health Canada, out of which, more than 100 have received the 6-month pediatric data protection extension.[23]

Pilot on Pediatric Development Plans and Studies

To address gaps in the availability of pediatric data to support evidence-based decision-making for pediatric therapies, Health Canada launched a pilot on February 26, 2024, encouraging manufacturers to submit pediatric studies for drugs approved for adults.[24] This initiative applies to all NDS and SNDS, for any new indications, new dosage forms, or new routes of administration. The objective of the pilot is to encourage timely submission of safety and efficacy data for pediatric use, provide more information to health care

providers and patients, and inform future policy. Participation is voluntary and does not affect the review timeline or outcome, nor does it affect labelling requirements.[24]

As a part of the pilot, Health Canada has published guidance[25] on submitting pediatric development plans (PDPs) and pediatric studies, which outlines their policy on submitting a pediatric study to help sponsors align their submissions. As per this policy, Health Canada will request that sponsors submitting an NDS or SNDS incorporate a PDP with their submission. The PDP should outline any current or proposed pediatric studies and may offer reasons for not studying the drug in certain pediatric groups or entirely. The guidance pertains to specific categories of drugs under Section 2 of the *Food and Drugs Act* for human use, encompassing prescription and nonprescription pharmaceutical drugs, biologic drugs listed in Schedule D of the Act, including biotechnology products, vaccines, and fractionated blood products, as well as radiopharmaceutical drugs listed in Schedule C of the Act.[25]

Manufacturers have the choice to submit either a foreign PDP or a PDP specific to Canada. The foreign PDP option allows sponsors to incorporate a preapproved US FDA initial pediatric study plan or an approved European Medicines Agency pediatric investigation plan, along with guidance on completing these plans. Additionally, sponsors can include an addendum specific to Canada to a foreign plan if necessary. Alternatively, sponsors may opt for a PDP specific to Canada if no suitable foreign plan is available from the US FDA or European Medicines Agency.[25]

Other Relevant Health Canada Guidelines

In 2003, Health Canada issued guidance to set the standards on inclusion of pediatric populations in clinical trials with the adoption of the International Council for Harmonisation (ICH) Guidance: *Clinical Investigation of Medicinal Products in the Pediatric Population E11*.[26] This also included an addendum to the portions of the 1997 draft Health Canada guidance, which has since been withdrawn, on *Inclusion of Pediatric Subjects in Clinical Trials*[23] which were not specifically addressed by the ICH guidance.[27] The adopted guideline aims to promote the timely development of pediatric medicinal products by offering insights into critical issues and methodologies for conducting clinical studies in pediatric populations. It covers a range of topics, including the initiation of pediatric programs, the timing of studies, the types of studies required (such as pharmacokinetic, efficacy, and safety studies), pediatric formulations, age classification of pediatric patients, and ethical considerations in pediatric research such as recruitment and consent. While not exhaustive, the guidance provides a valuable framework that complements existing resources from organizations like the ICH and regional regulatory authorities.[26] Health Canada has also provided guidance on how information specific to pediatric populations should be included in the product monographs including pediatric-specific indication (or lack of) for specific age ranges, warning and precaution, and clinical trial adverse reaction.[28]

In 2019, Health Canada published a guidance document called *Elements of Real-World Data/Evidence Quality throughout the Prescription Drug Product Life Cycle*. This document outlines the protocol elements and data quality that should be taken into account when collecting data and assessing the quality of real-world evidence.[29,30] The purpose of this guidance is to encourage high-quality real-world evidence submissions, that broaden the evidence-based indications for populations that are usually excluded from clinical trials, such as children.[29,30]

Federal Initiatives to Increase Availability and Access to Pediatric Medicine

Children and youth are considered vulnerable populations,[5,23] and the federal government of Canada has had several initiatives including issuing guidance to address the unique need of this population. These include the establishment of the Office of Pediatric Initiatives[32] (currently archived), Pediatric Expert Advisory Committee (currently archived[1,33]), Pediatric Drug Action Plan,[34] and the Centre for Policy, Pediatrics, and International Collaboration,[31,35] and Health Canada's Forward Regulatory Plan for 2024 to 2026.[17] Table 2 provides an overview of these initiatives.

Table 2: Initiatives of the Government of Canada Related to Medicines Used for Children (< 18 Years of Age)

Initiatives	Date	Overview
Office of Pediatric Initiatives **[Archived]**	2005 to 2010	The initiative focused on health products and food including pharmaceuticals, and biologicals, such as vaccines and biotechnical products. The goal of the initiative was to support "an integrated approach on a range of science and regulatory activities that affect children and pregnant and nursing women" including "coordinating the development of pediatric information (through the regulatory system and/or other means), coordinating how this information is made available and accessible, raising awareness of child and maternal health needs and safety issues related to the development and use of health products and food, and promoting conditions that enable Canadians to make informed decisions about the health and nutrition of infants, children, youth, pregnant and nursing women."[32] [from original source]
PEAC **[Archived]**	2009	The advisory body focused on pediatric and maternal health.[1,33] The 15-member committee consisted of pediatric specialists, university professors, pharmacists, and researchers, representatives from industry and patient groups, not-for-profit organizations, and parents.[33] PEAC offered broad strategic advice to Health Canada on matters related to children aged birth to 18 years, as well as maternal health and safety concerns linked to the regulation of food and health products such as pharmaceuticals, medical devices, biologics including vaccines and natural health products. This advice covered all aspects of the life cycle of these products including development, testing, approval, and licensing, and continued monitoring of their safety and effectiveness monitoring once they are available on the market.[36]
CPPIC *Pediatric Drug Action Plan* *Includes NPLPD and Pilot on Pediatric Development Plans and Studies*	2020 to present	Comprised of the Pediatric Therapeutics Division and Office of Pediatric Therapeutic Policy, the centre oversees Health Canada's policies, processes, and regulations for therapeutic products in children and youth.[31,35] The centre has developed the Pediatric Drug Action Plan to ensure that medications for children and youth meet the same standards as those established for adult medications, and that children and youth in Canada have access not only to the medicines they need, but also to age-appropriate formulations.[31] The 3 goals of the Pediatric Drug Action Plan are to:[31] • "improve access to pediatric medicines and formulations • increase the development of pediatric medicines and formulations, and • provide more information to people in Canada on pediatric activities and data."[31] The initial focus of the Pediatric Drug Action Plan is to: • modernize regulations to require drug manufacturers to provide Health Canada with meaningful information about the safety and effectiveness of drugs in children and youth • develop an NPLPD (priority list) that are available elsewhere and needed in Canada

Initiatives	Date	Overview
		• identify the regulatory pathways and flexibilities that can be implemented to encourage industry to bring these products to Canada.[31] As a part of the initiative, Health Canada is collaborating with government departments, external partners, and global regulators, such as the European Medicines Agency, US FDA, and WHO, to enhance their expertise in pediatrics and align their activities. They are also working with the Goodman Pediatric Formulation Centre to improve access to pediatric formulations in Canada; analyzing ways to encourage companies to test health products in children and submit pediatric data to Health Canada; and developing a data strategy to analyze the availability of health products for children, trends in pediatric trials, and associated drug safety issues.[34]
	January 2023 to 2025	As a part of the initiative, Health Canada via the PERG developed an NPLPD which identifies drugs needed for pediatric populations that are approved in other jurisdictions, but not yet available in Canada. Drugs nominated for this list must address an area of high unmet need, be approved in a select foreign jurisdiction, and not currently approved for sale in Canada for the proposed indication and/or formulation. Health Canada has consulted on the proposed NPLPD and issued the final list in 2025.[31,37]
	February 2024 (duration of 2 years)	The aim of the pilot on Pediatric Development Plans and Studies is to encourage sponsors to submit pediatric studies for drugs approved for adults in Canada.[24] All NDS and SNDS for a new indication, dosage form, and/or route of administration are eligible for the pilot by including a PDP. The objectives are to increase timely submission of safety and efficacy information for drugs expected to be used in pediatric populations, and to enhance the availability of information available to health care providers, patients and their families, and policy-makers. Participation in the pilot is voluntary.
Health Canada's Forward Regulatory Plan for 2024 to 2026[17]	2014 to present	As part of Health Canada's Forward Regulatory Plan for 2024 to 2026, a proposal to amend the Food and Drug Regulations outsourced drug preparation (formerly Commercial Compounding) is under way. The proposal supports regulatory oversight for drugs prepared by outsourced drug preparation facilities with the intent of protecting people in Canada from drugs that are made using unsafe, poor quality practices. Health Canada consulted provincial and territorial pharmacy regulatory authorities, as well as provincial and territorial representatives, and plan to consult provinces, territories, and other interested parties before prepublishing the proposal in the Canada Gazette, Part I for public consult.

CPPIC = Centre for Policy, Pediatrics and International Collaboration; NDS = new drug submission; NPLPD = National Priority List of Pediatric Drugs; PEAC = Pediatric Expert Advisory Committee; PERG = Pediatric External Reference Group; PDP = pediatric development plan; SNDS = supplemental new drug submission.

Federal Policies on Compounded Products in Canada

An extemporaneous preparation (compound) is a drug or mixture of drugs prepared or compounded in a pharmacy according to the order of a prescriber.[38,39] We identified 2 national-level policy documents with regards to compounding of nonsterile pharmaceutical compounds at hospital or retail pharmacies. These include Health Canada's *Policy on Manufacturing and Compounding Drug Products in Canada*[39] and National Association of Pharmacy Regulatory Authorities' (NAPRA) guidance document "for Pharmacy compounding of nonsterile preparations."[38] Neither of the documents were specific to compounding drugs for children; however, the principles may be of relevance to this population.[38,39]

According to Health Canada's *Policy on Manufacturing and Compounding Drug Products in Canada*, compounding a drug by a pharmacy should be done in limited quantities and limited to situations where there is a therapeutic necessity or an unavailability of the required product. Additionally, the compounded product must provide a customized therapeutic solution that enhances patient care, without duplicating any authorized drug product. Only in cases where there is a shortage or no supply of a commercially accessible product and a medical need has been established by a health care professional, can the product be compounded, but only during the period of shortage or no supply.[39]

According to the general guidelines of compounding activities described in the regulatory framework section of NAPRA's guidance document, compounding must always be conducted within a patient–health care professional relationship. Compounders can also prepare a product without a patient-specific prescription, if a prescriber orders the compounded product for office use; it is prepared in a suitable amount, duration, or frequency; and the compounded product is used within a patient–health care professional relationship. In addition, compounders are permitted to prepare a limited amount of compounded product in advance of future prescriptions.[38] NAPRA also has model standards for pharmacy compounding related to nonhazardous sterile preparations, and hazardous sterile preparations[38]

Pharmacy regulatory bodies in respective provinces and territories have the authority to implement the model standards for compounding at pharmacies. These regulatory bodies adopt or have adapted to the standards established by NAPRA while establishing their own process for the implementation of the standards in their jurisdiction.[38,40-48]

Compounding presents potential risks such as dosage errors, overdose in children, reduced drug uniformity due to compounding, which can impact safety, bioavailability, stability, and potency of compounded medicine. Variation in compounding methods between pharmacies may also lead to inconsistent composition, dosing errors, and reduced therapeutic effectiveness.

Reimbursement Policies for Commercially Available Non-Oncology Drugs by Public Drug Programs

Commercially available refers to medicines that are manufactured by pharmaceutical manufacturers and have received regulatory approval for marketing in a jurisdiction.

Commercially Available and Listed in the Public Drug Plan Formulary

Public drug plans provide reimbursement for drugs that are listed in their formularies, as well as through various programs which are based on parameters such as age (e.g., children), income (prespecified income threshold), and/or a medical condition (e.g., cystic fibrosis).[15,49]

Commercially Available but Off-Label Use

Public drug plans may reimburse the use of drugs for children that are off label (i.e., outside of the approved use of the drug in Canada). These drugs may be reimbursed with the requirement for prior authorization or on a case-by-case basis. Table 3 presents the benefit status categories for restricted benefit status and

case-by-case review by public drug plans. Restricted benefit refers to drugs with usage limited by specific clinical criteria or to a defined patient subgroup.

Table 3: Benefit Status Categories

Public drug plan	Restricted benefit status category	Nonbenefits (case-by-case) review
Newfoundland and Labrador	Special authorization	Exception review process
Prince Edward Island	Special authorization	—
Nova Scotia	Exception status drugs	—
New Brunswick	Special authorization	Formulary exception review process
Quebec	Exceptional medication — uncoded	Exception patient program
Ontario	Exceptional access program	Exceptional access program
Manitoba	Exception drug status	Exceptional case-by-case review
Saskatchewan	Exception drug status	Exceptional case-by-case review
Alberta	Special authorization	—
British Columbia	Special authority— limited coverage drug	—
Yukon	Exception drug status	—
Non-Insured Health Benefits	Limited use — prior authorization required	Exception

Note: Benefit status categories for federal, provincial, and territorial public drug plans across Canada.[49-51]

Reimbursement of Compounded Medicine by Public Drug Plans in Canada

The following section presents the policies by public drug plans in Canada specific to the eligibility of compounds for reimbursement by the public drug plans. Allowable compounding or dispensing fees, claims submission procedure, as well as any standards on compounding procedures were out of scope of this ES. Relevant information was identified at BC PharmaCare, Manitoba Pharmacare, Ontario Drug Benefit (ODB) program, Régie de l'assurance maladie du Québec (RAMQ), Newfoundland and Labrador Prescription Drug Program, New Brunswick Drug Plans, Nova Scotia Pharmacare, and NIHB.

Reimbursement policies for compounded medicines do not make special reference to pediatrics. These include policies regarding compounding of oral suspension (e.g., ODB and BC PharmaCare) and compounding to change the route of administration when there is evidence of therapeutic benefit (e.g., Newfoundland and Labrador Prescription Drug Program). Further, Manitoba Pharmacare also notes a provision for a case-by-case review for the reimbursement of compounded medicines that do not fall under its eligibility criteria.

The absence of information for public drug plans not outlined within the report does not infer that policies do not exist; however, they were not found on publicly available resources.

BC PharmaCare

Information on compounding policies was gathered from the PharmaCare Policy Manual, Section 5.13 Compounded Prescriptions,[52] and compound costing worksheet, 2017.[53]

The BC PharmaCare covers eligible compounded medicine only when no suitable alternative is available commercially, specific eligibility criteria for the ingredient are met, a medical practitioner's prescription is on file, and the compound is produced by trained staff using appropriate and cost-effective ingredients and procedures.[52] Compounds that are not eligible may also be reimbursed provided PharmaCare has granted special authority approval before the compound is dispensed.[52,53]

BC PharmaCare has outlined the criteria for coverage for compounded oral suspensions, dermatological compounds, topical antifungals, retinoic acid, preservative-free sterile eye drops, Plan P injectable analgesics – continuous ambulatory delivery device pumps and Plan P intrathecal analgesics. Among these, specific reference to pediatrics is made only in the criteria for coverage of compounded oral suspensions. Oral suspensions are reimbursed for pediatric patients who cannot swallow a tablet or capsule due to age or disability; and when prescribed dosage is not commercially available or cannot be achieved safely by modifying a commercial product. The active ingredient must be a BC PharmaCare benefit in another oral form or the patient must have an active special authority granted for the active ingredient.[52]

Compounds of commercially available drugs discontinued by manufacturers, even if it was a benefit under BC PharmaCare, may be reimbursed through a special authority coverage mechanism only if the need for the specific drug and dosage form has been reassessed by a medical practitioner and if the product is not available through Health Canada's special access program. Compounds intended to replace products unavailable due to a manufacturer shortage, may only be reimbursed only after verification of shortage and expected duration of the shortage with the manufacturer.[52]

Manitoba Pharmacare

Information on compounding policies was gathered from the Claims Submission Procedure – Extemporaneous Products (Compounding) (effective 2017);[50] Special Authority Compounding (effective 2017);[54] and Manitoba Designated Drug Shortages (effective 2018).[55]

Claims for extemporaneous preparations are approved for processing if there is no similar commercial drug product marketed in Canada. In addition, the main therapeutic ingredient must be either listed on the formulary or covered as an exception drug status benefit; or is an equivalent raw material identified with a scientific name and a Chemical Abstracts Service number approved for use in Canada. Alternatively, they may be approved if a provincial drug program has preapproved an extemporaneous product recipe and assigned a product identification number to that product, in a situation of specific patient need. However, no extemporaneous products will be approved if the drug is reconstituted with water only.[50]

In exceptional circumstances, specialty compounds that are nonbenefit may be reimbursed. These requests are reviewed on a case-by-case basis, leading to full, partial, or no coverage for a special authority compounding request.[50,54]

Compounding is also permitted in cases of a drug shortage, including any temporary disruptions or permanent discontinuances in the production and supply of a drug. In these circumstances, a special compounding product identification number is assigned to the drug, which is used when submitting a claim until the shortage is resolved.[55]

Ontario Drug Benefit Program

Information on compounding policies (referred to as extemporaneous preparations) was gathered from the Ontario Drug Programs Reference Manual (2024).[51]

An extemporaneous preparation that meets the general guidelines of compounding activities (as described in the NAPRA guidance document[38] to be a designated pharmaceutical product) is eligible for reimbursement through general or restricted benefit under the ODB program provided. Extemporaneous preparations need to meet additional eligibility criteria and none of the exclusion criteria for reimbursement. The product(s), which are an ODB benefit(s), in an extemporaneous preparation, must meet all other reimbursement conditions for that respective product under the ODB program including any clinical criteria for use or generic substitution regulations and policies, among others. Compounded liquid or capsule preparations, for oral consumption, containing a single ODB benefit that is a solid oral dosage form and contains no other medicinally active substance are eligible. Similarly, eligibility criteria are outlined in the reference manual for preparations for dermatological or topical use, ophthalmic administration, and injectable administration. Among others, reconstitution of an ODB benefit or transferring an ODB benefit into a new dosage delivery format, are ineligible for reimbursement.[51]

The Ontario Drug Programs Reference Manual[51] outlines the following as part of restrictions and ineligibility for reimbursement through ODB:

“An extemporaneous preparation that is equivalent to a commercially manufactured product unless the product is for oral administration and is not commercially available, meaning it has a dormant status on Health Canada’s Drug Product Database or there is a documented shortage of the product either by being listed on Canada’s Drug Shortages website or the manufacturer has confirmed the shortage in writing.”[51,56,57]

Additional restrictions to eligibility include transferring manufactured products and delivery format, insertion of an infusion set, non-ODB benefit products from medicinally active bulk drug substances, reconstitution of commercially available dry powders, altering solid oral dosage forms without added excipients (e.g., cutting or crushing tablets and opening capsules), and filling a vessel with nonmedicinal ingredients.

Régie de L'assurance Maladie Du Québec

Information on compounding policies was gathered from the RAMQ list of medications (2024).[58]

Extemporaneous preparations are eligible for coverage if the compound consists of products listed on the list of medications, and the compound is not equivalent to a commercially available product. Eligible compounds include those consisting of a systemic-effect preparation manufactured from oral forms of drugs listed in the list of medications and consisting of a single active substance. RAMQ has also listed eligible compounds that are mouthwash preparation, ophthalmic preparations, topical use preparation, as well as preparations for oral use (e.g., sodium benzoate, clomiphene citrate, and solution or oral suspension of folic acid, dexamethasone, methadone, phytonadione, and vancomycin).[58]

Newfoundland and Labrador Prescription Drug Program

Information on compounding policies was gathered from the Program Claiming Policies (2024).[59]

For compounds to qualify as benefits, they must be tailored to the prescription of the prescriber and contain 1 or more drugs that are presently considered as an open benefit under the program for which the individual is eligible. Moreover, the compounds must not be diluted or altered in their formulation or the route of administration of the drug, which could lead to a product that offers no clear therapeutic advantage compared to a listed open benefit. An open benefit compound is a product that is compounded in a therapeutic concentration and includes at least 1 ingredient in a specified formulation that is an open benefit of the program. A nonbenefit compounded product is 1 that does not contain any benefit ingredients. Alternatively, a compounded product is considered nonbenefit if there is a change in the drug's route of administration.[59]

Special authorization approval is required for a compounded product that includes a special authorization drug(s), or that includes an open benefit drug where the route of administration is changed but there is evidence to support therapeutic benefit.[59]

Extemporaneous preparations that include 3 or more ingredients are reimbursed at a higher rate than compounds containing only 2 ingredients.[59]

New Brunswick Drug Plans

Information on compounding policies was gathered from the New Brunswick Drug Plans Formulary (2024).[60]

Compounds are eligible for reimbursement under the New Brunswick Drug Plans if they contain 1 or more regular benefit drugs, 1 or more special authorization drugs for which approval has been granted, a combination of regular benefit drugs and special authorization drugs for which approval has been granted, or if the compound has been approved through special authorization. Regular benefits comprise drugs listed on the New Brunswick Drug Plans Formulary that do not require special authorization, as well as the drugs and ingredients listed in the regular benefit compounds list in the formulary.[60] If there is a shortage or no supply of a commercially available product and a health care professional has deemed it medically necessary, a compounded product may be used, but only during the shortage or no supply period.[60]

Any compound for which an alternative is commercially available is not eligible for reimbursement. Other ineligible compounds include those that contain a drug or product on the exclusion list; a nonbenefit form of a drug (e.g., using powder versus tablets) unless special authorization approval has been granted, or custom-compounded bioidentical hormones. Further, compounds made using a proprietary recipe with an undisclosed ingredient list are also not eligible for reimbursement. Additionally, manipulation of the drug or product to alter its direction of use (e.g., mixing, reconstituting, or prefilling syringes) is not considered an extemporaneous preparation.[60]

Nova Scotia Pharmacare

Information on compounding policies was gathered from the Nova Scotia Formulary (2023).[61]

Specific compounding policies were not identified. The formulary provided a list of compounds eligible for reimbursement. All eligible compounds were oral suspensions of various eligible drugs.[61]

Non-Insured Health Benefits

Information on compounding policies was gathered from the guide on the NIHB program through Indigenous Services Canada for eligible First Nations, Inuit, or Métis and its policies relevant to pharmacy benefit coverage.[16]

The NIHB program will consider reimbursement of compounded mixtures when no suitable alternative is commercially available and prescribed in-line with prescribing policies. Mixtures that are not open benefit are required to be submitted for review and prior approval. Types of compounded mixtures requiring prior approval are set out in the guide on drugs and pharmacy benefits for First Nations, Inuit, or Métis. Prior approval exceptions may apply for shortage or back-order of certain products.[16]

Conclusion

While efforts have been made to recognize and address the unique considerations of pediatric medicines through various programs and initiatives, there remains a notable gap in clinical trial evidence, and consequently regulatory approval for drugs used in pediatric indications. Insufficient clinical data are also a challenge for HTAs and decisions on public reimbursement. All of which contribute to the use of off-label medicines in pediatric patients and the need for compounded medicines.

This ES identified initiatives, both active and completed, which encourage data generation, and submission by manufacturers to seek regulatory approval for pediatric indications in Canada. However, less than one-third of innovative medicines have pursued expanding regulatory approval to the pediatric population. The initiation of a pilot program by Health Canada in 2024 may encourage pediatric studies for drugs approved in adults. Furthermore, Health Canada's National Priority List of Pediatric Drugs, in collaboration with external experts from the pediatric medical community, presents another step toward enhancing access to medicines for pediatric patients in Canada.

Public drug plans provide reimbursement for pediatric populations for drugs listed in their formulary through 1 or more programs, including compounded medicines which may apply to the pediatric population.

There is a scarcity of detailed information on pediatric medicine-specific policies including reimbursement of compounded and off-label drugs that are not listed in public drug plan formularies. In addition, there are varying programs that exist across the country for drug reimbursement. As such, there is an opportunity to harmonize the development of programs and policies to increase equitable access to medicines for the pediatric population. As an HTA organization in Canada, we are committed to engaging with our health system partners to develop strategies to bridge gaps in access to pediatric medicines in Canada.[62] For example, our Formulary Management Expert Committee (FMEC) initiative addresses a previous gap for an HTA and reimbursement recommendation for pediatric indications for drugs later in their life cycle when there is a lack of an industry sponsor.[63]

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