Ontario

Ontario Drug Benefit Formulary/Comparative Drug Index

Edition 43

Drug Programs Policy and Strategy Branch
Health Programs and Delivery Division
Ministry of Health

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Introduction

Part I: Introduction

A. About the Formulary

The Ministry of Health (MOH) issued the first Comparative Drug Index (CDI) in 1970 and Edition 1 of the Ontario Drug Benefit (ODB) Formulary was published in 1971. The integrated Formulary/CDI was first produced in 1974, to list the benefits available to eligible persons under the *Ontario Drug Benefit Act* (ODBA). The Formulary/CDI was developed in consultation with the ministry's external expert drug advisory committee, the Drug Quality and Therapeutics Committee (DQTC), now known as the Committee to Evaluate Drugs (CED). For many years, the Formulary/CDI has set the provincial standard for price, quality and interchangeability of drug products. The MOH has liaised with the Ontario Medical Association (OMA), the Ontario Pharmacists Association (OPA), the Ontario College of Pharmacists (OCP), pharmaceutical manufacturers and other professional and patient groups as required on the content and policies embodied in this publication.

The ODB program is one of the most generous drug benefit programs in Canada, providing coverage for over 5,000 drugs and other substances, including some nutrition products, diabetic testing agents, valved holding chambers and flash glucose monitoring systems. With funding provided by the MOH and the Ministry of Children, Community and Social Services, the ODB program covers most of the cost of prescription drug products listed in the Formulary. As well, drugs that are not listed in the Formulary may be considered for coverage, on a case-by-case basis, through the ministry's Exceptional Access Program (EAP).

1.Purpose

The Formulary/CDI serves as a:

- Guide to prescribers and pharmacists regarding drug products which are eligible for coverage under the ODB program
- Guide for pharmacists regarding conditions for payment
- Guide to professional committees in hospitals and institutions in the selection of drug products
- Guide to drug product interchangeability in respect of drug products that have been designated interchangeable under the Drug Interchangeability and Dispensing Fee Act (DIDFA)
- Comparative pricing guide for drug product

2.Recipient Eligibility

The ODB program provides community-based drug benefits to the following groups of Ontario residents:

- *People entitled to receive drug benefits under the Ontario Disability Support Program Act*, *1997* or the *Ontario Works Act*, *1997*.
- Insured persons under the *Health Insurance Act* who satisfy any of the following criteria:
    1. Aged 65 years or older
    2. Aged 24 years or under who do not have a private plan
    3. Residing in a Home for Special Care or Community Home for Opportunity (CHO)
    4. Residing in a long-term care home
    5. Registered in the Trillium Drug Program
- Individuals who are receiving:
    - a professional service (other than training) under O. Reg 187/22 (Home and Community Care Services) made under the Connecting Care Act, 2019 that is provided by a health service provider or Ontario Health Team; or
    - a substantially equivalent service that is provided by an Indigenous organization that has entered into an agreement with the Ministry of Health.

For additional details on recipient eligibility, please consult the Ontario Drug Programs Reference Manual.

To help make the ODB program sustainable and affordable for the future and to allow the government to continue to add new drugs as benefits, a cost sharing scheme was introduced in July 1996. Most classes of ODB recipients are required to pay a portion of their prescriptions. For more details about co-payments and deductibles, please refer to Section C.4 of Part I, entitled “Cost Sharing” and the Ontario Drug Programs Reference Manual.

3.Interchangeable Products

The *Drug Interchangeability and Dispensing Fee Act* (DIDFA) gives the Executive Officer (EO) of the Ontario Public Drug Programs (the “Executive Officer”) the authority to designate a product as interchangeable with one or more other products where the EO considers it advisable in the public interest to do so and certain requirements and conditions set out in the DIDFA and Regulation 935 made under the DIDFA are met. For example, a product can only be designated as interchangeable with another product if the product has the same amount of the same or similar active ingredient(s) in the same or similar dosage form as the other product. The onus is on the manufacturer to provide evidence of interchangeability.

The reimbursement of products on the current Formulary is based on a “lowest cost” policy, meaning that dispensers will only be reimbursed by the ministry for the lowest cost product listed in a category of drugs. This lowest cost policy is set out in the *Ontario Drug Benefit Act* (ODBA).

Off-Formulary Interchangeability

Off-Formulary Interchangeability (OFI) is the application of interchangeable designations to drug products that are not listed as ODB benefits in the Formulary/CDI. OFI became effective April 1, 2007 when changes to Regulation 935 made under the DIDFA came into force. OFI drug products are reviewed by the CED or by the ministry, and upon approval of the EO, are determined to be interchangeable with an original product.

Please note that some OFI products may be covered under the ODB program through the EAP.

Notice to Dispensers

There are occasions when a drug product that is the subject of an ongoing patent dispute in the courts is designated as interchangeable in the Formulary/CDI. The designation of such a drug product is not meant to be, and does not act as, a certification that the drug product is non-infringing under federal patent laws. Dispensers should seek their own advice in that regard. If a court finds a drug product to be patent infringing, the EO may, depending on the court’s finding or order, reconsider the listing status of the drug product.

4. The Committee to Evaluate Drugs (CED)

The Committee to Evaluate Drugs (CED) is the ministry’s independent expert advisory committee on drug-related issues and is established by Order-in-Council under the authority of section 9 of the *Ministry of Health Act*.

The CED provides an essential service to the ministry by evaluating the clinical value of drug products, interchangeability of generic drug products and cost-effectiveness of drugs through its rigorous and evidence-based reviews. These reviews result in recommendations being made to the EO regarding the designation of these products as benefits under the ODB program, and as interchangeable under the DIDFA. The EO makes the final decision regarding designations, taking into consideration the recommendations of the CED and public interest. The CED also provides the ministry with advice on a broad range of policy issues relating to the use of drugs.

The CED is comprised of a chair and 16 members appointed by the Lieutenant Governor in Council. Two of the 16 CED members are patient representatives. The remaining CED members include an economist, and practicing physicians and pharmacists, who have expertise in a wide range of specialties including endocrinology, pediatrics, infectious disease, internal medicine, family medicine, pharmacology, health economics, epidemiology and other disciplines. Additional information on the CED membership and its terms of reference can be accessed through the Ontario Public Appointments' website at: Ontario Public Appointments Secretariat Web Site.

To support improved transparency and accountability, the CED's recommendations and the EO's decisions are publicly available on the MOH website at:
EO Decisions and CED Recommendations.

For drug products to be eligible for listing in the Formulary, a drug manufacturer must provide a complete submission in accordance with the prescribed conditions set out in:

- O. Reg. 201/96 made under the ODBA; and
- Regulation 935 made under the DIDFA.

Interpretive guidelines have been published to assist manufacturers in making their submissions and are available on the ministry's website at:
Guideline and Template Downloads.

Following its review, the CED makes recommendations to the EO as to whether a drug product should be designated as a benefit under the ODB program and/or as interchangeable under the DIDFA. As well, the CED makes recommendations as to which drug products should be available through the EAP.

Drug products reviewed by the national process of Common Drug Review (CDR) and the pan-Canadian Oncology Drug Review (pCODR) do not require a routine review by CED. On a case-by-case basis, the Health Programs and Delivery Division may seek CED's advice on drug products previously reviewed by the CDR or pCODR.

More information on how drugs are approved can be found on the ministry's website at:
How Drugs Are Approved.

B. How to Use the Formulary

The Formulary/CDI identifies over 5,000 drug products designated as benefits under the ODB program, as well as drug products that are considered to be interchangeable, and serves as a reimbursement guide for prescribers and pharmacists.

The Formulary/CDI consists of a compilation of pharmaceutical products arranged in comparative categories and groupings according to the name, strength and dosage form of the active therapeutic ingredients.

This information requires knowledgeable interpretation and is intended primarily for health care professionals, pharmacies, hospitals and organizations associated with the manufacture, distribution and use of pharmaceutical preparations.

Part III-A ODB Formulary/Comparative Drug Index

Part III-A of the ODB formulary is available through the searchable electronic formulary (e-Formulary) online at: Formulary Search.

Classification

Drugs are indexed by pharmacologic-therapeutic classification based on the classification system of the American Hospital Formulary Service (AHFS) of the American Society of Health-System Pharmacists. Permission to use this classification system has been granted by the Society, which is not responsible for the accuracy of any reproduced content.

The pharmacologic-therapeutic classification under which any drug is listed may be found by consulting the index in Part V of the Formulary/CDI. Drugs with multiple indications are listed under only one of the common uses.

Interchangeable Categories

Where there is more than one drug product listed in a specific category, the products have been designated as interchangeable under the DIDFA, unless otherwise noted. The Drug Benefit Price (DBP) is listed for each drug product as well as the **lowest DBP** for an interchangeable category. The ODB program will reimburse dispensing physicians and pharmacies the lowest DBP within an interchangeable category.

If a pharmacy dispenses an interchangeable product to a patient who does not receive benefits under the ODB program, the pharmacy cannot charge more than the lowest DBP amongst the interchangeable products in its inventory when dispensing the product (see subsection 7(2) of the DIDFA).

Drug Identification Number (DIN)

For each drug product, the Formulary/CDI lists the eight-digit drug identification number (DIN) assigned by Health Canada's Therapeutic Products Directorate*. The DIN uniquely identifies each drug product as to its manufacturer, active ingredient(s), strength of active ingredient(s), route of administration and pharmaceutical dosage form. Please note that only products with DINs or Product Identification Numbers (PINs) that are listed as benefits in the Formulary/CDI are eligible for reimbursement under the ODB program.

*A small number of products, including drugs, nutrition products, diabetic test strips and valved holding chambers, have been assigned a product identification number (PIN) with leading digits 098 for the purposes of ODB claims. Ministry assigned PINs may differ from those shown on the manufacturer's label but must be used when submitting claims to the ODB program.

Natural Product Number (NPN)

For natural health products, the Formulary/CDI lists the eight-digit Natural Product Number (NPN) assigned by Health Canada. Natural health products, as defined in the Natural Health Products Regulations made under the federal *Food and Drugs Act* are excluded from the definition of "drug" in Ontario's *Drug and Pharmacies Regulation Act* (DPRA), unless the natural health product contains pseudoephedrine or its salts, ephedrine or its salts, or any combination of them (see clause 1(1)(f) of the DPRA and subsection 3(7) of O. Reg. 58/11 made under the DPRA). Please note that only natural health products with NPNs listed as benefits in the Formulary/CDI are eligible for reimbursement under the ODB program.

Limited Use Products

Limited Use (LU) products are listed in the Formulary/CDI with specific clinical criteria/conditions for use and will be reimbursed under the ODB program only when those criteria/conditions have been met (see section 23 of the ODBA). LU products will be reimbursed under the ODB program only when prescribed for an ODB-eligible recipient in accordance with the applicable LU criteria and only if the prescriber has provided the Reason for Use Code, either verbally, electronically or in written format with the prescription.

For more details about the LU reimbursement process, please refer to Section C.9 of Part I, entitled "Limited Use Products" as well as to Part XII of the Formulary/CDI.

Therapeutic Notes

Many therapeutic notes contain specific clinical criteria that apply to some general benefit products as listed in the ODB Formulary. The therapeutic notes provide guidance to prescribers on where the product can be used in the most appropriate/cost-effective manner as advised by the ministry's expert advisory committee, the CED. Therapeutic notes define appropriate therapy; and therefore, the expectation is that both prescribers and dispensers should follow them.

Product Listing Agreements

A Product Listing Agreement (PLA) refers to a negotiated agreement between a pharmaceutical manufacturer and the EO. Ontario participates in the pan-Canadian Pharmaceutical Alliance (pCPA) and may work with other provinces and territories to negotiate these agreements. These agreements support reimbursement of some products in the Formulary and other Ontario public drug programs, such as the New Drug Funding Program.

Agreements are intended to provide access to new and existing drugs according to certain conditions and are based on a number of factors including the Canadian Agency for Drugs and Technologies in Health's (CADTH) and CED's recommendations, clinical evidence, therapeutic need and cost-effectiveness. Listing agreements may include multiple components:

- Commitment to promote appropriate use
- Requirement to collect outcomes data
- Requirement to gather further evidence related to clinical or economic information for future consideration by the CED
- Cost and utilization considerations

Part III-B Off-Formulary Interchangeable Drugs

Part III-B of the ODB formulary is available through the searchable electronic formulary (e-Formulary) online at: Formulary Search.

Off-Formulary Interchangeable (OFI) drug products are listed by a pharmacologic-therapeutic classification based on the same classification system as applied to products in Part III-A of the Formulary/CDI. None of the drug products listed in Part III-B of the Formulary/CDI are formulary benefits.

Drug product prices, as reported by the respective manufacturers to the ministry, have been listed for each product for information purposes only. In accordance with paragraph 7 of subsection 8(1) Regulation 935 made under the DIDFA, manufacturers of these drug products shall give the EO notice of every change in the manufacturer's list price for their drug products.

Part III-C Temporary Benefits

The list of Temporary Benefits can be accessed through the electronic ODB Formulary (e-Formulary) on the ministry's website at: Formulary Search

A Temporary Benefit on the ODB Formulary is a clinically-appropriate alternate drug that is publicly funded on a short-term basis to facilitate the management of a drug shortage. Certain drug submission requirements are waived to allow for the short-term funding. The Temporary Benefit will be designated as such on the Formulary

Part IV Section Currently Not In Use

Part V Index of Pharmacologic-Therapeutic Classification

An index of the pharmacologic-therapeutic classification is provided in this section in ascending order.

Part VI Facilitated Access Drug Products

This part lists specific products that are reimbursed through the Facilitated Access mechanism under the ODB program for treatment of ODB recipients receiving palliative (end-of-life) care. Products listed in this section can be accessed by eligible patients without the need for a patient-specific application to the Exceptional Access Program (EAP). Prescribers must be identified on the Facilitated Access Prescribers List that is appropriate for the patient and product being prescribed.

Part VII Trillium Drug Benefit Program

The ministry provides benefits through the Trillium Drug Program to help individuals and families who have high prescription drug expenses in relation to their incomes. Part VII explains how the Trillium Drug Benefit Program works and provides a list of allowable expenses for the purpose of satisfying deductible requirements under the Program.

Part VIII Exceptional Access Program (EAP)

The ministry may consider requests for coverage of drug products not listed in the Formulary/CDI for ODB-eligible persons. Part VIII provides an overview of the EAP.

Part IX Additional Benefits

Nutrition Products

This section includes a maximum allowable reimbursement mechanism for Nutrition Products covered under the ODB program. Physicians and nurse practitioners must complete a Nutrition Products form and forward a copy with the prescription to the pharmacy for each Nutrition Product prescribed. Claims for Nutrition Products are reimbursed only for patients who are eligible for ODB coverage and who also meet the eligibility criteria described in Part IX of the ODB Formulary. The ODB program does not provide coverage for Nutrition Products for residents of long-term care homes, Homes for Special Care and Community Homes for Opportunity. Long-term care homes, Homes for Special Care and Community Homes for Opportunity are responsible for providing Nutrition Products to their residents when required.

Reimbursement of Nutrition Products is not considered through the EAP.

Diabetic Testing Agents

Blood glucose test strips covered by the ODB program are listed in Part IX of the ODB Formulary. These products are available to ODB-eligible recipients with a valid prescription from a physician or nurse practitioner. Please see section on diabetic testing agents in Part IX for more information, including the reimbursement prices for diabetic testing agents.

Valved Holding Chambers

Effective January 1, 2018, all Ontario Drug Benefit recipients aged 12 years and under with a valid prescription from a physician or nurse practitioner are eligible to receive an ODB-funded valved holding chamber.

Part X Abbreviations

This part contains a list of abbreviations for the names of manufacturers whose products are listed in the Formulary/CDI and a list of abbreviations for dosage forms.

Part XI Section Currently Not In Use

Part XII Limited Use

This section contains a guide for prescribers and pharmacists on how to complete an LU prescription.

C. Dispensary Reimbursement/Procedure

1. Health Network System

The Health Network System (HNS) links all Ontario dispensers participating in the ODB program to the ministry computer system and allows online claims processing and adjudication in real-time. The collection, use and disclosure of personal information on the HNS are governed by section 13 of the ODBA and the *Personal Health Information Protection Act*, 2004.

2. Drug Utilization Review (DUR)

The HNS assists pharmacists in providing quality health care through a drug utilization review (DUR) mechanism. The DUR program, part of the HNS, provides an analysis of both previous prescription information/claims data and current prescription data to identify potential problems. Its primary function is to enhance the current principles of good pharmacy practice with additional information sources. The HNS's prospective DUR currently monitors for:

- Potential drug interactions
- Potential double doctoring
- Duplicate prescriptions
- Potential multiple pharmacy use
- Refill too soon/too late

Retrospective claims analysis will also provide insights into drug trends and issues. It can help identify patterns that could form the basis for further study and the development of strategies leading to more rational drug use.

3. Drug Cost

The drug cost in the Formulary is the Drug Benefit Price (DBP) as defined in the *Ontario Drug Benefit Act* (ODBA) and the DIDFA. The DBP for a drug in a particular dosage form and strength reflects the amount, calculated per gram, millilitre, tablet, capsule or other appropriate units, for which a funded drug product in that dosage form and strength will be reimbursed by the ministry. Some drug products are listed in package ("Pk") sizes (i.e., pressurized inhalers). For these products, the DBP is for the package size listed. For ointments, creams, powders and liquids the DBP is usually per gram or per millilitre. For tablets, capsules and suppositories, other than those designated "Pk," the DBP is per unit dosage form. Claims must be submitted in alignment with the product listing.

Products that are benefits are reimbursed under the ODB program at the listed DBP (or if interchangeable products are listed, at the lowest DBP for an interchangeable category) plus a mark-up plus the lesser of a pharmacy's posted usual and customary fee or the ODB dispensing fee, minus the applicable co-payment amount for every ODB prescription filled.

4. Cost Sharing

Most classes of ODB recipients are required to contribute a co-payment amount for each prescription.

There are two categories of co-payments:

1) Subject to the rule described below for children and youth aged 24 years of age and under and long-term care home residents, ODB recipients may be charged up to $2 toward the dispensing fee for each prescription funded by the ODB program if they are one of the following:

   - A senior who either has no spouse or does not cohabit with his/her spouse because the spouse is residing in a long-term care home, Home for Special Care, or Community Home for Opportunity ("senior single"), has an annual net income equal to or less than $25,000 and is enrolled in the ministry's Seniors Co-Payment Program
   - A senior who cohabits with his or her spouse ("senior couple"), has (with their spouse) a combined annual net income is equal to or less than $41,500, and is enrolled in the ministry's Seniors Co-Payment Program
   - An individual entitled to receive drug benefits under the *Ontario Works Act, 1997* or the *Ontario Disability Support Program Act*, *1997*
   - A resident of a Home for Special Care or Community Home for Opportunity
   - An individual eligible for benefits under the Trillium Drug Program once their deductible for the quarter has been paid
   - An individual who is receiving:
     - a professional service (other than training) under O. Reg 187/22 (Home and Community Care Services) made under the Connecting Care Act, 2019 that is provided by a health service provider or Ontario Health Team; or
     - a substantially equivalent service that is provided by an Indigenous organization that has entered into an agreement with the Ministry of Health.

2) Single seniors with annual net income greater than $25,000 or a senior couple with a combined annual net income greater than $41,500 each pay their first $100 (i.e., deductible) each year on the eligible products. After that, each senior may be charged up to $6.11 (i.e., co-payment) toward the dispensing fee for each prescription funded under the ODB program.

All children and youth aged 24 years and under who are ODB recipients, except those who are only eligible for benefits under the Trillium Drug Program, have no co-payment. Similarly, all residents of long-term care homes have no-copayment. For additional details regarding co-payments and deductibles, please consult the Ontario Drug Programs Reference Manual.

5. Drug Quantity

For most ODB-eligible recipients the maximum quantity that may be charged under the ODB program, for which the Executive Officer is required to pay, would be a supply sufficient for a 100-day course of treatment. The quantity dispensed is subject to the rules set out in the ODBA, and the DIDFA as well as to the details of the prescription as directed by the prescriber. In the case of medications to which the Trial Prescription Program applies, the maximum quantity for which the EO is required to pay is a quantity sufficient for 30 days.

Additional quantity restrictions are also enforced by the HNS for some Trillium recipients receiving prescriptions in the third and fourth quarter of the benefit year. Please refer to Part VII for additional drug quantity restrictions related to the Trillium Drug Program.

The HNS provides pharmacists with a “refill too soon” warning for claims where additional supplies are submitted more than ten days prior to the end of a previous supply. Pharmacists should use their professional judgment in consultation with the prescriber and patient when dispensing the second prescription. The ministry recognizes that there are circumstances in which recipients have a valid and appropriate reason for obtaining an early refill of a medication (e.g., dose change). In these cases, the reason for the early refill must be documented. The ministry will monitor claims to ensure that pharmacies comply with the HNS warnings and recoveries of payments will be made where claims are submitted inappropriately.

Effective March 1, 1999, ODB recipients traveling outside the province for at least 100 days, may obtain an early refill (up to a 100-day supply) of medication before leaving the province. In order to obtain an early refill for a vacation supply, ODB recipients must provide the pharmacist with a letter, or a copy of their travel insurance, confirming that they are leaving the province for at least 100 days. The letter or copy of travel insurance must be maintained and be readily retrievable by the pharmacist for a period of 24 months, for audit purposes. It is recommended that these documents be maintained in a separate file, instead of attaching to the prescription hardcopy. Pharmacists must have the letter or copy of their travel insurance confirming travel outside of Ontario ***before*** submitting claims for a vacation supply and overriding any rejections generated by the HNS (use intervention code “MV” to override the “duplicate claim” rejection if two claims for 100-day supply of medication are submitted for the recipient on the same day). Please refer to Part VII for Trillium vacation supply information.

6. Payment of Dispensing Fees under the Ontario Drug Benefit (ODB) Program

Conditions on Payment of Dispensing Fees

In order to receive payment of a dispensing fee under the ODB program, the dispenser must supply at one time the ***lesser*** of:

1. The maximum quantity of the listed drug product that the dispenser is authorized to supply at one time; or
2. The maximum quantity permitted under section 18 of O. Reg. 201/96.

The amount referred to above (in either item 1 or 2) is the “Maximum Quantity.”

In most cases, the Maximum Quantity is a 30-day supply for the Trial Prescription Program, or a 100-day supply. The dispenser is permitted to dispense a quantity that is not the Maximum Quantity only if one of the following conditions applies:

1. The ODB recipient is a resident of a long-term care home (Conditions for Payment of a Dispensing Fee under the ODB Program).* (Note, only applicable for secondary pharmacy service providers. See more info here: https://wayback.archive-it.org/16312/20220505190337/https://health.gov.on.ca/en/pro/programs/drugs/opdp_eo/notices/exec_office_20191216_2.pdf)
2. The ODB recipient is a resident of any other residential facility funded by the Government of Ontario that is designated by the Executive Officer (e.g., Home for Special Care) and published on the ministry website at: (Conditions for Payment of a Dispensing Fee under the ODB Program).*
3. The listed drug product is a product or belongs to a class of drug product that is specified by the Executive Officer and published on the ministry website at: (Conditions for Payment of a Dispensing Fee under the ODB Program) and the dispenser has determined that the quantity supplied should be less than the Maximum Quantity because, in the dispenser’s professional opinion,
    - The safety of the ODB recipient is a concern, or
    - There is a risk of abuse or diversion if the drug product is supplied to the ODB recipient.**
4. The dispenser has determined that the quantity supplied should be less than the Maximum Quantity because,
    a. In the dispenser’s professional opinion, the ODB recipient is incapable of managing his or her medication as a result of physical, cognitive or sensory impairment; and

b. The ODB recipient or the person presenting the prescription agrees that the quantity supplied should be less than the Maximum Quantity.***

*Note: In the case of Exceptions 1 to 3, ODB recipients who are deemed to require more frequent dispensing should be assessed regularly to verify an ongoing need for more frequent dispensing.

**Note: In the case of Exception 3, the dispenser must perform all of the following:

- The dispenser must make a written record of the reasons for his or her opinion;
- The dispenser must notify the prescriber in writing about the assessment and retain a copy of the notification; and
- Upon request, the dispenser must provide the ministry with copies of the written record and the written notification to the prescriber.

***Note: In the case of Exception 4, the dispenser must perform of all the following:

- The dispenser must make a written record of the reasons for his or her opinion;
- The dispenser must notify the prescriber in writing about the assessment and retain a copy of the notification;
- The dispenser shall obtain in writing the agreement of the ODB recipient or the person presenting the prescription;
- Upon request, the dispenser must provide the ministry with copies of the written record, agreement and notification to the prescriber; and
- The exception is only valid for a period of 365 days. A dispenser's assessment that a patient requires more frequent dispensing because of a physical, cognitive or sensory impairment must be re-assessed annually. Records of this annual assessment must be maintained as part of the ODB recipient's permanent pharmacy health record.

All claims are subject to recovery if found to be ineligible for reimbursement under the ODB program.

Two Fees / 28 Days

In most cases, the Executive Officer will only pay a dispenser a maximum of two (2) dispensing fees per 28 days for the supply of a listed drug product, even if the prescription directs more frequent dispensing. This rule is subject to the rule respecting Chronic-Use Medications (see section below).

The two-dispensing-fees-per-28-days rule does not apply if:

- The ODB recipient is a resident of a long-term care home (Conditions for Payment of a Dispensing Fee under the ODB Program). (Note, only applicable for secondary pharmacy service providers. See more info here: https://wayback.archive-it.org/16312/20220505190337/https://health.gov.on.ca/en/pro/programs/drugs/opdp_eo/notices/exec_office_20191216_2.pdf)
- The ODB recipient is a resident of any other residential facility funded by the Government of Ontario that is designated by the Executive Officer (e.g., Home for Special Care, Community Home for Opportunity) and published on the ministry website at: (Conditions for Payment of a Dispensing Fee under the ODB Program).
- The listed drug product is supplied in the Maximum Quantity (see definition in previous section "Conditions on Payment of Dispensing Fees") and is a product or belongs to a class of drug product that is specified by the Executive Officer and published on the ministry website at: (Conditions for Payment of a Dispensing Fee under the ODB Program).
- The listed drug product is a product or belongs to a class of drug product that is specified by the Executive Officer and published on the ministry website at: (Conditions for Payment of a Dispensing Fee under the ODB Program) and the dispenser has supplied the drug in a quantity that is *less than* the Maximum Quantity because, in the dispenser's professional opinion,
    - The safety of the ODB recipient is a concern, or
    - There is a risk of abuse or diversion if the drug product is supplied to the ODB recipient.

Note: Where the dispenser has supplied *less than* the Maximum Quantity for safety/abuse/diversion reasons, the dispenser must make a written record of the reasons for his or her opinion, notify the prescriber in writing about the assessment, and retain copies of the written record and prescriber notification. All claims are subject to recovery if found to be ineligible for reimbursement under the ODB program.

Dispensing Fees for Chronic-Use Medications

Effective October 1, 2015 changes were made to Ontario Regulation 201/96 made under the *Ontario Drug Benefit Act* to establish a limit on the number of dispensing fees that can be billed to the Executive Officer for certain chronic-use medications.

Dispensers are entitled to receive a maximum of five (5) dispensing fees per 365-day period, commencing on the day the first claim for an identified chronic-use medication is submitted to the ministry on or after October 1, 2015. Dispensers are encouraged to provide most ODB recipients with a 100 days' supply of most chronic-use medications to ensure that they receive a dispensing fee for each dispensing event.

The chronic-use medications subject to this new rule are listed on the ministry website: (Chronic-use Medications List by Generic Name).

This limit on the number of dispensing fees for chronic-use medications does not apply in the circumstances listed below. In these circumstances, the general rule of a maximum of two-dispensing-fees-per-28-days applies, unless the dispensing event is also exempt from that rule (see section above).

Exceptions:

1. ODB recipients who are residents of long-term care homes (Conditions for Payment of a Dispensing Fee under the ODB Program). (Note, only applicable for secondary pharmacy service providers. See more info here: https://wayback.archive-it.org/16312/20220505190337/https://health.gov.on.ca/en/pro/programs/drugs/opdp_eo/notices/exec_office_20191216_2.pdf)
2. ODB recipients who are residents of any other residential facility funded by the Government of Ontario that is designated by the Executive Officer (e.g., Home for Special Care, Community Home for Opportunity) and published on the ministry website (Conditions for Payment of a Dispensing Fee under the ODB Program).
3. The listed drug product dispensed is an extemporaneous preparation.
4. ODB recipients who are on a complex medication regime where patient safety is at risk and who require more frequent dispensing of the listed drug product to assist with the proper administration of the medication regime.**
5. ODB recipients who require more frequent dispensing due to an established physical, cognitive or sensory impairment.**

ODB recipients who are deemed to require more frequent dispensing must be assessed regularly to verify an ongoing need for more frequent dispensing.

**Note: In the case of Exceptions 4 and 5, the dispenser must perform all of the following:

- The dispenser must make a written record of the reasons for his or her opinion;
- The dispenser must notify the prescriber in writing about the assessment and retain a copy of the notification;
- The dispenser shall obtain in writing the agreement of the ODB recipient or the person presenting the prescription;
- Upon request, the dispenser must provide the ministry with copies of the written record, agreement and notification to the prescriber; and
- Exceptions 4 and 5 are only valid for a period of 365 days. A dispenser's assessment that a patient requires more frequent dispensing because of a physical, cognitive or sensory impairment or because the patient is on a complex medication regime, must be re-assessed annually. Records of this annual assessment must be maintained as part of the ODB recipient's permanent pharmacy health record.

All claims are subject to recovery if found to be ineligible for reimbursement under the ODB program.

Note: Any reference in this section to the term “written”, “in writing” or “written record” includes electronic records and electronic copies of written records.

7. Cost-to-Operator Claims

Effective March 1, 2007, in accordance with clause 14(3)(b) of O. Reg 201/96 made under the ODBA, the allowable use of the ‘MI’ (Cost-to-Operator or ‘CTO’) intervention code is restricted to cases where a pharmacy is unable to acquire the lowest DBP product in an interchangeable category and must dispense the original product or a higher-priced interchangeable drug product. Supporting documentation (manufacturer’s or wholesaler’s invoice), which clearly indicates that the generic product had been ordered and was unavailable during the appropriate time period, must be retained on file for 24 months for post-payment verification. Overpayments due to inappropriate submission of MI intervention codes are subject to recovery through post-payment verification.

8. Medically Necessary “No Substitution” Claims

The ministry will provide reimbursement of a higher-cost interchangeable product in medically necessary circumstances — where a patient has experienced an adverse reaction to **two** (2) lower-cost interchangeable drug products, where available. When a prescriber identifies a patient for which it is medically necessary that a higher-cost interchangeable product be provided, the prescriber must:

- Complete, sign and forward to the pharmacist a copy of the Health Canada adverse drug reaction form for each lower-cost interchangeable drug product trialed (Canada Vigilance Adverse Reaction Reporting Form); and
- Write “No Substitution” or “No Sub” on a written prescription or indicate “No Substitution” to the pharmacist in the case of a verbal prescription.

The prescriber should keep a copy of the completed form in the patient’s record for future use and reference.

When the pharmacist receives a prescription with the written notation “No Substitution,” reimbursement will be provided for the higher-cost interchangeable product only if the prescription is accompanied by a completed Health Canada adverse drug reaction form for **each** of the lower-cost interchangeable drug product trialed. This form must be completely filled out noting the details of the adverse reaction and signed by the prescriber.

Upon receipt, the **pharmacist** must:

- Clearly note on the adverse drug reaction form – “ODB NO SUBSTITUTION”; and
- Fax or mail the completed and signed form to Health Canada’s Canada Vigilance Program; and

- Retain his or her copy of the completed and signed adverse drug reaction form.

The adverse drug reaction form will not have to be renewed. However, in accordance with sections 19 and 29 of O. Reg. 201/96 made under the ODBA, the dispensary must retain a copy of the prescription and the required Health Canada adverse drug reaction forms (completed and signed by the prescriber). The prescriber must write “No Substitution” or “No Sub” on renewal or subsequent new written prescriptions, and indicate “No Substitution” on subsequent new oral prescriptions.

The dispenser will be reimbursed the DBP plus a mark-up and the lesser of the posted usual and customary fee or the ODB dispensing fee minus the applicable ODB co-payment amount. Where a completed, signed adverse reaction form is not available at the pharmacy during an audit, the difference between the cost of the higher-cost product and the lowest DBP listed for the interchangeable category will be recovered.

The pharmacist must mail or fax the completed form to:

Canada Vigilance Program, Marketed Health Products Directorate,
Health Canada,
Postal Locator 0701E, Ottawa, Ontario K1A 0K9
Fax: 1-866-678-6789

Please refer to Health Canada’s Canada Vigilance Program website to obtain a copy of the adverse drug reaction (Canada Vigilance Drug Reaction Reporting) form at: Canada Vigilance Adverse Reaction Reporting Form.

For additional information on the Canada Vigilance Program, please call 1-866-234-2345 or visit: Canada Vigilance Program.

An ODB recipient with a valid “no substitution” prescription that was filled prior to October 1, 2015 will be permitted to renew and refill their brand therapy as directed, as long as the appropriate documentation remains on file.

9. Limited Use (LU) Products

Designating Listed Drugs as LU Benefits

Drug products reimbursed under the ODB program are evaluated and recommended for listing by the ministry’s expert drug advisory committee, the CED. LU drugs are those drugs recommended by the CED as having value in specific circumstances, but are not appropriate for general listing in the Formulary/CDI. LU drugs may:

- Have the potential for widespread use outside the indications for which benefit and cost-effectiveness have been demonstrated
- Be clinically useful, but are associated with predictable severe adverse effects and a less toxic alternative is available as a general benefit
- Be very costly and a lower-cost alternative is available as a general benefit

As a result, the CED may recommend that a drug product be reimbursed only when specific clinical criteria/conditions have been met.

The CED and the ministry will continue to review existing LU products to determine if there are opportunities to transition a given product to a general benefit listing.

LU Reimbursement Process

The Reason for Use (RFU) code may be communicated in writing, electronically or verbally. The authorization periods for an LU prescription are noted with the drug listing in the Formulary and are based on the initial date that the first LU prescription is dispensed.

See Part XII for more detailed information about the LU claims process, including instructions for prescribers and pharmacists related to LU prescriptions.

ODB Inspection of LU Claims

The Inspection Unit of the Health Programs and Delivery Division routinely conducts on-site inspections of all pharmacies for post-payment verification of claims reimbursed under the ODB program. In addition, the ministry may request copies of LU prescriptions from pharmacies by mail for purposes of carrying off-site inspections relating to ODB claims for LU products. The ministry will recover monies paid for LU product claims if one of the following applies:

1. The LU (RFU) code indicated on the prescription does not meet the listed LU clinical criteria
2. The LU (RFU) code is not provided with the prescription
3. The prescription is incomplete (e.g., the date, drug, patient name or the correct CPSO number or college registration number is missing or the prescriber has not signed the prescription)
4. The LU authorization period is expired
5. A prescription with valid LU documentation was not obtained/retained in the pharmacy for 24 months

Pharmacists are reminded that copies of prescriptions with LU documentation must be retained by the pharmacy for 24 months as required by section 29 of O. Reg. 201/96 made under the ODBA.

10. Extemporaneous Preparations

An extemporaneous preparation is defined in section 1(1) of O.Reg 201/96 made under the ODBA as a “drug or combination of drugs prepared or compounded in a pharmacy according to a prescription.”

Section 17 of the ODBA gives the EO of Ontario Public Drug Programs (“the Executive Officer”) the authority to:

- Determine the conditions which must be met before an extemporaneous preparation is designated as a designated pharmaceutical product (“DPP”) and therefore deemed eligible for reimbursement as a listed drug product under the ODB program; and
- Determine the drug benefit price of a DPP including a formula by which the drug benefit price may be calculated.

An extemporaneous preparation that meets the general guidelines of compounding activities as described in the Regulatory Framework section of the *Guidance Document for Pharmacy Compounding of Non-Sterile Preparations* published by the National Association of Pharmacy Regulatory Authorities will be deemed by the EO to be a DPP and therefore eligible for reimbursement under the ODB program, if certain conditions are met. Please refer to Section 6.1 of the Ontario Drug Programs Reference Manual

for the conditions and requirements for extemporaneous preparations.

The information in the Ontario Drug Programs Reference Manual on the extemporaneous preparations is considered the authoritative source of information on the extemporaneous preparations policy.

Pharmacists are reminded that claims reimbursed under the ODBA are subject to post-payment verification. Questions can be directed to the ministry’s ODB Help Desk.

11. Professional Pharmacy Services

The Ontario government, on the advice from the Ontario Pharmacy Council, has launched a number of professional pharmacy services.

Please refer to the ministry’s website for information on the following professional pharmacy services at Professional Pharmacy Services:

- MedsCheck program
- MedsCheck at Home
- MedsCheck for Ontarians living with Diabetes
- MedsCheck for Long-Term Home Residents
- Pharmaceutical Opinion program
- Pharmacy Smoking Cessation program

D. Information and Assistance

1. Personal Health Information Protection Act, 2004 and Freedom of Information and Protection of Privacy Act

The information on ODB claims, including those on paper and electronic media, is collected for purposes related to the administration of the ODBA. It is collected under the authority of subsection 13(1) of the ODBA and clause 36(1)(h) of the *Personal Health Information Protection Act,* 2004.

For further information please contact:

Director

Drug Programs Policy and Strategy
Health Programs and Delivery Division
5700 Yonge Street, 3rd Floor
Toronto, ON M2M 4K5

Tel.: 416-212-4724
Fax: 416-325-6647
Website: Ministry of Health

2. Inquiries and Assistance

The following information is provided to assist prescribers, pharmacists and manufacturers in obtaining details on the Ontario Drug Benefit program, claims submission and payments.

Payments

Program Payments
Financial Management Branch
P.O. Box 48
Kingston, ON K7L 5J3

Manual Claims Submissions

Ministry of Health
Claims Services Branch
130 Dufferin Avenue 4th floor
London, ON N6A 5R2

For new ODB program registrations and registry inquiries, please contact:

Ministry of Health
Claims Services Branch
Provider Registry
P.O. Box 68
Kingston, ON K7L 5K1

Email: HNS-Registration.MOH@ontario.ca

Note: Dispensary operators are requested to notify the Provider Registry three weeks in advance of a change in status for openings, closures or transfers of ownership.

Inquiries and correspondence on this publication should be directed to:

Director
Drug Programs Policy and Strategy
Health Programs and Delivery Division
5700 Yonge Street, 3rd Floor
Toronto, ON M2M 4K5

Tel.: 416-212-4724
Fax: 416-325-6647

Website: Ministry of Health

Part II
Preamble
Ontario Drug Benefit Formulary

Effective April 1, 2024, the percentage of the Drug Benefit Price (the “mark-up”) of a listed drug product that is prescribed for the purpose of paragraph 3 of subsection 6(1) of the *Ontario Drug Benefit Act* is:

- 8.5% of the drug benefit price, if the total drug cost of the product when supplied is less than $100;
- 8% of the drug benefit price, if the total drug cost of the product when supplied is $100 or more but less than $500;
- 7% of the drug benefit price, if the total drug cost of the product when supplied is $500 or more but less than $1,000;
- 6% of the drug benefit price, if the total drug cost of the product when supplied is $1,000 or more but less than $2,000;
- 5.5% of the drug benefit price, if the total drug cost of the product when supplied is $2,000 or more but less than $4,000; and
- 5% of the drug benefit price, if the total drug cost of the product when supplied is $4,000 or more.

Total drug cost equals the Drug Benefit Price of the drug product supplied multiplied by the total quantity of the drug product supplied.

Part III
Formulary Listings

Part III-A
Benefits List

The list of benefits can be accessed through the electronic ODB Formulary (e-Formulary) on the ministry's website at: Formulary Search

Part III-B Off-Formulary Interchangeable Drugs (OFI)

Off-Formulary Interchangeability (OFI) is the application of interchangeable designations to drug products that are not listed as ODB benefits in the Formulary/CDI. OFI became effective April 1, 2007 when changes to Regulation 935 under the DIDFA came into force. Listed off-formulary interchangeable drug products are reviewed by the CED or by the ministry, and upon approval of the Executive Officer, are determined to be interchangeable with the brand non-benefit products.

The list of OFI drugs can be accessed through the electronic ODB Formulary (e-Formulary) on the ministry's website at: Formulary Search

Part III-C
Temporary Benefits

The list of Temporary Benefits can be accessed through the electronic ODB Formulary (e-Formulary) on the ministry's website at: Formulary Search

Part III-C: Temporary Benefits

Introduction

Amendments were made to Ontario Regulation 201/96 under the *Ontario Drug Benefit Act* to better enable the Ontario Drug Benefit (ODB) Program to respond to drug shortages. The amendments were deemed to have come into force retroactively on November 1, 2019. These amendments allow the ministry to provide short-term public funding of clinically-appropriate alternate drugs in response to a drug shortage on a temporary basis.

A Temporary Benefit on the ODB Formulary is a clinically-appropriate alternate drug that is publicly funded on a short-term basis to facilitate the management of a drug shortage. Certain drug submission requirements are waived to allow for the short-term funding. The Temporary Benefit will be designated as such on the Formulary.

Claim Submission Process

Each Temporary Benefit drug product has a Drug Identification Number (DIN) or is assigned a Product Identification Number (PIN) by the ministry. The DIN or PIN must be used for online claims submitted through the Health Network System (HNS). Billing procedures are the same as the billing procedures for other listed drug products on the ODB Formulary.

Generally, pharmacies are eligible to be reimbursed for the Drug Benefit Price (DBP) associated with the DIN or PIN, plus the applicable mark-up and the pharmacy's usual ODB dispensing fee, minus any applicable co-payment amount. The usual conditions for payment of a dispensing fee under the ODB program must be followed.

For billing purposes, pharmacy documentation must be maintained in a readily available format for the purpose of post-payment verification for a minimum of 2 years. Overpayments due to inappropriate claim submissions are subject to recovery.

Reimbursement Policy

Pharmacies should continue to dispense regular, non-temporary Formulary benefits (i.e., General Benefit or Limited Use) as long as there is supply in stock. The Temporary Benefit should only be dispensed in situations where a regular, non-temporary Formulary benefit is required but unavailable due to shortages in the supply chain.

Generally, Temporary Benefit drug products are not interchangeable with the drug product in shortage. A new prescription may be required.

The ministry will monitor the supply and shortage status of the original listed product. Once resolved and if the temporary listing is no longer in the public interest, the removal of the Temporary Benefit drug product from the formulary will be communicated in a future announcement.

Please call ODB Pharmacy Help Desk for additional information on Temporary Benefits.

Part IV
Section Currently Not In Use

Part V
Index of Pharmacologic-Therapeutic Classifications

Part V: Index of Pharmacologic-Therapeutic Classifications

Classification	Name
4:00	**ANTIHISTAMINES**
8:00	**ANTI-INFECTIVE AGENTS**
8:08	Anthelmintics
8:12	Antibiotics
8:12:04	Antifungals
8:12:07	Carbapenems
8:12:12	Erythromycins
8:12:16	Penicillins
8:12:24	Tetracyclines
8:12:28	Other Antibiotics
8:14	Antifungals
8:14:08	Azoles
8:16	Antitubercular Agents
8:18	Antivirals
8:20	Plasmodicides (Antimalarials)
8:24	Sulfonamides
8:30	Antiprotozoals
8:32	Trichomonacides
8:36	Urinary Anti-Infectives
8:40	Miscellaneous Anti-Infectives
10:00	**ANTINEOPLASTIC AGENTS**
12:00	**AUTONOMIC AGENTS**
12:04	Parasympathomimetic (Cholinergic) Agents
12:08	Parasympatholytic (Cholinergic Blocking) Agents
12:08:08	Antimuscarinics/Antispasmodics
12:12	Sympathomimetic (Adrenergic) Agents
12:20	Skeletal Muscle Relaxants
20:00	**BLOOD FORMATION AND COAGULATION**

Classification	Name
20:04	Antianemia Drugs
20:12	Coagulants and Anti-Coagulants
20:12:04	Direct Factor Xa Inhibitors
20:12:16	Hemostatics
20:16	Hematopoietic Agents
20:24	Hemorrheologic Agents
24:00	**CARDIOVASCULAR DRUGS**
24:04	Cardiac Drugs
24:06	Antilipemic Drugs
24:06:24	PCSK9 Inhibitors
24:08	Hypotensive Drugs (For Diuretics See 40:28)
24:08:16	Central Alpha-Agonists
24:12	Vasodilating Drugs
24:32	Renin-Angiotensin Aldosterone Inhibitors
24:32:08	Angiotensin II Receptor Antagonists
28:00	**CENTRAL NERVOUS SYSTEM DRUGS**
28:08	Analgesics
28:08:04	Nonsteroidal Anti-Inflammatory Agents
28:08:08	Opiate Agonists
28:08:12	Opiate Partial Agonists
28:08:92	Miscellaneous Analgesics and Antipyretics
28:10	Opiate Antagonists
28:12	Anticonvulsants
28:16	Psychotherapeutic Agents
28:16:04	Antidepressants
28:16:08	Tranquilizers
28:16:12	Other Psychotropics
28:20	C.N.S. Stimulants
28:24	Sedatives and Hypnotics
28:36	Antiparkinsonian Agents
28:36:08	Anticholinergic Agents
28:36:20	Dopamine Receptor Agonists

Classification	Name
28:92	Miscellaneous Central Nervous System Drugs
36:00	**DIAGNOSTIC AGENTS**
36:04	Adrenal Insufficiency
40:00	**ELECTROLYTIC, CALORIC AND WATER BALANCE**
40:12	Replacement Agents
40:18	Potassium-Removing Resins
40:18:19	Phosphate-Removing Agents
40:28	Diuretics
40:40	Uricosuric Drugs
48:00	**COUGH PREPARATIONS**
48:04	Antitussives
48:08	Expectorants
52:00	**EYE, EAR, NOSE AND THROAT PREPARATIONS**
52:04	Anti-Infectives
52:04:04	Antibiotics
52:04:12	Other Anti-Infectives
52:08	Anti-Inflammatory Agents
52:08:92	Anti-Inflammatory Agents, Miscellaneous
52:16	Local Anesthetics
52:20	Miotics
52:24	Mydriatics
52:32	Vasoconstrictors
52:36	Other Eye, Ear, Nose and Throat Agents
56:00	**GASTROINTESTINAL DRUGS**
56:04	Antacids and Adsorbents
56:08	Antidiarrhea Agents
56:12	Cathartics
56:16	Digestants
56:22	Antiemetics and Antinauseants
56:40	Miscellaneous G.I. Drugs
60:00	**GOLD COMPOUNDS**
64:00	**HEAVY METAL ANTAGONISTS**

Classification	Name
68:00	**HORMONES AND SUBSTITUTES**
68:04	Corticosteroids
68:08	Androgens
68:12	Contraceptives
68:16	Estrogens
68:20	Anti-Diabetic Agents
68:20:02	Oral Anti-Diabetic Agents
68:20:06	Incretin Mimetics
68:20:10	Insulins (Rapid Acting)
68:20:12	Insulins (Intermediate Acting)
68:20:14	Insulins (Long Acting)
68:20:16	Insulins (Pre-Mixed)
68:24	Parathyroid Agents
68:28	Pituitary Agents
68:32	Progestogens and Oral Contraceptives
68:36	Thyroids
68:38	Anti-Thyroids
84:00	**SKIN AND MUCOUS MEMBRANE PREPARATIONS**
84:04	Anti-Infectives
84:04:04	Antibiotics
84:04:08	Fungicides
84:04:12	Parasiticides
84:04:16	Other Anti-Infectives
84:06	Anti-Inflammatory
84:28	Keratolytic Agents
84:36	Miscellaneous Skin and Mucous Membrane Agents
86:00	**SPASMOLYTICS**
86:12	Genitourinary Smooth Muscle Relaxants
86:12:04	Antimuscarinics
88:00	**VITAMINS**
88:08	Vitamin B
88:12	Vitamin C

Classification	Name
88:16	Vitamin D
88:28	Multivitamins
92:00	**UNCLASSIFIED THERAPEUTIC AGENTS**
92:20	Biologic Response Modifiers
92:36	Disease-Modifying Antirheumatic Agents
92:44	Immunosuppressive Agents
92:92	Other Miscellaneous Therapeutic Agents
96:00	**MISCELLANEOUS**
96:01	Nutrition Products
96:05	Diabetic Testing Agents
96:08	Valved Holding Chamber

Part VI
Facilitated Access Drug Products

Part VI-A
Section Currently Not In Use

Part VI-B Facilitated Access to Palliative Care Drug Products

Part VI-B: Facilitated Access to Palliative Care Drug Products

Formulary modernization activities in 2017 enabled the ministry to transition the majority of drugs used in patients requiring palliative care to the formulary and enable their access through the formulary as Limited Use drugs.

The following list of drug products used to treat ODB eligible patients undergoing palliative care continues to be reimbursed through the Facilitated Access (FA) mechanism under the EAP. Under this mechanism, a select group of participating prescribers do not need to submit an application to EAP, if the prescriber determines that the patient's circumstances meet the reimbursement criteria. If the reimbursement criteria are met, then the prescribing of the therapy shall be deemed to satisfy the requirements in section 16 of the ODBA for an EAP approval.

Eligibility Criteria

Patient

Palliative care medication claims to be reimbursed under the ODB program must be prescribed in accordance with the following patient eligibility criteria: The patient has a progressive, life-limiting illness and requires the requested medication for symptom management.

Physician List

Pharmacies have been provided with a list of physicians approved to participate in the Facilitated Access mechanism. Any changes to this list are communicated to pharmacies.

The Ontario Medical Association (OMA) is responsible for determining physician eligibility to participate based on the following criteria:

- Physicians who do more than 20 palliative care consults in a year
- Physicians who do more than 30 palliative care visits in a year
- Physicians who have been identified as a provider of palliative care by a regional director for Cancer Care Ontario (CCO)
- Physicians who have been identified as a provider of palliative care by the executive of the section of palliative medicine at the OMA
- Physicians who have been identified as a provider of palliative care by the Regional Palliative Care Network
- Physicians who are members of a Palliative Alternate Funding Plan (AFP)
- Physicians who work in collaboration with a Palliative Care Physician or PCFA approved Nurse Practitioner (NP)

Physicians wishing to obtain further information can contact the Ontario Medical Association at (416) 599-2580 ext. 3265, or 1-800-268-7215 ext. 3265, or by e-mail at pcfa@oma.org.

Physicians who are not registered on the PCFA prescribers list may be able to obtain case-by-case access to the PCFA high-strength long-acting opioid drug products (morphine 200 mg SR Tabs and ER Caps, hydromorphone 24 mg and 30 mg CR Caps, fentanyl 75 mcg/hour and 100 mcg/hour Transdermal Patches) for patients requiring palliative care by contacting the EAP's Telephone Request Service (TRS). These physicians must meet the criterion of having consulted with a PCFA-registered prescriber regarding palliative care treatment using the requested high-strength long-acting opioid(s). The approval duration will be granted for up to 12 months for requests meeting the specified criteria. For renewals, a new call to TRS and a new consultation from a registered PCFA prescriber is required. It should be noted that the EAP may validate with the identified PCFA prescriber that a consultation has occurred.

Case-by-case access to non-opioid products on the PCFA drug products list for patients who require these medications for palliative purposes may also be obtained via TRS for prescribers who are not registered on the PCFA prescribers list with the OMA. Consultation with a PCFA prescriber is not required for non-opioid products or opioid products that are not included in the above group of high-strength long-acting opioid drug products.

The Telephone Request Service is available between 8:30 am to 5:00 pm Monday to Friday (excluding statutory holidays) and can be reached by calling the Health Programs and Delivery Division toll-free at 1-866-811-9893. Select the TRS option when prompted.

Nurse Practitioner List

Effective February 9, 2018, the Palliative Care Facilitated Access (PCFA) Drug Products mechanism is expanded to include certain nurse practitioners who are authorized to prescribe controlled drugs and substances. The PCFA nurse practitioner prescribers list, prescriber eligibility criteria and registration are maintained by the Nurse Practitioners' Association of Ontario (NPAO) and the Registered Nurses' Association of Ontario (RNAO).

All nurse practitioners in Ontario are eligible to register for the Palliative Care Facilitated Access (PCFA) prescriber list if they meet the following criteria.

A nurse practitioner who wishes to be added to the PCFA prescriber list must:

- Hold a current certification in the extended class [RN(EC)] with the College of Nurses of Ontario; and
- Be authorized to prescribe controlled drugs and substances; and
- Have no restrictions on the nurse practitioner certification that impact their ability to practice; and
- Provide evidence of continuing education in palliative and end of life care.

In addition, the nurse practitioner must:

- Provide 20 or more palliative care consults in a year; or
- Provide 30–50 or more palliative care visits in a year; or
- Have been identified by the nurse practitioner's employer as a nurse practitioner provider of palliative care; or
- Work in collaboration with a palliative care physician or PCFA-approved nurse practitioner.

Each nurse practitioner must resubmit information annually to demonstrate continued compliance with the above eligibility requirements to maintain PCFA nurse practitioner prescriber registration.

Nurse practitioners wishing to apply to the PCFA nurse practitioner prescriber list or to obtain further information can contact either of the following organizations:

Nurse Practitioners' Association of Ontario
Phone: (416) 593-9779
E-mail: admin@NPAO.org

Registered Nurses' Association of Ontario
Phone : 416-599-1925
E-mail : PCFA@RNAO.ca

Dispensing PCFA Drug Products

For the medications that are on the PCFA drug products list (Part VI-B of the ODB Formulary/CDI), Product Identification Numbers (PINs) have been created. For a claim related to a PCFA drug product, pharmacists must enter the ministry-assigned PIN. For a claim related to an authorization through the EAP TRS mechanism, the actual Drug Identification Number (DIN) of the product should be used in the claim.

To facilitate the reimbursement process at the pharmacy for a PCFA request, the prescriber is asked to indicate either “Palliative” or “P.C.F.A.” on the prescription to signify that the patient meets the above-noted eligibility criteria. The PCFA prescriber’s college registration number must be included on the prescription for purposes of verification. For prescriptions written by physicians who have consulted a registered PCFA prescriber, the prescription should contain “TRS,” indicating to the pharmacist that the physician has obtained approval through TRS.

Please note that the interchangeability of different brands of drugs available through this mechanism has not been evaluated by the ministry, unless they are designated as interchangeable in Part III-A, or Part III-B of the Formulary/CDI. Where interchangeability has not been designated, the prescription must specify the generic drug name or the particular brand name in order for it to be reimbursed by the ministry under the FA mechanism.

Pharmacists must ensure each prescription is accompanied by the required information for approval and dispensing. Pharmacists are reminded that supporting documentation must be kept on file at the pharmacy.

The identity of PCFA prescribers is sent to pharmacies by the ministry as regular updates. Pharmacists are reminded that the PCFA prescribers list is strictly confidential and should not be shared with non-pharmacy staff. The ministry expects pharmacists to take responsibility for ensuring this information is treated accordingly.

For questions, please contact the ODB Help Desk

Facilitated Access Palliative Care Drugs

Generic Name	Strength	Dosage Form	Brand Name	PIN	Mfr
Fentanyl Transdermal System	75mcg/hr	Trans Patch	Apo-Fentanyl Matrix	09857577	APX
		Trans Patch	Co Fentanyl Matrix Patch	09857578	COB
		Trans Patch	PMS-Fentanyl MTX	09857580	PMS
		Trans Patch	Ran-Fentanyl Matrix Patch	09857581	RAN
		Trans Patch	Sandoz Fentanyl Patch	09857582	SDZ
		Trans Patch	Teva-Fentanyl	09857584	TEV
Fentanyl Transdermal System	100mcg/hr	Trans Patch	Apo-Fentanyl Matrix	09857585	APX
		Trans Patch	Co Fentanyl Matrix Patch	09857586	COB
		Trans Patch	PMS-Fentanyl MTX	09857588	PMS
		Trans Patch	Ran-Fentanyl Matrix Patch	09857589	RAN
		Trans Patch	Sandoz Fentanyl Patch	09857590	SDZ
		Trans Patch	Teva-Fentanyl	09857592	TEV
Hydromorphone HCl	24mg	CR Cap	Hydromorph Contin	09857574	PFP

Generic Name	Strength	Dosage Form	Brand Name	PIN	Mfr
Hydromorphone HCl	30mg	CR Cap	Hydromorph Contin	09857576	PFP
Methadone HCl	1mg/mL	O/L	Metadol	09857221	PMS
	10mg/mL	O/L	Metadol	09857223	PMS
Methadone HCl	1mg	Tab	Metadol	09857217	PMS
			Apo-Methadone	09858328	APX
	5mg	Tab	Metadol	09857218	PMS
			Apo-Methadone	09858329	APX
	10mg	Tab	Metadol	09857219	PMS
			Apo-Methadone	09858330	APX
	25mg	Tab	Metadol	09857220	PMS
			Apo-Methadone	09858331	APX
Morphine HCl	1mg/mL	O/L	Doloral 1	09857653	LAA
	5mg/mL	O/L	Doloral 5	09857654	LAA
Morphine Sulfate	200mg	ER Cap	M-Eslon	09857573	ETH
	200mg	SR Tab	MS Contin	09857571	PFP
			Novo-Morphine SR	09857572	NOP
			Sandoz Morphine SR	09857617	SDZ
Oxycodone HCl	5mg	Tab	Oxy.IR	09857243	PFP
			PMS-Oxycodone	09857318	PMS
			Supeudol	09857232	SDZ
	10mg	CR Tab	OxyNEO	09857408	PFP
Oxycodone HCl	10mg	Tab	Oxy.IR	09857241	PFP
			PMS-Oxycodone	09857319	PMS
			Supeudol	09857233	SDZ
	15mg	CR Tab	OxyNEO	09857409	PFP
Oxycodone HCl	20mg	Tab	Oxy.IR	09857242	PFP
			PMS-Oxycodone	09857321	PMS
			Supeudol	09857234	SDZ

Generic Name	Strength	Dosage Form	Brand Name	PIN	Mfr
Oxycodone HCl	20mg	CR Tab	OxyNEO	09857410	PFP
	30mg	CR Tab	OxyNEO	09857411	PFP
	40mg	CR Tab	OxyNEO	09857412	PFP
	80mg	CR Tab	OxyNEO	09857413	PFP
Pamidronate Disodium	3mg/mL	Inj Sol-10mL Vial	Aredia	09857300	NOV
			Pamidronate Disodium	09857302	SDZ
			Pamidronate Disodium Omega	09857399	OMG
			Pamidronate Disodium for Injection	09857628	FKC
	6mg/mL	Inj Sol-10mL Vial	Aredia	09857317	NOV
			Pamidronate Disodium	09857304	SDZ
			Pamidronate Disodium Omega	09857402	OMG
			Pamidronate Disodium for Injection	09857629	FKC
	9mg/mL	Inj Sol-10mL Vial	Aredia	09857301	NOV
			Pamidronate Disodium	09857305	SDZ
			Pamidronate Disodium Omega	09857403	OMG
			Pamidronate Disodium for Injection	09857630	FKC

Part VII
Trillium Drug Program

Part VII: Trillium Drug Program

The Trillium Drug Program (TDP) was established on April 1, 1995, to help people who have high drug costs in relation to their incomes. This is an annual provincial government program. Each year starting August 1, drug costs must be paid up to the deductible level before eligibility for coverage begins. The TDP deductible is based on household income and family size.

The TDP benefit year runs from August 1 of one year to July 31 of the following year. The annual deductible is paid in four installments over the Trillium benefit year. For example, a family with an annual deductible of $500, will pay $125 for prescriptions purchased at the start of each quarter on August 1, November 1, February 1, and May 1. After the deductible is paid in each quarter, the family will receive benefits for that quarter and may be asked to pay up to $2 co-payment per prescription for an eligible drug product. Any unpaid deductible in a quarter will be added to the next quarter's deductible. By regulation costs covered by other entities (private insurers and employers), are not counted towards the TDP deductible. TDP deductibles must be paid by the household's out-of-pocket expenditure.

As of April 1, 2019, children who are 24 years old or younger, have OHIP coverage, and do not have a private plan are automatically covered under the ODB Program instead of TDP. This means that, unlike other TDP family members, they will not have to pay deductibles or the $2 co-payments.

New applicants to Trillium can choose the date within the program year on which they wish to be enrolled. The deductible is prorated based on the number of days left in the program year. The prorated deductible applies only for the first year of enrollment into the program.

People may qualify for the TDP if they:

- Have a valid Ontario Health card number; and
- Are not currently eligible to receive drug benefits under the ODB program; and
- Do not have prescription drug costs fully covered by a private insurance plan; and
- Are paying a large part of their income for prescription drugs.

The following are considered to be allowable prescription drug expenses that can be counted toward the Trillium deductible:

- Products listed as ODB benefits
- Products on the Facilitated Access list in Part VI of the Formulary/CDI
- Any drug product which has been approved by the EO on an individual basis, under section 16 of the ODBA
- Listed substances (e.g. see Nutrition Products list, Diabetic Testing Agents list, Valved Holding Chambers list in Part IX of the Formulary/CDI)
- Extemporaneous products designated as pharmaceutical products under the regulations made under the ODBA
- Products listed in Schedule 2 to O. Reg. 201/96 (insulin, adrenocorticotrophic hormones, nitrate vasodilators)

For Trillium-eligible recipients, the ministry will pay for the lesser of a 100 days' supply or a quantity sufficient to extend up to 30 days after the end of the Trillium eligibility period (e.g., in July, a quantity sufficient to last until August 30 will be covered). In addition, to ensure proper application of the Trillium program for households that have not met their annual deductibles as of the third quarter, the days' supply for claims submitted during this period cannot exceed more than 30 days beyond the end of the third quarter (i.e., beyond May 30th of each benefit year). The HNS automatically calculates the days' supply in these circumstances and will not reimburse any exceeded amounts.

During the first and second quarters of the Trillium benefit year (August 1 – January 31 of the following calendar year), a vacation supply claim of up to 100 days may be allowed (in addition to the regular 100 maximum days' supply) for Trillium recipients travelling outside the province for at least 100 days, before they leave Ontario.

In order to obtain a refill for a vacation supply of up to 100 days of ODB medication, provided that the prescription allows for the additional supply, recipients must provide the pharmacist with documentation confirming that they are leaving the province for at least 100 days including either:

- A letter signed and dated by the recipient indicating travel dates
- A copy of the recipient's travel documentation (e.g., travel insurance)

Vacation supply claims must not be submitted through the HNS for Trillium recipients during the third and fourth quarters of the Trillium benefit year (February 1- July 31). Trillium recipients must pay for their vacation supply for the third and fourth quarters of the benefit year.

Pharmacists should advise Trillium recipients that the ministry will not reimburse vacation supplies paid for out-of-pocket during the third and fourth quarters of the benefit year except in rare circumstances.

Each program year, Trillium recipients enrolled in the previous program year will automatically be renewed unless one of the following conditions applies:

- Household members have declined to give consent for the ministry to access household income information directly from Canada Revenue Agency (CRA), or consent is missing
- Any household member is turning 16 years of age prior to August 1
- The household has not utilized the TDP for the previous two benefit years
- All members of the household are over 65 years of age

A confirmation letter is mailed to households starting June of each year confirming TDP details for the program year. It is required that households inform the program of any changes or incorrect information.

Trillium applications can be obtained through the TDP at 1-800-575-5386, from local pharmacies, or can be downloaded from the ministry's website at:
The Trillium Drug Program (TDP)

Part VIII
Exceptional Access Program (EAP)

Part VIII: Exceptional Access Program (EAP)

The Exceptional Access Program (EAP) facilitates patient access to drugs and products not listed on the ODB Formulary/CDI. In order to receive coverage through the EAP, the patient must be eligible to receive benefits under an ODB funding program.

The EO, on behalf of the ministry, considers requests for coverage of drug products that are not listed in the ODB Formulary/CDI. Funding decisions for drug products considered by the EAP are based on recommendations and guidelines from national and provincial expert advisory committees that include the Canadian Agency for Drugs and Technologies in Health's (CADTH) Canadian Drug Expert Committee (CDEC) and the pan-Canadian Oncology Drug Review's Expert Review Committee (pERC), the CED, advice from experts, other ministry staff, input from stakeholder committees (e.g., pharmacy and citizens' councils), and as negotiated with manufacturers through national and provincial processes and approved by the EO. Also, the program is supported by an extensive roster of expert medical advisers who may be involved in criteria development and/or the review of individual requests for the coverage of drug products. All EAP requests will be considered according to the policies described below to ensure a fair and consistent review of each request. Modernization initiatives to facilitate the EAP process are ongoing.

Funding Decision

EAP requests are only considered for a drug or indication(s) which has been reviewed through the established national and provincial processes and approved for funding by the EO. For Health Canada approved indications, the onus is on the manufacturer to submit information to the Health Programs and Delivery Division to request a product review.

EAP pharmacists and pharmacy technicians assess incoming requests which are approved for funding if the reimbursement criteria are met. Please note, the EAP does not consider funding for non-drug products, which include diabetic test strips, medical or assistive devices, natural health products, or nutrition products. Please refer to Part IX of the ODB Formulary/CDI for nutrition products and diabetic test strips that are covered under the ODB program.

The EO makes the final decision regarding the reimbursement of the product.

EAP Criteria

For a drug to be considered for funding, the EAP reimbursement criteria must always be met prior to the initiation of treatment with the drug being requested, unless otherwise specified within the criteria. This includes:

- Funding for continued treatment that was previously supplied through a clinical trial, or paid for by other means (such as a third party payer)
  Note: First time applications for the funding of ongoing treatments must meet both initial and renewal criteria for the drug being requested (unless otherwise specified)
- Funding for a renewal beyond the previously approved initial period, unless otherwise specified

Selected drug-specific criteria used in the consideration of EAP requests are available on the ministry's website, in order to improve transparency and assist physicians and nurse practitioners in making EAP drug requests.

EAP Application Process

To apply through the EAP, the patient's prescriber (i.e. physician or nurse practitioner) must submit a request documenting complete and relevant medical information to the ministry, providing the clinical rationale for requesting the unlisted drug and reasons why covered benefits are not suitable. All requests are reviewed according to the guidelines and criteria as informed and recommended by the established national and provincial processes and expert committees and approved by the EO. This review includes a thorough assessment of the patient's specific case and clinical circumstances, as provided by the prescriber, as well as the scientific evidence available. If EAP approval is granted, the coverage period begins as of the effective date and extends only to the specified date.

To assist prescribers applying for exceptional access, please refer to the Request for an Unlisted Drug Product – Exceptional Access Program (EAP) Form on the ministry's website at: Request for an Unlisted Drug Product – Exceptional Access Program (EAP)

Additionally, the Drug Identification Numbers (DIN) and criteria for the funding of frequently requested drugs considered through the EAP are posted on the ministry's website at: Exceptional Access Program

Prescribers (physicians and nurse practitioners) are encouraged to utilize this resource to ensure that they provide the adequate clinical information necessary for the EAP to assess the requested drug(s). Currently, only physicians and nurse practitioners practicing in Ontario may request coverage for an EAP drug. However, the province has implemented a Provincial borders program to enable physicians from Manitoba and Quebec to submit EAP requests for Ontarians they are overseeing. (See next section.)

Requests should be sent to the attention of:

Exceptional Access Program (EAP)
Delivery and Eligibility Review Branch
Health Programs and Delivery Division
3rd Floor, 5700 Yonge Street
Toronto ON M2M 4K5
Fax: (416) 327-7526
Toll free fax: 1-866-811-9908

(Faxed requests are preferred – DO NOT mail in a previously faxed request)

Questions from prescribers related to a specific request should be directed to the EAP unit by calling the Health Programs and Delivery Division main telephone number: 416-327-8109 or toll-free at 1-866-811-9893 and listen for the prompts to select the EAP status line. Pharmacies and/or pharmacists with questions regarding billing or adjudication questions related to an individual's coverage for a specific EAP drug should call the ODB Help Desk.

To minimize delays, please ensure that your request is written legibly. Each request should include a concise clinical description and therapeutic plan which must include, but is not limited to, the following:

- Authorized prescriber's name, CPSO/CNO registration/license number, street address, fax number, telephone number, prescriber's signature (mandatory)
- Patient's name, date of birth, health card number (HCN) / ODB eligibility number
- Trade or generic name, strength and dosage form of the requested drug product
- Specific diagnosis for which the drug is requested or reason for use
- If the patient has been taking the product, provide duration of therapy and objective evidence of its efficacy
- Details of both drug and non-drug alternatives that have been tried to treat the condition including dosages (for drugs), length of therapy and response to therapy
- Where alternatives are not appropriate, outline the reasons
- Concomitant drug therapy to treat other conditions, and relevant details of these co-morbid conditions
- Other relevant information (e.g., culture and sensitivity reports, serum drug levels, laboratory results, bone mineral density reports, consultation reports) that are part of the approval criteria for reimbursement

Provincial Borders Drug Program (PBDP)

The Provincial Borders Drug Program (PBDP), which became effective February 9, 2015, is for ODB Program clients who require access to EAP products and whose closest physician is in Manitoba or Quebec. The program allows Manitoba physicians who are licensed by the College of Physicians and Surgeons of Manitoba (CPSM) and Quebec physicians who are licensed by the Collège des Médecins du Québec (CMQ) to submit funding requests on behalf of any ODB client for an EAP product. The drugs, indications and reimbursement criteria covered under the PBDP are identical to those covered under the EAP and must be dispensed by an Ontario community pharmacy.

Physicians from Manitoba and Quebec can apply on behalf of an ODB client, by completing and submitting the standard "Request for an unlisted Drug Product – Exceptional Access Program (EAP)" application, noting their Manitoba or Quebec license number instead of the required College of Physicians and Surgeons of Ontario (CPSO) number. The request should include all the relevant medical information, including but not limited to the clinical rationale for requesting the unlisted drug and the reasons why covered benefits are not suitable.

Extension of Coverage for EAP Drugs

If it is anticipated that a patient will continue to require the product beyond the approval period, the prescriber is required to request an extension or renewal of coverage. It is recommended that the request for continued reimbursement and all supporting documentation (including details of current dose and clinical status) be submitted to the ministry at least four to six weeks prior to the expiration of the current approval.

It should be noted that coverage will not be continued automatically between expiration and re-issuance of approval. Prescribers are encouraged to review the EAP criteria for renewal consideration of individual drugs to ensure that sufficient and appropriate information is provided to facilitate a timely response. The request should include a summary of the patient's progress on the drug product, any changes in drug therapy, the rationale for the continued need for the product and a list of all concomitant drug therapies.

Please refer to the EAP Reimbursement Criteria for further information at:
Exceptional Access Program

EAP – Telephone Request Service

The Telephone Request Service (TRS) offers prescribers another way to submit EAP requests for a group of selected drugs. In most cases, these requests will be assessed in real-time. Prescribers or their delegates may call the TRS to submit their requests and obtain a faster funding decision for selected drugs and indications. Please visit the ministry's website for the evaluation questionnaires and reimbursement criteria at:
Exceptional Access Program

Prescribers and their delegates are encouraged to review the TRS Reimbursement Criteria before calling to ensure that the drug they are requesting is one that can be considered through this service and additionally, to ensure that they provide the necessary information for EAP staff to make a funding decision during the call. Requests for drug products or indications not currently available through TRS will be asked to be submitted via fax.

Prescribers and their delegates may call 1-866-811-9893 or 416-327-8109 and select the TRS option. The hours of operation of EAP's TRS are from 8:30 AM to 5:00 PM Monday to Friday. Service is not available on weekends, provincial statutory holidays, including Easter Monday and Remembrance Day.

Please refer to the ministry's web posting for additional information at:
Exceptional Access Program

Compassionate Review Policy

Where there are rare clinical circumstances in immediately life-, limb-, or organ-threatening conditions, the EO considers requests for drugs or indications in the absence of a final funding decision. Requests must meet the criteria for the Compassionate Review Policy.

Note: For cancer drugs, Cancer Care Ontario (CCO) administers the Case-by-Case Review Program (CBCRP) on behalf of the MOH. The CBCRP extends and adapts the Compassionate Review Policy to therapies that will be administered to patients with cancer.

The CBCRP considers funding requests for cancer drugs (both oral therapies and injectable drugs) for cancer patients who have a rare clinical circumstance that is immediately life threatening (i.e., death is likely within a matter of months) and who require treatment with an unfunded drug, because there is no other satisfactory and funded treatment. For further information on CBCRP including eligibility criteria and how to apply, please visit the CCO website at: Cancer Care Ontario.

While CCO administers the CBCRP, the EO of Ontario Public Drug Programs makes all final funding decisions.

Funding for Drugs being used in Clinical Trials

This section is intended to clarify the circumstances in which EAP funding will be considered for drugs being used within the context of a clinical trial. Generally, the ODB program does not fund drugs being studied under a clinical trial. These costs should be funded by the trial organizer and accounted for within the study budget. Supportive therapies may be considered for funding under all of the following circumstances:

- Funding will only be considered for ODB-eligible recipients (must be ODB eligible at the time of enrollment in the trial)
- Funding will only be considered for products currently funded by the ODB program according to their approved criteria
- EAP request should indicate that the requested product is being used as supportive therapy as part of a clinical trial

Manufacturer-sponsored trials will be excluded, and it is expected that manufacturers will provide funding for study treatments as part of the trial budget. For trials that are not manufacturer sponsored, investigators are asked to provide prior notification to the ministry of impending requests for funding of supportive therapies for a clinical trial. Requestors should indicate trial details, funding details, patient numbers, and timelines for their request prior to submitting the first request to EAP.

Inquiries regarding the EAP should be directed to:

Exceptional Access Program
3rd Floor, 5700 Yonge St.
North York, ON M2M 4K5
E-mail: EAPFeedback.MOH@ontario.ca

Phone: 416-327-8109 or 1-866-811-9893
Fax: 416-327-7526 or 1-866-811-9908

Reimbursement

The decision on reimbursement of individual requests will be communicated by letter to the requesting prescriber. If coverage is approved, the prescriber should provide a copy of the ministry's response letter to the patient to take to their pharmacy. It should be noted that while pharmacies are not required to keep a copy of the response letter on file, retaining a copy of the letter may facilitate the pharmacy's awareness of covered products and approved dosage and may also assist in the monitoring of the approval duration of the request to avoid a gap in treatment should ongoing coverage be required.

(Note: The ministry is aware of its obligations under the *Personal Health Information Protection Act,* 2004 (PHIPA) to ensure the confidentiality of all personal patient information which it holds on file as provided by requesting prescriber. Physicians and nurse practitioners are requested to ensure continuation of this vigilance as it relates to patient privacy issues, particularly when transmitting EAP approval information to other parties.)

The HNS adjudicates EAP claims online. Coverage begins on the specified coverage date and is valid until the expiration date noted on the authorization letter.

For drugs approved under the EAP, the ministry will reimburse pharmacists an amount equal to the Drug Benefit Price as outlined in the Formulary/CDI or listed on the ministry's website, plus a mark-up, and the lesser of a pharmacy's posted usual and customary fee or the ODB dispensing fee, minus the applicable co-payment amount. For products not listed in the Formulary/CDI or the ministry website, the ministry will pay dispensers the acquisition cost plus a mark-up and the lesser of a pharmacy's posted usual and customary fee or the ODB dispensing fee minus the applicable co-payment amount. The EO may enter into agreements with manufacturers to establish DBPs for products reimbursed under the EAP, which is published on the ministry's website. In such cases, drug products reimbursed under the EAP will be adjudicated at the established DBP. Please refer to the ministry's website for further information at: Exceptional Access Program

Products are approved for reimbursement under the EAP for a specific timeframe (i.e., days, weeks, one or more years), depending on the drug product and medical condition in question. Retroactive reimbursement of approved requests may be considered by the EO on a case-by-case basis.

Effective November 1, 2016, if an EAP drug has an interchangeable generic product designated through the Off-Formulary Interchangeable (OFI) mechanism, the ministry will only approve the funding of the generic product. Where Ontario Drug Benefit (ODB) recipients have had a documented adverse reaction to at least two (2) generic versions (where applicable), the ministry will reimburse the higher-cost brand product. Similar to products listed on the ODB Formulary, the "No Substitution" policy will apply (See Part I Section C-8).

Pharmacists must dispense an OFI generic product in the pharmacy's inventory to ODB recipients with an EAP approval from the ministry. Pharmacists will be reimbursed the cost of the generic product that is dispensed.

Part IX
Additional Benefits: Nutrition Products/ Diabetic Testing Agents/ Valved Holding Chambers/
Flash Glucose Monitoring System

Part IX-A
Additional Benefits: Nutrition Products

Part IX-A: Additional Benefits: Nutrition Products

Nutrition Products (NPs) are listed substances reimbursed as additional benefits for ODB-eligible persons in defined circumstances.

Enteral nutrition products are eligible for coverage under the ODB program only when prescribed by a physician or nurse practitioner as the patient's sole source of nutrition. Patients tolerating some solid foods and requiring only supplementation in addition to food are not eligible for coverage.

Eligibility Criteria:

Enteral nutrition products will be reimbursed for ODB-eligible persons when prescribed as the patient's sole source of nutrition and when one of the following criteria is met:

- Oropharyngeal or gastrointestinal disorders resulting in esophageal dysfunction or dysphagia (e.g., head and neck surgery, neuromuscular disorder, or cerebral vascular disease where dysphagia prevents eating)
- Maldigestion or malabsorption disorder and/or significant gut failure where food is not tolerated; (e.g., pancreatic insufficiency, biliary obstruction, short bowel syndrome)
- For patients requiring the use of a chemically defined diet as a primary treatment of a disease where the therapeutic benefit has been demonstrated (i.e., Crohn's disease)

Each claim for reimbursement must be supported by a valid and **fully completed** Nutrition Product form.

Nutrition Product forms are valid for one year following the date completed. Physicians and nurse practitioners can print the Nutrition Product form from the ministry's website at: Nutrition Product Form

Pharmacists are required to retain a copy of the Nutrition Product form on file for 24 months after which any NP claim is submitted to the HNS. For example, an NP claim submitted for ODB reimbursement with a date of service on December 31, 2017, must be substantiated with a valid and completed Nutrition Product form signed and dated by the prescribing physician or nurse practitioner (from January 1, 2017 to December 31, 2017) and retained on file until December 31, 2019.

Exclusion Criteria:

An NP will not be reimbursed under the ODB program if it is intended for one of the following uses:

- Prescribed for weight loss in the treatment of obesity
- Food allergies
- Body building
- Voluntary meal replacement
- Nutritional supplement
- Convenience
- Used as a replacement for breastfeeding for infants with normal gastrointestinal absorptive function

After conducting a patient assessment, the prescriber (physician, nurse practitioner) or dietitian may select any Nutrition Product from the approved list; however, only the physician or nurse practitioner can complete the Nutrition Product form. Depending on which NP is prescribed, the ODB-eligible person may have to pay the pharmacy the difference between the cost the ministry will reimburse the pharmacy and the current listed price for that NP. In many cases, the maximum paid by the ministry covers the entire cost (see attached Maximum Allowable Reimbursement Schedule for the list and price of the approved NPs under the ODB program).

Reimbursement of NPs is not considered through the EAP.

Maximum Allowable Reimbursement Mechanism and Pricing Schedule — Nutrition Products

Administration

A valid prescription from a prescriber is required for pharmacists to dispense approved NPs under the ODB program to eligible recipients. Pharmacists and prescribers are reminded that the nutritional requirements for persons residing in long-term care homes, Homes for Special Care and Community Homes for Opportunity are met by the facility responsible for the care of these patients. Claims for NPs for these residents are not reimbursed under the ODB program.

Claims

Pharmacists should note the maximum amount the ministry will reimburse pharmacies for each approved NP. Cost-to-operator claims will not be accepted. NP claims are not eligible for a mark-up.

Reimbursement Process

The maximum allowable reimbursement process provides ODB-eligible recipients with coverage for the cost of NPs in a given category, up to a maximum price established for that category, minus the co-payment. The ministry will reimburse pharmacies the amount identified in the column **Amount MOH Pays** plus the lesser of the posted usual and customary fee or the ODB dispensing fee, minus the co-payment portion. No amount more than that shown in the column **Amount Patient Pays** plus the co-payment portion can be charged to recipients. The following maximum allowable reimbursement schedule lists those NPs that are approved for coverage and identifies a maximum price (per 1000kcal) for specific categories.

Maximum Allowable Reimbursement Schedule for Nutrition Products

A.1 COMPLETE POLYMERIC – LACTOSE FREE **MAXIMUM = 5.04**

Brand Name	Strength, Dosage Form, Package Size	PIN/NPN	Mfr	Cost ($) Per 1000 Kcal	Cost ($) Per Pkg	Amt ($) MOH Pays	Amt ($) Patient Pays
Boost 1.5 Plus Calories	1.5kcal/mL Liq-237mL Pk	97982610	NES	4.84	1.74	1.74	0.00
Ensure Plus	Liq-235mL Pk Cans	97904333	ABB	5.04	1.79	1.79	0.00
Isosource 2.0	2.0kcal/mL Ready-To-Hang 1000mL Pk	09858121	NES	5.04	10.08	10.08	0.00
NovaSource Renal	Liq-237mL Pk	09854258	NES	5.00	2.38	2.38	0.00
Resource 2.0	Liq-237mL Pk	09853170	NES	5.04	2.40	2.40	0.00
Suplena	Liq-235mL Pk	09853731	ABB	4.94	2.09	2.09	0.00
TwoCal HN	2kcal/mL Liq-235mL Pk	09854380	ROS	5.04	2.37	2.37	0.00

A.3 COMPLETE POLYMERIC – FIBRE CONTAINING MAXIMUM = 7.68

Brand Name	Strength, Dosage Form, Package Size	PIN/NPN	Mfr	Cost ($) Per 1000 Kcal	Cost ($) Per Pkg	Amt ($) MOH Pays	Amt ($) Patient Pays
Compleat 1.06	Liq-250mL Tetra Pk	97983330	NES	7.66	2.03	2.03	0.00
Compleat 1.06	Liq-1000mL Ready-To-Hang	09854231	NES	7.45	7.97	7.97	0.00
Glucerna 1.0 Cal	1kcal/mL Liq-235mL Pk	09854392	ABB	7.68	1.80	1.80	0.00
Isosource Fibre 1.2	1.2kcal/mL 250mL Tetra Pk	09857558	NES	7.68	2.30	2.30	0.00
Isosource Fibre 1.2	1.2kcal/mL Ready-To-Hang 1500mL Pk	09857559	NES	7.68	13.82	13.82	0.00
Isosource Fibre 1.5	1.5kcal/mL 250mL Tetra Pk	09857560	NES	7.67	2.88	2.88	0.00
Isosource Fibre 1.5	1.5kcal/mL Ready-To-Hang 1500mL Pk	09857561	NES	7.67	17.26	17.26	0.00
Jevity 1 Cal	1.06kcal/mL Liq-235mL Pk	97984060	ABB	7.68	1.92	1.92	0.00
Jevity 1 Cal	1.06kcal/mL Liq-1500mL Pk	09854479	ABB	7.68	12.22	12.22	0.00

Brand Name	Strength, Dosage Form, Package Size	PIN/NPN	Mfr	Cost ($) Per 1000 Kcal	Cost ($) Per Pkg	Amt ($) MOH Pays	Amt ($) Patient Pays
Jevity 1.2 Cal	1.2kcal/mL Liq-235mL Pk	09854096	ABB	7.70	2.17	2.17	0.00
Jevity 1.2 Cal	1.2kcal/mL Liq-1000mL Pk	09857109	ABB	7.61	9.13	9.13	0.00
Jevity 1.2 Cal	1.2kcal/mL Liq-1500mL Pk	09857117	ABB	7.61	13.70	13.70	0.00
Jevity 1.5 Cal	1.5kcal/mL Liq-235mL Pk	09857344	ABB	7.67	2.70	2.70	0.00
Jevity 1.5 Cal	1.5kcal/mL Liq-1000mL Pk	09857310	ABB	7.68	11.52	11.52	0.00
Jevity 1.5 Cal	1.5kcal/mL Liq-1500mL Pk	09857312	ABB	7.68	17.28	17.28	0.00
Resource Diabetic 1.05	1.06kcal/mL Liq-250mL Pk	09857427	NES	7.68	2.04	2.04	0.00

A.4 COMPLETE POLYMERIC – HIGH NITROGEN MAXIMUM = 5.11

Brand Name	Strength, Dosage Form, Package Size	PIN/NPN	Mfr	Cost ($) Per 1000 Kcal	Cost ($) Per Pkg	Amt ($) MOH Pays	Amt ($) Patient Pays
Isosource 1.2	1.2Kcal/mL, 250mL Tetra Pk	09857566	NES	5.11	1.53	1.53	0.00
Isosource 1.5	1.5Kcal/mL, 250mL Tetra Pk	09857568	NES	5.11	1.92	1.92	0.00
Isosource 1.5	1.5Kcal/mL, 1500mL Ready To Hang	09857569	NES	5.11	11.50	11.50	0.00
Osmolite 1 Cal	1.06kcal/mL Liq-1500mL Pk	09854452	ABB	5.04	8.01	8.01	0.00
Osmolite 1 CAL	Liq-235mL Pk	97973165	ABB	5.07	1.26	1.26	0.00
Osmolite 1.2 Cal	1.2kcal/mL Liq-1500mL Pk	09857095	ABB	5.04	9.07	9.07	0.00
Osmolite 1.2 CAL	Liq-235mL Pk	09854169	ABB	5.11	1.44	1.44	0.00

B. INCOMPLETE POLYMERIC **MAXIMUM = 8.50**

Brand Name	Strength, Dosage Form, Package Size	PIN/NPN	Mfr	Cost ($) Per 1000 Kcal	Cost ($) Per Pkg	Amt ($) MOH Pays	Amt ($) Patient Pays
Boost Fruit Flavoured Beverage	Liq-237mL Pk	09853154	NES	11.65	2.07	1.53	0.54

C.1 MODULAR – PROTEIN **MAXIMUM = 15.90**

Brand Name	Strength, Dosage Form, Package Size	PIN/NPN	Mfr	Cost ($) Per 1000 Kcal	Cost ($) Per Pkg	Amt ($) MOH Pays	Amt ($) Patient Pays
Beneprotein	25Kcal/7g Pd-7g Pk (Unflavoured)	09857634	NES	22.32	0.56	0.40	0.16
Beneprotein	810.7143Kcal/227g Pd-227g Pk Canister (Unflavoured)	09857635	NES	22.32	18.08	12.89	5.19

C.3 MODULAR – FAT

Brand Name	Strength, Dosage Form, Package Size	PIN/NPN	Mfr	Cost ($) Per 1000 Kcal	Cost ($) Per Pkg	Amt ($) MOH Pays	Amt ($) Patient Pays
MCT Oil	7.7kcal/mL Liq-946mL Pk	97904473	NES		34.49	34.49	0.00

D. CHEMICALLY DEFINED FORMULA **MAXIMUM = 35.26**

Brand Name	Strength, Dosage Form, Package Size	PIN/NPN	Mfr	Cost ($) Per 1000 Kcal	Cost ($) Per Pkg	Amt ($) MOH Pays	Amt ($) Patient Pays
Peptamen	Liq-250mL Pk	97984779	NES	28.46	7.12	7.12	0.00
Peptamen 1.5	1.5kcal/mL Liq-250mL Pk	09853090	NES	30.80	10.89	10.89	0.00
Peptamen 1.5	1.5kcal/mL Liq-1000mL Pk	09857126	NES	30.80	43.55	43.55	0.00
Peptamen with Prebio	1kcal/mL Liq-250mL Pk	09857101	NES	35.24	8.82	8.82	0.00
Peptamen with Prebio	1kcal/mL Liq-1500mL Pk	09857102	NES	35.26	52.89	52.89	0.00
Perative	Liq-237mL Pk	09854390	ROS	8.83	2.72	2.72	0.00
Perative	Liq-1000mL Pk	09854391	ROS	8.83	11.48	11.48	0.00
Pivot 1.5 CAL	1.5Kcal/mL Tetrapack - 237mL Pk	09858351	ABB	35.20	12.51	12.51	0.00
Pivot 1.5 CAL	1.5Kcal/mL Ready-to-Hang - 1L Pk	09858352	ABB	35.20	52.80	52.80	0.00
Portagen	1.02kcal/mL Pd-454g Pk	09854401	MJN	26.10	55.78	55.78	0.00
Tolerex	Pd-80g Pk	97982750	NES	16.82	5.05	5.05	0.00
Vital Peptide 1 Cal	1kcal/mL, Liq-Vanilla Flavour, 220mL Pk Bottle	09858101	ABB	24.42	5.37	5.37	0.00
Vital Peptide 1.5 Cal	1.5kcal/mL, Liq-Vanilla Flavour, 220mL Pk Bottle	09858102	ABB	23.48	7.75	7.75	0.00

Brand Name	Strength, Dosage Form, Package Size	PIN/NPN	Mfr	Cost ($) Per 1000 Kcal	Cost ($) Per Pkg	Amt ($) MOH Pays	Amt ($) Patient Pays
Vital Peptide 1.5 Cal	1.5kcal/mL, Liq-Vanilla Flavour, 1000mL Pk Ready to Hang container	09858103	ABB	23.48	35.21	35.21	0.00
Vivonex T.E.N.	Pd-80.4g Pk	09853618	NES	32.61	9.78	9.78	0.00
Vivonex Plus	Pd-79.5g Pk	97982830	NES	23.70	7.03	7.03	0.00

E.1 PEDIATRIC FORMULA, COMPLETE POLYMERIC – LACTOSE FREE MAXIMUM = 10.51

Brand Name	Strength, Dosage Form, Package Size	PIN/NPN	Mfr	Cost ($) Per 1000 Kcal	Cost ($) Per Pkg	Amt ($) MOH Pays	Amt ($) Patient Pays
Nutren Junior 1.0	1kcal/mL Liq-250mL Pk	09854215	NES	6.59	1.65	1.65	0.00
PediaSure	Liq-235mL Pk	97984370	ABB	10.51	2.47	2.47	0.00

E.2 PEDIATRIC FORMULA, COMPLETE POLYMERIC – FIBRE CONTAINING MAXIMUM = 10.51

Brand Name	Strength, Dosage Form, Package Size	PIN/NPN	Mfr	Cost ($) Per 1000 Kcal	Cost ($) Per Pkg	Amt ($) MOH Pays	Amt ($) Patient Pays
Compleat Junior 1.0	1kcal/mL Liq-250mL Pk	09857173	NES	10.37	2.59	2.59	0.00
Nutren Junior Fibre 1.0	1kcal/mL Liq-250mL Pk	09854223	NES	6.59	1.65	1.65	0.00
Pediasure Plus With Fibre	1.5kcal/mL Liq-235mL Pk	09857419	ROS	7.77	2.74	2.74	0.00

Brand Name	Strength, Dosage Form, Package Size	PIN/NPN	Mfr	Cost ($) Per 1000 Kcal	Cost ($) Per Pkg	Amt ($) MOH Pays	Amt ($) Patient Pays
Pediasure With Fibre	1kcal/mL Liq-235mL Pk	09854371	ROS	10.51	2.47	2.47	0.00
Resource Kid Essentials 1.5	1.5kcal/mL Liq-237mL Pk	09857142	NES	7.73	2.75	2.75	0.00

F. PEDIATRIC FORMULA, INCOMPLETE POLYMERIC MAXIMUM = 20.16

Brand Name	Strength, Dosage Form, Package Size	PIN/NPN	Mfr	Cost ($) Per 1000 Kcal	Cost ($) Per Pkg	Amt ($) MOH Pays	Amt ($) Patient Pays
RCF	Liq-384mL Pk	97973084	ABB	20.16	6.27	6.27	0.00

G.1 PEDIATRIC FORMULA, CHEMICALLY DEFINED – OLIGOMERIC (SEMI-ELEMENTAL) MAXIMUM=13.13

Brand Name	Strength, Dosage Form, Package Size	PIN/NPN	Mfr	Cost ($) Per 1000 Kcal	Cost ($) Per Pkg	Amt ($) MOH Pays	Amt ($) Patient Pays
Alimentum	Liq-4x237mL Pk	97984558	ABB	9.55	6.16	6.16	0.00
Nutramigen A+	5kcal/g Pd-454g Pk	09857345	MJN	8.78	19.94	19.94	0.00
Nutramigen A+ with LGG	5Kcal/g Pd-561g Can Pk	09857565	MJN	12.83	36.00	36.00	0.00
PediaSure Peptide 1 Cal	1.0kcal/mL Liq-237mL Pk Reclosable Plastic Bottle	09857523	ABB	11.35	2.69	2.69	0.00
Similac Alimentum	5.17kcal/g Pd-400g Can Pk	09857564	ABB	7.96	16.47	16.47	0.00

G.2 PEDIATRIC FORMULA, CHEMICALLY DEFINED – MONOMERIC (ELEMENTAL) MAXIMUM=35.15

Brand Name	Strength, Dosage Form, Package Size	PIN/NPN	Mfr	Cost ($) Per 1000 Kcal	Cost ($) Per Pkg	Amt ($) MOH Pays	Amt ($) Patient Pays
Alfamino Junior	1.0kcal/mL, Pd-400g Canister	09858320	NES	35.15	64.68	64.68	0.00
Essential Care Junior (Unflavoured)	1.0kcal/mL Pd-400g Pouch Pk	09858354	CAM	29.24	57.78	57.78	0.00
Neocate Junior (Unflavoured)	1kcal/mL Pd-400g Pk	09854207	NUT	28.38	54.27	54.27	0.00
Neocate Junior (Tropical Flavour)	1kcal/mL Pd-400g Pk	09857594	NUT	30.08	54.27	54.27	0.00
Neocate DHA & ARA	0.2071g/kcal Pd-400g Can Pk	09857627	NUT	32.40	62.56	62.56	0.00
Neocate Splash (Grape Flavour)	1kcal/mL Liq-237mL Pk	09857615	NUT	29.80	7.06	7.06	0.00
Neocate Splash (Orange-Pineapple Flavour)	1kcal/mL Liq-237mL Pk	09857616	NUT	29.80	7.06	7.06	0.00
Neocate Splash (Unflavoured)	1kcal/mL Liq-237mL Pk	09857603	NUT	29.80	7.06	7.06	0.00
Neocate Splash (Tropical Fruit Flavour)	1kcal/mL Liq-237mL Pk	09857604	NUT	29.80	7.06	7.06	0.00
PurAmino A+	5kcal/g Pd-400g Pk	09857369	MJN	27.90	55.79	55.79	0.00

H. PEDIATRIC FORMULA, OTHERS

MAXIMUM = N/A

Brand Name	Strength, Dosage Form, Package Size	PIN/NPN	Mfr	Cost ($) Per 1000 Kcal	Cost ($) Per Pkg	Amt ($) MOH Pays	Amt ($) Patient Pays
Enfamil EnfaCare A+	22kcal/30mL Pd For Liq-363g Pk	09857172	MJS	8.51	15.29	15.29	0.00
KetoCal 4:1 (Vanilla Flavour)	7.05kcal/g Pd-300g Pk	09857599	NUT	15.04	31.80	31.80	0.00
KetoCal 4:1 (Unflavoured)	1.5kcal/mL Liq-237mL Tetra Pk	09857497	NUT	16.16	5.75	5.75	0.00
KetoCal 4:1 (Vanilla Flavoured)	1.5kcal/mL Liq-237mL Tetra Pk	09857388	NUT	16.16	5.75	5.75	0.00
KetoVie 3:1	1.04kcal/mL, Liq-250mL Carton Box (Unflavoured)	09858166	CAM	25.17	6.55	6.55	0.00
KetoVie 4:1	1.56kcal/mL Liq-Chocolate Flavour, 250mL Pk	09858117	CAM	16.78	6.55	6.55	0.00
KetoVie 4:1	1.44kcal/mL Liq-Vanilla Flavour, 250mL Pk	09858118	CAM	18.18	6.55	6.55	0.00
KetoVie Peptide 4:1	1.49kcal/mL, Liq-250mL Pk	09858139	CAM	24.79	9.24	9.24	0.00
KetoVie 4:1 Plant Based Protein (Vanilla)	1.50kcal/mL, Liq-250mL Carton	09858245	CAM	24.65	9.24	9.24	0.00
KetoVie 4:1 Unflavoured	1.50kcal/mL, Liq-250mL Carton Box	09858161	CAM	17.45	6.55	6.55	0.00
Modulen	1kcal/mL Pd-400g Pk	09857393	NES	14.50	29.00	29.00	0.00

Brand Name	Strength, Dosage Form, Package Size	PIN/NPN	Mfr	Cost ($) Per 1000 Kcal	Cost ($) Per Pkg	Amt ($) MOH Pays	Amt ($) Patient Pays
Peptamen Junior	Liq-250mL Pk	09853588	NES	35.24	8.82	8.82	0.00
Peptamen Junior 1.5	1.5kcal/mL Liq-250mL Tetra Pk	09857562	NES	35.25	13.22	13.22	0.00
Renastart	1976kcal/400g, Pd-400g Can	09858140	VIT	20.06	39.63	39.63	0.00
Renastep	2kcal/mL-200mL Pk bottle	09858353	VIT	23.08	9.23	9.23	0.00
Similac Advance NeoSure	5.15kcal/g Pd-363g Pk	09857124	ABB	8.02	14.99	14.99	0.00

Part IX-B
Additional Benefits:
Diabetic Testing Agents

Part IX-B: Additional Benefits: Diabetic Testing Agents

Blood Glucose Test Strips (BGTS) are listed substances that are covered as additional benefits for ODB-eligible persons in defined circumstances when prescribed by an Ontario physician or nurse practitioner.

Effective August 1, 2013, the EO introduced limits to the reimbursement of BGTS for ODB-eligible persons.

General Rules and Maximums

The HNS will track and determine appropriate levels of reimbursement of BGTS based on the current diabetes therapy used by ODB-eligible persons.

When a claim is submitted for BGTS for ODB-eligible persons, the HNS will automatically review the anti-diabetes medications claims and prescription receipts in the previous 180 days, to identify claims and receipts for insulin products and other anti-diabetes medications. The HNS will then apply a maximum number of self-monitoring BGTS that may be reimbursed for the recipient in the following 365 days as follows:

Diabetes Treatment History	BGTS Allowed Within 365 Days
Patients managing diabetes with insulin	3000
Patients managing diabetes with anti-diabetes medication with high risk of causing hypoglycemia*	400
Patients managing diabetes using anti-diabetes medication with low risk of causing hypoglycemia**	200
Patients managing diabetes through diet/lifestyle therapy only (no insulin or anti-diabetes medications)	200

*Including but not limited to glyburide, gliclazide, chlorpropamide, tolbutamide, repaglinide, nateglinide, or glimepiride

**Including but not limited to metformin, sitagliptin phosphate monohydrate, saxagliptin, acarbose, rosiglitazone, pioglitazone, linagliptin, liraglutide, empagliflozin or dapagliflozin

Recipients will be allotted the indicated number of BGTS for use over the course of a 365-day period. The test strip allotment will apply to both online and paper claims submitted by pharmacies as well as prescription receipts submitted by ODB-eligible persons for reimbursement or to satisfy their TDP deductible.

When submitting a claim for insulin or anti-diabetes medication along with a claim for BGTS, **pharmacies must submit claims for insulin or anti-diabetes medications prior to entering the BGTS claim**. This ensures that the most current drug profile is included in the historical treatment review and patients are allocated the proper number of BGTS. Similarly, all related paper claims must be submitted for processing as soon as possible. Finally, where an ODB-eligible person pays for the BGTS, insulin or anti-diabetes medication out-of-pocket and intends to submit their prescription receipt to the ministry for reimbursement or to satisfy their TDP deductible, then the pharmacy should advise the person to submit their prescription receipt to the ministry as soon as possible to ensure the prompt updating of their claims history.

Administration

A valid prescription from a physician or nurse practitioner is required for pharmacists to submit a claim for payment to ODB for dispensing approved Blood Glucose Test Strips (BGTS) to eligible recipients.

Claims

Pharmacists should note the maximum amount the ministry will reimburse pharmacies for each approved test strip. Cost-to-operator claims will not be accepted. Test strips claims are not eligible for a mark-up.

Please note: Only one PIN for each brand of test strips can be used for billing. The PIN must match the brand of test strips that is prescribed and dispensed. Dispensing a brand of test strips that has not been prescribed or dispensing one brand of test strips and billing another brand, will result in invalid claims for payment that are subject to recovery. When billing test strips, the package size (e.g., one box) cannot be used since reimbursement is based on the number of unit strips of each product dispensed.

Reimbursement for Blood Glucose Test Strips

The ministry will reimburse pharmacies the amount identified in the column **Amount MOH Pays** on the e-Formulary plus the lesser of the posted usual and customary fee or the ODB dispensing fee, minus the co-payment portion. The pharmacy cannot charge eligible recipients any amount other than the co-payment for supplying BGTS under the ODB program.

For more information, please visit the ministry's website on diabetes test strips at: Reimbursement levels for Blood Glucose Test Strips.

Part IX-C
Additional Benefits: Valved Holding Chambers

Part IX-C: Additional Benefits: Valved Holding Chambers

Valved holding chambers (VHCs) are listed substances reimbursed as additional benefits for ODB-eligible persons in defined circumstances.

Valved holding chambers are used in conjunction with metered-dose inhalers to deliver inhaled asthma medications. A valved holding chamber includes a one-way valve at the mouthpiece. This device traps and holds the aerosolized medication, which improves drug delivery by allowing the patient to take slow, deep breaths to inhale all of the medicine. The one-way valve prevents patients from accidentally exhaling into the tube.

Eligibility Criteria

Valved holding chambers are eligible for coverage under the ODB program for all ODB recipients aged 12 years and under with a valid prescription from a physician or nurse practitioner.

Quantity Restriction

Eligible ODB recipients will be entitled to receive one (1) valved holding chamber (with or without mask/mouthpiece) per 365-day period.

Reimbursement Mechanism — Valved Holding Chambers

Administration

A valid prescription from a prescriber is required for pharmacists to dispense approved VHCs under the ODB program to eligible recipients.

Reimbursement

Claims for valved holding chambers listed on the electronic Formulary (e-Formulary) will be reimbursed by the ministry. Pharmacists should note the maximum amount the ministry will reimburse pharmacies for each approved VHC. Cost-to-operator claims will not be accepted. Pharmacies are eligible to be reimbursed in accordance with the following formula:

Amount MOH Pays + 8% Mark-up + the lesser of the posted usual and customary fee or the applicable ODB dispensing fee

As there is no cost to the recipient, the pharmacy cannot charge eligible ODB recipients any amount for supplying a VHC under the ODB program.

Pharmacy Billing Procedure

The Product Identification Number (PIN) of the VHC is to be used for billing purposes. Pharmacies will only be reimbursed for supplying valved holding chambers listed on the e-Formulary, subject to changes which will be communicated to pharmacies.

The claim submission follows the normal process for submitting claims on the HNS noting the following information:

- Product Identification Number (PIN): Select the appropriate PIN from the e-Formulary
- Quantity: Submit the value as “1”
- Days’ Supply: Submit the value as “1” (or any other value up to 100)

HNS Response Codes and Messages

- If a VHC claim is submitted for an ODB recipient aged 13 years and above, the claim will be rejected with a response code “CD – Patient Not Entitled to Drug Claimed”. VHCs are only eligible for ODB recipients 12 years of age or under.
- If a VHC claim is submitted that exceeds the claim count limit of one per 365-day period, the claim will be rejected with a response code “LO – Benefits Maximum Exceeded”. The HNS will automatically review whether any other funded VHC claim was submitted to the ODB Program in the past 365 days (since January 1, 2018). Only one funded VHC (with or without mask/mouthpiece) per 365-day period is eligible for coverage under the ODB Program.
- The HNS will send a message line “Remaining Qty: x until MMM DD, YYYY ” when a claim is approved or rejected due to the quantity restriction, for example: Remaining Qty: 0 until OCT 15, 2019.
- No HNS message will be sent when a claim is rejected due to age restriction. Only the rejection response code will be displayed.
- For billing purposes, pharmacy documentation must be maintained in a readily available format for the purpose of post-payment verification for a minimum of 2 years. Overpayments due to inappropriate claim submissions are subject to recovery.

Part IX-D
Additional Benefits:
Flash Glucose Monitoring Systems

Part IX-D: Additional Benefits: Flash Glucose Monitoring Systems

Effective September 16, 2019, Flash Glucose Monitoring (FGM) Systems are reimbursed as additional benefits (listed substances) for Ontario Drug Benefit (ODB) eligible persons in defined circumstances.

Eligibility Criteria

All ODB eligible recipients on insulin therapy with a valid prescription from a physician or nurse practitioner are eligible to receive ODB-funded FGM sensors and readers.

Only ODB-funded FGM readers and sensors supplied to an ODB eligible recipient with a valid prescription from a physician or nurse practitioner will be reimbursed.

Reimbursement

Claims for FGM sensors and readers listed below will be reimbursed by the ministry. Pharmacies are eligible to be reimbursed in accordance with the following formula:

Reimbursable amount + mark-up + applicable ODB dispensing fee

Pharmacy Billing Procedure

The Product Identification Number (PIN) is to be used for billing purposes. Pharmacies will be reimbursed for supplying FGM sensors and readers in accordance with the table below.

PIN	PIN Description	Manufacturer	Reimbursable Amount
09858147	FreeStyle Libre 2 Sensor	Abbott Diabetes Care	$91.0000
09858148	FreeStyle Libre 2 Reader	Abbott Diabetes Care	$49.0000

For billing purposes, pharmacy documentation must be maintained in a readily available format for the purpose of post-payment verification for a minimum of 2 years. Overpayments due to inappropriate claim submissions are subject to recovery.

Claims must be submitted online through the HNS. The claim submission follows the normal process for submitting claims through the HNS:

- Product Identification Number (PIN)
- Valid Pharmacist ID

Quantity Limits

Patients managing their diabetes with insulin are eligible for a maximum quantity of 33 sensors over the course of a 365-day period (one sensor lasts up to 14 days).

Pharmacists must adhere to the quantity restriction as noted above. In addition, conditions for payment of a dispensing fee under the ODB program must be followed. More information on conditions for payment of a dispensing fee is available here:

http://www.health.gov.on.ca/en/pro/programs/drugs/odbf_conditions_for_payment.aspx

Part X
Abbreviations

A. List of Manufacturer Abbreviations

Abbreviation	Manufacturer Name
MMH	3M Pharmaceuticals, Division 3M Canada Inc.
AAP	A A Pharma Inc.
ABD	Abbott Diabetes Care
ABB	Abbott Laboratories Limited
ABV	AbbVie Corporation
ACC	Accel Pharma Inc.
ACP	Accelera Pharma Canada, Inc.
ACH	Accord Healthcare Inc.
APC	Acerus Pharmaceuticals Corporation
ACO	Acon Laboratories Incorporated
AGP	Actavis Group PTC ehf
ACV	Actavis Pharma Company
ASC	Actavis Specialty Pharmaceuticals Co.
ACT	Actelion Pharmaceutiques Canada Inc.
CAM	Ajinomoto Cambrooke, Inc.
ALC	Alcon Canada Inc.
ALK	ALK Abello Inc.
ALL	Allergan Inc.
AMC	Allmedicus Co., Ltd.
ALH	Altius Healthcare Inc.
AMD	Amdipharm Limited
AMG	Amgen Canada Inc.
AMP	Amphastar Pharmaceuticals Inc.
ANG	Angita Pharma Inc.
APX	Apotex Inc.
ARA	ARA Pharmaceuticals Inc.
ARZ	Aralez Pharmaceuticals Canada Inc.
ADC	Ascensia Diabetes Care Canada Inc.
ASN	Aspen Pharma Trading Limited
ASE	Astellas Pharma Canada Inc.

Abbreviation	Manufacturer Name
AST	Astra Pharma Inc.
AZC	AstraZeneca
APU	Atnahs Pharma UK Limited
ATO	Aton Pharma Inc.
AUR	Auro Pharma Inc.
AVE	Aventis Pharma
AVP	Avir Pharma Inc.
BFI	Axcan Pharma Inc.
AYE	Ayerst Laboratories, Division of Ayerst, McKenna & Harrison
BAR	Barr Laboratories Inc.
BHC	Bausch Health Canada Inc.
BSH	Bausch & Lomb Canada Inc.
BLI	Bausch & Lomb Inc.
BAX	Baxter Corporation
BAY	Bayer Inc., Consumer Care Division
BAH	Bayer Inc., Health Care Division
BED	BD Consumer Healthcare
BGP	BGP Pharma ULC
BIG	Biogen Idec Canada Inc.
BIM	BioMarin International Ltd.
BMP	Biomed Pharma
BIN	Bionime Corporation
BIO	Biovail Pharmaceuticals Canada
BOE	Boehringer-Ingelheim (Canada) Ltd./Ltee
BQU	Bristol Myers Squibb Canada Inc.
BWE	Burroughs Wellcome Inc.
CBF	C.B. Fleet Company Inc.
CEL	Celgene Inc.
CCP	CellChem Pharmaceuticals Inc.
CEH	Celltrion Healthcare Co. Ltd.
CDC	Church & Dwight Canada Corp., Inc.
CHE	Cheplapharm Arzneimittel GmbH

Abbreviation	Manufacturer Name
CIP	Cipher Pharmaceuticals Inc.
CPL	Clay-Park Labs Inc.
CCI	Clement Clark International Ltd.
COB	Cobalt Pharmaceuticals Company
COV	Covis Pharma B.V.
COP	Covis Pharma GmbH
CRY	Crystaal Corp.
CYI	Cytex Pharmaceutical Co.
DES	Desbergers Limited
DPC	Dominion Pharmacal
DRR	Dr. Reddy's Laboratories Canada Inc.
BJH	Draxis Health Inc.
DUI	Duchesnay Inc.
ECL	ECL Pharma Group Ltd.
EIS	Eisai Limited
ELA	Elan Pharmaceuticals, Inc.
LIL	Eli Lilly Canada Inc.
ELV	Elvium Life Sciences
EDO	Endo Pharmaceuticals Inc.
EPI	Endo Par Innovation Company, LLC
EVL	Endo Ventures Ltd.
EHS	Entra Health Systems.
ERF	Erfa Canada Inc.
ETH	Ethypharm Inc.
FAM	Famy Care Ltd.
FEI	Ferring Inc.
FOM	Formative Pharma Inc.
FOU	Fournier Pharma Inc.
HOR	Frank W. Horner Inc.
FKC	Fresenius Kabi Canada Ltd.
GPB	G Pohl Boskamp GMBH & Co KG, hohenlockstedt
GAC	Galderma Canada Inc.

Abbreviation	Manufacturer Name
GEI	Geigy Pharmaceuticals,Division of Ciba-Geigy Canada Ltd.
GMP	Generic Medical Partners Inc.
GEM	Genmed, A Division of Pfizer Canada Inc.
GZM	Genzyme Canada Inc.
GIL	Gilead Sciences Canada, Inc.
GLA	Glaxo Canada Inc.
GLW	Glaxo Wellcome Inc.
GCH	GlaxoSmithKline Consumer Healthcare Inc.
GCU	GlaxoSmithKline Consumer Healthcare ULC
GSK	GlaxoSmithKline Inc., GlaxoSmithKline Consumer Health Care
GLP	Glenmark Pharmaceuticals Canada Inc.
GRA	Graceway Pharmaceuticals
HAL	Halewood Chemicals Limited
HEA	Healthpoint Canada
HLN	Haleon Canada ULC
HLS	HLS Therapeutics Inc.
HMR	Hoechst Marion Roussel Canada Inc.
HRU	Hoechst-Roussel Canada Inc.
HLR	Hoffmann-La Roche Limited
HOM	Home Diagnostics Inc.
HOS	Hospira Healthcare Corporation.
HRA	HRA Pharma Rare Diseases
IDL	Ideal Life Inc.
IND	Indivior UK Limited
IPL	Insight Pharmaceuticals, LLC
INT	InterMune Canada, Inc.
IOB	Iolab Canada Inc.
IPS	Ipsen Limited
ISE	I-Sens, Inc.
IVA	Ivax Laboratories Incorporated
JPC	Jamp Pharma Corporation
JAN	Janssen Inc.

Abbreviation	Manufacturer Name
JNO	Janssen-Ortho Inc.
JAJ	Johnson & Johnson Inc.
JOU	Jouveinal Inc.
JUN	Juno Pharmaceuticals Corp.
KNT	Knight Therapeutics Inc.
KVR	KVR Pharmaceuticals
RIA	Laboratoire Riva Inc.
LAF	Laboratoires Fournier S.A.
LBT	Laboratoires Thea
LBI	Leadiant Biosciences, Inc.
LED	Lederle Division-of Cyanamid Canada Inc.
LEA	Lee-Adams Lab.
LEO	Leo Pharma Inc.
LIF	Lifescan Canada Ltd.
VLH	Lundbeck Canada Inc.
LUP	Lupin Pharma Canada Limited
MAL	Mallinckrodt Canada ULC
MAT	Mantra Pharma Inc.
MAR	Marcan Pharmaceuticals Inc.
MRR	Marion Merrell Dow Canada
MAY	Mayne Pharma (Canada) Inc.
MCL	McNeil Consumer Products Co.
MDI	MDA Inc.
MJS	Mead Johnson Canada
MJC	Mead Johnson & Company LLC
MJN	Mead Johnson Nutritionals
MAB	Meda AB
MDX	Medexus Inc.
MPI	Medexus Pharmaceuticals Inc.
MEF	Medical Futures Inc.
MEH	MediHub International Inc., Ajax
MEP	MedTech Products Inc.

Abbreviation	Manufacturer Name
MEK	Merck Canada Inc.
FRS	Merck Frosst Canada & Cie, Merck Frosst Canada & Co.
MFC	Merck Frosst Canada Ltd.
MSD	Merck Sharp & Dohme Canada, Division of Merck Frosst Canada
MEZ	Merz Pharmaceutical Gmbh
MIN	Mint Pharmaceuticals Inc.
MMT	MM Therapeutics Inc.
MYL	Mylan Pharmaceuticals ULC
NDA	Nadeau Laboratory Ltd.
NAT	Natco Pharma (Canada) Inc.
NEC	Nestle Canada Inc.
NES	Nestle Clinical Nutrition
NSA	Nestle Enterprises S.A.
NEU	Neuraxpharm Arzneimittel GmbH
NRA	Nora Pharma
NOB	Nova Biomedical Corporation.
NON	Novartis Nutrition Corporation
NOV	Novartis Pharma Canada Inc.
NOO	Novo Nordisk Canada Inc.
NOP	Novopharm Ltd.
NUT	Nutricia North America
NYC	Nycomed Canada Inc.
ODN	Odan Laboratories Ltd.
OMG	Omega Laboratories Ltd.
ORC	Orchid Healthcare
OCI	Organon Canada Inc.
ORG	Organon Canada Ltd./Ltee
ORI	Orimed Pharma
OMC	Ortho McNeil
OTS	Otsuka Pharmaceutical Co. Ltd.
OVA	Ovation Pharmaceuticals Inc.
PAL	Paladin Labs Inc.

Abbreviation	Manufacturer Name
PDA	Parke-Davis,Division Warner-Lambert Canada Inc.
PAR	Patriot, A Division of Janssen Inc.
MAN	Paul Maney Labs., Division of Canapharm Ind. Inc.
PED	Pediapharm Licensing Inc.
PEN	Pendopharm, Division of Pharmascience Inc.
PFI	Pfizer Canada Inc.
PHS	Pharma Stulln Inc.
PMJ	Pharmacia & Upjohn
PHC	Pharmacosmos A/S
PHP	Pharmapar Inc.
PRZ	Pharmaris Canada Inc.
PMS	Pharmascience Inc.
PHE	Pharmel Inc.
PHB	Phebra Canada
PRE	Prempharm Inc.
PGI	Proctor & Gamble Inc.
PGP	Proctor & Gamble Pharmaceuticals Canada, Inc.
PFP	Purdue Pharma
QUO	Questcor Operations Ltd.
RAN	Ranbaxy Pharmaceuticals Canada Inc.
RPH	Ratiopharm Inc.
RRD	Respironics Respiratory Drug Delivery (UK) Ltd.
RPR	Rhone-Poulenc Rorer Consumer Inc.
RPP	Rhone-Poulenc Rorer-Ethical Division
RIP	Richmond Pharmaceuticals Inc.
RBT	Roberts Pharmaceutical of Canada Inc.
RCH	Roche Diabetes Care GmbH
ROD	Roche Diagnostics, a division of Hoffmann-La Roche Limited
ROS	Ross Laboratories-Abbott (Nutritional Products)
ROG	Rougier Pharma, Division of Ratiopharm Inc.
SAL	Salix Pharmaceuticals Inc.
SAM	Samsung Bioepis Co. Ltd

Abbreviation	Manufacturer Name
SDZ	Sandoz Canada Inc.
SAI	Sanis Health Inc.
SAV	Sanofi Aventis Pharma
SAC	Sanofi-Aventis Canada Inc.
SCO	Sanofi Consumer Health Inc.
SAG	Sanofi Genzyme, a Division of Sanofi-Aventis Canada Inc.
SCH	Schering Canada Inc.
SCP	Schering-Plough Canada Inc.
SLP	Searchlight Pharma Inc.
SEA	Searle Canada Inc.
SET	Septa Pharmaceuticals Inc.
SEV	Servier Canada Inc.
SHE	Shenzhen Techdow Pharmaceutical Co., Ltd.
SHI	Shire Pharma Canada ULC
SIG	Sigma-Tau Pharmaceutical Inc.
SIV	Sivem Pharmaceuticals ULC
SKY	Skymed Corporation
SNE	Smith & Nephew Inc.
SMJ	Smith Kline Beecham Pharma Inc
SPH	Solvay Pharma Inc.
STL	Stallergenes Canada Inc.
STA	Stason Pharmaceuticals Inc., Irvine
STE	Sterimax Inc.
STN	Sterinova Inc.
STI	Stiefel Canada Inc.
SPC	Sun Pharma
SUO	Sunovion Pharmaceuticals Canada Inc.
SYN	Syntex Inc.
TAI	Taidoc Technology Corporation
TAK	Takeda Canada Inc.
TPA	Takeda Pharmaceuticals America Inc.
TAV	Tanvex BioPharma USA, Inc.

Abbreviation	Manufacturer Name
TAR	Taro Pharmaceuticals Inc.
TPH	TaroPharma, a Division of Taro Pharmaceuticals Inc.
TCI	Teligent Canada Inc.
TEL	Teligent OU
TEP	Teligent Pharma Inc.
TRS	TerSera Therapeutics LLC
TBP	Teva Branded Pharmaceutical Products R&D Inc.
TEI	Teva Canada Innovation.
TEV	Teva Canada Limited
TEW	Teva Women's Health Inc.
UPJ	The Upjohn Company of Canada
TER	Therasense Canada Inc.
TIP	Tillotts Pharma AG
TOL	Tolmar International Ltd.
TRE	Tremblay Harrison Inc.
TMI	Trudell Medical International
UCB	UCB Canada Inc.
UJC	Upjohn Canada ULC
VAL	Valeant Canada Ltd.
VAE	Valeo Pharma Inc.
VET	Verity Pharmaceuticals Inc.
VIH	ViiV Healthcare ULC
VIT	Vitaflo USA, LLC
VIU	Vivus Inc.
VPI	VPI Pharmaceuticals Inc.
WAR	Warner Chilcott Canada Co.
WAT	Watson Laboratories Inc.
WEL	WellSpring Pharmaceutical Canada Corp.
WSQ	Westwood Squibb Pharmaceuticals
WHB	Whitehall-Robins Inc.
WYE	Wyeth Ltd.
WAY	Wyeth Pharmaceuticals

Abbreviation	Manufacturer Name
WYA	Wyeth-Ayerst Canada Inc.
XED	Xediton Pharmaceuticals Inc.
ZIL	Zila Pharmaceuticals Inc.

B. List of Dosage Form Abbreviations

Abbreviation	Dosage Form
Act	Actuation
Aero	Aerosol
Amp	Ampoule
App	With Applicator
Auto	Automatic
Cap	Capsule
Cart	Cartridge
Chew	Chewable
Cl Lot	Cleansing Lotion
Combi Pk	Combination Pack
CR	Controlled Release
Cr	Cream
DR	Delayed Release
Eff	Effervescent
Emol	Emollient
Emuls	Emulsion
EC	Enteric Coated
Ent	Enteric Coated
Ent Microsph Cap	Enteric Coated Microspheres in Capsules
ER	Extended Release
Aq	In Water
Fl	Fluid
Gran	Granule
Gtt	Drop(s)
Hr	Per Hour
Inh	For Inhalation
Inh Pd	Inhale Powder

Abbreviation	Dosage Form
Inh Solution	Inhale Solution
Inj	Injectable
Inj Sol	Injectable Solution
Inj Susp	Injectable Suspension
IV	Intravenous
LA	Long Acting
Liq	Liquid
Lot	Lotion
Loz	Lozenge
mcg	Microgram
mL	Millilitre
MR Tab	Modified-Release Tablet
MD	Multi Dose
Multi Dose Vial	Multiple Dose Vial
Nas-Inh	Nasal Inhaler
Nas-Sp	Nasal Spray
ODT	Orally Disintegrating Tablet
Oily	In Oil
Oint	Ointment
O/L	Oral Liquid
Oph	Ophthalmic
Oph Sol	Ophthalmic Solution
Oral Pd	Oral Powder
Oral Susp	Oral Suspension
Ot	Otic
Ot Sol	Otic Solution
Pd	Powder
Pd Inh	Powder for Inhalation
Ped	Pediatric

Abbreviation	Dosage Form
Pk	Package
Pref Autoinj	Prefilled Autoinjector
Pref Pen	Prefilled Pen
Pref Syr	Prefilled Syringe
Prolong-Rel	Prolonged-Release
Rect	Rectal
Rect Aero	Rectal Aerosol Foam
SC	Subcutaneous
SG Cap	Soft Gelatin Cap
SL	Sublingual
Sol	Solution
Sp	Spray
Sprinkle Cap	Sprinkle Capsule
SR	Sustained Release
Sup	Suppository
Susp	Suspension
Syr	Syrup
Tab	Tablet
Top	Topical
Top Aero Foam	Topical Aerosol Foam
Top Cr	Topical Cream
Top Gel	Topical Gel
Top Sol	Topical Solution
Vag	Vaginal

Part XI
Section Currently Not In Use

Part XII
Limited Use Drug Products

Part XII: Limited Use Drug Products

Introduction

Please refer to the e-Formulary to access up-to-date information on Limited Use (LU) product listings and their clinical criteria. For information about the designation of LU benefits, see Part I of the Formulary/CDI.

Finding an LU Drug Product and its Designated Clinical Criteria

LU drug products are listed in the Formulary/CDI with specific clinical criteria/conditions for use. These LU criteria identify the clinical conditions for which these drugs will be reimbursed by the ODB program. Each LU criterion has a corresponding RFU code. LU drugs are eligible for coverage only in situations where the clinical criteria have been met. Any other indication may be considered through the EAP described in Part VIII of the Formulary/CDI.

LU Reimbursement Process

Completing an LU Prescription

Claims for LU drugs will be reimbursed under the ODB program only when prescribed for an ODB-eligible recipient in accordance with the criteria outlined for each product and accompanied by a valid, fully completed prescription with the appropriate LU documentation (RFU code). The pharmacist should review the prescription and process the claim only if all the required information is provided.

The LU authorization is valid for the duration indicated by the listed LU criteria. As of September 27, 2005, some LU drugs used in chronic conditions have been granted extended authorization periods beyond one year. For drugs with an “indefinite” authorization period, it is only necessary for the prescriber to confirm that the patient meets the LU clinical criteria by completing an LU prescription once.

For other drugs with a defined LU authorization period, a new LU prescription must be completed according to the authorization period provided in the LU criteria (usually on an annual basis).

An exception to this policy may occur in situations where LU criteria have changed. In situations where LU criteria have changed, prescribers must consider whether recipients meet the new criteria. If so, a new LU prescription must be completed within three months of the change in LU criteria.

Documentation that the patient meets the LU criteria may be provided on a regular prescription form according to the following instructions. Failure to have the RFU code appropriately documented on the prescription may result in:

- Prescription not being filled by the pharmacist
- Recoveries of monies paid to pharmacies by the ministry
- Patient being required to pay for the LU drug prescription

All LU prescriptions require an RFU code to be completed by the prescriber. The RFU code verifies that the patient meets the LU criteria. Effective May 16, 2008, the RFU code can be communicated by one of the following methods:

- Writing on an LU prescription
- Electronically on an electronically-generated LU prescription
- Verbally during a verbal order of an LU prescription by a prescriber*
- Verbally during an LU prescription transfer between pharmacies*

*Note: Verbal communications of RFU codes must be documented by the receiving pharmacy in writing.

LU prescriptions preprinted by manufacturers or generated by a dispensary's computer software, are neither valid nor acceptable by the ministry. Faxed copies of LU prescriptions are acceptable (pharmacies should copy thermal paper faxes onto regular paper for record-keeping purposes). Pursuant to subsection 29(1) of O. Reg. 201/96 made under the ODBA, a valid LU prescription with RFU code must be kept on file for 24 months to support the LU claim.

Monitoring and Accountability Framework

Reimbursement for LU claims is made under the authority of section 23 of the ODBA and can only be made if the LU clinical criteria set out in the Formulary/CDI have been met. By writing the RFU code on a prescription for the LU drug product, the authorized prescriber affirms that the patient meets the clinical criteria.

For the purposes of claims review under the ODBA, it may be necessary on occasion for prescribers to provide supporting documents on request. Pursuant to section 46(1) of the *Personal Health Information Protection Act,* 2004, a health information custodian may be required to disclose personal health information about an individual to the ministry for the purpose of monitoring or verifying claims for payment for health care funded wholly or in part by the ministry. LU prescriptions may therefore be monitored by the ministry to ensure that the RFU code indicated is in accordance with the LU criteria listed in the Formulary/CDI.

A Guide to Completing LU Prescriptions for Prescribers

In order to ensure the LU prescription is fully completed, write the prescription as you normally would. In addition it is necessary to:

- Provide the appropriate RFU code (e.g., RFU# 123); and
- Sign and date the prescription; and
- Fill in your CPSO number (for prescribers other than physicians, fill in your college registration number and indicate the professional college to which you belong).
- The initial LU prescription with the RFU code must be fully complete before patients take the prescription to the pharmacy, or prescribers fax it directly to the pharmacy.

All LU prescriptions require an RFU code to be completed by the prescriber. The RFU code verifies that the patient meets the LU criteria. Effective May 16, 2008, the RFU code may be communicated by one of the following methods:

- Writing on an LU prescription
- Electronically on an electronically-generated LU prescription
- Verbally during a verbal order of an LU prescription by a prescriber

The LU authorization will be valid for the duration indicated by the listed LU criteria. During this period, any repeat prescription may be given verbally to a pharmacist. For drugs with extended or indefinite authorization periods, a new prescription may be required after a certain period of time to allow the drug to be dispensed in accordance with the regulations of the OCP.

If a patient has met the LU criteria before being eligible for ODB coverage, and supporting documentation is available (e.g., the diagnostic test was done prior to the person turning 65), that information can still be used to verify the LU claim.

For instance, a patient who had step-up therapy in the past will not have to have step-up therapy again to prove eligibility to receive an LU drug as long as supporting documentation is available.

Reimbursement for LU claims is made under the authority of section 23 of the ODBA and can only be made if the authorized LU criteria have been met.

Prescribers should not complete an LU prescription if the patient’s clinical condition does not meet one of the listed LU criteria. A written request for special consideration for coverage can be made under the ODB program’s EAP (see Part VIII).

The pharmacist must have a fully completed prescription with the appropriate RFU code before submitting an ODB claim.

A Guide to LU Prescriptions for Pharmacists

All drug products, including LU drugs, are to be dispensed in accordance with the regulations of the OCP.

Pharmacists must ensure that all of the following information has been provided by the prescriber:

- The appropriate RFU code
- The date and prescriber's signature
- The physician's CPSO number (for prescribers other than physicians, the prescriber's college registration number is required)

Only the prescriber may fill in this information. If the CPSO or college registration number is missing, pharmacists may enter it only if they are certain it is the correct number. Claims for LU products must contain a valid CPSO or college registration number (i.e., 99999 is not acceptable). Please note:

- Payments made in respect of LU claims with incomplete documentation (i.e., prescriptions that do not include the appropriate RFU code, date, prescriber's signature, CPSO number or college registration number) will be subject to recovery by the ministry
- Pharmacists should ensure the LU criteria have been applied appropriately
- Where a pharmacist has concerns about whether the clinical criteria have been met, the pharmacist should discuss it with the prescriber and record the outcome of the discussion on the prescription according to standard pharmacy practice
- The initial LU prescription with the RFU code must be fully complete before dispensing
- All LU prescriptions require an RFU code to be completed by the prescriber. The RFU code verifies that the patient meets the LU criteria. The RFU code may be communicated by one of the following methods:
    - Writing on an LU prescription
    - Electronically on an electronically-generated LU prescription
    - Verbally during a verbal order of an LU prescription by a prescriber

Pharmacists may also communicate the RFU code verbally during an LU prescription transfer between pharmacies. Verbal communications of RFU codes must be documented by the receiving pharmacy in writing.

The LU authorization must be documented and will be valid for the duration indicated by the listed LU criteria. During this period any repeat prescription may be given verbally by a prescriber to a pharmacist. For drugs with extended or indefinite authorization periods, a new prescription may be required after a certain period of time to allow the drug to be dispensed in accordance with the regulations of the OCP.

If a patient has met the LU criteria before being eligible for ODB, and supporting documentation is available (e.g., the diagnostic test was done prior to the person turning 65), that information can still be used to verify the LU claim. For instance, a patient who had step-up therapy in the past will not have to have step-up therapy again to prove eligibility to receive an LU drug as long as supporting documentation is available.

Reimbursement for LU claims is made under the authority of the ODBA and can only be made if the authorized LU criteria have been met. Pursuant to subsection 29(1) of O. Reg. 201/96 made under the ODBA, a valid LU prescription with RFU code must be kept on file for 24 months to support the LU claim.

Note: if the pharmacist is prescribing the drug therapy according to his/her scope of practice, the pharmacist can complete the LU documentation to confirm that the patient meets the LU criteria. As the prescriber of the medication, documentation of the assessment must be recorded appropriately before the claim is submitted. Documentation may be requested for post-payment verification.

The pharmacist must have a fully completed prescription with the appropriate RFU code before submitting an ODB claim.