

ONTARIO'S PUBLIC DRUG PROGRAMS

Ontario Public Drug Programs provide coverage through six provincial drug plans:

Ontario Drug Benefit (ODB) Program

Drug benefits for Ontarians aged 65 and older, residents of long-term care homes and homes for special care, recipients of professional home services and social assistance and recipients of the Trillium Drug Program.

Trillium Drug Program

Drug benefits to Ontario residents that have high drug costs in relation to their household income. Any Ontario resident that does not qualify under any of the other plans can apply for the Trillium Drug Program.

Special Drugs Program

Drug benefits for Ontarians with a valid Health Card for certain outpatient drugs used to treat specific diseases or conditions.

New Drug Funding Program for Cancer Care

Drug Benefits for newer, intravenous drugs, typically administered in hospitals and cancer care facilities. The Ministry provides about 75% of the overall funding for intravenous cancer drugs in Ontario and hospitals fund the remaining 25% through their operating budgets.

Inherited Metabolic Diseases Program

Benefits for Ontarians with a valid Health Card for certain outpatient drugs, supplements and specialty foods used in the treatment of specific metabolic disorders.

Respiratory Syncytial Virus Prophylaxis for High-Risk Infants Program
 Funds palivizumab for infants who are at high risk for hospitalization and complications from a Respiratory Syncytial Virus infection.

For More Information call: ServiceOntario, Infoline at: 1-866-532-3161 (Toll-free) In Toronto, (416) 314-5518 TTY 1-800-387-5559. In Toronto, TTY 416-327-4282

Hours of operation: Mon to Fri 8:30am - 5:00pm

ONTARIO DRUG BENEFIT PROGRAM

Eligibility: Through the Ontario Drug Benefit (ODB) Program, the Ministry of Health and Long-Term Care covers most of the cost of prescription drug products listed in the Ontario Drug Benefit (ODB) Formulary as well, drugs that are not listed in the Formulary are considered for coverage, on a case-by-case basis, through the ministry's **Exceptional Access Program (EAP).**

The following groups of Ontario residents are eligible for community-based, outpatient drug coverage through the ODB program:

- people 65 years of age and older;
- residents of long-term care homes;
- residents of Homes for Special Care;
- people receiving professional services under the Home Care program;
- Trillium Drug Program registrants.

Exceptional Access Program (EAP)

The Exceptional Access Program (EAP) facilitates patient access to drugs not funded on the Ontario Drug Benefit (ODB) Formulary, or where no listed alternative is available. In order to receive coverage, the patient must be eligible to receive benefits under the Ontario Drug Benefit (ODB) program.

The Executive Officer, on behalf of the ministry, makes funding decisions for drug products covered under the ODB program's EAP based on recommendations and guidelines from the ministry's expert advisory committee, the Committee to Evaluate Drugs (CED). All EAP requests will be considered according to the policies described below to ensure a fair and consistent review of each request. Other modernization initiatives will minimize the impact of the EAP on prescribers and will make the process more transparent to prescribers and patients.

- Funding Decision
- EAP Criteria
- EAP Application Process: How to Apply
- Reimbursement criteria for EAP Frequently Requested Drugs
- EAP Coverage Durations
- Turnaround Times
- Provincial Borders Drug Program (PBDP)
- Compassionate Review Policy
- Funding for Drugs being used in Clinical Trials

What's covered?

The Ontario Drug Benefit covers **most of the cost of more than 4,400** prescription drug products.

The ODB also helps you pay for:

- allergy shots and Epipen (used in response to severe allergic reaction)
- some products used in monitoring and testing for diabetes
- some prescribed over-the-counter drugs under specific circumstances (e.g. Ibuprofen 200mg, Ferrous sulphate 300)
- some nutrition products
- some drugs used in treatment of HIV/AIDS
- some drugs used in palliative care

What's not covered?

The Ontario Drug Benefit is for residents of the province only. Make sure your health card is valid (e.g. hasn't expired). Your pharmacist will need it to confirm your Ontario Drug Benefit eligibility and submit a claim to the ministry.

To be covered by the ODB, the prescription must be filled in a pharmacy in the province.

The following will not be covered by the Ontario Drug Benefit:

- prescription drugs that you buy outside Ontario
- drugs that are not listed on the Ontario Drug Benefit Formulary, or are not approved for the Exceptional Access Program

Ontario Drug Benefit Formulary

Your doctor, nurse practitioner and pharmacist keep track of all brand-name and generic drugs – and products – covered by the Ontario Drug Benefit using the Formulary. It's updated and published every month.

Search the Formulary

You can <u>search the Formulary online</u> to see if a generic or brand-name drug or product is covered by the ODB. But it's best to verify the results of your search with your doctor, nurse practitioner or pharmacist because some of the information is technical.

Brand-name vs. generic drugs

When a company develops a new drug, it will claim the sole right to make (based on a formula) and sell the drug (under a brand name) for a set period of time. That's called the patent.

When the patent ends, other companies are allowed to make and sell their own version of the drug. These are called generics and usually cost less than brand-name drugs, but they are tested and proven to work in the same way.

You can get covered for **both brand-name and generic drugs**, **whichever costs less**. But there are exceptions, such as:

- when a generic is not yet approved for coverage, even though it's available on the market
 - o e.g. manufacturer of a generic drug has not submitted it to ministry for approval as interchangeable with a brand-name drug
- when you have had adverse reactions to at least two generics

Costs

With the Ontario Drug Benefit, you pay a portion of prescription-drug costs based on your yearly income (after taxes) and marital status. You can get coverage as a single senior (including widowed spouses) or as a couple (includes spouses who are married, same-sex or common-law partners).

Choose from one of these income groups to find out what you pay:

- Single senior with income above \$19,300
- Senior couple with income above \$32,300
- Single senior with income of \$19,300 or less
- Senior couple with combined income of \$32,300 or less

You may pay a different rate if you are:

- living in a long-term care home or home for special care
- enrolled in Ontario Works, Ontario Disability Support Program or Home Care

Single senior with income above \$19,300

A single person aged 65 or older with a yearly income above \$19,300 after taxes pays:

- the **first \$100** of total prescription costs each year
 - o called the deductible paid down each time a prescription is filled
- after paying the deductible, up to \$6.11 for each drug prescribed, filled or refilled
 - o this amount is called the co-payment

How it works

We will send you a letter reminding you that your ODB coverage is about to begin. The letter is sent three months before coverage starts.

This is a good time to tell your doctor, nurse practitioner and pharmacist. They can plan ahead to make sure you're prescribed one of the more than 4,400 drugs approved for coverage.

Then, go to your pharmacy on the first day of the month after you turn 65 (e.g. if you turn 65 on April 15, go on May 1). This is your official start date in ODB.

Don't forget your Ontario health card to show the pharmacist.

Senior couple with combined income above \$32,300

A couple (one or both spouses aged 65 or older), with a combined yearly income above \$32,300 after taxes, pays:

- the first \$100 per person of total prescription costs each year
 - o called the deductible paid down each time a prescription is filled
- after paying the deductible, up to \$6.11 for each drug that is filled or refilled
 - o called the co-payment

How it works

We will send you and/or your spouse a letter confirming you qualify for ODB. The letter is sent three months before your coverage begins.

This is a good time to tell you and/or your spouse's doctor, nurse practitioner and pharmacist. They can plan ahead to make sure to prescribe one of the more than 4,400 drugs approved for coverage.

Then, go to the pharmacy on the first day of the month after you or your spouse turn 65 (e.g. if you turn 65 on April 15, go on May 1). This is your official start date for ODB.

Don't forget your Ontario health card to show the pharmacist.

Calculating first-year deductible

For your first year of ODB eligibility, depending on the month you turn 65, the deductible may be lower than \$100.

That's because the amount of the deductible is based on the number of months between your official start date (the first day of the month after you turn 65) and July 31 – the last day of the Ontario Drug Benefit cycle.

For example, if you turned 65 on April 15, your official start date would be May 1. Counting from May 1 to July 31 your deductible for the first year would be \$25.

Single senior with income of \$19,300 or less

If you're a single senior, with a yearly income of \$19,300 or less after taxes, you pay up to \$2 for each drug filled or refilled—and you do not have to pay a deductible.

Before this can take effect, you must fill out a Co-payment Application for Seniors.

Senior couple with combined income of \$32,300 or less

A senior couple (one or both people aged 65 or older), with a combined yearly income of \$32,300 or less after taxes, pays up to \$2 for each drug filled or refilled—and **does not** have to pay a deductible.

Before this can take effect, a Co-payment Application for Seniors must be filled out.

Fill out Co-payment Application for Seniors

If you're a single senior with annual income of \$19,300 or less after taxes, or a senior couple (one or both spouses 65 or older) with annual income of \$32,300 or less (after taxes), you must fill out and submit this form – before you can start paying the \$2 co-payment.

The Ministry of Health and Long-Term Care will send you a letter confirming you qualify for ODB three months before your coverage begins. The letter can be your reminder to fill out the form.

Get a copy of the application:

- by phone
 - o 1-888-405-0405 (toll free)
 - 416-503-4586 (Toronto area)
- in person at your pharmacy

Mail the completed application

Completed applications, including all required signatures and supporting documents, must be sent by mail to:

Ontario Drug Benefit Program Ministry of Health and Long-Term Care PO Box 384, Station D Etobicoke, Ontario M9A 4X3

How to get a 3-month supply

If you receive the ODB, or are in the Ontario Disability Support Program or the Trillium Drug Program, you can request a three-month supply of some drugs used to treat certain chronic conditions, such as:

- diabetes
- high cholesterol
- high blood pressure

Getting a three-month supply of your prescription means you will pay co-payment fees less often.

Talk to your pharmacist to find out which drugs qualify and to learn how to request a three-month supply.

TRILLIUM DRUG PROGRAM

The Trillium Drug Program (TDP) is intended for Ontario residents who have high prescription drug costs in relation to their net household income. The TDP provides coverage for prescription drug products (in the same manner as the Ontario Drug Benefit program) that are listed on the Formulary:

Please note that deductibles and co-payments will apply to this income-based program. Patients can register in the Trillium Drug Program if they:

- Comply with all requirements set out in the regulations under the ODBA
- Do not have private insurance coverage or their private insurance does not cover 100% of their prescription drug costs;
- Have valid Ontario Health Insurance (OHIP) and are a resident of Ontario;
- Are **not** eligible for drug coverage as another category of recipient under the Ontario Drug Benefit (ODB) Program (i.e., not a senior over 65 years of age, not a social assistance recipient, not receiving professional Home Care services, or not a resident of a Long-Term Care Home or Homes for Special Care).

<u>Trillium Drug Program Application Forms and Guides</u> are available at local pharmacies, online, or by calling 416-642-3038 or 1-800-575-5386 (toll free).

For more information Contact Us.

SPECIAL DRUG PROGRAM

Through the Special Drugs Program, the Ministry of Health and Long-Term Care covers the full cost of certain outpatient drugs used in the treatment of specific conditions. The program covers:

- Specific drugs for the treatment of cystic fibrosis;
- Amoxicillin, ascorbic acid (Vitamin C), deferoxamine, folic acid, hydrocortisone injection, penicillin and trimethoprim/sulfamethoxazole for the treatment of thalassaemia;
- Zidovudine (AZT) for the treatment of HIV infection;
- Erythropoietin (EPO) for people with end stage renal disease
- Cyclosporine for people who have had a solid organ or bone marrow transplant
- Human growth hormone for children with growth failure
- Clozapine for treatment of schizophrenia
- Alglucerase for people with Gaucher's Disease

The Special Drugs Program will cover costs for the above drugs if the patient:

- Is an Ontario resident with valid Ontario Health Insurance (OHIP)
- Is a patient with one of the diseases or conditions covered
- Meets the established clinical criteria
- Is under the care of an approved physician/designated care centre.

As a way for the ministry to ensure that the appropriate treatments for the diseases and conditions are prescribed, special facilities (usually at hospitals) have been designated to distribute these drugs. In some cases, special review committees have been established to ensure that the clinical criteria are met.

NEW DRUG FUNDING PROGRAM FOR CANCER CARE

The New Drug Funding Program (NDFP), which is administered by Cancer Care Ontario on behalf of the Ministry of Health and Long-Term Care, provides about 75% of the overall funding for intravenous cancer drugs. NDFP funding is for new and approved intravenous cancer drugs administered in hospitals. The other 25% is for older drugs approved before the NDFP was created and is covered by the hospitals' budgets.

The Executive Officer decides what drugs are funded, relying on advice from an expert advisory committee.

Historically, each hospital paid for its own intravenous cancer drugs, which led to unequal access at different hospitals across the province. Decisions were not always based on evidence about medical benefit and value for money. The NDFP was created to ensure that Ontario patients would have equal access to high-quality intravenous drugs.

The <u>list of NDFP-covered drugs</u>, and the indications for which they are covered, are posted in the Cancer Drugs section of the <u>Cancer Care Ontario</u> website.

Information on approval of new drugs for cancer care is available on the CED/Cancer Care Ontario (CCO) Subcommittee page of the Drug Submission section of this website.

Evidence Building Program (EBP)

In March 2011, the MOHLTC announced a new Evidence Building Program (EBP) for cancer drugs. The EBP complements and strengthens Ontario's NDFP and the process for drug funding decisions in Ontario. The EBP seeks to resolve uncertainty around clinical- and cost-effectiveness data related to the expansion of cancer-drug coverage within Ontario.

For a drug to be included in the EBP, there must be mounting evidence of its benefits, such that funding for a fixed period will allow CCO to gather real-world data about its efficacy and cost-effectiveness. Data collected through the EBP will be evaluated and will inform a final funding decision by the Executive Officer of Ontario Public Drug Programs. Information on the EBP including FAQs and the inclusion criteria are available on the CCO website at: www.cancercare.on.ca/ebprogram.

Case-by-Case Review Program (CBCRP)

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. Program policies, FAQs and how to apply to the CBCRP online are on the CCO website at: www.cancercare.on.ca/cbcrp.

While CCO administers the EBP and the CBCRP, the Executive Officer of Ontario Public Drug Programs makes all final funding decisions.

INHERITED METABOLIC DISEASES PROGRAM

Through the Inherited Metabolic Diseases (IMD) Program, the Ministry of Health and Long-Term Care covers the full cost of certain outpatient drugs, supplements and specialty foods used in the treatment of specific inherited metabolic disorders. The IMD Program covers:

- Specific drugs and supplements
- Modified L-Amino Acid mixtures ("medical foods")
- Special Low Protein Foods
- Other supplements
- Infant Feeds
- Complete Enteral Feeds

Only the metabolic disorders and Funded Products as listed in the <u>List of Disorders, Covered Drugs, Supplements and Specialty Foods</u> are covered by the IMD Program. As a means to ensure that appropriate treatments are being provided to IMD Program patients, special treatment facilities have been designated to distribute the Funded Products. Decisions about what products are funded are made by the Executive Officer of Ontario Public Drug Programs based on expert advice provided by an advisory committee. For more information on metabolic conditions, visit the ministry's website on <u>Newborn Screening</u>.

The IMD Program will cover the costs of the foregoing types of products ("Funded Products"), provided that the patient:

- Is an Ontario resident with valid Ontario Health Insurance (OHIP);
- Has been diagnosed with an inherited metabolic disorder for which one of the Funded Products has been prescribed as a treatment;

- Is under the care of a physician from a designated treatment centre;
- Obtains the Funded Products from a designated treatment centre.

To register a patient in the IMD Program, an <u>application and consent form</u> must be completed and submitted to the ministry.

Fabrazyme (agalsidase beta) and Replagal (agalsidase alfa) for the treatment of Fabry Disease

Effective September 2013 the funding of agalsidase for Fabry Disease was transitioned from the national process through the University Health Network (UHN) to the Ontario Public Drug Programs (OPDP). The Canadian Fabry Disease Initiative (CFDI) will continue to assess new patient applications, annual renewals, and manage the ordering of enzyme replacement therapy (ERT) from the manufacturers. All current and new patients must continue to be eligible for ERT according to the current Canadian Fabry Disease Treatment Guidelines.

To apply for treatment funding, an <u>assessment or renewal form</u> must be completed and submitted to the CFDI.

For more information, please contact:

Canadian Fabry Disease Initiative (CFDI) c/o Syed Wasim Ontario Coordinator for CFDI Metabolic Genetics & Fabry Disease Clinic University Health Network & Mount Sinai Hospital Tel: 416-586-4800 ext. 4231; Fax: 416-619-5523

Email: Syed.Wasim@uhn.ca

Aldurazyme (laronidase) for the treatment of Hurler and Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I):

Effective October 1, 2011, the administration and funding of laronidase was transitioned from the University Health Network (UHN) to the IMD program. All current and new patients will be enrolled in the IMD program. Patients must meet the funding criteria as outlined in the reimbursement guidelines:

- Reimbursement Guidelines
- Request Form

Inquiries regarding the IMD Program should be directed to:

Ontario Public Drug Programs

5700 Yonge Street, 3rd Floor

Toronto ON M2M 4K5 Tel.:416-327-8109

Fax: 416-327-8123

Email: PublicDrugPrgrms.moh@ontario.ca

RESPIRATORY SYNCYTIAL VIRUS PROPHYLAXIS FOR HIGH RISK INFANTS PROGRAM

Through the Respiratory Syncytial Virus Prophylaxis for High-Risk Infants Program, the Ministry of Health and Long-Term Care covers the full cost of the drug palivizumab used to prevent a serious lower respiratory tract infection caused by the Respiratory Syncytial Virus (RSV) in infants who are less than 2 years of age at the start of the RSV season and who are at high risk for RSV disease.

The drug is only provided during the active season to infants who meet the ministry's eligibility criteria for funding. The active season is generally from November to April, with variations in various regions of Ontario.

Palivizumab will be funded for RSV prophylaxis in infants who are residents of Ontario, have a valid Ontario health card and if they meet one of the following clinical criteria:

- Infants born prematurely at ≤ 32 completed weeks gestation and aged ≤ 6 months at the start of, or during, the local RSV season; or
- Infants 33 35 completed weeks gestation and aged ≤ 6 months at the start of, or during the local RSV season, who DO NOT live in isolated communities AND have a Risk Assessment Tool Score of 49 to 100; or
- Infants 33 35 completed weeks gestation and aged ≤ 6 months at the start of, or during the local RSV season, and who LIVE IN isolated communities where paediatric hospital care is not readily accessible and ambulance transportation for hospital admission is required; or
- Infants < 24 months of age with Down Syndrome / Trisomy 21; or
- Infants < 24 months of age with bronchopulmonary dysplasia/chronic lung disease (BPD/CLD) and who required oxygen and/or medical therapy within the 6 months preceding the RSV season; or
- Infants < 24 months of age with hemodynamically significant (HS) cyanotic or acyanotic congenital heart disease (CHD); requiring corrective surgery or is on cardiac medication for hemodynamic significant disease.

Infants with other specific medical illnesses that places them at high risk of hospitalizations and complications from a RSV infection may also be considered for prophylaxis, if they meet necessary requirements. The enrolment forms for these infants will be reviewed on a case-by-case basis by the ministry's medical consultant(s) with expertise in RSV prophylaxis.

The following are the links to the guidelines, general information, answers to frequently asked questions and applicable forms for the current RSV prophylaxis season for health care professionals:

Information and Guidelines

- 2016-2017 RSV Prophylaxis Season Information to healthcare professionals (PDF)
- 2016-2017 Season Enrolment and Drug Ordering Process (PDF)
- RSV Prophylaxis Program Frequently Asked Question (PDF)

Forms

Enrolment Form: <u>English</u> / <u>French</u>

Product Order Form: English / French