Ontario Drug Programs Reference Manual

Drug Programs Delivery Branch
Drugs and Devices Division
Ministry of Health

NOVEMBER 27, 2019

Ontario

Table of Contents

Introduction

The Drugs and Devices Division (DDD) of the Ministry of Health (MOH or Ministry) administers several publicly funded drug programs, the largest of which is the Ontario Drug Benefit (ODB) Program. The *Ontario Drug Benefit Act* ("ODBA") and the *Drug Interchangeability and Dispensing Fee Act* ("DIDFA") provide the legislative framework under which the ODB program is administered.

Purpose

The purpose of the Ontario Drug Programs Reference Manual ("Reference Manual") is to direct pharmacies how to:

- complete the required application to register for the Health Network System (HNS)
- submit online and paper claims for payment (claims), and reversals of claims
- submit claims for professional pharmacy services
- submit narcotics monitoring transactions
- understand claim response codes and intervention codes
- understand the Drug Utilization Review (DUR) module.

A pharmacy is required to comply with the Reference Manual, pursuant to its HNS Subscription Agreement with the Ministry, and, in the case of the ODB Program, pursuant to Ontario Regulation 201/96 under the ODBA.

This Reference Manual is an update to the previous Reference Manual dated September 1, 2005.

Background

Health Network System (HNS)

The HNS is a province-wide communication network that links Ontario pharmacies to the Ministry's online claims processing and adjudication system and the Narcotics Monitoring System (NMS) in real-time.

The HNS provides pharmacies with the following benefits:

- timely reconciliation and payment of claims
- real-time adjudication of claims, 24 hours per day, seven days per week
- DUR, including narcotic monitoring review
- real-time notification of a recipient's deductible and ODB eligibility status.

The HNS also provides increased quality of care and potential cost savings to the health care system by identifying:

- potential drug interactions
- duplicate prescriptions
- potential multiple prescribers and multiple pharmacy use
- inappropriate or fraudulent use of the system
- verification of some reimbursement conditions/criteria.

Pursuant to the HNS Subscription Agreement, a dispenser must ensure that all claims for payment submitted to the Ministry comply with the requirements outlined in the Reference Manual. Claims for payment that do not comply with these requirements may be recovered by the Ministry.

Further information on the HNS registration process can be found in *Section 2*.

As part of the HNS registration process, pharmacies must also register for access to the ONE® Mail email system to receive information on changes to drug benefits, programs, policies, and payment information, as well as advisories and reminders. Pharmacies are reminded that under the terms of the HNS Subscription Agreement, they are required to log on to the ONE® Mail email system at least once per week. Further information on the ONE® Mail registration process can be found in *Section 13*.

Narcotics Monitoring System

The misuse, abuse and diversion of monitored drugs (prescription narcotics and other controlled substances) are a public health and safety concern for Ontarians. The Narcotics Monitoring System (NMS) was introduced to help reduce misuse, addiction, unlawful activities and deaths related to these medications.

The NMS was established under the authority of the *Narcotics Safety and Awareness Act, 2010* ("NSAA") and collects community pharmacy dispensing data about all monitored drugs i.e., pharmacy dispensed narcotics and other controlled substances, regardless of whether the prescription is paid for under a publicly funded drug program, through private insurance, or by cash. The collected data may be reviewed and analyzed by the Ministry for a variety of purposes, including: educational and public health purposes, reporting possible professional misconduct to regulatory health profession colleges and reporting possible criminal conduct to law enforcement agencies.

The Monitored Drugs List (MDL) provides a list of products that the Ministry has selected for monitoring. This list can be used as a reference to determine if a submission to the NMS is required for the product being dispensed. Pursuant to Section 8 of the NSAA, all pharmacy

dispensers are required to submit dispensing information to the NMS about all monitored drugs dispensed to people, and must also do so in accordance with the NMS Pharmacy Reference Manual.

Drug Profile Viewer

In 2005, the Ministry implemented the Drug Profile Viewer (DPV), a secure, web-enabled application that provides authorized health care providers across the province with real-time electronic access to the prescription drug and pharmacy service history of ODB recipients to help facilitate the provision of timely and appropriate treatment.

The DPV contributes to improved quality and efficiency of health care delivery by:

- Reducing the need for individuals to repeat drug information to multiple health care providers and assisting individuals who have difficulty remembering or recounting what medications they are taking upon a visit to a health care provider.
- Increasing the speed and accuracy of diagnoses and improving the ability of clinicians to identify and prevent adverse drug reactions.
- Assuring better continuity of pre-existing drug therapy, if required, while a patient receives treatment in hospital.

Digital Health Drug Repository

The Digital Health Drug Repository (DHDR), which has replaced the Drug Profile Viewer (DPV), contains information about publicly funded dispensed drugs and pharmacy services, as well as information about all pharmacy dispensed monitored drugs (narcotics and controlled substances), regardless of payor. Authorized health care providers (e.g., physicians, pharmacists, nurse practitioners) in various community care settings (e.g., pharmacies, community health or mental health centres, long-term care facilities, public health units) have access to DHDR information through the provincial clinical viewers (ClinicalConnect and Connecting Ontario).

With DHDR, authorized health care providers are able to securely view their patient's comprehensive drug and pharmacy service profile, at point of care, informing appropriate prescribing and supporting the clinician's ability to prepare the Best Possible Medication History (BPMH) to assist the clinical drug assessment for their patient.

Developing an accurate BPMH can help prevent specific adverse drug events (ADEs) that can result from prescribers' incomplete knowledge of their patients' medication and pharmacy service history. ADEs harm patients and result in the need for costly interventions. Effective implementation of medication reconciliation is considered essential to reduce preventable ADEs occurring at transitions between community and hospital care and between prescribers (e.g., family physician and specialists, and when a patient changes prescribers).

The DHDR provides the ability to drive and support quality-based care. Access to a comprehensive drug and pharmacy service history can support patient safety through medication reconciliation processes and digitally-enabled decision aids. Similarly, making up-to-date dispensed medication information from the NMS readily available can help physicians and pharmacists when making decisions concerning opioid prescribing and dispensing.

The DHDR currently leverages existing HNS/NMS data sets and assets. In the future, it is hoped that the DHDR will expand to include more data sources (e.g., privately paid dispensing data, prescribed events information) and additional clinically relevant data, and to include additional clinical viewers, consumer portals, and other point-of-service systems.

The DHDR is currently part of the province's Electronic Health Record (EHR) and is shareable within the patient's health care team across multiple health care settings (e.g., hospitals, community pharmacies, hospital in-patient pharmacies, family health teams, community health centres), significantly extending the reach of the Drug Profile Viewer.

Health care providers and health care organizations (including community pharmacies) can obtain access to the EHR through the clinical viewer organizations if they meet the privacy and security requirements to access the provincial assets.

Ontario Public Drug Programs Forms

All forms discussed in this Reference Manual may be revised by the Ministry from time to time. Up-to-date versions of the forms can be obtained from the Ministry's website or the Ontario central forms repository. Where appropriate, links to specific forms will be made available under the corresponding section of the Reference Manual.

Section 1: Updates

Overview

Pharmacies are reminded that under the terms of the HNS Subscription Agreement, claims are to be submitted in accordance with “Ministry Policies”, which is defined to include the Reference Manual and any other policies, directives, protocols, rules or guidelines applicable to the pharmacy operator that may be published by the Executive Officer or otherwise communicated to the operator from time to time.

The Ministry will provide information and/or updates to the Reference Manual as changes occur. Communications may be in the form of ONE® Mail notices or other mailings/postings.

Section 2: Registration and Notice of Changes

Overview

Ontario Drug Programs (ODP) registration allows pharmacies to submit online claims and claim reversals through HNS.

Pharmacies must also register for a ONE® Mail email system account to receive information on changes to drug benefits programs, policies and payment information, as well as advisories and reminders. Pharmacies are reminded that under the terms of the HNS Subscription Agreement, they are required to log on to the ONE® Mail email system at least once per week *(see Section 13)*.

This section outlines specific instructions for:

ODP registration *(see Section 2.1)*

Notification of ODP registration changes (*see Section 2.2)*

Closure or sale of a pharmacy *(see Section 2.3)*

2.1 Program Registration

Pharmacy Registration

A pharmacy registration package will need to be completed and submitted to the Ministry if you are applying for a new HNS account to obtain billing privileges under the ODBA. Such situations can occur when:

- opening a new Ontario pharmacy
- purchasing or acquiring an existing Ontario pharmacy
- a new accreditation number is assigned to a pharmacy with an existing ODP account by the Ontario College of Pharmacists (OCP) (e.g., relocation)
- there is an ownership change in an Ontario pharmacy.

The pharmacy registration package can be obtained via email at: HNS-Registration.MOH@ontario.ca or by contacting the Ministry via fax to number 613-545-4470. The pharmacy registration package includes the following:

- Pharmacy Registration Checklist
- Ontario Drug Programs Application
- HNS Subscription Agreement for Pharmacy Operators
- ONE® Mail account registration form.

To register for an ODP account, please submit a fully completed registration package either by email at: HNS-Registration.MOH@ontario.ca, or via fax to: 613-545-4470.

Note: Pharmacies that do not register for an HNS account are still required to obtain access to NMS in order to be compliant with the monitored drug submission requirements under Section 8 of the NSAA. A copy of the NMS pharmacy registration form can be requested by email at: HNS-Registration.MOH@ontario.ca, or via fax: 613-545-4470.

The activation of an HNS account involves the granting of billing privileges under section 4.1 of the ODBA. The granting of billing privileges under the ODBA is a discretionary power exercised in the public interest. In order for the Executive Officer of Ontario Public Drug Programs to consider granting billing privileges to a pharmacy operator, the Executive Officer must be satisfied that, among other things, the operator will submit claims for reimbursement that are valid and in accordance with the law.

Corporations/Officers/Directors/Shareholders/Designated Managers of pharmacy operators that have had their ODP account(s) terminated may have restrictions on their ability to receive a new ODP account and be required to comply with certain conditions. Such conditions must be met in order for billing privileges to be granted.

Remote Dispensing Location(s)

For pharmacies wishing to register for one or more remote dispensing location(s), a complete registration package including the ODP application, HNS Subscription Agreement and ONE® Mail account registration form, must be submitted to the Ministry for consideration.

All publicly funded prescriptions dispensed from a remote dispensing location must be submitted using the remote dispensing location's pharmacy identification (ID) number.

Note: Remote dispensing locations are not eligible to make MedsCheck and/or Pharmaceutical Opinion Program (POP) claims or publicly funded influenza vaccine administration claims.

Health Network System

HNS must only be used for the following purposes:

- Submitting claims or claim reversals for adjudication for prescriptions or pharmacy services which were dispensed or conducted at the location of the account for which the HNS Subscription Agreement was signed.
- Receiving responses to submitted claims or claim reversals.
- Receiving remittance (payment) information and Ministry communications through the ONE® Mail system.

HNS **cannot** be used for:

- Unauthorized access to other networks or email systems.
- Any transaction that contravenes the HNS Subscription Agreement, the ODBA or its regulation, or any other applicable law (e.g., submitting claims or transactions for products or services which were dispensed or had occurred at another location).
- Transactions not authorized by the Ministry.

In the event that misuse is detected, the Ministry will notify the pharmacy. The pharmacy will be required to take immediate corrective action. Failure to take corrective action may result in revocation of the pharmacy's access to HNS and its billing privileges under the ODBA.

The Executive Officer may allow for expanded uses of HNS by providing notice to pharmacy operators through the ONE® Mail system.

Pharmacy ID Number

Upon registration, the pharmacy/remote dispensing location will be assigned a unique identification (ID) number known as the pharmacy ID number.

For accredited pharmacies, the pharmacy ID number begins with the characters "ON" followed by a two-character (numeric) prefix, followed by the OCP pharmacy accreditation number. The process for assignment of the pharmacy ID number for accredited pharmacies is in alignment with the Canadian Pharmacists Association (CPhA) Claim Standard Version 3.

The pharmacy ID number is required for online transaction processing and ONE® Mail access, which is required in order to receive correspondence from the Ministry.

The pharmacy ID number will become effective on the activation date (i.e., when the pharmacy connects online to HNS).

It is important to be online as soon as possible since claims with a date of service prior to the pharmacy's activation date will not be processed.

Activation of the pharmacy ID number and initiation of access to HNS is available during the hours of 8:30 a.m. to 5 p.m., Monday through Friday (excluding Statutory Holidays).

New accreditation numbers are issued by the OCP each time there is a change in pharmacy ownership, location, etc. For each change in pharmacy accreditation number assigned by the OCP, the Ministry will assign a new pharmacy ID number and a new HNS agency ID. This process involves completion of an ODP application, the signing of a new HNS Subscription Agreement (to reflect the updated pharmacy details), and completion of a new ONE® Mail account registration form.

The Ministry's process of issuing a new pharmacy ID number includes a review of the application to ensure the pharmacy operator will be in compliance with the HNS Subscription Agreement. This process generally takes several business days after receipt of all required paperwork from the applicant and the OCP. Occasionally, additional information is required from the applicant before the registration process can proceed.

In order to ensure that this process is as seamless and efficient as possible, it is suggested that new applicants, as well as current HNS account operators who will be receiving new accreditation numbers, should inform the Ministry as soon as possible to allow sufficient time to process applications. The Ministry’s review process may be commenced prior to final issuance of new accreditation numbers by OCP.

Pharmacist ID Number

All pharmacists submitting claims to the ODB program must be registered within HNS. To register a pharmacist ID number, (i.e., the pharmacist license number) please call the ODB Help Desk at 1-800-668-6641 or via fax at 613-545-4470 during normal business hours.

2.2 Notification of Change(s)

Pharmacies are required to notify the Ministry in writing of any change(s) affecting their ODP registration no later than seven days after the change, including any changes in:

- pharmacy information (e.g., trade name, address, phone number)
- ownership type
- type of pharmacy (e.g., retail pharmacy, rural pharmacy, hospital outpatient dispensary)
- software vendor information
- network connection
- banking information
- Owner/Partner/Director/Shareholder/Designated Manager information
- authorized personnel signing authority

- transmission of remittance totals.

To notify the Ministry of any change(s) affecting ODP registration, pharmacies must forward a complete and signed Notification of Change form either by email to: HNS-Registration.MOH@ontario.ca, or via fax to: 613-545-4470.

The notification of change form for ODP registration can be obtained by contacting the ODB Help Desk at 1-800-668-6641 or via fax at 613-545-4470.

Note: For pharmacies with an active HNS account that are assigned new OCP accreditation numbers, the existing HNS account must be closed and new ODP application, new HNS Subscription Agreement and new ONE® Mail registration form must be submitted.

2.3 Closure or Sale of Pharmacy

In the event that a pharmacy is being closed or sold, the Ministry must be notified in writing no later than 30 days prior to the date of closure or sale either by email at: HNS-Registration.MOH@ontario.ca, or via fax to: 613-545-4470.

- **Note:** Claims will only be accepted for prescriptions dispensed up to the date of closure.
- A pharmacy owner is not permitted to assign its ODP registration or HNS Subscription Agreement to a new owner.
- The new owner cannot submit claims with a date of service prior to the activation date of its new pharmacy ID number.
- At the time of sale or closure, all Electronic Funds Transfer (EFT) payments are automatically reverted to cheque payments and are mailed to the pharmacy address on file, unless the Ministry receives a written notice signed by an authorized signing officer for whom the Ministry has confirmation of signing authority on file, directing otherwise.

Section 3: Confidentiality and Security

Overview

In accordance with applicable privacy legislation and the HNS Subscription Agreement, pharmacies are responsible for maintaining the confidentiality and security of data transmitted and received over HNS.

The Ministry's online claims adjudication system requires that specific information pertaining to the dispensing of drugs be collected and transmitted over the HNS. The Ministry's collection, use and disclosure of personal information through the HNS are governed by Section 13 of the ODBA and the *Personal Health Information Protection Act, 2004* ("PHIPA"). This information is necessary to adjudicate the claim and to administer payment. In addition, the prospective DUR systems will use this information to identify potential drug related problems.

The Ministry may also securely disclose information of Ontarians about their publicly-funded drugs and pharmacy services, as well as all dispensed narcotics and other controlled substances regardless of payor, to authorized health care providers in multiple health care settings for the purpose of informing clinical decision making and supporting the provision of health care.

This section explains the policies and procedures to ensure:

Confidentiality of patient information (*see Section 3.1*)

On-site physical security and password (network access) security (*see Section 3.2*)

3.1 Privacy of Patient Information

A pharmacy's collection, use, disclosure and retention of patients' personal health information are governed by PHIPA. Pharmacists should consult the OCP regarding the application of PHIPA to their practice and to obtain any guidelines or best practices pertaining to the collection, use and disclosure of patients' personal health information.

Learn more about privacy protection in Ontario.

3.2 Security

HNS access must be:

- Restricted to those whose access is required to perform their professional duties.
- Authorized by the pharmacy owner or designated manager of the registered OCP pharmacy.

Transactions submitted via an Acquirer Host network (i.e., third party network service provider) are subject to the security measures implemented by the Acquirer Host.

Section 4: Eligibility

Overview

This section explains:

Recipient eligibility under the ODB program and procedures for identifying recipients (*see Section 4.1*)

The policy with respect to Health Card Version Code when processing claims (*see Section 4.2*)

The policy for establishing eligibility for payment that may apply under certain eligibility streams and a summary of the availability and limitations applicable to the policy (*see Section 4.2*)

4.1 Program Eligibility

The ODB program provides community-based drug benefits to:

1) Individuals entitled to receive drug benefits under the *Ontario Disability Support Program Act, 1997* ("ODSPA") including Assistance for Children with Severe Disabilities (ACSD), and the *Ontario Works Act, 1997* ("OWA") including Temporary Care Assistance (TCA); and
2) Individuals who are insured persons under the *Health Insurance Act* ("HIA") and who are:
   a) 65 years of age or older (seniors)
   b) 24 years of age and under (children and youth) who do not have a private plan.
   c) receiving social assistance benefits (Ontario Disability Support Program and Ontario Works)
   d) receiving certain professional services provided or arranged for under the *Home Care and Community Services Act, 1994*
   e) residents of Long-Term Care (LTC) homes
   f) residents of Homes for Special Care (HSC) or Community Homes for Opportunity (CHO)
   g) enrolled in the Trillium Drug Program (TDP)

Details of recipient eligibility criteria are outlined on the following pages.

Seniors

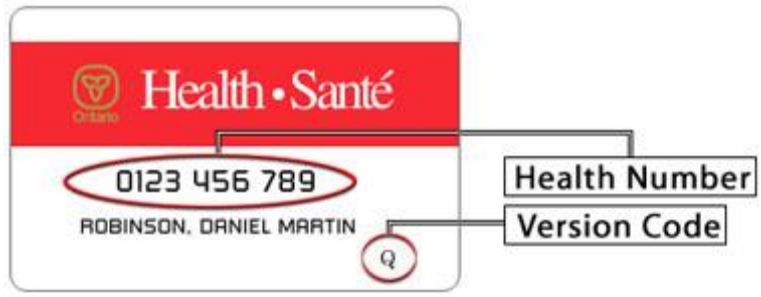
All residents of Ontario (including permanent residents) who are eligible for coverage under OHIP will qualify for drug benefits under the ODB program on the first day of the month following their 65th birthday. For example, if a resident's 65th birthday is April 15th, he/she will become eligible for coverage under the ODB program on May 1st.

Policy for establishing eligibility for payment does not apply (see Section 4.2).

How recipients are identified:

- Seniors (65 years of age or older) who present with a valid Ontario Health number.

Health card samples:



Required claim information:

- Enter the Health number in the Client ID # field
- Include the version code if embossed on the Health Card

Deductible/co-payments:

There are two categories of co-payments for seniors based on net income level:

1) A higher-income co-payment category and
2) A lower-income co-payment category.

Higher-income co-payment:

Single seniors with annual net income greater than $19,300 or a senior couple with a combined annual income greater than $32,300 are included in the higher-income co-payment category. Seniors in this category are each responsible for paying the first $100 (i.e., deductible) in prescription costs each year. After that, each senior may pay up to $6.11 (i.e., co-payment) toward the ODB dispensing fee on each prescription for an eligible benefit.

The ODB deductible for newly eligible seniors in the higher-income co-payment category is prorated based on the number of months they are eligible for ODB coverage in their first year of eligibility. The ODB benefit year begins August 1st of each year and ends on July 31st of the subsequent year. HNS will automatically track and notify pharmacists of an individual's deductible based on the month when they become eligible in their first year of ODB coverage. A response message is returned to the pharmacy indicating how much of the deductible has been paid. Once the deductible has been reached, HNS adjudicates claims with a $6.11 co-payment.

Only allowable drug expenses will count towards the $100 deductible, namely, amounts spent on co-payments in respect of prescriptions for drug products listed as benefits in the Ontario Drug Benefit Formulary (ODBF)/Comparative Drug Index (CDI), amounts spent in respect of prescriptions for nutrition products and diabetic testing agents approved as benefits under the ODB program, extemporaneous products that are designated pharmaceutical products under the ODBA and products that are approved under the Exceptional Access Program (EAP).

The deductible is 'paid' only through accumulated allowable drug expenses. The pharmacy may not collect $100 as a one-time payment, or any portion of that amount from the senior in excess of any allowable drug expenses accumulated on individual prescription claims.

Lower-income co-payment:

Single seniors with an annual net income equal to or less than $19,300 or a senior couple with a combined annual net income equal to or less than $32,300 are included in the lower-income - co-payment category and may pay up to $2 (co-payment) for each prescription for an eligible benefit. There is no annual deductible for these seniors.

To become eligible for the lower income co-payment category, these seniors must complete an Co-payment Application for Seniors form and submit it to the Seniors Co-payment Program (SCP).

Once the application has been processed, seniors are notified by mail and HNS will process claims based on the lower-income co-payment category, if applicable.

The foregoing co-payment rules only apply to a senior if he/she is not part of any other class of eligible persons (e.g., ODSP, OW, LTC home resident, HSC or CHO resident, home care

recipient). If a senior citizen belongs to one of these other eligibility categories, then only a $2 co-payment may be charged.

Questions regarding the SCP application/guide should be directed to:

In Toronto, call: 416-503-4586

Toll-free: 1-888-405-0405

Email: seniors@ontariodrugbenefit.ca

Children and Youth 24 Years and Under Who Do Not Have a Private Plan (OHIP+)

Ontario children and youth, aged 24 years and under, who have OHIP coverage, and do not have a private plan, also qualify for drug benefits under the ODB program. This coverage ends on the person's 25th birthday unless the person has other ODB coverage through another eligibility stream.

How recipients are identified:

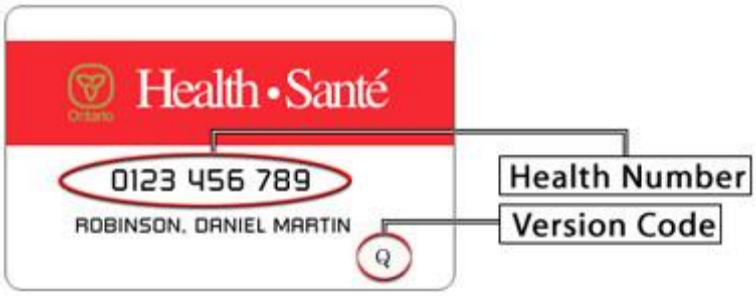
- Children and youth, aged 24 years and under, who present with a valid Health number and who do not have a private plan.
- Pharmacies are required to confirm whether the child or youth (aged 24 and under) has a private plan before submitting the claim to the HNS for adjudication with the Special Service Code (SSC) "U" **- No-Private-Insurance Attestation**"

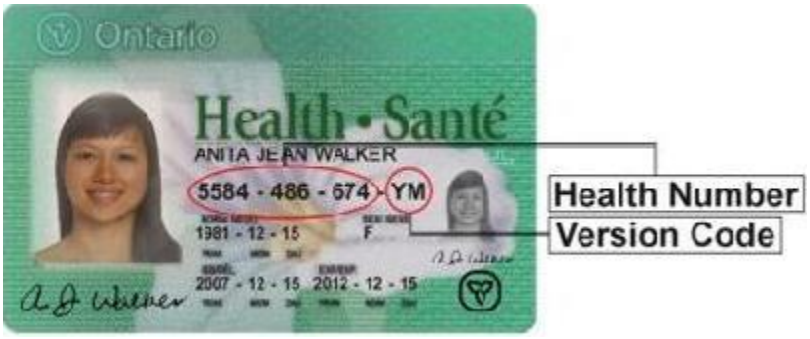
Private plan definition:

"Private plan" is defined to mean an employer, group or individual plan, program or account, however described, that could provide coverage for drug products, including the provision of funding that could be used to pay for drug products, regardless of whether:

- The private plan covers the particular drug for which coverage is sought,
- The child or youth or another person captured under the private plan is required to pay a co-payment, deductible, or premium, or,
- The child or youth has reached their annual maximum under the private plan and no further coverage is available

Health card samples:





Required claim information:

- Enter the Health number in the Client ID # field
- Include the Version Code if there is one on the Health Card
- If the child/youth or the parent/guardian/agent confirms the child/youth does not have a private plan, enter "U" in the Special Service Code (SSC) field
- The SSC "U" must be included as part of every claim submission for eligible children/youth who do not have a private plan. Failure to do so could result in a rejection by the HNS with one of the following response codes:

"PM"	No-Private-Insurance-Attestation Missing *(i.e., claim was submitted for a child/youth 24 years of age and under and confirmation of no private plan was missing)*
"ZR"	Submit receipt to TDP or Attest to No PI *(i.e., claim was submitted for child/youth 24 years of age and under who is enrolled in TDP)*

Note: For response codes "PM" and "ZR", there is no override code. Reconfirm the patient's private plan status:

- If the child/youth does not have a private plan, resubmit the claim with SSC "U"

- If the child/youth has a private plan, submit the claim to the private plan. If the recipient is also enrolled in TDP, advise the recipient to submit private plan information and receipts for out-of-pocket expenses to TDP.

Deductible/co-payments:

There are no deductibles or co-payments for OHIP+ recipients.

Ontario Disability Support Program and Ontario Works

Most social assistance clients do not receive a paper Drug Benefit Eligibility card each month and will be required to present their Ontario Health number when filling prescriptions under the ODB program, consistent with requirements for other ODB program recipients.

Verifying social assistance eligibility where coverage cannot be validated by the HNS:

When the HNS returns a response message that indicates the client is not eligible for ODB, there are two channels available for social assistance verification **before utilizing the "ML" or "MK" intervention codes to establish eligibility for clients**. It is important to confirm eligibility **before** establishing eligibility for a client.

Pharmacies are able to verify social assistance eligibility by using the monthly statement of assistance to look up the client's eligibility for ODB in the **Social Assistance Verification (SAV) Portal. This should be used as the primary mechanism for the social assistance eligibility verification.** The SAV portal can be accessed from the following web address: https://www.verify.sa.MCSS.gov.on.ca.

The SAV Portal should only be used for verifying social assistance eligibility and should not be used for other purposes, such as to obtain the Health number for clients who are eligible for OHIP coverage.

Pharmacies should use the SAV Helpline only in the event that the SAV Portal is unavailable to verify social assistance eligibility. The SAV Helpline is a provincially managed call centre and available toll-free at 1-888-284-3928.

Both the SAV Portal and the SAV Helpline will also provide the client's assigned temporary health reference number to the pharmacy to support the claims submission process.

For inspection and claim validation purposes, the MOH requires pharmacies to provide a record log for claims where social assistance recipients' eligibility for coverage was confirmed through the SAV Portal or SAV Helpline.

The SAV Portal allows a pharmacy to print the results of the search, which would contain the necessary information for claim validation purposes. Documentation must be retained on file and be readily available for two years following the last claim date. If a printed copy of the search results is not retained, documentation must be retained that contains:

- Reference number
- Date of search ('Eligibility Result as of')
- Type of Coverage ('Plan Code C' or 'Plan Code D')
- Results of the search (e.g., eligible or ineligible)

Clients who are not eligible for an Ontario Health number or do not have other government identification or statement of assistance, and clients with specific circumstances, will continue to receive a paper drug card to access the ODB program, including First Nations clients receiving assistance from Ontario Works administrators except for M'Chigeeng First Nations.

For these social assistance clients who continue to receive paper drug cards as proof of eligibility, pharmacies must continue to retain paper drug cards on file and readily accessible for two years past the last claim date, for claim validation purposes. Discarding paper drug cards prior to the two-year period may result in claim recoveries.

Further details can be accessed through the Executive Officer Communications webpage at: http://www.health.gov.on.ca/en/pro/programs/drugs/opdp_eo/eo_communiq.aspx.

For additional program related questions about the paperless drug card, please contact the MCCSS e-mail account at SASM-Q&A@ontario.ca.

For all ODB related questions, please call the ODB Help Desk at: 1-800-668-6641.

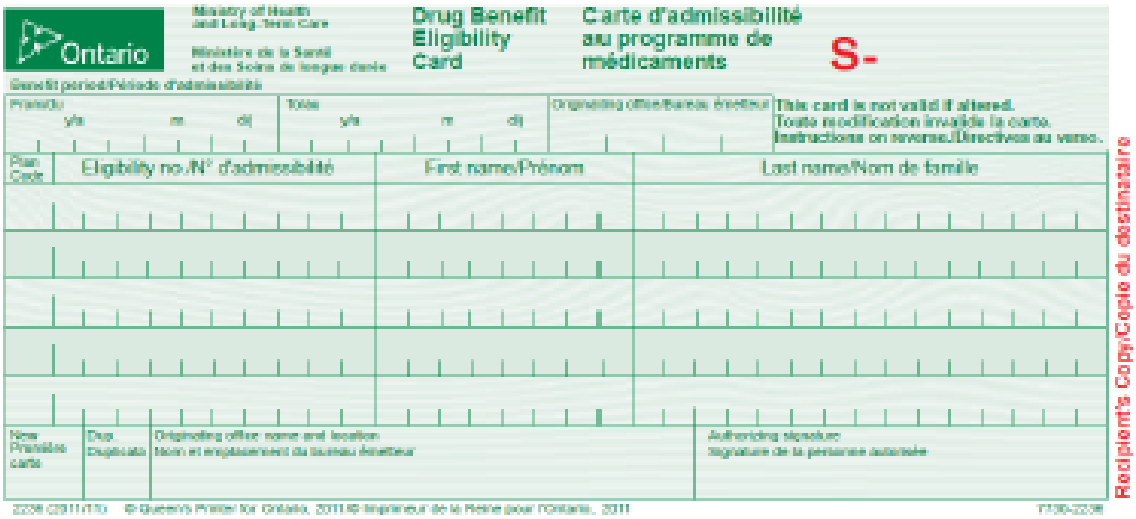
Policy for establishing eligibility for payment applies (see Section 4.2).
See Acceptable Supporting Documentation requirements.

How recipients are identified:

- Recipients who present with a valid Ontario Health number or present with a Drug Benefit Eligibility Card valid for the date of service.

Health Card Samples:

Paper Drug Benefit Eligibility sample:



Required claim information:

If the social assistance recipient presents his/her Health number:

- Enter the Health number in the Client ID # field

- Include the version code if embossed on the Health Card
- If the claim is rejected at the time of dispensing due to recipient ineligibility, the pharmacy may establish eligibility by entering an appropriate intervention code if appropriate documentation is first obtained (*see Section 4.2* for further details) once eligibility has been confirmed by SAV Portal or SAV Helpline in the event the SAV Portal is unavailable. Documentation of the eligibility verification results should be recorded and retained in a readily-accessible format for two years from the last claim date for claim validation.

If the social assistance client presents other government identification or monthly statement of assistance:

- Access the SAV Portal to verify social assistance eligibility and obtain the temporary health reference number, if one has been assigned. Ensure documentation required prior to submitting a claim for payment [see section 12 Inspection].

If the social assistance client presents a paper Drug Benefit Eligibility Card:

- Enter the eligibility number from the Drug Benefit Eligibility Card in the Client ID # field (omit any letter preceding the Eligibility Number)
- If the recipient also presents a Health number and it differs from the eligibility number on the Drug Benefit Eligibility Card, in addition to the above, also:
    - Enter the Health number in the Provincial Health Care ID Code field
    - Include the version code if embossed on the Health Card
- Ensure the Drug Eligibility Card or a copy of the card is retained in a readily-accessible format for two years past the last claim date for inspection purposes.
    - *Note, in accordance with O. Reg. 264/16 made under the Drug and Pharmacies Regulation Act* ("DPRA"), *all pharmacies are required to keep patient records for a period of at least 10 years or until 10 years after the day on which the patient reaches or would have reached the age of 18 years, whichever is longer.*

Co-payment:

- Recipients 25 years of age or older may pay up to $2 (co-payment) for each prescription for an eligible benefit
- Recipients 24 years of age and under have no co-payment

Home Care

Individuals receiving certain professional services provided or arranged for under the *Home Care and Community Services Act, 1994* are eligible to receive benefits under the ODB program. The Local Health Integration Networks (LHINs) determine eligibility for coverage.

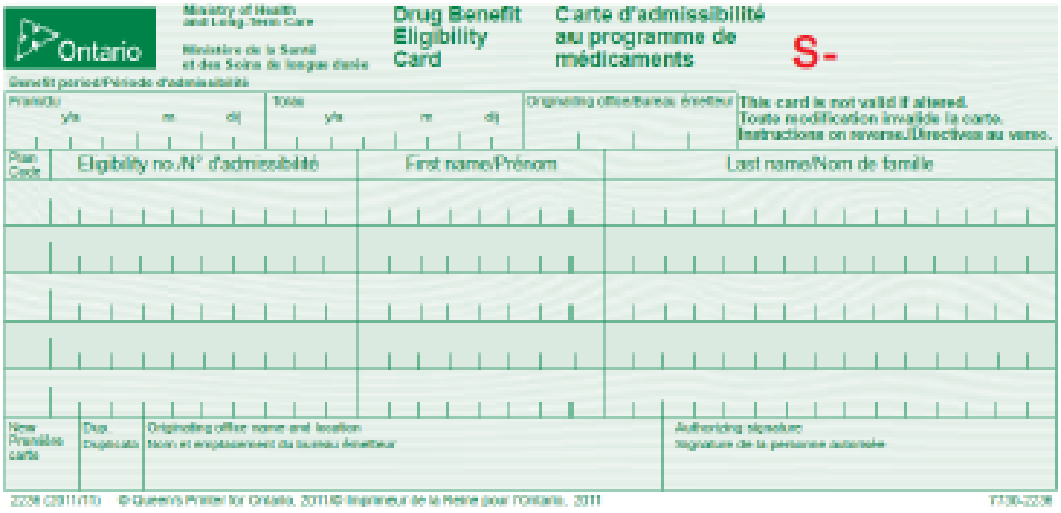
Policy for establishing eligibility for payment applies (see Section 4.2).

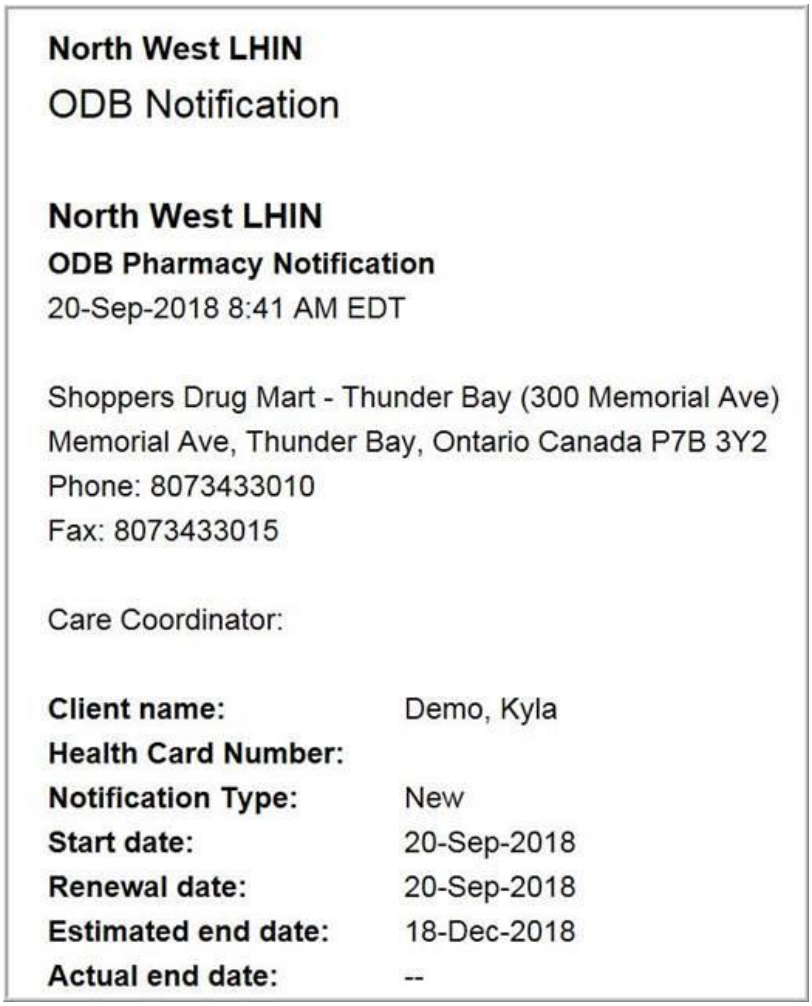
See Acceptable Supporting Documentation requirements.

How recipients are identified:

- Recipients may present a Drug Benefit Eligibility Card valid for the date of service or the LHIN may fax a copy of the Drug Benefit Eligibility Card or other notification indicating eligible recipients directly to the pharmacy.

Samples of Drug Benefit Eligibility Card and Notification of Eligibility for home care recipients:





North West LHIN

ODB Notification

North West LHIN

ODB Pharmacy Notification

20-Sep-2018 8:41 AM EDT

Shoppers Drug Mart - Thunder Bay (300 Memorial Ave)
Memorial Ave, Thunder Bay, Ontario Canada P7B 3Y2
Phone: 8073433010
Fax: 8073433015

Care Coordinator:

Client name:	Demo, Kyla
Health Card Number:	
Notification Type:	New
Start date:	20-Sep-2018
Renewal date:	20-Sep-2018
Estimated end date:	18-Dec-2018
Actual end date:	--

Required claim information:

- Enter the eligibility number from the Drug Benefit Eligibility Card in the Client ID # field (omit any preceding letters).
- If the LHIN has provided other written notification to establish eligibility:
    - enter the Health number in the Client ID # field
    - include the version code if embossed on the Health Card.

Co-payment:

- Recipients 25 years of age or older may pay up to $2 (co-payment) for each prescription for an eligible benefit.
- Recipients 24 years of age and under have no co-payment

Note: If a person is discharged from home care professional services prior to the expiry date of the Drug Benefit Eligibility Card, the individual is no longer eligible to receive benefits under the ODB program unless otherwise eligible (e.g., resident of an LTC home, senior, eligible through

the TDP, etc.). The Drug Benefit Eligibility Card is valid only during the time the recipient is receiving certain professional services provided or arranged for under the *Home Care and Community Services Act, 1994*. The eligibility of an individual discharged from such professional services may only be re-established if the individual begins receiving such professional services again and a new Drug Benefit Eligibility Card is presented.

If the pharmacy receives a notification fax from the LHIN with an updated (actual) end date, then the individual will no longer be eligible to receive benefits under the ODB program after that date, even if an earlier notification fax from the LHIN included a later end date for coverage.

Long-Term Care Home Residents

Residents of an LTC home licensed under the *Long-Term Care Homes Act, 2007* ("LTCHA") are eligible for benefits under the ODB program.

Policy for establishing eligibility for payment applies (see Section 4.2).
See Acceptable Supporting Documentation requirements.

How recipients are identified:

- Names and Health numbers of eligible recipients will be provided by the LTC home.
- Prescriptions for LTC home residents are provided on prescriber order/reorder sheets which designate the LTC home.

Required claim information:

- Enter Health number in Client ID # field
- Include version code if embossed on Health Card
- Enter the LTC home identification number (ODP number) in the Group Number field
- A valid LTC agency ID number (ODP number) must be included as part of the claim submission for LTC residents. Failure to do so could result in a rejection by HNS with response code "**31"- Group Number Error**

The first claim of every calendar month for most LTC recipients who are not a senior with coverage under another ODB eligibility stream will initially be rejected. LTC eligibility must be established for the current month by entering an appropriate intervention code (ML or MK) (see Section 4.2).
If a recipient is discharged from an LTC home, the pharmacy should call the ODB Help Desk with the date of discharge and request that LTC eligibility coverage be terminated as program eligibility may need to be adjusted.
If response code "31"- Group Number Error is received when submitting a claim for a person who is not an LTC home resident, please contact the ODB Help Desk to adjust program eligibility. Submission of claims and/or establishing ODB eligibility under an unauthorized program can be considered an invalid claim and may result in recovery of payments by the Ministry.

Co-payment:

- Recipients 25 years of age and older may pay up to $2 (co-payment) for each prescription for an eligible benefit.
- Recipients 24 years of age and under have no co-payment

Proposed Changes to Reimbursement for Pharmacy Services for Long-Term Care Home Residents

The Ministry is proposing to change the reimbursement model for pharmacies that provide pharmacy services, including prescription dispensing and MedsCheck / Pharmaceutical Opinion programs, to residents of Long-Term Care Homes from a fee-for-service model to a per-bed-fee capitation model.

The proposal would also eliminate the per prescription co-payment for residents, for eligible Ontario Drug Benefit claims.

If the proposed changes are approved, pharmacies would be notified by an EO Notice and via email to the pharmacy's ONE® Mail account.

Homes for Special Care / Community Homes for Opportunity

Residents of HSC licensed under the *Homes for Special Care Act* ("HSCA") are eligible for benefits under the ODB program. Residents of homes that are a part of the Ministry's Community Homes for Opportunity program are also eligible for benefits under the ODB program.

Policy for establishing eligibility for payment applies (see Section 4.2).
Patient eligibility (i.e., residents of Homes for Special Care/Community Homes for Opportunity) can be confirmed by contacting the MOH's Financial Management Branch (FMB) at: 416-326-9842.
See Acceptable Supporting Documentation requirements.

How recipients are identified:

- Names and Health numbers of eligible recipients are provided by the home

Required claim information:

- Enter Health number in Client ID # field
- Include version code if embossed on Health Card
- Enter the HSC/CHO identification number (ODP number) in the Group Number field
- If the claim is rejected at the time of dispensing due to recipient ineligibility, the pharmacy may establish eligibility by entering an appropriate intervention code (*see Section 4.2* for

further details) once eligibility has been confirmed by FMB. Documentation of the call (including ODB Help Desk ticket # if it was contacted) should be recorded for claim validation.

Co-payment:

- Recipients 25 years of age and older may pay up to $2 (co-payment) for each prescription for an eligible benefit
- Recipients 24 years of age and under have no co-payment

Trillium Drug Program

The Trillium Drug Program (TDP) helps people who have high drug costs in relation to their incomes. The TDP benefit year begins August 1st and an annual deductible is determined for each household. The deductible is payable quarterly, and ODB eligible drug costs must be paid by the individual up to the deductible level before eligibility for coverage begins for that quarter. All claims are also subject to ODB payment rules (e.g., drug benefit price, dispensing fees, mark-up). The TDP deductible is based on income and household size.

Individuals may qualify for TDP if they:

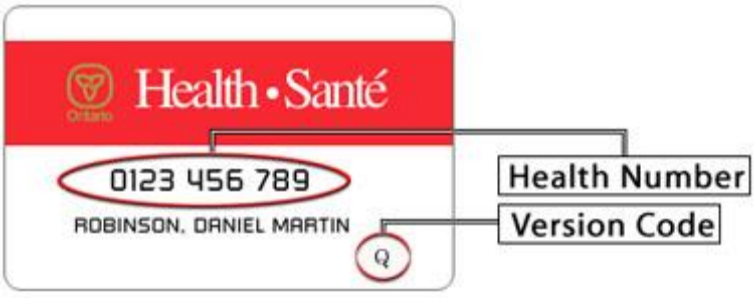
- Have a valid Ontario Health number
- Are not currently eligible to receive drug benefits under the ODB program
- Do not have prescription drug costs fully covered by a private insurance plan
- Have high drug costs relative to their income (usually three to four per cent).

Policy for establishing eligibility for payment does not apply (see Section 4.2).

How applicants/recipients are identified:

- TDP recipients who have enrolled in the program will present a valid Health number.

Health Card Samples:



Required claim information:

- Enter the Health number in the Client ID # field
- Include the version code if embossed on the Health Card

Deductible/co-payment:

For TDP recipients who **have not met the deductible requirements**, HNS will process the prescription claim showing progress toward the quarterly deductible. Applicants with a private insurance plan that includes drug benefits who have not met their TDP deductible should submit their original prescription receipts to the TDP that show the amount that they spent **out-of-pocket** towards their ODB eligible prescriptions. Once the receipts are received by the TDP, they will be processed manually and the amount that was spent on ODB eligible benefits will be applied to the quarterly deductible. Once the deductible has been met, HNS can process ODB eligible prescription claims with a $2 co-payment amount.

For TDP recipients who have **met deductible requirements**, HNS will process ODB prescription claims with a $2 co-payment amount.

To enroll in TDP, applicants must complete and submit an Application for Trillium Drug Program form along with all necessary documents to TDP (e.g., prescription drug receipts, private insurance documentation, and financial documentation). A Guide to Understanding the Trillium Drug Program can be found on the Government of Ontario's website.

In addition, program details and deadlines may be obtained from:

Trillium Drug Program

P.O. Box 337, Station D

Etobicoke, ON

M9A 4X3

Tel: 416-642-3038

Fax: 416-642-3034

Toll-Free: 1-800-575-5386

TTY: 1-800-387-5559

Email: trillium@ontariodrugbenefit.ca

Further Information on the Trillium Drug Program:

The TDP benefit year runs from August 1st of one year to July 31st of the following year. The annual deductible is paid in four installments over the TDP 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 1st, November 1st, February 1st, and May 1st.

After the deductible is paid in each quarter, the household will receive benefits for that quarter and may be charged up to $2 per prescription for an eligible drug product. Any unpaid deductible in a quarter will be added to the next quarter's deductible. Any unpaid deductible amount at benefit year-end does not transfer to the following benefit year. The household is re-assessed, and a new annual deductible is calculated at the start of each new benefit year.

By regulation, drugs costs covered by any third party (i.e., private insurers, employers or manufacturers / patient support programs) do not count towards the TDP deductible. **TDP deductibles must be paid out-of-pocket by the household.**

Any claim for a TDP recipient that causes a quarterly deductible for the TDP household to be reached will receive the following response code:

Response Code	Message Description
"EM"	ODB pricing-TDP deductible reached

New applicants to TDP can choose the date within the program year on which they wish eligibility to begin (i.e. start date). Applicants are not required to select a start date at the time they submit the application. They may apply and be enrolled, with a start date to be selected later. When a household is ready to select a start date, the pharmacy may contact the TDP during business hours with the selected start date, which will be applied immediately.

The deductible is prorated based on the number of days left in the benefit year. The prorated deductible applies only for the first year of enrollment into the program.

Prescriptions filled and paid for by the individual or household prior to the chosen start date will not count towards the prorated deductible. Claims submitted for a date of service prior to the chosen enrolment start date will be rejected with one of the following response codes:

Response Code	Message Description
"EL"	Prior to prorated start date
"C8"	No record of beneficiary

Each benefit year, Trillium recipients enrolled in the previous benefit 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 1st.
- The household has not utilized the TDP for the two consecutive previous 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 renewal details for the upcoming benefit year. Households are required to inform the program of any changes or incorrect enrolment information.

Eligible expenses that can be counted towards TDP deductible:

Allowable, out-of-pocket drug expenses that will count towards the Trillium deductible include the cost (i.e., product price and dispensing) of the following products, if used by a member of the TDP household:

- Drug products listed as ODB benefits in the ODBF/CDI (e.g., General Benefits, General Benefits with Therapeutic Notes, Limited Use (LU) Benefits (if clinical criteria are met), products on the Facilitated Access list).
- Therapeutic substances listed as benefits in the ODBF/CDI (e.g., nutrition products, diabetic testing agents, and valved holding chambers if applicable eligibility criteria are met, see section 7.7).
- Extemporaneous preparations designated as pharmaceutical products under the ODBA.
- Products approved under the EAP.
- Products listed in Schedule 2 to O. Reg. 201/96 (i.e., insulin, adrenocorticotrophic hormones, or nitrate vasodilators).

Note: As there are no co-payments or deductibles for children and youth 24 years of age and under who are ODB eligible outside of the TDP (e.g. OHIP+, social assistance), there will be no out-of-pocket expenditures for these household members to count towards the TDP annual deductible.

Drug quantity:

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 TDP 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 TDP 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 quarter (i.e., beyond May 30th of each benefit year). HNS automatically calculates the days' supply in these circumstances and will not reimburse any excess amounts. The TDP 100 days' supply limit applied to TDP recipients will be reduced for each day after February 20th (i.e., the days' supply limit for a February 21st dispense date will be 99 reducing by 1 with each passing day). The last two months of the benefit year are left open to collect outstanding deductible contributions prior to the end of the benefit year.

Health Card Version Codes

Version codes were introduced to uniquely identify a Health Card and allow the Ministry to verify the status of a Health Card to reduce fraud. While all photo Health Cards have a version code, some red and white Health Cards do not.

Enter the one- or two-character version code in the Client ID # field, appearing immediately after the Health number, if shown (or embossed) on the Health Card:

Processing of claims with missing or incorrect version codes will result in the following response code:

Response Code	Message Description
"CK"	Health Card Version Code error (Information Message only*)

**Information Messages may be cautionary in nature or may simply provide additional information. Do not respond to an Information Message. The claim has been approved for payment.*

An attempt to override the "**CK"** response code with an intervention/exception code will cause the claim to reject.

Contact the recipient to obtain his/her accurate (current) Health Card version code information and update your records.

If discrepancies in Health Card version codes are not resolved, recipients can contact ServiceOntario. Find the closest ServiceOntario location online or contact the ServiceOntario INFOline at 1-866-532-3161 for more information.

4.2 Policy for Establishing Payment Eligibility

The Ministry has implemented a policy for establishing eligibility for recipients who are not deemed eligible on HNS.

Claim Validation
Supporting documentation may be requested by the Ministry at any time.
Pharmacies are required to retain supporting documentation that verifies a patient's eligibility on file for two years from the day the last claim is submitted to HNS for the eligible person. The supporting documentation that must be obtained and retained is specific to the type of eligible person. Please see Acceptable Supporting Documentation requirements or Section 4.1 for further details.

In accordance with O. Reg. 264/16 made under the Drug and Pharmacies Regulation Act ("DPRA"), all pharmacies are required to keep patient records for a period of at least 10 years or until 10 years after the day on which the patient reaches or would have reached the age of 18 years, whichever is longer.

Response Codes

HNS will reject claims for recipients deemed ineligible at the time of dispensing with one of the following response codes:

Response Code	Message Description
"32"	Client ID # error (*i.e., Health number incorrectly entered in the Client ID # field or incorrect in the HNS database)*
"C2"	Service provided before effective date
"C3"	Coverage expired before service
"C8"	No record of this beneficiary *(i.e., Ministry not advised of eligibility of recipient)*
"CJ"	Patient not covered by this plan *(i.e., may be covered under another plan)*

Note: The policy for establishing eligibility for payment does not apply to:

- Seniors
- TDP households

If HNS rejects a claim for seniors or TDP households who have proof of eligibility under one of these programs, you may refer:

- TDP households to the Ministry 416-642-3038, or 1-800-575-5386 (outside Toronto)
- Seniors to ServiceOntario INFOline at 1-866-532-3161

Eligibility Override Codes

If proof of eligibility has been established, Eligibility Override Codes can be used by pharmacies to override the Response Code and complete the dispensing transaction for the following ODB eligibility classes only:

- ODSP
- OW
- Home Care
- LTC
- HSC/CHO
- Children and youth who do not have a private plan (OHIP+)

The pharmacy has access to two levels of Eligibility Override Codes:

- Level 1: Standard Override
- Level 2: Emergency Override

Level 1: Standard override (applies to response code "**C2", "C3", "C8"** or "**CJ"**)

If the recipient:

- presents with a valid Drug Benefit Eligibility Card
- in the case of a child or youth, presents with an Ontario Health number or the detachable portion of the Ontario Health Coverage Infant Registration Form and confirms that they do not have a private plan
- has been confirmed as eligible through the SAV helpline
- is a confirmed resident of an LTC home or HSC/CHO

and the eligibility number is rejected, the pharmacy may establish eligibility by entering:

- Carrier ID (or Plan Code, as shown on the Drug Benefit Eligibility Card or as indicated in the table below)
- Date of Birth
- Gender
- **"ML"** in the Intervention/Exception Code field
- **Pharmacist ID**

Note: If intervention code "**ML"** does not change the response code, advise the recipient to contact the agency responsible for the recipient's ODB eligibility or Ontario Health number in the case of children and youth (e.g., MCCSS, LHIN, ServiceOntario, etc.).

The eligibility established by a standard override is effective from the date established until the end of the eligibility establishment period.

For children and youth who do not have a private plan, the eligibility established by the standard override ("**ML**") is effective for one day only (i.e., the date of service). Eligibility can be re-established on subsequent days if required.

Level 2: Emergency override (applies to response code "**32"**)

When a Client ID # error is detected, the pharmacy must verify the Client ID # with the referring agency. If the pharmacy deems that the recipient's health may be at risk, eligibility can be established by entering:

- Carrier ID (or Plan Code, as shown on the Drug Benefit Eligibility Card)
- Date of Birth
- Gender
- **"MK"** in the Intervention/Exception Code field

- **Pharmacist ID**

The eligibility established by an emergency override ("MK") is effective for one day only (i.e., the date of service).

Processing of claims exceeding the limitation will result in the following response code:

Response Code	Message Description
"CL"	Exceeds good faith limit

The eligibility establishment limitation can be overridden, with valid reason, by entering:

- **"MW"** in the Intervention/Exception Code field
- **Pharmacist ID**

Eligibility Establishment Summary

The policy for establishing eligibility for payment has different eligibility establishment (availability) periods and limitations depending upon the program, and is only applicable when recipients present proof of eligibility.

Availability periods and limitations are shown below for the different programs:

Carrier ID (Plan Code)	Program	Eligibility Establishment Availability Periods (Level 1: Standard Override)	Eligibility Establishment Availability Periods (Level 2: Emergency Override)
"A"	Higher Income Seniors	Not available	Not available
"E"	LTC	To end of current month	Date of service only (one day)
"P"	Home Care	30 days	Date of service only (one day)
"C"* **	MCCSS-ODSP	To end of current month*	Date of service only (one day)
"D"* **	MCCSS-OW	To end of current month*	Date of service only (one day)
"H"	HSC/CHO	Current month + one month**	Not available
"T"	TDP	Not available	Not available
"R"	Lower Income Seniors	Not available	Not available

Carrier ID (Plan Code)	Program	Eligibility Establishment Availability Periods (Level 1: Standard Override)	Eligibility Establishment Availability Periods (Level 2: Emergency Override)
"J"	Children and Youth	Date of service only	Not available

**Limitation: 15 claims per recipient per program year.* For more details on ODSP and OW eligibility, please refer to section 4.1

***Contact FMB at 416-326-9842 to request confirmation of patient eligibility.*

****Only plan code C or D should be used for patients eligible for social assistance. Historically, individual OW offices used specific plan codes, such as L, M, N and Y. Some OW offices continue to issue paper drug cards using these other plan codes. The system has been centralized and all OW clients are under Plan D. If pharmacists receive an error response code, even after entering the claim using Plan D, they would confirm the client's social assistance eligibility for the period in question through the SAV helpline.*

Section 5: Standard Online Claims

Overview

This section explains the procedures on how to:

Submit a standard online claim (*see Section 5.1*)

Submit a standard (or non-standard) online claim reversal (*see Section 5.2*)

Reconcile online claim and reversal transactions (*see Section 5.3*)

Request payment information for any of the most current seven days

Daily Totals *(see Section 5.4)*

Claim Details *(see Section 5.5)*

Same Day Reversal Details *(see Section 5.6)*

Prior Day Reversal Details *(see Section 5.7)*

This section also outlines the different HNS generated system responses that confirm payment approval or transaction rejection, and how pharmacies may intervene by reversing and resubmitting a claim and/or by including applicable intervention/exception codes with each transaction.

Conditions for 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 of a listed drug product for which the Executive Officer is required to pay under section 18 of O. Reg. 201/96.

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

This condition for receiving a dispensing fee does not apply in the following scenarios:

1. The ODB recipient is a resident of a long-term care home (see "Exempted LTC Homes List").*

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: "Other Homes List".*
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: "Exempted Medication List No. 1" and the dispenser has determined that the quantity supplied should be less than the Maximum Quantity because, in the dispenser's professional opinion,
    a. The safety of the ODB recipient is a concern, or
    b. There is a risk of abuse or diversion if the drug product is supplied to the ODB recipient.* and **
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 eligible person is incapable of managing his or her medication as a result of physical, cognitive or sensory impairment, and
    b. the eligible person 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 pharmacy 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 dispensing fees are subject to recovery if found to be ineligible for payment under the ODB program.

Two Fees/28 Days

In most cases, the Executive Officer will only pay a pharmacy a maximum of two 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).

Subject to any additional requirements in the ODBA Regulation, the two-dispensing-fees-per-month rule does not apply if:

- The ODB recipient is a resident of a long-term care home (see "Exempted LTC Homes List").
- 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., Homes for Special Care) and included in the "Other Homes List".
- The listed drug product is a product or belongs to a class of drug product that is specified by the Executive Officer and included in the "Exempted Medication List No. 1" 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.
- The listed drug product is supplied in the Maximum Quantity (see definition above) and is a product or belongs to a class of drug product that is specified by the Executive Officer and included in the "Exempted Medications List No. 2".

Dispensing Fees for Chronic-Use Medications

There is a limit on the number of dispensing fees that can be billed to the Executive Officer for certain **chronic-use medications** included in the "Chronic Medications List". Dispensers are entitled to receive a maximum of five dispensing fees per 365-day period, commencing on the day the first claim for an identified chronic-use medication is submitted to the Ministry. 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. Subject to any requirements in O. Reg. 201/96, 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).

1. The ODB recipient is a resident of a long-term care home (see "Exempted LTC Homes List").

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 included in the list below (see "Other Homes List").
3. The listed drug product dispensed is an extemporaneous preparation.
4. The ODB recipient is on a complex medication regime where patient safety is at risk and requires more frequent dispensing of the listed drug product to assist with the proper administration of the medication regime.
5. The dispenser dispenses less than the Maximum Quantity because 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 the ODB recipient has consented to obtaining the lesser quantity.

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

****Note:** In the case of Exception 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 must 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 dispensary health record.

All dispensing fees are subject to recovery if found to be ineligible for payment under the ODB program.

Note: Any reference in this section to the term "written", "in writing" or "written record" includes electronic scanned images of original paper documents or electronic records of written records.

5.1 To Submit a Standard Online Claim

A standard online claim must conform to the CPhA Pharmacy Claim Standard Version 3 and includes the following information:

Required Fields	Explanation
Bank ID Number	610054
Version Number	CPhA Pharmacy Claim Standard Version currently used (i.e., Version 3)
Transaction Code	**"01"**
Provider Software ID	CPhA-assigned code, identifying pharmacy software currently used
Provider Software Version	Pharmacy Software Vendor (PSV)-assigned code, identifying the version of the pharmacy software currently used
Pharmacy ID Code	CPhA number or Ministry-assigned number of the pharmacy, (*see Section 2.1*)
Provider Transaction Date	Date (YYMMDD) of service
Trace Number	Pharmacy system-generated number assigned to the transaction
Group Number or Code	LTC home number for recipients from LTC, or HSC number for recipients of HSC, (*see list of LTC homes and/or HSC*)
Client ID # or Code	Recipient identification number (*see Section 4*)
Patient First Name	First name of patient
Patient Last Name	Last name of patient
Provincial Health Care ID Code	To be provided, if different from the Client ID # or Code; otherwise, may be blank
Current Prescription Number	Unique prescription number (from the prescription label or record of service)
DIN/GP#/PIN	DIN/PIN of product, (*see Appendix A for Extemporaneous Mixture DIN/PINs, Appendix C for Emergency Authorization Products and Appendix D for Allergen Products*)
SSC	Required for claims for children and youth 24 years of age and under who have no private plan.
Quantity	Quantity dispensed
Days Supply	Estimated number of days (as accurate as possible) supplied by the prescription
Prescriber ID Reference	Reference number for prescriber, (*see prescriber ID reference chart noted below)*
Prescriber ID	Prescriber license number
Drug Cost/Product Value	Total drug cost or product value

Required Fields	Explanation
Cost Mark-up	Enter the mark-up amount, 8% when the total drug cost is less than $1,000.00 or 6% when the total drug cost is greater than or equal to $1,000.00
Professional Fee	Professional fee (i.e., the lesser of the pharmacist's usual/customary dispensing fee or the applicable ODB fee prescribed by regulation), can be equal to 0, (*see conditions for payment of dispensing fees*)

Please refer to your PSV manual for specific instructions on how to use your pharmacy software for this type of transaction.

Note: Additional fields may be required for non-standard online claims *(see Section 6)* and claim transactions where eligibility is established *(see Section 4.2)*.

Prescriber ID Reference Chart

Prescriber Regulatory College	Prescriber ID Reference
College of Physicians & Surgeons of Ontario	**01**
Royal College of Dental Surgeons of Ontario*	**02**
College of Chiropodists of Ontario	**03**
Carrier Designated Out of Province ID	**05**
Ontario College of Midwives	**08**
Ontario College of Pharmacists	**09**
College of Optometrists of Ontario	**43**
College of Nurses of Ontario	**44**
College of Naturopaths of Ontario	**N0**
Other (where all attempts to locate Prescriber ID, including contacting the ODB Help Desk, have failed)	**99**

For most dentists, the licensing number has a prefix, "D**", which should be entered for adjudications. However, for some dentists, no prefix is used (i.e., just submit the number), or the prefix may be an "**S**", "**A**", "**M**", or "**E**".*

Note: For unknown prescribers, pharmacists must enter prescriber ID = 99999 and prescriber ID reference = 99. This mechanism is to be used **only** as a last resort for the adjudication of ODB claims, and is **not permitted** on submissions to the NMS.

In circumstances where pharmacists are extending, adapting or initiating a prescription, the pharmacist becomes the prescriber of that medication and this must be recorded appropriately for the HNS claim that is submitted to the Ministry. For details on how to register a pharmacist's licence # in the HNS, please *see registration, Section 2.1.*

Pharmacists must include their pharmacist ID number (i.e., pharmacist license #) in the prescriber field for all expanded scope of practice activities. This includes but is not limited to:

- Prescribing under the expanded scope of practice (e.g., smoking cessation drugs).
- Authorizing renewals of chronic medications (without consulting the original prescriber).
- Administering publicly funded influenza vaccine.
- Providing professional pharmacy services (e.g., MedsCheck).

System Response: Standard (and Non-Standard) Online Claims

The system response will provide the following details:

Response Fields	Explanation
Adjudication Date*	Date (YYMMDD) assigned to the transaction by HNS
Trace Number	Pharmacy system-generated number assigned to the transaction
Transaction Code	**"51"**
Reference Number	Internal reference number assigned by HNS
Response Status	A = Accepted as transmitted, no adjustments B = Accepted with prescription price adjustment R = Rejected claim
Response Code	(*See Section 10.1 for valid response codes)*
Drug Cost/Product Value	Allowed drug cost or product value
Cost Mark-up	Allowed mark-up amount on cost of dispensed product
Professional Fee	Allowed professional fee
Compounding Charge	Allowed compounding charge
Deductible to Collect	Deductible or co-payment amount which provider collects from recipient
Plan Pays	Total amount payable for the claim
Message Data Line Number 1	Detailed response information
Message Data Line Number 2	Detailed response information
Message Data Line Number 3	Detailed response information

**The adjudication date allows for a uniform method of identifying timeframe for accounting and reconciliation purposes. It begins at 3:30 a.m. (Eastern Time) and concludes 24 hours later.*

Note: During early morning hours, the adjudication date will not be the same as the provider transaction date.

5.2 To Reverse a Standard (or Non-Standard) Online Claim

Online claims submitted on any one of the most recent seven days, including the current date, can be reversed online for any reason, including any of the following situations:

- The Ministry was overcharged
- Payment has been allocated for a prescription not picked up
- Erroneous claim (i.e., incorrect information) was submitted
- Subsequent to a DUR intervention

An online claim reversal conforms to the CPhA Pharmacy Claim Standard Version 3 and must include the following information:

Required Fields	Explanation
Bank ID Number	610054
Version Number	CPhA Pharmacy Claim Standard Version currently used (i.e., Version 3)
Transaction Code	**"11"**
Provider Software ID	CPhA-assigned code, identifying pharmacy software currently used
Provider Software Version	PSV-assigned code, identifying the version of the pharmacy software currently used
Intervention/Exception Code	Code used to reverse transactions as a result of DUR intervention, (*see Section 9.3)* (if applicable)
Pharmacy ID Code	CPhA number or Ministry-assigned number of the pharmacy, (*see Section 2.1)*
Provider Transaction Date	Date (YYMMDD) of service of claim to be reversed
Trace Number	Pharmacy system-generated number assigned to the transaction
Client ID # or Code	Recipient identification number entered on the claim to be reversed

Required Fields	Explanation
Current Prescription Number	Unique prescription number entered on the claim to be reversed
Adjudication Date	Date (YYMMDD) on which claim to be reversed was originally adjudicated

Please refer to your PSV manual for specific instructions on how to use your pharmacy software for this type of transaction.

Note: If more than seven days have elapsed since the claim was initially processed and accepted by HNS, the claim must be reversed manually using the Drug Benefit Claim Reversal form (*see Section 8*).

System Response: Online Claim Reversal

The system response will provide the following details:

Response Fields	Explanation
Adjudication Date	Date (YYMMDD) assigned to the transaction by HNS
Trace Number	Pharmacy system-generated number assigned to the transaction
Transaction Code	**"61"**
Reference Number	Internal reference number assigned by HNS
Response Status	R = Rejected Reversal V = Reversal Accepted
Response Code	(*See Section 10.1 for valid response codes)*

5.3 Reconciliation of Online Claims and Reversals

At the end of each business day (after all transactions have been processed), submit a request for Daily Totals to use for reconciliation (*see Section 5.4*).

You can submit and review online the Daily Totals (or details) for any one of the most recent seven days, including the current day. Outside of that range, your online request will be rejected.

Compare the claim totals provided by HNS against the claim totals generated by your pharmacy software. Identify and resolve any discrepancies.

For discrepancies that cannot be resolved, submit a request for claim details and reversal details for a specified adjudication date. Do a claim by claim comparison against the details generated by your pharmacy software (*see Section 5.5, Section 5.6 and Section 5.7*). The table below will help identify which claims details request to submit:

Discrepancies for:	**Details Request**
Total Number or Value of Claims Approved	Claim Details (*see Section 5.5*)
Total Number or Value of Same Day Reversals	Same Day Reversal Details (*see Section 5.6*)
Total Number or Value of Prior Day Reversals	Prior Day Reversal Details (*see Section 5.7*)

Before submitting a detailed request, identify an adjudication date during which the discrepancy may have occurred. This will enable you to narrow down the range/volume of details by specifying:

- Beginning of Record, i.e., the prescription number which precedes the prescription for which the request is to begin.
- End of Record, i.e., the prescription number of the last prescription to be included in the request.

The maximum number of details provided per system response is 14, sequenced in time of day order.

If you are unable to resolve discrepancies based on the first 14 details provided by the initial system response, submit another request for the next fourteen 14 details.

Please refer to your PSV manual for specific instructions on how to generate the claim totals using your pharmacy software.

5.4 To Request Daily Totals

Daily totals should be requested from HNS at the end of each business day and compared against the claim totals generated by your actual reimbursement as calculated through your accounting processes.

Daily totals can only be requested for claim transactions processed for any one of the most recent seven days, including the current day.

A daily totals transaction conforms to the CPhA Pharmacy Claim Standard Version 3 and must include the following information:

Required Fields	Explanation
Bank ID Number	610054
Version Number	CPhA Pharmacy Claim Standard Version currently used (, Version 03)
Transaction Code	**"30"**
Provider Software ID	CPhA-assigned code, identifying pharmacy software currently used
Provider Software Version	PSV-assigned code, identifying the version of the pharmacy software currently used
Pharmacy ID Code	CPhA number or Ministry-assigned number of the pharmacy, (*see Section 2.1)*
Provider Transaction Date	Date (YYMMDD) on which the pharmacy sends the request
Trace Number	Pharmacy system-generated number assigned to the transaction
Adjudication Date	Adjudication date (YYMMDD) for which daily totals are being requested

Please refer to your PSV manual for specific instructions on how to use your pharmacy software for this type of transaction.

System Response: Daily Totals

The system response will provide the following details:

Response Fields	Explanation
Adjudication Date	Date (YYMMDD) assigned to the transaction by HNS
Trace Number	Pharmacy system-generated number assigned to the transaction
Transaction Code	**"80"**
Reference Number	Internal reference number assigned by HNS
Response Status	Y = Accumulated Daily Totals R = Request Rejected

Response Fields	Explanation
Response Code	(*See Section 10.1 for valid response codes*)
Total Number of Claims Approved	Number of approved claims for requested date
Total Value of Claims Approved*	Value of claims approved for requested date
Total Number of Reversals	Number of reversals processed against claims approved for requested date
Total Value of Reversals*	Value of reversals processed against claims approved for requested date
Total Number of Prior Reversals	Number of reversals processed on requested date against claims processed previously
Total Value of Prior Reversals*	Value of reversals processed on requested date against claims processed previously
Date of Payment	Date of payment (by cheque or EFT deposit) (*See Section 11.4, Payment Schedule*)

**To calculate the net amount approved for payment for the requested adjudication date:*

Net Amount Payable for the Adjudication Date = (Total Value of Claims Approved) – (Total Value of Reversals) – (Total Value of Prior Reversals)

5.5 To Request Claim Details

Pharmacies can request claim details for claim transactions processed for any one of the most recent seven days, including the current day.

Note: Submit a request for claim details only if a discrepancy is noted for total number or value of claims approved.

A claim details transaction conforms to the CPhA Pharmacy Claim Standard Version 3 and must include the following information:

Required Fields	Explanation
Bank ID Number	610054
Version Number	CPhA Pharmacy Claim Standard Version currently used (i.e., Version 03)

Required Fields	Explanation
Transaction Code	**"31"**
Provider Software ID	CPhA-assigned code, identifying pharmacy software currently used
Provider Software Version	PSV-assigned code, identifying the version of the pharmacy software currently used
Pharmacy ID Code	CPhA number or Ministry-assigned number of the pharmacy, (*see Section 2.1*)
Provider Transaction Date	Date (YYMMDD) on which the pharmacy sends the request
Trace Number	Pharmacy system-generated number assigned to the transaction
Adjudication Date	Adjudication date (YYMMDD) for which claim details are being requested.
Beginning of Record*	Rx number of the last prescription that precedes the prescription for which the request is to begin
End of Record*	Rx number of the last prescription to be included in the request

**This will enable you to narrow down the range/volume of claim details by specifying these fields. If the value is zero, Beginning of Record defaults to the first prescription submitted on the requested date.*
End of Record defaults to the last prescription submitted on the requested date.

Please refer to your PSV manual for specific instructions on how to use your pharmacy software for this type of transaction.

System Response: Claim Details

The system response will provide the following details:

Response Fields	Explanation
Adjudication Date	Date (YYMMDD) assigned to the transaction by HNS
Trace Number	Pharmacy system-generated number assigned to the transaction
Transaction Code	**"81"**
Reference Number	Internal reference number assigned by HNS
Response Status	Z = Detailed Record as Requested R = Request Rejected
Response Code	(*See Section 10.1 for valid response codes*)

Response Fields	Explanation
Number of Detail Records	Number of claim details included
Current Rx Number*	Prescription number of claim
Amount Payable*	Value of claim

**Current Rx Number and Amount Payable will be repeated for each claim detail.*

The maximum number of claim details per system response is 14, sequenced in time of day order.

For additional claim details beyond the first 14 provided by the initial system response, submit another request for the next 14 claim details.

5.6 To Request Same Day Reversal Details

A same day reversal is a claim reversal processed on the same adjudication date as the original claim submission.

Note: Submit a request for same day reversal details only if a discrepancy is noted for total number or value of same day reversals.

A same day reversal details transaction conforms to the CPhA Pharmacy Claim Standard Version 3 and must include the following information:

Required Fields	Explanation
Bank ID Number	610054
Version Number	CPhA Pharmacy Claim Standard Version currently used (e.g., Version 03)
Transaction Code	**"32"**
Provider Software ID	CPhA-assigned code, identifying pharmacy software currently used
Provider Software Version	PSV-assigned code, identifying the version of the pharmacy software currently used
Pharmacy ID Code	CPhA number or Ministry-assigned number of the pharmacy, (*see Section 2.1*)
Provider Transaction Date	Date (YYMMDD) on which the pharmacy sends the request
Trace Number	Pharmacy system-generated number assigned to the transaction

Required Fields	Explanation
Adjudication Date	Adjudication date (YYMMDD) for which same day reversal details are being requested.
Beginning of Record*	Rx number of the last prescription that precedes the prescription for which the request is to begin
End of Record*	Rx number of the last prescription to be included in the request

**This will enable you to narrow down the range/volume of reversal details by specifying these fields. If the value is zero,*
Beginning of Record defaults to the first reversal transaction submitted on the requested date.
End of Record defaults to the last reversal transaction submitted on the requested date.

Please refer to your PSV manual for specific instructions on how to use your pharmacy software for this type of transaction.

System Response: Same Day Reversal Details

The system response will provide the following details:

Response Fields	Explanation
Adjudication Date	Date (YYMMDD) assigned to the transaction by HNS
Trace Number	Pharmacy system-generated number assigned to the transaction
Transaction Code	**"82"**
Reference Number	Internal reference number assigned by HNS
Response Status	Z = Detailed Record as Requested R = Request Rejected
Response Code	(*See Section 10.1 for valid response codes.*)
Number of Detail Records	Number of reversal details included
Current Rx Number*	Prescription number of reversal
Amount Reversed*	Value of reversal

**Current Rx Number and Amount Reversed will be repeated for each reversal detail.*

The maximum number of reversal details per system response is 14, sequenced in time of day order.

For additional reversal details beyond the first 14 provided by the initial system response, submit another request for the next 14 reversal details.

5.7 To Request Prior Day Reversal Details

A prior day reversal is a claim reversal processed on a later adjudication date than the original claim submission.

Pharmacies can request prior day reversal details for prior day reversals processed within the most recent seven days, including the current day.

Note: Submit a request for prior day reversal details only if a discrepancy is noted for the total number or value of prior reversals.

A prior day reversal details transaction must include the following information:

Required Fields	Explanation
Bank ID Number	610054
Version Number	CPhA Pharmacy Claim Standard Version currently used (i.e., Version 03)
Transaction Code	**"33"**
Provider Software ID	CPhA-assigned code, identifying pharmacy software currently used
Provider Software Version	PSV-assigned code, identifying the version of the pharmacy software currently used
Pharmacy ID Code	CPhA number or Ministry-assigned number of the pharmacy, (*see Section 2.1*)
Provider Transaction Date	Date (YYMMDD) on which the pharmacy sends the request
Trace Number	Pharmacy system-generated number assigned to the transaction
Adjudication Date	Adjudication date (YYMMDD) for which prior day reversal details are being requested.
Beginning of Record*	Rx number of the last prescription that precedes the prescription for which the request is to begin
End of Record*	Rx number of the last prescription to be included in the request

**This will enable you to narrow down the range/volume of reversal details by specifying these fields. If the value is zero (0).*
Beginning of Record defaults to the first reversal transaction submitted on the requested date.
End of Record defaults to the last reversal transaction submitted on the requested date.

Please refer to your PSV manual for specific instructions on how to use your pharmacy software for this type of transaction.

System Response: Prior Day Reversal Details

The system response will provide the following details:

Response Fields	Explanation
Adjudication Date	Date (YYMMDD) assigned to the transaction by HNS at the time the request was processed
Trace Number	Pharmacy system-generated number assigned to the transaction
Transaction Code	**"83"**
Reference Number	Internal reference number assigned by HNS
Response Status	Z = detailed record as requested R = request rejected
Response Code	(*See Section 10.1 for valid response codes.*)
Number of Detail Records	Number of reversal details included
Current Rx Number*	Prescription number of reversal
Amount Reversed*	Value of reversal

**Current Rx Number and Amount Reversed will be repeated for each reversal detail.*

The maximum number of reversal details per system response is 14, sequenced in time of day order.

For additional reversal details beyond the first 14 provided by the initial system response, submit another request for the next 14 reversal details.

Section 6: Submit Non-Standard Online Claims

Overview

This section outlines specific instructions for online submission of each of the following non-standard claims, and highlights the significant differences from the procedure for submitting standard online claims (*as discussed in Section 5.1*):

Extemporaneous Preparations (*see Section 6.1*)

Medically Necessary "No Substitution" Claim *(see Section 6.2)*

Limited Use Products *(see Section 6.3)*

Claim Submission for Prescription with Drug Costs over $10,000 (see *Section 6.4*)

Approved Non-Prescription Drug Products and Emergency Authorization Drugs to Long-Term Care Homes *(see Section 6.5)*

Allergen Claims *(see Section 6.6)*

Cost-to-Operator Claims *(see Section 6.7)*

Duplicate Claim Submission including Vacation Supply and Methadone Claims *(see Section 6.8)*

Exceptional Access Program *(see Section 6.9)*

Compassionate Review Policy (see *Section 6.10*)

Nutrition Products *(see Section 6.11)*

Diabetic Testing Agents *(see Section 6.12)*

Thirty-Day Prescription Program *(see Section 6.13)*

Special Drugs Programs *(see Section 6.14)*

Universal Influenza Immunization Program *(see Section 6.15)*

6.1 Extemporaneous Preparations

This policy effective on January 1, 2020 replaces the previous extemporaneous preparation policy.

Section 17 of the *Ontario Drug Benefit Act* (ODBA) gives the Executive Officer of the Ontario public drug programs (the "Executive Officer") the authority to:

a) determine the conditions which must be met before a pharmaceutical product, including an extemporaneous preparation, is designated as a designated pharmaceutical product (DPP) and therefore eligible for reimbursement under the Ontario Drug Benefit (ODB) Program; and

b) determine the drug benefit price of a DPP including a formula by which the drug benefit price may be calculated.

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".

In this policy "ODB benefit" refers to any of the following:

- A General Benefit on the Formulary;
- A General Benefit with Therapeutic Notes on the Formulary, where the Therapeutic Note requirements are satisfied by the patient or prescriber, as applicable;
- A Limited Use Benefit on the Formulary, where the Limited Use criteria are satisfied by the patient and the required Reason for Use code appears on the prescription for the patient;
- A drug product approved for the patient under the Exceptional Access Program[1]

[1]It is the responsibility of the dispenser to refer to the list of drugs requiring authorization of funding through the Exceptional Access Program. A searchable list is provided on the Ministry website at the following URL: https://www.ontario.ca/page/check-medication-coverage/

The ODB benefit utilized in an extemporaneous mixture must meet all other reimbursement conditions for that product under the ODB program (e.g., Limited Use Criteria, generic

substitution regulations and policies, Medically Necessary "No Substitution" claims, Cost-to-Operator claims).

Only the cost of the quantity of each ingredient used in the preparation of a DPP is eligible for reimbursement. Drug costs for unused or wasted portions of any ingredient are not eligible for reimbursement.

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 Executive Officer to be a DPP and therefore eligible for reimbursement under the ODB Program, in the circumstances set out in paragraphs 1 to 4 below, provided that the preparation does not meet any of the exclusion criteria in paragraph 5:

1. The preparation is compounded into a liquid or capsule for internal oral consumption and contains a single ODB benefit that is a solid oral dosage form and no other medicinally active substance. For example, compounded lozenges, lollipops, or other solid or semi-solid formulations are not eligible for funding.

2. The preparation is for dermatological/topical use and:

    a) Contains a single ODB benefit approved by Health Canada for dermatological/topical use and no other medicinally active substances other than one or more of the following: camphor, compound benzoin tincture, hydrocortisone powder, liquor carbonis detergens, menthol, salicylic acid, sulfur or tar distillate; or

    b) is a dermatological/topical nitrogen mustard preparation; or

    c) is a dermatological/topical preparation consisting of liquor carbonis detergens, salicylic acid, sulfur and/or tar distillate, but no other medicinally active substances, and is compounded in petrolatum jelly or lanolin.

    Note: In this section the term "dermatological/topical" refers to a formulation intended for use on the surface of the skin and does not include suppositories or formulations intended for other routes of administration (e.g., intrathecal, intranasal, rectal, intravaginal).

    The combining of two or more ODB benefits (e.g., combining two or more topical ODB benefits approved by Health Canada for dermatological/topical use) is not eligible for reimbursement as a DPP.

3. The preparation is for ophthalmic administration and contains either:

   a) Amikacin, cefazolin or vancomycin; or
   b) Gentamicin or tobramycin in a concentration greater than three milligrams per millilitre.

4. The preparation is for injectable administration and contains:

   a) An ODB benefit that is approved by Health Canada for injectable administration; or

   b) Ingredients used in the preparation of a DPP which is an extemporaneous Total Parenteral Nutrition (TPN) solution; or

   c) An injectable drug product which received a Notice of Compliance from Health Canada on or prior to September 3, 2003 or which is listed by Health Canada with an original market date on or prior to September 3, 2003, except:

      - Injectable vitamins, minerals, amino acids, lipids, botanicals and other natural health products (NHPs)
      - Vaccines
      - Alprostadil injection
      - Ketorolac injection
      - Injectable products funded under the Ministry's Special Drugs Program, Visudyne Program, Inherited Metabolic Disease Program, Respiratory Syncytial Virus (RSV) Program, or the New Drugs Funding Program

5. Restrictions Regarding the Reimbursement of Extemporaneous Preparations:

   Note that the following are ineligible for reimbursement:

   a) An extemporaneous preparation that is equivalent to a commercially manufactured product.

   b) Transferring a manufacturer prepared drug solution to another vessel.

   c) Transferring an ODB benefit into a new dosage delivery format (e.g., pre-filling insulin syringes).

d) Insertion of an infusion set into a manufacturer prepared preparation.

e) Products prepared from medicinally active bulk drug substances that are not an ODB benefit. These may include medicinally active substances in dry powder or solution that are used to prepare a sterile or non-sterile medicinally active drug product used to treat patients by any route of administration.

f) Reconstitution of an ODB benefit provided by a manufacturer in a dry powder format that is to be used for any route of administration (for example, oral, injectable, rectal, intrathecal, intravaginal)

g) Cutting or crushing of tablets, opening capsules, or otherwise altering any solid oral dosage form, including transferring the altered dosage form into an empty capsule or other vessel without added excipients.

h) Filling a capsule or other vessel with non-medicinal ingredients.

Pharmacists are reminded that claims reimbursed under the *Ontario Drug Benefit Act* are subject to post-payment verification.

Questions can be directed to the Ministry's ODB Health Network System (HNS) Help Desk at 1-800-668-6641.

Extemporaneous Preparations Claim Requirements

Aside from the fields indicated in *Section 5.1*, there are additional fields required (or certain exceptions applicable to specific fields) when submitting claims for extemporaneous preparations (DPPs), namely:

Fields	Required (Y/N)	Explanation
DIN/GP#/PIN	Y	Enter the DIN or Ministry-assigned PIN of the listed drug product with the highest cost for a Formulary benefit, OR Enter the specific compounding PIN (*see Appendix A, Extemporaneous Preparation Table.)* (if applicable)

Fields	Required (Y/N)	Explanation
Quantity	Y	Enter total volume or weight of compound dispensed unless otherwise indicated. (e.g., if using seven tablets to compound 100mL, enter 100; if compounding injection into one 50mL cassette/bag/vial, enter 1)
Unlisted Compound *	Y	If a DIN (not a Ministry-assigned extemporaneous PIN) is entered for a Formulary benefit product (or EAP approved product), enter the appropriate Compound Type Code (see below) in the Unlisted Compound field Ministry-assigned extemporaneous PIN's require the Unlisted Compound field to be blank. 0 = compounded topical cream (category 4) 1 = compounded topical ointment (category 4) 2 = compounded external lotion (category 4) 3 = compounded internal use liquid (category 2) 5 = compounded internal powder (category 2) 6 = compounded injection or infusion (category 3) 7 = compounded ear/eye drop (category 7 & 8) (*See Appendix A, Extemporaneous Preparation Table*.)
Drug Cost/Product Value	Y	Enter the total cost of all ingredients used, based on the following: For Formulary products, use the Drug Benefit Price (DBP). For non-Formulary products, such as products granted approval of reimbursement by the Exceptional Access Program, refer to the Ministry website for Drug Benefit Price at http://www.health.gov.on.ca/en/pro/programs/drugs/odbf/odbf_except_access.aspx If the DBP of a product used in the preparation of a DPP is not listed on the Ministry website or on the e-Formulary, use the actual or net Acquisition Cost (equal to manufacturer's or wholesaler's invoice

Fields	Required (Y/N)	Explanation
		amount minus discounts). Do not include mark-ups and/or HST in this field. *(Refer to Acquisition Cost in Section 6.7).*
Cost Mark-up	Y	Enter the mark-up amount, 8% when the total drug cost is less than $1,000.00 or 6% when the total drug cost is greater than or equal to $1,000.00.
Compounding Charge*	Y	Enter the total amount billed for compounding the prescription (equal to Compounding Rate x Compounding Time)
Compounding Time*	Y	Enter the actual time required to mix the ingredients. This does not include weighing, measuring, and other dispensing activities.

The asterisk (*) indicates additional fields.

6.2 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 a significant adverse reaction with 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 side effect reporting form for each lower-cost interchangeable drug product trialed (Side Effect Reporting Form(s)); 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.

In the case of a written prescription, when the pharmacist or dispensing physician receives a prescription with the written notation "No Substitution" or "No Sub", reimbursement will be

provided for the higher-cost interchangeable product only if the prescription is accompanied by a completed Health Canada Side Effect Reporting Form for each of the lower-cost interchangeable drug products trialed. This form must be completely filled out noting the details of the adverse reaction and signed by the prescriber.

In the case of a verbal prescription, the prescriber must satisfy the operator of the pharmacy or dispensing physician that a completed Health Canada Side Effect Reporting Form for each of the lower-cost interchangeable drug products trialed has been completed and signed by the prescriber. A written record of this verbal prescription and the completed Health Canada Side Effect Reporting Form must be received by the pharmacy prior to claim submission.

Upon receipt, the **pharmacist** must:

- Clearly note on the side effect reporting form - "ODB NO SUBSTITUTION"; and
- Fax, submit online 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 Side Effect Reporting Form.

The Side Effect Reporting 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 pharmacy must retain a copy of the prescription that contains a direction that there be no substitution and the required Health Canada Side Effect Reporting Form (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 Side Effect Reporting Form is not available at the pharmacy during an inspection, the difference between the cost of the higher-cost product and the lowest DBP listed for the interchangeable category will be recovered.

Claim Validation
Supporting documentation may be requested.
Pursuant to O. Reg. 201/96 made under ODBA, the pharmacy must retain a copy of the prescription that contains a direction that there be no substitution and the Health Canada Side Effect Reporting Form for each of the lower cost interchangeable drug products (completed and signed by the prescriber), for a period of two years from the day the last claim is submitted to HNS for the eligible person

If two (2) completed and signed Side Effect Reporting Forms are not available at the pharmacy during an inspection, the claim will be subject to recovery, in the case where two or more products have been designated as interchangeable with the drug product supplied and are generally available for sale in Ontario.

In accordance with O. Reg. 264/16 made under the Drug and Pharmacies Regulation Act ("DPRA"), all pharmacies are required to keep patient records for a period of at least 10 years or until 10 years after the day on which the patient reaches or would have reached the age of 18 years, whichever is longer.

The pharmacist must fax, submit online or mail the completed Side Effect Reporting Form(s) to:

Canada Vigilance Program
Marketed Health Products Directorate
Health Canada
Address Locator 1908C
Ottawa, Ontario
K1A 0K9

Fax: 1-866-678-6789 (toll-free)

Additional information on the Canada Vigilance Program can be accessed online or by calling 1-866-234-2345.

Claim Requirements

Aside from including the fields indicated in *Section 5.1*, there are additional fields required (or certain exceptions applicable to specific fields) when submitting medically necessary "no substitution" claims, namely:

Fields	Required (Y/N)	Explanation
Product Selection*	Y	Enter reason code "**1**" to indicate prescriber-directed medically necessary "**No Substitution**"
Medical Reason Reference*	Y	Enter "**B**" (i.e., ODB reason for use codes)
Medical Condition/Reason for Use*	Y	Enter "**901**" to indicate that a Side Effect Reporting Form has been completed and signed by the prescriber **Note:** If the product claimed is a Limited Use (LU) product, enter the appropriate Reason for Use code instead of "**901**"
Drug Cost/Product Value	Y	Enter the Drug Benefit Price or Unit Cost

Fields	Required (Y/N)	Explanation
Cost Mark-up	Y	Enter the mark-up amount, 8% when the total drug cost is less than $1,000.00 or 6% when the total drug cost is greater than or equal to $1,000.00

The asterisk (*) indicates additional fields.

6.3 Limited Use Products

LU drug products are listed in the ODBF/CDI with specific clinical criteria/conditions for use. The LU criteria identify the clinical conditions for which these drugs will be reimbursed under the ODB program. Each LU criterion has a corresponding Reason for Use (RFU) code.

LU products will be reimbursed under the ODB program only when prescribed for an ODB program eligible recipient in accordance with the applicable LU criteria and the prescriber has provided the RFU code with the prescription.

To search for a list of LU products, their LU criteria, and the RFU codes, refer to the ODB e-Formulary.

Monitoring and Accountability Framework

Reimbursement for LU claims is made under the authority of Section 23 of ODBA and can only be made if the LU criteria set out in the ODBF/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 LU criteria.

For the purposes of claims review under ODBA, it may be necessary on occasion for prescribers to provide supporting documents on request. Pursuant to section 14(2) of the ODBA, inspectors may require physicians to provide supporting documentation if the inspector believes on reasonable grounds that the documentation will assist the inspector in determining the accuracy and completeness of LU claims submitted to the Ministry for payment. 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 ODBF/CDI.

Pharmacists must ensure that the appropriate RFU code has been provided by the prescriber for the LU prescription. Where the 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 LU prescription according to standard pharmacy practice.

In instances where an ODB program eligible patient does not meet the listed LU criteria, prescribers may make a written request for special consideration for coverage under the EAP.

Ontario Drug Benefit Inspection of Limited Use Claims

The Pharmaceutical Strategy Unit of DDD routinely conducts inspections of all pharmacies for claim validation and reimbursement under the ODB program. The Ministry will recover monies paid for LU product claims if any of the following apply:

- The RFU code is not provided with the prescription.
- The prescription is incomplete (e.g., the date, drug, patient name or the correct regulatory college registration number is missing, or the authorized prescriber has not signed the prescription).
- The LU authorization period is expired.
- A prescription with valid LU documentation was not obtained/retained in the pharmacy for two years.
- The dispensed prescription does not comply with the applicable LU criteria (e.g., days' supply exceeds authorization period, or patient does not satisfy criteria).

Pharmacists are reminded that prescriptions with LU documentation must be retained by the pharmacy for two years from the date on which the prescription was received, as required by the regulation under ODBA. In addition, in accordance with O. Reg. 264/16 made under the Drug and Pharmacies Regulation Act ("DPRA"), all pharmacies are required to keep patient records for a period of at least 10 years or until 10 years after the day on which the patient reaches or would have reached the age of 18 years, whichever is longer.

Limited Use Reimbursement Process

Completing a Limited Use Prescription

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

Limited Use Authorization Period

The LU authorization is valid for the duration indicated by the listed LU criteria. 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 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 annually). 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.

Reason for Use Code

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*
- verbally during a LU prescription transfer between pharmacies*.

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

RFU code "279" (the "grand-parenting" code) may be used in the following two situations associated with LU claims:

If the RFU code has changed due to a change in LU criteria:

RFU Code "**279"** may be used for up to three months until a new LU prescription is received. The dispensing pharmacist cannot use the "**LU**" intervention code with RFU Code "**279**". This RFU Code is **only valid for claims submissions** and is not to be used by prescribers on LU prescriptions.

If the RFU code has been discontinued:

"RFU Code 279" may be used for claim submission for the remaining duration of the original LU authorization period, or up to 12 months, whichever comes first.

Note: Continued or incorrect use of the RFU code 279 will be subject to recoveries during the claim validation process.

RFU Code "979" (New residents of LTC Homes):

This three-month transition RFU code may be used to submit claims for ODB program recipients first entering LTC homes to allow physicians time to ensure the patient's eligibility for the LU drug.

Note: This RFU code cannot be used for non-LTC patients and is subject to claim validation as per standard procedure.

Documentation

Pharmacies are required to retain LU documentation on file for two years (from the day the last claim was submitted to the HNS) for the purposes of claim validation. Documentation must be complete at the time of claim submission.

In addition, in accordance with O. Reg. 264/16 made under the *Drug and Pharmacies Regulation Act* ("DPRA"), all pharmacies are required to keep patient records for a period of at least 10 years or until 10 years after the day on which the patient reaches or would have reached the age of 18 years, whichever is longer.

The pharmacist should review the prescription and process the claim only if all the required information is provided. Pharmacists must ensure that the following information has been provided by the prescriber, in addition to the usual information required for a prescription in accordance with the regulations of the OCP:

- The appropriate RFU code
- The date and prescriber's signature
- The prescriber's college registration number

Only the prescriber may fill in this information or communicate it to the pharmacy. If the prescriber's 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)**.

Incomplete LU documentation (e.g., prescriptions that do not include the appropriate RFU code, date, prescriber's signature and college registration number) will be subject to recoveries.

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 requirements 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 years of age), 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. In these cases, a prescription that contains an RFU code is still required.

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, including a prescription that contains an RFU code. Documentation may be requested for claim validation.

Limited Use Claim Requirements

Aside from including the fields indicated in *Section 5.1,* there are additional fields required (or certain exceptions applicable to specific fields) when submitting LU product claims, namely:

Fields	Required (Y/N)	Explanation
Medical Reason Reference*	Y	Enter "**B**" (i.e., ODB Reason for Use codes)
Medical Condition/Reason for Use*	Y	Enter the appropriate Reason for Use code to indicate that a LU prescription has been completed and signed by the prescriber, *Refer to the Formulary/CDI for Reason for Use codes*
Intervention/ Exception Code	Y (for initial LU claim only)	Enter **"LU"** (i.e., start new LU authorization)
Drug Cost/Product Value	Y	Enter the Drug Benefit Price
Cost Mark-up	Y	Enter the mark-up amount, 8% when the total drug cost is less than $1,000.00 or 6% when the total drug cost is greater than or equal to $1,000.00

The asterisk (*) indicates additional fields.

All initial claims for LU products (i.e., when the pharmacist receives a LU prescription) must be submitted with the intervention code "**LU**" in order to start a new LU authorization period on HNS.

Promoting Compliance with Limited Use Criteria for the Fentanyl Transdermal Patch

DDD is committed to supporting the appropriate prescribing and dispensing of opioids and addressing the issue of prescription opioid misuse and abuse. A network rule has been implemented in the HNS to promote the safe and effective use of fentanyl transdermal patches by promoting compliance with the LU criteria.

Fentanyl transdermal patches are listed under the ODB program as an LU benefit with RFU code 511: For the treatment of chronic pain in patients who cannot tolerate, or have failed treatment with a long-acting opioid. Intolerance or failed treatment with a long acting opioid will be subject to verification at the time of dispensing. LU Authorization Period: One year.

For ODB eligible recipients, the HNS assists pharmacists to ensure that patients meet the applicable clinical criteria for fentanyl transdermal patches at the time of dispensing, promoting the appropriate prescribing and dispensing of these products. This network rule utilizes the dispensing histories contained in both the HNS and the NMS to determine if a patient received a long-acting opioid or a fentanyl transdermal patch in the previous 180-day period.

- If a dispensing record is found for a long-acting opioid or a fentanyl transdermal patch in the previous 180 days, the current claim for fentanyl transdermal patch will be accepted.
- If no prior dispensing records are found in the HNS or the NMS, then the current claim for fentanyl transdermal patch will be rejected with response code QM (No Record of Required Prior Therapy).
- An override code MZ (Required Prior Therapy Documented) can be used to allow pharmacists to use their professional judgement to submit the claim as appropriate by confirming the patient meets the RFU code criteria. Documentation may be requested for claim validation verification.

This HNS feature is only applicable to the listed Formulary fentanyl transdermal patches, 25 mcg/hour and 50 mcg/hour strengths. Fentanyl transdermal patches funded under the Exceptional Access Program or through Palliative Care Facilitated Access are not subject to the rule.

6.4 Claim Submission for Prescription with Drug Costs $10,000 or Over

Since the current pharmacy claim standard does not support drug costs exceeding $9,999.99, the Ministry allows pharmacists to submit online claims for prescriptions with a drug cost of $10,000 or more by splitting the claim into multiple submissions, with the exception of claims for extemporaneous compounds. Extemporaneous compounds with drug costs of $10,000 or more must be submitted using the standard paper claims process.

Claims can only be split for the purpose of online claim submission. There are no changes to the paper claim submission process.

In order for HNS to adjudicate the "split" claims appropriately, pharmacists are required to submit the claims according to the following rules:

- The quantity supplied must be split into approximately equal portions without any changes to the submitted price per unit (each split claim with drug costs less than $10,000);
- The day's supply must be split accordingly (please note DUR responses such as refill too soon, and duration of therapy messages would be based on this reduced day's supply);
- Mark-up remains at 6% on all split claims; and,
- A dispensing fee must be submitted for the first split claim only.

Additional details can be found in the frequently asked questions (FAQ) document.

6.5 Approved Non-Prescription Drugs

The Ontario Government Pharmaceutical and Medical Supply Service (OGPMSS) centrally purchases and distributes Approved Non-Prescription Drugs (ANPDs) to LTC homes. DDD is responsible for the reimbursement of drugs provided to residents of LTC homes through the ODB program, including the cost of drugs provided as ANPDs.

Dispensing Solid Oral Dosage Forms of Approved Non-Prescription Drugs to LTC Home Patients

Pharmacists can order and receive solid oral dosage form ANPD stock directly from OGPMSS to be included with pre-packaged prescription medications which are provided to residents of LTC homes. This stock can only be dispensed to residents of LTC homes licensed under the *Long-Term Care Homes Act, 2007.*

This initiative is voluntary. Participation requires that interested pharmacists obtain an account with OGPMSS to order and receive ANPD stock. Stock will be provided to pharmacies at no charge. No reimbursement will be provided for dispensing ANPD products and no additional charges can be passed on to the LTC homes or their residents. New client application forms can be obtained by contacting OGPMSS by telephone at 416-327-0837.

Pharmacies are required to submit claims for each ANPD prescription that is dispensed. **PINs are provided that must be used for claim submission** (*see Appendix B*).

Approved Non-Prescription Drug Claim Requirements

Aside from including the fields indicated in *Section 5.1,* there are additional fields required (or certain exceptions applicable to specific fields) when submitting ANPD claims, namely:

Fields	Required (Y/N)	Explanation
Intervention/ Exception Code	N	Leave blank
Group Number or Code	N	LTC home number (*see* Appendix A.1 - *for a list of LTC homes*
Client ID # or Code	Y	Enter ODB eligibility number
Patient First Name	Y	ODB recipient's first name
Patient Last Name	Y	ODB recipient's last name
Drug Cost/Product Value	Y	Enter "0"
Cost Mark-up	Y	Enter "0"
Professional Fee	Y	Enter "0" for allowed professional fee.
DIN/GP#/PIN	Y	Enter the ANPD PIN (*Refer to Appendix B*)

Please be reminded that claims submitted to HNS are subject to claim validation.

Emergency Authorization to Dispense Approved Non-Prescription Drug Products to Long-Term Care Homes

In certain situations (e.g., a product is on backorder), the Ministry will provide authorization for a pharmacy to dispense ANPD items usually provided directly to LTC homes by OGPMSS.

In order to receive emergency authorization, contact the OGPMSS at 416-327-0837.

The authorization must be kept on file by the pharmacy for two years from the date of the claim for the purposes of claim validation.

Emergency Authorization to Dispense Approved Non-Prescription Drug Claim Requirements

Aside from including the fields indicated in *Section 5.1*, there are additional fields required (or certain exceptions applicable to specific fields) when submitting emergency authorization claims, namely:

Fields	Required (Y/N)	Explanation
Intervention/ Exception Code*	Y	Enter "**MJ**" (i.e., OGPMSS authorized claim)
Group Number or Code	Y	Enter the number for the LTC home receiving services. (*See a list of LTC homes and/or HSC*)
Client ID # or Code	N	Leave blank
Patient First Name	N	Leave blank
Patient Last Name	N	Leave blank
Pharmacist ID*	Y	Enter the Pharmacist ID
Drug Cost/Product Value	Y	Enter the actual Acquisition Cost (equal to manufacturer's or wholesaler's invoice amount minus discounts). Do not include mark-ups here. HST is not applicable, *(refer to Acquisition Cost Calculations in Section 6.7)*
Cost Mark-up	Y	Enter the mark-up amount **Note**: Up to 1/3 of the drug cost mark-up is payable
Professional Fee	Y	Enter 0 for allowed professional fee
DIN/GP#/PIN	Y	Enter the PIN of the product authorized (*Refer to Appendix C*)

The asterisk (*) indicates additional fields.

Claim Validation
Supporting documentation may be requested.
A copy of the authorization to dispense items usually provided to LTC homes by the OGPMSS must be kept on file for two years.

6.6 Allergen Program

The Allergen Program provides coverage for ODB program eligible recipients to receive certain products used to treat allergies and allergic reactions. Products reimbursed through the Allergen Program may be provided by an allergen vendor that has an agreement with the OPDP and has received an HNS account from the Ministry or may also be provided through an accredited retail pharmacy that has an HNS agreement and has received an HNS account from the Ministry.

For a complete list of products funded through the Allergen Program, please see *Appendix D.*

Special Authorization Allergen Form

Except for epinephrine products listed in *Appendix D,* a valid Special Authorization Allergen (SAA) form is required before an allergen claim can be processed. The SAA form is valid for two years commencing on the date it is signed by the prescriber and applies to the allergen extract described in the form that has been prescribed by the prescriber and any renewals of that prescription.

In order for an SAA form to be valid, the following conditions must be met:

Section A of the form must be completed (in writing) by the prescriber before forwarding to the pharmacy.

The allergen product that is claimed and dispensed must match the allergen product that is written on the SAA form by the prescriber.

If the allergen product is being provided by an authorized allergen vendor that has an account with the Ministry, the allergen vendor must complete section B of the SAA form and submit it to the Ministry for reimbursement within six months of the date of service.

If the allergen product is being supplied by an accredited retail pharmacy, the recipient provides the prescription and the SAA form (with Section A completed by the prescriber) to the pharmacy. The pharmacist completes section B of the SAA form, submits an online claim to the ODB program through HNS using the DIN/PIN of the product, and maintains the completed SAA form on file, as supporting documentation for the allergen product claim.

The drug cost submitted can only include the drug cost, mark up and professional fee, and can not include costs for training, other professional fees, equipment used in preparation, packaging of the product, or delivery of the product.

The SAA form must be kept on file for two years from the day on which the last allergen product has been dispensed to an eligible person for claim validation.

Effective December 1, 2017, a completed SAA form is not required for claims for epinephrine products reimbursed through the Allergen Program. A valid prescription is required, and billing procedures remain the same.

Special Authorization Allergen Claim Requirements

Aside from including the fields indicated in *Section 5.1*, there are additional fields required (or certain exceptions applicable to specific fields) when submitting Allergen claims, namely:

Fields	Required (Y/N)	Explanation
DIN/GP#/PIN	Y	Enter the DIN/PIN of the product authorized, (*refer to Appendix D*)
Drug Cost/Product Value	Y	Enter the actual Acquisition Cost (equal to manufacturer's or wholesaler's invoice amount minus discounts) Do not include mark-ups and/or HST in this field *(refer to Acquisition Cost in Section 6.7)*
Cost Mark-up	Y	Enter the mark-up amount, 8% when the total drug cost is less than $1,000.00 or 6% when the total drug cost is greater than or equal to $1,000.00

For SAA forms submitted for children and youth 24 years of age and under who do not have a private plan, the SSC (Special Service Code) box must be populated with a "U" code to confirm that the recipient does not have a private plan.

Claim Validation
Supporting documentation may be requested for claim validation.
1) The SAA form (completed and signed by the prescriber) must be kept on file for two years from the last day on which the allergen product was dispensed to an eligible person (e.g., for an ODB allergen claim dispensed on January 1, 2014, the SAA form must be kept on file until December 31, 2015).
2) Copy of the manufacturer/wholesaler's invoice must be kept on file for two years from the day on which any allergen product has been dispensed to an ODB eligible person.
3) A valid prescription for the allergen product(s) dispensed.

Deductible and co-payment rules in O. Reg. 201/96 made under the ODBA do not apply to products supplied under the Allergen Program. As a result, accredited retail pharmacies are not entitled to charge patients any deductible or co-payment when dispensing a product covered under the Allergen Program to an ODB recipient.

6.7 Cost-to-Operator Claims

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 two years for claim validation. Overpayments due to inappropriate submission of MI intervention codes are subject to recovery through claim validation.

Acquisition Cost

If the pharmacy is unable to acquire an interchangeable drug product and must dispense either the original product or an interchangeable product with a higher DBP, the pharmacy will be reimbursed the Acquisition Cost of the drug product (also known as cost-to-operator or CTO).

Cost-to-Operator Claim Requirements

Aside from including the fields indicated in *Section 5.1*, there are additional fields required (or certain exceptions applicable to specific fields) when submitting CTO claims, namely:

Fields	Required (Y/N)	Explanation
Intervention/ Exception Code*	Y	Enter **"MI"** (e.g., pharmacy unable to acquire the lowest DBP product)
Pharmacist ID*	Y	Enter the Pharmacist ID
Drug Cost/Product Value	Y	Enter the actual or net Acquisition Cost (equal to manufacturer's or wholesaler's invoice amount minus discounts). Mark-ups and HST are not applicable
Cost Mark-up	Y	Must be equal to 0

The asterisk (*) indicates additional fields.

Claim Validation
Supporting documentation may be requested. Pursuant to O. Reg. 201/96, the dispenser must obtain and retain a copy of:
(a) The manufacturer's or wholesaler's invoice which clearly indicates that the generic product had been ordered and was unavailable during the appropriate time period
(b) The supplier's invoice, and

(c) A detailed calculation of the cost of purchasing the drug product (in accordance with section 14 of O. Reg. 201/96 under the Ontario Drug Benefit Act).
These records must be kept on file for two years from the date on which the invoice is received. The supplier's invoice must clearly indicate that the lower priced interchangeable product had been ordered and was unavailable during the appropriate time.

6.8 Duplicate Claim Submission Including Vacation Supply and Methadone Claims

A duplicate claim occurs when two or more claims are submitted with the:

- same date of service; and
- same recipient; and
- same DIN, PIN, or interchangeable product

OR, when two or more claims are submitted with the:

- same date of service; and
- same prescription number; and
- same pharmacy.

Vacation Supply - Ontario Drug Benefit Program Recipients

Most ODB program recipients traveling outside the province for at least 100 days within six months of their last filled prescription may obtain an early refill (up to a 100-day supply) of medication before leaving the province. The normal co-payments and deductibles apply to the 100-day supply.

In order to obtain an early refill for a vacation supply, ODB program recipients must provide documentation confirming that they are leaving the province for more than 100 days including either:

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

Documentation associated with verifying the validity of vacation supply claims are subject to claim validation. The letter, or copy of travel documentation, must be kept on file for a period of two years for inspection purposes. It is suggested 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).

ODB program recipients under the OW program may no longer be eligible for benefits if they leave the province for more than seven days without prior approval from MCCSS. ODB program recipients under the ODSP program may no longer be eligible for benefits if they leave the province for more than 30 days without prior approval from MCCSS. Patients should contact their caseworker to discuss potential plans for extended absences from Ontario.

If written confirmation of approval has been provided to the pharmacy by the local OW or ODSP office for an absence out of the province beyond seven days for OW and beyond 30 days for ODSP, a sufficient supply of medication for the required period, up to a 100-day supply, may be dispensed with appropriate documentation.

Note: Pharmacies must have proof of eligibility before dispensing vacation supplies. Confirmation of eligibility is required for the entire time period that ODB program recipients are out of the province.

Vacation supply - Trillium Drug Program Recipients

Additional rules apply to people who access the ODB program through the Trillium Drug Program (TDP). Based on the specific quarter in the TDP benefit year, some TDP recipients traveling outside the province for at least 100 days may be eligible to obtain an early refill (up to a 100-day supply) of medication before leaving the province.

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 TDP recipients travelling outside the province for between 100 and 200 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 more than 100 days including:

- A letter signed and dated by the patient indicating dates of travel; or
- A copy of the patient's travel documentation.

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

advise TDP recipients that the Ministry will not reimburse vacation supplies paid out-of-pocket during the third and fourth quarters of the benefit year except in rare circumstances.

Claim Validation
Supporting documentation may be requested for claim validation. The letter, or copy of travel documentation, must be kept on file for a period of two years from the day on which the vacation supply was dispensed in a readily retrievable location for inspection purposes.

In accordance with O. Reg. 201/96 made under the Drug and Pharmacies Regulation Act ("DPRA"), all pharmacies are required to keep patient records for a period of at least 10 years or until 10 years after the day on which the patient reaches or would have reached the age of 18 years, whichever is longer.

Duplicate Claim Submission Claim Requirements

Listed below are the only acceptable intervention/exception codes for submission of a duplicate claim:

Fields	Required (Y/N)	Explanation
Pharmacist ID*	Y	Enter the Pharmacist ID.
Intervention/ Exception Code*	Y	Enter any one of the following: **"MM"** = replacement claim, drug cost only[1] **"MN"** = replacement claim due to dosage change **"MR"** = replacement claim, item lost or broken **"UA"** = consulted prescriber and filled Rx as written **"UB"** = consulted prescriber and changed dose **"UC"** = consulted prescriber and changed instructions for use **"UE"** = consulted prescriber and change quantity **"UF"** = patient gave adequate explanation (Rx filled as written) **"MV"** = vacation supply

The asterisk (*) indicates additional fields.

[1]*Duplicate claims resulting from multiple directions on medications. (For example, "Drug X: Take 1 am and 2 hs" dispensed as two prescriptions, one labeled "Take one in the morning" and the other labeled "Take two at bedtime".) Additional fees will not be paid.*

Methadone Maintenance Treatment

The dispensing of methadone may result in duplicate claims. Under the *Methadone Maintenance Treatment (MMT) Reimbursement Policy, 2014*, a separate claim must be submitted online for each day's supply of methadone (i.e., one claim is submitted to the HNS for the witness dose and one claim is submitted for each daily carry that is provided to an ODB recipient). Claims for individual carry doses must be submitted on the date the carries are dispensed. This will result in an "**A3**"-"Identical claim processed" response code which can be overridden with an appropriate intervention code. Please see the table of acceptable intervention codes for submission of a duplicate claim for appropriate codes.

Co-payments may not be charged to the ODB eligible recipient.

Note: The practice of diluting a manufactured methadone product with any diluent including flavoured fruit crystals is not compounding and is not eligible for reimbursement as an extemporaneous compound. Compounding fees should not be submitted as part of claims for manufactured methadone products.

Compounded methadone (using methadone powder) under the MMT policy may only be dispensed to patients who have had an allergic reaction to all manufactured methadone products listed on the Formulary. EAP approval is required (see *Section 6.8*). In addition:

For further details on how to submit an extemporaneous compound claim, please see *Section 6.1 Extemporaneous Preparations*.

Pharmacists dispensing methadone are encouraged to familiarize themselves with the OCP MMT and Dispensing Policy and the *Methadone Maintenance Treatment (MMT) Reimbursement Policy, 2014*, for submitting MMT claims through the ODB program.

6.9 Exceptional Access Program

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

Submitting Exceptional Access Program Requests

Requests for authorization of EAP listed drugs can be submitted to the Ministry through one of the following channels:

1. The Special Authorization Digital Information Exchange (SADIE) portal.

   The SADIE portal enables the submission of web-based electronic requests directly to the program. Guided entry is available on the site for many EAP listed drug products. To help prescribers make decisions about submitting requests, the clinical criteria associated with most EAP products can be found on the SADIE portal.

2. Submitting the completed request form/information by fax to the EAP Toll-free to 1-866-811-9908 or 416-327-7526 (Toronto area).

3. For selected drugs, the Telephone Request Service is available to authorized prescribers or their designates. In most cases, the funding decision is provided by the end of the call and processed within one business day. The TRS can be accessed by calling toll-free at 1-866-811-9893 or 416-327-8109 (Toronto area) and select the TRS option. (See broader description in the section below.)

4. EAP requests for drugs for children and youth who are 24 years of age or younger without a private plan and eligible for OHIP+ may be submitted through the OHIP+ fax line Toll free to 1-844-227-6590.

5. EAP requests for hospitalized patients who are imminently awaiting hospital discharge may be submitted on the hospital discharge form and faxed toll-free to 1-844-829-6807 or 416-314-3857 (Toronto area).

6. For authorized prescribers unable to use any of the above options, requests may be mailed to:

   Exceptional Access Program
   3rd Floor, 5700 Yonge St.
   North York, ON M2M 4K5

   Submission by mail may delay the receipt of the request by the Exceptional Access Program.

Only members of an Ontario regulated health profession authorized to prescribe drugs may request coverage for an EAP drug. In addition, the EAP's Provincial Borders Drug Program enables physicians in Manitoba and Quebec to submit requests for approval of EAP drugs for Ontario patients. (see section below)

The patient's authorized prescriber must submit a request documenting complete and relevant medical information in accordance with the approved clinical criteria associated with the drug and indication being requested. This may include providing the clinical rationale for requesting the drug and reasons why drug products listed on the ODBF/CDI are not suitable.

All requests are reviewed according to the guidelines and criteria recommended through an established national and/or provincial process and as approved by the Executive Officer (EO) of the OPDP. This review includes a thorough assessment of the patient's specific case and clinical circumstances, as provided by the authorized 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 which are provided on the Ministry response letter to the prescriber.

The criteria for the funding of frequently requested drugs considered through the EAP are posted on the Ministry's website at: Exceptional Access Program and can also be found on the SADIE portal.

Authorized prescribers are encouraged to utilize these resources to ensure that they provide the clinical information necessary for the EAP to assess the requested drug(s).

The Ministry accepts requests on drug-specific forms that have been developed for selected products by specialty groups and pharmaceutical manufacturers in collaboration with the Ministry. Additionally, many requests made through SADIE benefit from guided entry of information to ensure that complete information is provided. Authorized prescribers may also submit requests using the Request for an Unlisted Drug Product - EAP Form on the Ministry's website, however, it is advised that they refer to the required criteria for coverage and input this information on the form or attach this information to the standard form.

Exceptional Access Program Application Process

To apply through the EAP, the patient's authorized prescriber (physician or nurse practitioner) must submit a request documenting complete and relevant medical information to the Ministry, providing the clinical rationale for requesting the drug and reasons why covered benefits are not suitable. To assist authorized prescribers applying for exceptional access, please refer to the Request for an Unlisted Drug Product - EAP Form on the Ministry's website.

All requests are reviewed according to the guidelines and criteria recommended through a national or provincial established process of review and approved by the Executive Officer (EO) of the OPDP. This review includes a thorough assessment of the patient's specific case and clinical circumstances, as provided by the authorized 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.

The criteria for the funding of frequently requested drugs considered through the EAP are posted on the Ministry's website at: Exceptional Access Program.

Authorized prescribers 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). Only authorized prescribers practicing in Ontario may request coverage for an EAP drug. (The Provincial Borders Drug Policy allows ODB clients to access EAP products even if their prescriber is in Manitoba or Quebec. More information can be found here: http://health.gov.on.ca/en/pro/programs/drugs/eap_mn.aspx#7).

Requests should be sent to the attention of:

Exceptional Access Program
3rd Floor, 5700 Yonge St.
North York, ON M2M 4K5
Fax: 416-327-7526 or 1-866-811-9908
Email: EAPFeedback@ontario.ca

Exceptional Access Program Approvals

Following assessment, the Ministry will fax a decision to the prescriber who submitted the request. For requests that meet EAP criteria and are approved, the effective date of coverage and the expiry date of coverage will be communicated to the authorized prescriber in the Ministry's response letter.

Although it is not mandatory, authorized prescribers should provide a copy of the response letter to the patient and/or the patient's pharmacy as this letter identifies the name of the drug(s) approved, the drug identification number or product identification number for the funded product, and the coverage period. This information may help with oversight of the duration of coverage of products and avoid gaps in treatment if an extension/renewal of the funding is required. It should be noted that the EAP may not cover all manufactured brands of a specific drug and that the response letter does not list all funded off-formulary interchangeable (OFI) products that may be covered since interchangeable products may change, be added or be withdrawn from the ODBF/CDI over time. It is the pharmacy's responsibility to ensure that they are dispensing an ODB funded brand by referring to the status of OFI drugs listed on the ODBF/CDI. Any prescription which fails to be adjudicated at the time of dispensing should be further investigated to validate the individual coverage status.

Pharmacists are not required to keep a copy of the Ministry's response letter on file.

Exceptional Access Program Coverage Duration

For requests that meet EAP criteria and are approved, the effective date of coverage and the expiry date of coverage will be communicated to the authorized prescriber in the Ministry's response letter.

Authorized prescribers should provide a copy of the response letter to the patient and/or the pharmacy as this may help to avoid a gap in treatment if an extension/renewal of funding is required.

The coverage period for approved requests generally will begin on the day that the request is received by the program. However, the EAP applies a standard approval procedure to qualified requests that may backdate the coverage period by up to 30 business days from the date the request is received by the program to recognize that authorized prescribers may not submit an EAP request at the same time as the clinical decision to prescribe an unlisted drug is made.

Only eligible approved requests that meet EAP clinical criteria at the time they are received by the program will be aligned. For example, alignment will not be provided for requests with a short duration of approval (e.g., an antibiotic, a drug required before surgery); for renewal requests that are approved before the expiry date of an existing approvals; for requests that do not meet EAP criteria at the time of receipt; for requests made through the Telephone Request Service (TRS); or for requests made through the Compassionate Review Policy (CRP). Additionally, coverage periods will not be provided to a date prior to the effective date of provincial coverage of the EAP drug product and indication. Other exceptions may apply.

EAP approvals are not guaranteed as requests must meet EAP clinical criteria. Patients who choose to purchase unlisted drugs in advance of an EAP decision are responsible for out-of-pocket costs.

To receive funding for a drug approved by the EAP, the patient must be ODB-eligible. Additionally, only ODB-eligible costs are considered for reimbursement. For example, drug costs over ODB - eligible costs, credit card and banking charges will not be reimbursed.

Off-Formulary Interchangeability and Generic substitution of Exceptional Access Program Drugs

Off-Formulary Interchangeability (OFI) is the application of interchangeable designations to generic drug products that are not listed benefits under the ODBA. OFI became effective April 1, 2007 when changes to Regulation 935 under the DIDFA came into force.

If a drug has been approved by the EAP, authorization will automatically be granted for the generic interchangeable product(s) of the same strength if they are listed as an OFI. It should be noted that the EAP response letter does not identify all OFI drug products and not all generic products of the same strength are deemed interchangeable. As such, pharmacists should refer to the ODBF/CDI for interchangeable OFI funded EAP products. Pharmacists should forward any questions regarding authorization of a specific EAP claim, including requests to change the DIN, dosage form or strength of a drug product, to the ODB Help Desk or directly to the EAP. If contacting the EAP, queries should be e-mailed to EAPFeedback@ontario.ca.

Generic substitution applies to the EAP.

Under this policy, if an EAP drug has an interchangeable generic product designated through the OFI mechanism, the Ministry will only approve the funding of the generic product. Where ODB recipients have had a documented adverse reaction to at least two (2) generic versions, the Ministry will reimburse the higher-cost brand product. Similar to products listed on the ODB Formulary, the "No Substitution" policy applies.

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. Given that inventory selection differs from pharmacy to pharmacy, the Health Network System (HNS) will have system rules in place, to reduce the value of the "Amount MOHLTC Pays" for a brand name OFI drug product to that of the highest-cost generic in the interchangeable category. This information can be found in the e-formulary.

In order for ODB to reimburse the brand name product, prescribers are required to complete, sign and forward to the pharmacist, a copy of the Health Canada Side Effect Reporting Form for **each** interchangeable drug product trialed, and are required to write "no substitution" on a written prescription or indicate "no substitution" to the pharmacist in the case of a verbal prescription. The form(s) must be completely filled out noting the details of the adverse reaction(s) and signed by the prescriber. This process aligns with the rules for formulary listed benefit products.

If ODB recipients choose to exercise their personal preference for the brand therapy without complying with the ODB policy on generic substitution, it will be the responsibility of the recipient to pay for the cost difference as determined by the pharmacy.

Exceptional Access Program Renewal of Coverage

If it is anticipated that a patient will continue to require the product beyond the approval period, the authorized prescriber is required to request an extension of coverage. Coverage will not be continued automatically between expiration and re-issuance of approval. It is recommended that the request for continued reimbursement and all supporting documentation be submitted to the

Ministry to enable re-evaluation of the request within the timeframe appropriate to the approval duration granted. For instance, drugs that are granted coverage for one or more years duration should submit extension of coverage requests six to eight weeks prior to the expiration of the current approval. For EAP drugs approved for shorter coverage durations, evaluation of the response to the drug should occur within a time period that provides clinically relevant information to meet renewal criteria requirements.

Authorized 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 address the renewal criteria required for the specific drug (as applicable) and include a summary of the patient's response to therapy typically as progress on the drug product compared to "baseline" before starting the treatment or as compared to a prior renewal, any changes in drug therapy, or dose/dose regimen, the rationale for the continued need for the product, and a list of all concomitant drug therapies.

Provincial Borders Drug Program

The Provincial Borders Drug Program (PBDP) policy allows ODB clients who are residents of Ontario to access EAP products even if their prescriber is in Manitoba or Quebec. The intent of this program is to ensure that patients who are living in close proximity to the provincial borders are able to receive EAP drugs, even when provided by a prescriber who is not licensed in Ontario. 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 requests on behalf of any ODB client for an EAP product. The policies, drugs, indications and reimbursement criteria associated with the Exceptional Access Program for Ontario licensed prescribers apply to requests that are submitted under the PBDP. Drugs approved by the EAP must be dispensed by an Ontario community pharmacy registered with the Ministry and must meet the criteria for reimbursement within Ontario. Prescriptions dispensed by Manitoba and Quebec pharmacies are not reimbursed through the ODB program, which includes drugs authorized for funding under the EAP and drugs approved under the PBDP.

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. Authorized prescribers or their delegates may call the TRS to submit their requests and obtain a faster decision for selected drugs and indications. Additional information, including evaluation questionnaires and the reimbursement criteria for drugs that can be considered through the TRS, is posted on the Exceptional Access Program – Telephone Request Service web page.

Authorized 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 to ensure that they have the necessary information readily available to receive a decision during the call. Requests for drug products or indications not currently available through TRS must be submitted via Special Authorization Digital Information Exchange (SADIE) or fax.

Authorized 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 a.m. to 5 p.m. Monday to Friday. Service is not available on weekends, provincial statutory holidays, Easter Monday or Remembrance Day.

Exceptional Access Program Claim Requirements

Aside from including the fields indicated in *Section 5.1*, there are additional fields required (or certain exceptions applicable to specific fields) when submitting a claim for an EAP authorized drug product, namely:

Fields	Required (Y/N)	Explanation
DIN/GP#/PIN	Y	Enter the DIN/PIN of the product authorized
Quantity	Y	Enter the quantity to be billed (in units)
Drug Cost/Product Value	Y	Enter the DBP (if available in the Formulary/CDI or posted on the M) or the actual Acquisition Cost (equal to manufacturer's or wholesaler's invoice amount minus discounts). Do not enter mark-ups here. HST is not applicable (*refer to Acquisition Cost Calculations in Section 6.7*)
Cost Mark-up	Y	Enter the mark-up amount, 8% when the total drug cost is less than $1,000.00 or 6% when the total drug cost is greater than or equal to $1,000.00

Note: The Ministry is aware of its obligations under PHIPA to ensure the confidentiality of all personal patient information which it holds on file as provided by requesting prescribers. Prescribers are requested to ensure continuation of this vigilance as it relates to patient privacy issues, particularly when transmitting EAP approval information to other parties.

Claim Validation ***Supporting documentation may be requested.***

Where Acquisition Cost is being claimed, the pharmacy must retain on file for two years a copy of: (a) the supplier's invoice, and (b) a detailed calculation of the cost of purchasing the drug product (in accordance with section 14 of the O. Reg. 201/96under the Ontario Drug Benefit Act).

6.10 Compassionate Review Policy

The Compassionate Review Policy (CRP) enables consideration of coverage of requests for drugs and indications which have not been reviewed through the established national/and or provincial processes for a final provincial funding decision by the Executive Officer of the OPDP. The CRP is used to review requests for funding for rare clinical circumstances in immediately life-, limb-, or organ-threatening conditions. The CRP is not to be used to bypass the established processes for decisions related to provincial drug funding, and it will not be used to consider coverage of a reviewed drug and indication where the Executive Officer has made a decision not to fund. Requests must meet the criteria for the Compassionate Review Policy (CRP).

The CRP may be used in situations where a drug has undergone a clinical review through the established national/provincial processes and is awaiting completion of the negotiations with the manufacturer towards a final provincial funding decision by the Executive Officer. The CRP may be used to consider coverage of requests on a case by case basis for individuals who have been urgently hospitalized due to an immediate life-, limb-, or organ threatening complication which aligns to the drug and indication under negotiations. The hospitalization must be directly related to the clinical indication for which the negotiations of the drug are ongoing. Interim EAP approval of a request will be limited to a maximum of six months and will begin once the patient is discharged from hospital. Further coverage may not be approved once final criteria have been established.

Under CRP, the Executive Officer will also consider requests for drugs without a Notice of Compliance (NOC) and DIN issued by Health Canada if the prescriber indicates in the request that approval has been obtained through the Health Canada Special Access Program (SAP).

For requests for drugs (oral or injectable) that are used to treat cancer that have not been reviewed through the established national or provincial processes, Cancer Care Ontario (CCO) administers the Case-by-Case Review Program (CBCRP) on behalf of the Ministry. The CBCRP extends and adapts the Compassionate Review Policy to unreviewed therapies that are administered for the treatment of cancer in life-, limb-, and organ-threatening situations. Consideration through CBCRP must be for the treatment of cancer. A cancer drug used to treat a non-cancer condition would not be considered under CBCRP.

Further information on the CBCRP including eligibility criteria and how to apply is available on the CCO website.

While CCO administers the CBCRP, the Executive Officer of OPDP makes all final funding decisions.

6.11 Nutrition Products

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

Patient Eligibility Criteria for Coverage of Nutrition Products

Enteral nutrition products will be reimbursed for ODB eligible persons when prescribed by a physician or nurse practitioner as the patient's **sole source** of nutrition **and** when any 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).

Exclusion Criteria

A nutrition product will not be reimbursed under the ODB program if it is intended for one of the following uses:

- prescribed weight loss in the treatment of obesity
- food allergies
- body building
- voluntary meal replacement
- nutritional supplement
- convenience
- replacement for breast-feeding for infants with normal gastrointestinal absorptive function.

Nutrition products are eligible for coverage under the ODP 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.

Nutrition Products Form

Each claim for reimbursement must be supported by a valid and fully completed Nutrition Products form. A valid Nutrition Products form is required before any claim for reimbursement can be processed.

In order for a Nutrition Products form to be valid, the following conditions must apply:

- The recipient must meet the patient eligibility criteria for coverage of nutrition products.
- The Nutrition Products form must be fully completed and signed by eligible prescriber*.
- The nutrition product that is claimed and dispensed must match the nutrition product that is written by the eligible prescriber on the Nutrition Products form.
- The Nutrition Products form will be valid only for one year from the initial date it was completed and signed by the eligible prescriber.

*Nutrition products are designated as listed substances under ODBA and require a valid Nutrition Products form signed by an eligible prescriber in order to be eligible for reimbursement under the ODB program.

A valid and complete Nutrition Products form supporting an ODB eligible nutrition product claim must be kept on file for two years from the day the nutrition product claim was submitted. (*For example, a Nutrition Product claim submitted for ODB reimbursement with a date of service on December 15, 2017, must be substantiated with a valid and completed Nutrition Product form signed and dated by the prescriber (dated from December 16, 2016 to December 15, 2017) and retained on file until December 15, 2019 to support claim validation.)*

Prescribers can obtain an Nutrition Products form from the Ministry website.

Pharmacists should note the maximum amount the Ministry will reimburse pharmacies for each approved nutrition product. **CTO claims will not be accepted**. **Nutrition Products are not eligible for a mark-up.**

For more information regarding the reimbursement of nutrition products, including the specific nutrition products approved for coverage and the maximum price up to which they will be reimbursed, please refer to the Maximum Allowable Reimbursement (MAR) Schedule of the ODBF/CDI.

Note: Nutritional requirements for residents of LTC homes and HSC are met by the home responsible for their care. Nutrition product claims for these residents are not reimbursed under the ODB program.

Nutrition Product Claim Requirements

Aside from including the fields indicated in *Section 5.1*, there are additional fields required (or certain exceptions applicable to specific fields) when submitting a nutrition product claim, namely:

Fields	Required (Y/N)	Explanation
DIN/GP#/PIN	Y	Enter the PIN of the product, as listed in the ODBF/CDI
Quantity	Y	Enter the quantity to be billed, in terms of package size (not as mL or g) based from the Cost per Pack column in Part IX of the ODBF/CDI For example, a 500 mL product (Pkg Size = 250 mL) must be billed as two
Drug Cost/Product Value	Y	Enter the actual or net Acquisition Cost (equal to manufacturer's or wholesaler's invoice amount minus discounts). Mark-ups and HST are not applicable, refer to pricing information in ODBF/CDI
Cost Mark-up	Y	Must be equal to zero

Claim Validation
Supporting documentation may be requested for claim validation.
A valid prescription, and valid and complete Nutrition Products form (completed and signed by the prescriber) must be kept on file for two years from the day on which any nutrition product has been submitted to HNS.
In accordance with O. Reg. 264/16 made under the Drug and Pharmacies Regulation Act ("DPRA"), all pharmacies are required to keep patient records for a period of at least 10 years or until 10 years after the day on which the patient reaches or would have reached the age of 18 years, whichever is longer.

6.12 Diabetic Testing Agents

Blood Glucose Test Strips (BGTS) that are listed substances in the ODB Formulary are covered as additional benefits for ODB program eligible persons.

General Information

BGTS are designated as listed substances under the ODBA and require a valid prescription signed by an eligible prescriber in order to be eligible for reimbursement under the ODB program.

Pharmacists should note the maximum amount the Ministry will reimburse pharmacies for each approved test strip. **CTO claims will not be accepted. Test strips are not eligible for a mark-up**.

Note: Only one PIN for each brand of test strips can be used for billing. Package size should not be used since reimbursement is based on the number of units (i.e., strips) of each product dispensed.

Blood Glucose Test Strips Reimbursement Maximums

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

When a claim is submitted for BGTS for eligible ODB program recipients, the HNS will automatically review the anti-diabetes medications claims within the **previous six months** to identify claims 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, based on both online and paper claims as follows:

Diabetes Treatment Category	Number of BGTS allowed over the course of 365 days
Patients managing diabetes with insulin	3,000
Patients managing diabetes with anti-diabetes medication with high risk of causing hypoglycemia[1]	400
Patients managing diabetes using anti-diabetes medication with low risk of causing hypoglycemia[2]	200
Patients managing diabetes through diet/lifestyle therapy only (no insulin or anti-diabetes medications)	200

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

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

Recipients will be allotted the indicated number of test strips for use over the course of a 365-day period. The test strip allotment will apply to both online and paper claims.

When a claim is submitted, HNS calculates whether the recipient has met his/her allotted maximum for the year. If the recipient has not reached his/her maximum number of allotted test strips, he/she will be eligible to receive test strips up to that maximum number.

The test strip allotment is based on a patient's current treatment method, as based on the drug claims through the HNS. Pharmacies may override the current test strip allotment for patients who receive medications not billed through the HNS that put them at higher risk of hypoglycemia, up to the maximum as outlined in the table above. See override codes below.

However, in exceptional clinical circumstances where some people may require more frequent testing, in order to obtain a greater number of BGTS, a physician or nurse practitioner must indicate the reason for the higher than recommended monitoring schedule and the specific testing frequency on the BGTS prescription.

Note: When submitting a claim for insulin or anti diabetes medication along with a claim for BGTS, pharmacists should **submit all 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 test strips. Similarly, all related paper claims should be submitted for processing as soon as possible.

Diabetic Testing Agents Claim Requirements

Pharmacies may not charge eligible ODB recipients any amount other than the co-payment for supplying BGTS under the ODB program. The Ministry will reimburse pharmacies the amount identified in the column "**Amount MOHLTC Pays" in the Formulary. No mark-up will be permitted for BGTS. CTO claims will not be accepted.**

Aside from including the fields indicated in *Section 5.1*, there are additional fields required (or certain exceptions applicable to specific fields) when submitting a diabetic testing agent claim, namely:

Fields	Required (Y/N)	Explanation
DIN/GP#/PIN	Y	Enter the PIN of the specific brand of test strips that is dispensed, as listed in the ODBF/CDI
Quantity	Y	Enter the quantity to be billed, in terms of number of units (not as package size) dispensed

Fields	Required (Y/N)	Explanation
		For example, one box of 50 test strips must be billed as units = 50
Drug Cost/Product Value	Y	Enter the actual Acquisition Cost (equal to manufacturer's or wholesaler's invoice amount minus discounts). Mark-ups and HST are not applicable, refer to pricing information in the ODBF/CDI
Cost Mark-up	Y	Must be equal to zero

Blood Glucose Test Strips Claim Submission Responses

If the maximum number of test strips is exceeded in a 365-day period for a given patient, a response code is provided to the pharmacist indicating that the recipient has reached his/her limit and the claim is rejected. Two different response codes may be provided by HNS in this scenario:

Response Code	Message Description	Explanation of condition generating response code
"OC"	Quantity Reduction Required	This response code will be displayed if the claim can be accepted by reducing the quantity. A message data line* will be included to advise of the remaining allowable number of test strips for the recipient.
"LO"	Maximum Benefit Exceeded	This response code indicates that the recipient has exceeded his/her maximum benefit and cannot receive any additional test strips without an override. A message data line* will be included to advise of the remaining allowable number of test strips for the recipient.

HNS tracks and determines the BGTS reimbursement level based on each patient's diabetes treatment to help monitor the number of strips an ODB program recipient has received during a 365-day period. To assist ODB program recipients and pharmacists in tracking a patient's BGTS utilization and identifying the next period start date for their patients, a response message data line is delivered to pharmacies after adjudicating claims for BGTS.

HNS Response Message Data Line for BGTS Claims

"Remaining Qty: #### until MMM DD, YYYY".

For example: "Remaining Qty: 100 until FEB 15, 2019".

This response message data line is sent in addition to the reject response codes sent to pharmacy systems after processing a BGTS claim.

Override Codes

There may be exceptional clinical circumstances where patients may require additional test strips. When a patient has reached his/her limit of available test strips in a 365-day period, two intervention codes are available for pharmacists. Documentation to support the application of each intervention code is required. Pharmacists must keep this information on file at the pharmacy for not less than two years for inspection purposes.

Intervention Code	Message Description	Explanation of condition generating response code
"NF"	**Override-Quantity Appropriate**	This intervention code may be used for patients who require more test strips in a 365-day period, because they had claims for insulin and/or anti-diabetes medications with high risk of causing hypoglycemia in the previous six months, that were not reimbursed under the ODB program. The identified anti-diabetes medications that were reimbursed by private drug insurance plans or paid by the patient must be documented and readily available for inspection purposes.
"MG"	**Override-Clinical Reasons**	This override code will allow for 100 additional test strips at a time to be reimbursed for patients who have been directed by a healthcare professional to monitor blood glucose levels more frequently for a specific clinical reason. If additional 100 strips are required, a new script with the proper documentation would have to be submitted by the prescriber for each individual request. Documentation must include the reason for exceeding the recommended frequency of monitoring and the name of the referring healthcare professional and the dispensing pharmacist's OCP license number.

Claim Validation
Supporting documentation may be requested for claim validation.

Reasons for override must be clearly documented on the prescription. If intervention codes are entered to override the test strip limit, documentation must be available on the prescription hard copies for a period of two years.

In accordance with O. Reg. 264/16 made under the Drug and Pharmacies Regulation Act ("DPRA"), all pharmacies are required to keep patient records for a period of at least 10 years or until 10 years after the day on which the patient reaches or would have reached the age of 18 years, whichever is longer.

6.13 30-Day Prescription Program

New prescriptions for ODB program recipients are generally limited to a maximum of 30 days' supply if the medication has not been received by the recipient in the preceding 12 months. If the newly prescribed medication is well tolerated after 30 days, the remainder of the prescription can be dispensed up to a maximum 100 days' supply. All claims that do not meet the requirements of the 30-day Prescription Program will be rejected by HNS with the following response code:

"OF" = initial supply for the claim exceeds 30 days.

Claims for insulin, diabetic testing agents, methadone maintenance, nutritional products, and allergen products are exempt from this program.

If necessary, the response code **"OF"** (rejection) can be overridden by entering the intervention code **"NH"**. This will allow the claim to adjudicate normally. The **"NH"** intervention code can only be submitted if:

- The patient had the product in the preceding 12 months but it was not recorded on HNS.
- The patient will be out of province for more than 100 days.
- The patient is unable to return to the pharmacy within the 30-day period.

Reasons for override must be clearly documented on the prescription.

Response code	Message description	Explanation of condition generating response code	Intervention/ Override Code
"OF"	Initial Rx Days' Supply Exceeded	An initial prescription for a drug product must not exceed 30 days' supply	**"NH"** = Initial Rx Program Declined

If a rejected claim is resubmitted but the quantity has not been reduced (e.g., only the days' supply is changed on the claim), the claim will be rejected with the response code "**OC**." If the

quantity does not need to be reduced for the initial 30 days, the intervention code "**NF**" can be used.

Response code	Message description	Explanation of condition generating response code	Intervention/ Override Code
"OC"	Quantity Reduction Required	An initial prescription that previously rejected with response code "**OF"** (= Initial Rx Days' Supply Exceeded) was resubmitted with a reduced Days' Supply, but the corresponding quantity was not reduced accordingly	**"NF"** = Override - Quantity Appropriate

30-Day Prescription Program Claim Requirements

Fields	Required (Y/N)	Explanation
Pharmacist ID*	Y	Enter the Pharmacist ID.
Intervention/Exception Code*	Y	To override response code "**OF**"- enter "**NH**" (= Initial Rx Program Declined) To override response code "**OC**"- enter "**NF**" (= Override-Quantity Appropriate)

The asterisk (*) indicates additional fields.

Claim Validation
Supporting documentation may be requested for claim validation.
Reasons for override must be clearly documented on the prescription. If intervention codes are entered to override the 30-day limitation, documentation must be available on the prescription hard copies for a period of two years.

In accordance with O. Reg. 264/16 made under the Drug and Pharmacies Regulation Act ("DPRA"), all pharmacies are required to keep patient records for a period of at least 10 years or until 10 years after the day on which the patient reaches or would have reached the age of 18 years, whichever is longer.

6.14 Special Drugs Program

The Special Drugs Program (SDP) covers the full cost of specified hospital outpatient drugs for all Ontario residents with a valid Ontario Health number and who meet the criteria for coverage. Drugs covered under SDP include:

- erythropoietins for anemia in patients with end-stage renal disease,
- cyclosporine for patients with solid-organ or bone-marrow transplants,
- human growth hormone for patients with endogenous growth hormone deficiency,
- clozapine for treatment-resistant schizophrenia,
- imiglucerase for Gaucher disease,
- zidovudine and pentamidine for HIV/AIDS, and
- specified drug products for the treatment of cystic fibrosis and thalassemia.

The SDP is distinct from the ODB program, with different legislative authority, method of drug distribution and payment structure. The SDP is governed by the *Health Insurance Act*, and Regulation 552 made under that Act. The drugs must be prescribed by a prescriber affiliated with an authorized hospital and dispensed from an authorized hospital pharmacy. Hospitals dispensing drugs for certain SDP diseases (e.g., cystic fibrosis), must be listed as part of a specific hospital group class under the *Public Hospitals Act*.

Patients do not pay deductibles or co-payments. In addition, hospital pharmacies are reimbursed for actual drug costs only. No cost mark-up or fees apply to prescriptions dispensed under the SDP.

Hospital pharmacies submit claims either manually or online (in real-time) through the HNS for actual drug acquisition cost reimbursement. Manual claims are submitted with wholesaler or manufacturer issued invoices to support claims for reimbursement. The SDP is strictly a hospital service and both the manual and online claims processes are ONLY applicable to specific authorized hospital pharmacies and not to community pharmacies, unless permitted by the Ministry.

Special Drugs Program Claim Requirements

SDP online claims are processed by the HNS in the same manner as other standard online claim transactions.

SDP hospitals are identified in HNS as agencies with authority to dispense the identified drug products through HNS.

Deductibles and co-payments are not applicable.

No cost mark-up or dispensing fee will be paid.

Eligibility will not be set up on the HNS prior to a patient's first prescription under SDP. HNS will reject the initial claim for recipients without established eligibility at the time of dispensing with a response code of **"*KT-Assess Recipient SDP Eligibility*"**.

SDP patients will be enrolled on HNS by submitting a standard online transaction as noted below. When a claim is submitted and paid with the **"NC"** intervention code, the system will automatically enroll the recipient under the SDP for a one-year period based on the dispensing date of the claim. Patients will need to be re-enrolled annually for SDP coverage.

Although the maximum days' supply is 180 days, SDP hospitals are encouraged to dispense minimum quantities to reduce wastage.

Aside from including the fields indicated in *Section 5.1*, there are additional fields required (or certain exceptions applicable to specific fields) when submitting a claim for an SDP authorized drug product, namely:

To enroll SDP recipient:

Fields	Required (Y/N)	Explanation
DIN/GP#/PIN	Y	Enter the PIN of the SDP product authorized
Pharmacist ID	Y	Enter the Pharmacist ID of the pharmacist involved in the intervention
Intervention/ Exception Code	Y (annually for each recipient)	**"NC"** = Patient SDP Eligibility Confirmed
Carrier-ID		"V = Special Drugs Program"
Client ID # or Code, Patient First Name, Patient Last Name, Patient Gender and Patient Date of Birth	Y	Enter recipient's Health number, name, sex and DOB.

Other fields:

Fields	Required (Y/N)	Explanation
Days' Supply	Y	Maximum of 180 days.
Intervention/ Exception Code for high cost claims	Y	Claims up to $9,999.99 may be billed online without an intervention code

Fields	Required (Y/N)	Explanation
		Claims of $10,000 or more, can be submitted by splitting the claim (see *Section 6.4*) into multiple submissions: The quantity supplied must be split in approximately equal portions without any changes to the submitted price per unit (each split drug claim with drug costs less than $10,000) The days' supply must be split accordingly (please note Drug Utilization Review (DUR) responses such as refill too soon, and duration of therapy messages would be based on this reduced days' supply) **"MP"** = valid claim value $1,000 to $9,999.99 Submit to override response code D6 (maximum cost exceeded) **"MM"** = replacement claim, drug costs only Submit to override response code "**A3"** (identical claim has been processed)
Intervention/ Exception Code for initial 30 days' supply	N	30-Day Prescription Program does not apply

Claim Validation
Invoices may be required to validate claims. Utilization may be periodically reviewed.

In accordance with O. Reg. 264/16 made under the Drug and Pharmacies Regulation Act ("DPRA"), all pharmacies are required to keep patient records for a period of at least 10 years or until 10 years after the day on which the patient reaches or would have reached the age of 18 years, whichever is longer.

6.15 Universal Influenza Immunization Program

Ontario's Universal Influenza Immunization Program (UIIP) helps with the administrative costs associated with the delivery of the publicly funded influenza vaccines administered by pharmacists.

For more information, pharmacists must access the notice from the Executive Officer for detailed information including submitting claims for pharmacist-administration of the influenza vaccine using HNS for the current influenza season.

Under the UIIP, trained pharmacists are authorized to administer publicly funded influenza vaccines to Ontarians five years of age and older who have a valid Ontario Health number.

Only pharmacists who are registered with the OCP as having successfully completed an OCP approved injection training program and hold current CPR and First Aid certification may administer the publicly funded influenza vaccine.

Only pharmacies that are approved by the Ministry via a User Agreement can provide the influenza vaccine to the public. In order for a pharmacy to be approved to administer the influenza vaccine, pharmacy managers must complete the Ministry's *User Agreement for Pharmacies Requesting Publicly Funded Influenza Vaccine* each year.

Further information on the UIIP, including requirements under the annual User Agreement is available by emailing UIIP.MOH@ontario.ca .

Restrictions

The following are some of the requirements for pharmacist-administered influenza vaccines under the UIIP (the list is not exhaustive):

Patients must be five years of age and older.

The publicly funded influenza immunization service fee may not be claimed for residents of long-term care homes, hospital in-patients or residents of other licensed institutions (ex. Correctional facilities).

Patients are expected to provide their Ontario Health number for the service. Should a patient not have a valid Ontario Health number, pharmacists may refer him/her to the local Public Health Unit for influenza immunization.

Alternatively, patients without a valid Ontario Health number who can provide proof that they live, work or study in Ontario may receive the influenza vaccine from the pharmacist, however, pharmacists will NOT be paid the administration fee for these doses. Pharmacists must also complete the required documentation of administration and submit it to their local Public Health Unit. For more information, contact: UIIP.MOH@ontario.ca.

Publicly funded influenza vaccines must only be administered within the physical boundaries of the pharmacy. **Exception:** a pharmacist may administer publicly funded influenza vaccines to patients in their private home or in a retirement home (but not hospital in-patients or residents of LTC homes), if patients are not able to attend the pharmacy due to a physical and/or mental condition, and they regularly receive dispensing services from the same pharmacy (i.e., a pharmacist can only administer publicly funded influenza vaccine in these alternate settings, if they are providing service to their regular patients).

Administration of non-publicly funded vaccine or injection products will not be reimbursed under the UIIP for influenza immunization or through HNS for the administration fee.

Pharmacists may not transfer UIIP influenza vaccine inventory to another pharmacy.

The Ministry does not accept paper claims for pharmacist administered influenza vaccines.

A pharmacist's recommendation to a prescriber that a patient get his/her influenza vaccine, whether it is publicly funded or not, does not meet the criteria of Pharmaceutical Opinion Program and is therefore not a billable service under that program.

Claim Requirements for Pharmacists Administering Influenza Vaccine

The claim for payment for administration of the influenza vaccine should be submitted through HNS after administering the influenza vaccine to the patient on the same day of administration.

Pharmacies will be reimbursed $7.50 per injectable vaccine and $5.00 per nasal spray vaccine per eligible claim for the administrative costs associated with the delivery of one of the publicly funded influenza vaccines. This includes providing patients with a written record of influenza immunization as per the User Agreement.

Influenza products that are publicly funded under the UIIP may differ from year to year. Please see the Ministry's website for more specific information on the publicly funded influenza vaccines available for the current Influenza Immunization Season

The pharmacist who administers the publicly funded influenza vaccine must use their Pharmacist ID as the Prescriber ID when submitting a claim for the influenza vaccine.

If the influenza vaccine was administered off-site and in compliance with the requirements of the User Agreement, pharmacists may submit the claim on the next business day provided the correct date and time of administration is noted on the record.

Claims must be submitted for publicly funded influenza vaccine only using the appropriate DIN/PIN of the vaccine that was administered to the patient. **Pharmacists must not enter a drug cost or a dispensing fee or a mark-up on publicly funded influenza vaccines.**

Aside from including the fields indicated in *Section 5.1*, there are additional fields required (or certain exceptions applicable to specific fields) when submitting a claim for a pharmacist-administered influenza vaccine, namely:

Fields required for all claims for pharmacist administered influenza vaccines (ODB program recipients and non-ODB program recipients):

Fields	Required (Y/N)	Explanation
Intervention Code	Y	**"PS"** = Professional Care Service
DIN/GP#/PIN	Y	Enter the appropriate DIN or PIN if applicable as per the publicly funded influenza vaccine administered **Note:** Influenza products that are publicly funded under the UIIP may differ from year to year. Please see the Ministry's website for more specific information on the publicly funded influenza vaccines available for the current Influenza Immunization Season and the associated DINs.
Pharmacist's ID code	Y	Pharmacist License #
Professional Fee	Y	$7.50 (injectable influenza vaccine) $5.00 (nasal spray influenza vaccine), if available

Additional fields required for non-ODB recipients:

Fields	Required (Y/N)	Explanation
Intervention Code	Y	**"PS"** = Professional Care Service **"ML"** = Eligibility established-Standard coverage
Patient Gender	Y	"F" = female, "M" = male
Patient Date of Birth	Y	YYYYMMDD
Client ID # or Code	Y	Health number
Carrier ID	Y	"**S**"

Reimbursement of Epinephrine Auto-Injection for Emergency Treatment

In the event of an adverse drug reaction resulting immediately after a pharmacist's administration of the publicly funded influenza vaccine to an eligible Ontarian five years of age or over, the Ministry will reimburse pharmacies the Acquisition Cost of the epinephrine auto-injection when used for emergency treatment in the pharmacy or at the immunization location.

Under the *Regulated Health Professions Act, 1991*, any pharmacist may render emergency first aid or temporary assistance in an emergency situation. However, pharmacists are advised to speak with the Ontario College of Pharmacists if they have any additional questions.

Restrictions:

Epinephrine auto-injection will not be reimbursed in the following situations (other examples may apply):

- Providing the epinephrine auto-injection to the patient to self-administer or take home (e.g., in the event the patient may experience an adverse event after leaving the pharmacy)
- Pharmacist emergency injection of epinephrine auto-injection that is not due to an adverse drug reaction resulting from the administration of the publicly funded influenza vaccine
- Pharmacist emergency injection of epinephrine auto-injection at a nurse-led pharmacy clinic
- Pharmacist emergency injection after providing any injection or inhalation for the purpose of demonstration or education.

The Ministry does not accept paper claims for epinephrine auto-injection claims submitted for this purpose.

Claim Requirements for Epinephrine Injection for Emergency Treatment

The Acquisition Cost of epinephrine auto-injection will be reimbursed by the Ministry if the above requirements are met.

If administering for emergency use, the epinephrine auto-injection PIN should be billed as a second claim following the influenza vaccine claim on the same day of service. Please note the cost of the epinephrine auto-injection for this transaction will appear in the Dispensing Fee field of the claim.

Pharmacists must use their Pharmacist ID as the Prescriber ID when submitting a claim for epinephrine injection.

Claims must be submitted using the PIN associated with the epinephrine product. Only the Acquisition Cost of the drug is eligible for reimbursement. **Do not enter the DIN or a mark-up or a dispensing fee.**

Aside from including the fields indicated in *Section 5.1*, there are additional fields required (or certain exceptions applicable to specific fields) when submitting a claim for reimbursement of epinephrine auto-injection for emergency treatment, namely:

Fields required for reimbursement of all claims for epinephrine auto-injection for emergency treatment (ODB program recipients and non-ODB program recipients):

Fields	Required (Y/N)	Explanation
Intervention Code	Y	**"PS"** = Professional Care Service
DIN/GP#/PIN	Y	Enter the appropriate PIN as per the epinephrine auto-injection administered. Please see the current influenza season's Notice from the Executive Officer on the Ministry's website for the current list of epinephrine auto-injection products that will be funded for this purpose.
Pharmacist's ID code	Y	Pharmacist License #

Fields	Required (Y/N)	Explanation
Professional Fee	Y	Please note that the cost of the epinephrine auto-injection will appear in the Dispensing Fee field of the claim.

Additional fields required for non-ODB recipients:

Fields	Required (Y/N)	Explanation
Intervention Code	Y	**"PS"** = Professional Care Service **"ML"** = Eligibility established – Standard coverage
Patient Gender	Y	"**F**" = female, "**M**" = male
Patient Date of Birth	Y	YYYYMMDD
Client ID # or Code	Y	Ontario Health number
Carrier ID	Y	"**S**"

Claim Validation
Pharmacies are required to keep a record of every dose of publicly funded influenza vaccine administered. Required documentation includes:

- ***Name of Patient***
- ***Name and Lot # of the publicly funded vaccine that was administered***
- ***Time and date the vaccine was administered***
- ***Name and signature of the trained pharmacist who administered the vaccine***
- ***Signed, dated patient consent form***
- ***Written record of influenza immunization provided to the patient***

Pharmacy documentation must be maintained in a readily retrievable format for the purpose of Ministry inspections.
In accordance with O. Reg. 264/16 made under the Drug and Pharmacies Regulation Act ("DPRA"), all pharmacies are required to keep patient records for a period of at least 10 years or until 10 years after the day on which the patient reaches or would have reached the age of 18 years, whichever is longer.

Claim Validation

Pharmacies are required to keep a record of when an epinephrine auto-injection was administered for emergency use following a pharmacist-administered influenza injection. Required documentation includes:

- ***Name and signature of the pharmacist who administered the epinephrine auto-injection***
- ***Name of the epinephrine auto-injection that was administered***
- ***Name of Patient***
- ***Time and date the epinephrine auto-injection was administered***
- ***Cross-reference to the Vaccine Administration claim for the patient receiving epinephrine***

Pharmacy documentation must be maintained in a readily retrievable format for the purpose of Ministry inspections.

In accordance with O. Reg. 264/16 made under the Drug and Pharmacies Regulation Act (“DPRA”), all pharmacies are required to keep patient records for a period of at least 10 years or until 10 years after the day on which the patient reaches or would have reached the age of 18 years, whichever is longer.

Section 7: Professional Pharmacy Services

Overview

The Ontario government compensates pharmacists through the HNS for providing a number of professional pharmacy services.

This section outlines the different programs available and the billing requirements for submitting professional pharmacy services via the Ministry's HNS including:

- MedsCheck Programs (see Section 7.1)
  - MedsCheck Annual Medication Review and Follow-Up
  - MedsCheck Diabetes
  - MedsCheck at Home
  - MedsCheck LTC
- Pharmaceutical Opinion Program (*see* Section 7.2)
- Pharmacy Smoking Cessation Program (*see* Section 7.3)
- Ontario Naloxone Program for Pharmacies (see Section 7.4)
- Reimbursement and Claims Submission using the Health Network System relating to Drugs for Medical Assistance in Dying (see Section 7.5)
- Reimbursement and Claim Submissions for Mifepristone/Misoprostol (Mifegymiso) (see Section 7.6)

Please refer to the Professional Pharmacy Services Guidebook 3.0 for program details and mandatory requirements.

Pharmacists are required to use the fillable Ministry forms and templates, or an adapted version based on the Ministry template. The pharmacy system software must match the Ministry forms and templates exactly unless otherwise specified.

7.1 MedsCheck Program

The Ministry compensates pharmacists for providing professional pharmacy services in its MedsCheck program through a framework developed collaboratively with the Pharmacy Council established under section 1.4 of the ODBA. The program also includes MedsCheck LTC, MedsCheck for Diabetes and MedsCheck at Home.

Ontarians who meet the respective MedsCheck program criteria are eligible for one annual MedsCheck review each year.

MedsCheck medication reviews take place in the community pharmacy. Exceptions apply for the MedsCheck at Home and MedsCheck for LTC.

Pharmacists are required to follow up on potential drug-related problems resulting from all MedsCheck reviews (*see Section 7.2* for the Pharmaceutical Opinion Program (POP)).

Pharmacists may bill for one MedsCheck annual review per patient per year provided patients meet the respective program criteria.

Note: Billing a MedsCheck service without complete documentation or without patient consent or for purposes that are outside of the specified program criteria may be subject to recovery.

Examples of improper billing include MedsCheck for patient monitoring programs, medication reviews conducted over the phone or by video-conferencing, and medication reviews incorporated in medical directives.

The Professional Pharmacy Services Guidebook 3.0 contains further details on the program including:

- eligibility Criteria
- location for service provision (where applicable)
- mandatory requirements, including the completion of the new MedsCheck forms
- documentation requirements for each of these services

MedsCheck Programs

Please see below for a brief description of the various MedsCheck programs. For more information please refer to the Professional Pharmacy Services Guidebook 3.0 :

- MedsCheck Annual
- MedsCheck Follow-up
- MedsCheck for Diabetes

- MedsCheck At Home
- MedsCheck for LTC

Program details and requirements for the MedsCheck programs, including patient acknowledgement of services, the use of a worksheet for the pharmacist's professional notes as well as sharing the MedsCheck personal medication record with the primary physician, are available in the Professional Pharmacy Services Guidebook 3.0.

MedsCheck Annual

The MedsCheck Annual medication review is a one-on-one, in-person medication review between the pharmacist and the patient that takes place in the community pharmacy for patients who are currently taking **a minimum of three prescription medications for a chronic condition.** The MedsCheck annual review will help patients understand their medications (drug names, strengths, adverse effects and usage instructions) and ensure that they are taking them as prescribed and if necessary, with any concerns to be referred to a prescriber. It will also provide patients with an accurate and up to date medication list.

MedsCheck Follow-Up

The MedsCheck follow-up medication review is an additional medication review for those patients who may benefit from a second MedsCheck within the annual time frame due to any of the following criteria:

- A hospital discharge (within two weeks of the discharge)
- A planned hospital admission
- A physician or nurse practitioner referral
- A pharmacist's documented decision due to:
    - Significant changes made to an existing medication profile or the addition of new medications
    - Documented evidence of a patient's non-compliance with a medication plan
    - Patient has changed both his/her place of residence and his/her pharmacy thus necessitating further review of his/her medications by the pharmacist.

The pharmacist must document in writing the reason for the MedsCheck follow-up for the purposes of claim validation.

MedsCheck for Diabetes

The MedsCheck Diabetes program is an annual medication review by a community pharmacist for Ontarians living with type 1 or type 2 diabetes. There is no minimum number of prescription medications that the patient must be taking. Patients may be on fewer than three prescription medications, not yet taking medication for their diabetes or managing their diabetes through diet alone. It provides an opportunity for the pharmacist to engage patients in a focused medication

review including advice, training, blood glucose monitoring and education on diabetes. As many patients living with diabetes may have other medical conditions, pharmacists are expected to provide advice on overall therapy management as well as for diabetes.

Eligible patients may receive a MedsCheck for Diabetes medication review assessment service once per year based on the date that the recipient had his/her previous MedsCheck for Diabetes service. Should a patient require follow-up education and/or communication, the pharmacist will include this plan as part of the annual assessment with the projected monitoring, training, education and communication as appropriate with the patient. Patients targeted for education are eligible for a Diabetes Education service within the same year. The Diabetes Education service does not include a medication review component and the visit must take place at the same pharmacy that provided the MedsCheck for Diabetes service. Once a patient is the recipient of the MedsCheck for diabetes, he/she is not eligible to receive a MedsCheck Annual.

MedsCheck at Home

The MedsCheck at Home medication review program conducted by a community pharmacist is for those patients who are not able to physically attend the community pharmacy in person for a MedsCheck due to their physical and/or mental health condition. Patients who may benefit from the program include those who are at risk of drug therapy problems because of their co-morbidities, age or social circumstances. During the home visit, pharmacists are required to conduct a medicine cabinet review and remove unused and expired drugs for proper disposal at the pharmacy.

MedsCheck for Long-Term Care

The MedsCheck LTC program is a two-part medication review, consisting of quarterly medication reviews and an annual in-depth interdisciplinary medication review. Both medication reviews are conducted in the LTC home by the pharmacist. A copy of the review should be kept on file in the patient's chart at the LTC home.

Confidentiality

Pharmacists are reminded to take all reasonable precautions to ensure personal health information is treated with the greatest sensitivity and to respect the patient's privacy when discussing this information with the patient and/or other health care professionals. (Refer to Section 3.1, Privacy of Patient Information)

Acknowledgement of Services

Patient acknowledgement of professional pharmacy services is facilitated with the use of a mandatory form and, when completed by the patient, confirms the patient's understanding of the MedsCheck service.

This Patient Acknowledgment of Professional Pharmacy Service Form: *(Refer to the Professional Pharmacy Services Guidebook 3.0 for information on Forms)*

- Must be completed annually and provided to the patient; a completed copy is maintained at the pharmacy.
- Aims to build patient awareness and understanding of professional pharmacy services.
- Replaces the patient's signature on the MedsCheck personal medication record.
- May be reproduced / generated by pharmacy software vendors to exactly match the Ministry form.

Pharmacists will ensure the patient has:

- Signed and dated the annual Patient Acknowledgment of Professional Pharmacy Service form to confirm their agreement and understanding of the MedsCheck services.
- Signed the form **before** the pharmacist conducts the MedsCheck service and before the pharmacist bills the Ministry for the MedsCheck service through the HNS.

Residents of LTC homes are exempt from signing the Patient Acknowledgment of Professional Pharmacy Service form.

Claim Requirements for MedsCheck Programs

A claim for payment is submitted on the day the MedsCheck takes place, unless the MedsCheck was conducted outside the pharmacy as in the case of the MedsCheck for LTC or MedsCheck at Home; in these instances, pharmacists may submit the claim for service up to one business day later.

Pharmacists should make every effort to complete a MedsCheck review and submit claims to the Ministry on the same day the patient visits the pharmacy for their consultation. This includes resolving any drug therapy problems that can be immediately addressed and ensuring all required documentation is complete.

The completed signed/dated MedsCheck Personal Medication Record form must be shared with the patient and primary prescriber as soon as possible. Documentation of the MedsCheck should support the date of service submitted. Dates of service that cannot be supported with documentation may be subject to recovery.

Pharmacists must use their Pharmacist ID as the prescriber ID when submitting a claim for a MedsCheck service.

A paper-based system must cross-reference the ODB claims Transaction Number.

Aside from including the fields indicated in Section 5.1, there are additional fields required (or certain exceptions applicable to specific fields) when submitting a claim for a MedsCheck, namely:

Fields required for all MedsCheck claims (ODB/TDP recipients and non-ODB recipients):

Claims for MedsCheck Annual + MedsCheck Follow-up Reviews:

Fields	Required (Y/N)	Explanation
Intervention Code	Y	**"PS"** = Professional Care Service
DIN/GP#/PIN	Y	Enter the appropriate Professional Care Service PIN: 93899979 = MedsCheck Annual 93899981 = MedsCheck Follow-up: Hospital Discharge 93899982 = MedsCheck Follow-up: Pharmacist Decision 93899983 = MedsCheck Follow-up: MD/NP Referral 93899984 = MedsCheck Follow-up: Hospital Admission
Pharmacist's ID code	Y	Pharmacist License #
Professional Fee	Y	MedsCheck Annual fee = $60 per year MedsCheck Follow-up: Hospital Discharge = $25 Pharmacist Decision = $25 MD/RN(EC)Referral = $25 Hospital Admission = $25

Claims for MedsCheck Diabetes Annual + Diabetes Follow-up Reviews:

Fields	Required (Y/N)	Explanation
Intervention Code	Y	**"PS"** = Professional Care Service
DIN/GP#/PIN	Y	Enter the appropriate Professional Care Service PIN:

Fields	Required (Y/N)	Explanation
		93899988 = MedsCheck Diabetes Annual Assessment Summary 93899989 = Diabetes Education Follow-up
Pharmacist's ID code	Y	Pharmacist License #
Professional Fee	Y	MedsCheck Diabetes Assessment: Annual Summary = $75 per year/patient Education Follow-up = $25 (at same pharmacy as diabetes annual assessment)

Claims for MedsCheck at Home:

Fields	Required (Y/N)	Explanation
Intervention Code	Y	**"PS"** = Professional Care Service
DIN/GP#/ PIN	Y	Enter the appropriate Professional Care Service PIN: 93899987 = MedsCheck Home Assessment Summary
Pharmacist's ID code	Y	Pharmacist License #
Professional Fee	Y	MedsCheck Home Assessment Summary: $150 per year/patient

Claims for MedsCheck for residents of LTC Homes:

Fields	Required (Y/N)	Explanation
Intervention Code	Y	**"PS"** = Professional Care Service
DIN/GP#/PIN	Y	Enter the appropriate Professional Care Service PIN: 93899985 = MedsCheck LTC Home resident: Annual payment 93899986 = MedsCheck LTC Home resident: Quarterly monitoring

Fields	Required (Y/N)	Explanation
Pharmacist's ID code	Y	Pharmacist License #
Professional Fee	Y	MedsCheck for LTC Homes residents: Annual payment = $90 once per year Quarterly monitoring = $50 up to 4 per year

Additional fields required for non-ODB/TDP recipients for all types of MedsCheck claims:

Fields	Required (Y/N)	Explanation
Intervention Code	Y	**"PS"** = Professional Care Service **"ML"** = Eligibility established - Standard coverage
Patient Gender	Y	**"F"** = female, **"M"** = male
Patient Date of Birth	Y	YYYYMMDD
Client ID # or Code	Y	Health number
Carrier ID	Y	"S" = Non ODB MedsCheck Service Plan Code

Claim Validation of MedsCheck Claims:
MedsCheck program documentation must be readily retrievable and includes "original records" that could be original paper documents, electronic scanned images of original paper documents or electronic records.
Required documentation that must be available at the pharmacy in a readily retrievable format includes:

- ***MedsCheck Patient Acknowledgement of Professional Pharmacy Services (standardized form). The completed form replaces the patient signature on the final MedsCheck Personal Medication Record.***
- ***Pharmacist's worksheet/professional notes — for every MedsCheck, pharmacists must have professional notes and/or a worksheet. Notes may be shared with the patient and/or primary prescriber on request.***
- ***MedsCheck Personal Medication Record (standardized form). The record must be signed and dated by the pharmacist indicating the date of the consultation and all drug therapy problems must be followed up or have a plan for resolution prior to providing the form to the patient.***
- ***MedsCheck Patient Take-Home Summary. This record, if used or if offered to the patient, must be signed and dated by both the pharmacist and the patient.***

- ***Mandatory Fax/Letter to the primary prescriber (standardized form). Pharmacists must share the MedsCheck record with the primary prescriber using this form, thereby indicating the MedsCheck was shared with the patient's prescriber.***
- ***Other documents, as necessary, as referenced in the Professional Pharmacy Services Guidebook 3.0.***

It is important to document all patient interactions to support payment. Documentation may be requested for inspection purposes. MedsCheck documents must be kept in a readily retrievable format (either electronically or as a hard copy) at the pharmacy. Please note that in accordance with O. Reg. 264/16 made under the Drug and Pharmacies Regulation Act ("DPRA"), all pharmacies are required to keep patient records for a period of at least 10 years or until 10 years after the day on which the patient reaches or would have reached the age of 18 years, whichever is longer.
Note: Billing a MedsCheck service without complete documentation or without patient consent or for purposes that are outside of the specified program criteria may be subject to recovery.
Examples of improper billing include MedsChecks for patient monitoring programs, medication reviews conducted over the phone or by video-conferencing; medication reviews incorporated in medical directives.
Program details and mandatory requirements on the MedsCheck program are detailed in the Professional Pharmacy Services Guidebook 3.0.
The Ministry may recover funds for claims lacking documentation meeting mandatory requirements.

7.2 Pharmaceutical Opinion Program

The Pharmaceutical Opinion Program (POP) refers to the identification by the pharmacist of a potential drug therapy problem during the course of dispensing a new or repeat prescription, or when conducting a MedsCheck medication review.

Pharmacists must follow all the necessary steps as per the POP criteria in order to create a valid billable service. Documentation needs to outline what has occurred.

Steps include:

- Identifying a potential drug therapy problem in the course of filling a new or repeat prescription or when conducting a valid MedsCheck (please see link below for more details).
- Initiating contact with the prescriber to discuss the drug related problem or issue and making a recommendation.

- Documenting the issue (including the main elements of discussion with the prescriber) and outcome (either not filled as prescribed, no change to prescription therapy or change to prescription therapy) on the prescription or on the MedsCheck worksheet.
- Communicating with the patient (or caregiver) of the outcome.
- Updating the MedsCheck medication review if necessary.

As a result of implementing a pharmaceutical opinion, the following outcomes are expected:

Not filled as prescribed. Prescription not filled resulting from a confirmed forged or falsified prescription or not filled due to a clinical concern based on prescriber consultation.

No change to prescription therapy; filled as prescribed. Recommendations by the pharmacist were discussed with the prescriber and no change was made to the prescription therapy. Prescription filled as prescribed; prescription therapy continued as prescribed in the case of a MedsCheck.

Change to prescription therapy. Recommendations by the pharmacist were discussed with the prescriber and led to a change in therapy as prescribed.

To be eligible for a professional services fee, the pharmacist must document and make a recommendation to the prescriber regarding the medication with the intent of achieving objectives of POP outlined in the Professional Pharmacy Services Guidebook 3.0.

Other than a confirmed prescription forgery or falsified prescription, a pharmaceutical opinion may not be claimed if the pharmacist has not made a recommendation to the prescriber.

Note: Only ODB program recipients are eligible for the POP (see *Section 4.1* for ODB Patient Eligibility). All claims will be monitored by the Ministry. Claims submitted for non-ODB program recipients will automatically be recovered from a future ODB payment.

The Professional Pharmacy Services Guidebook 3.0 contains additional details on the program, including:

- Types of prescription interventions in a pharmaceutical opinion
- Definitions of prescription intervention terms or drug therapy problems
- Program restrictions
- Process
- Documentation and recordkeeping
- Contacting the prescriber and communicating with the patient

Claim Requirements for Pharmaceutical Opinion Program

POP claims for payment may only be submitted for ODB program recipients.

A claim for payment is made after:

- The pharmaceutical opinion has occurred
- The patient has been informed
- The prescriber has been contacted
- Documentation is completed and signed by the pharmacist.

All POP claims documentation must be cross-referenced to the prescription or the MedsCheck Personal Medication Record and include the reason for the pharmaceutical opinion.

It is imperative that pharmacists submit POP claims using the appropriate PIN indicating the outcome of the drug therapy intervention that was conducted in relation to the prescription presented or to the MedsCheck medication review.

Pharmacists must use their Pharmacist ID as the Prescriber ID in the HNS system when submitting a POP.

Aside from including the fields indicated in Section 5.1, there are additional fields required (or certain exceptions applicable to specific fields) when submitting a POP claim, namely:

Fields	**Required (Y/N)**	**Explanation**
Intervention Code	Y	**"PS"** = Professional Care Service
DIN/GP#/PIN	Y	Enter the appropriate Professional Care Service PIN: 93899991 = Forgery confirmed / Not Filled 93899992 = No Change to Rx therapy 93899993 = Change to Rx therapy
Pharmacist's ID code	Y	Pharmacist License #
Professional Fee	Y	$15.00

The claim submission follows the same process for submitting a claim for other professional services with the use of a PIN that is associated with the pharmaceutical opinion outcome.

Claim Validation for POP Claims:
Documentation must be on the patient's electronic profile, pharmacist's worksheet or on the prescription hardcopy record. All documentation must be in a readily retrievable format. The use of a pharmaceutical opinion form is also accepted as documentation provided the pharmaceutical opinion is cross-referenced with the original prescription and revised prescription if applicable.

Please note in accordance with O. Reg. 264/16 made under the Drug and Pharmacies Regulation Act (“DPRA”), all pharmacies are required to keep patient records for a period of at least 10 years or until 10 years after the day on which the patient reaches or would have reached the age of 18 years, whichever is longer.
The Ministry may recover funds for claims lacking documentation meeting mandatory requirements.

7.3 Pharmacy Smoking Cessation Program

Community pharmacists are funded by the Ontario Government for their expertise in providing a smoking cessation program to ODB program recipients.

The Pharmacy Smoking Cessation Program is outlined in the Professional Pharmacy Services Guidebook 3.0 and provides an opportunity for community pharmacists to provide a one-to-one support service and advice to ODB program recipients who want to give up smoking. The program includes a readiness assessment where a patient may enroll in the smoking cessation program with the pharmacy as well as a first consultation and a number of follow-up counselling sessions over a one-year period.

Please note that pharmacists are required to take a smoking cessation training program to ensure that they have a basic level of training, including training on motivational interviewing strategies, more involved smoking cessation counselling and quit smoking planning.

The Professional Pharmacy Services Guidebook 3.0 provides further details on the program.

The Ministry website outlines form requirements for the Pharmacy Smoking Cessation Program.

Claim Requirements for Pharmacy Smoking Cessation Program

Smoking cessation claims for payment may only be submitted for ODB program recipients.

The claim submission follows the same process for submitting a claim as the MedsCheck Program by using a special product identification number (PIN).

A claim is submitted after the first meeting provided that the readiness assessment is completed, agreement is signed, and consent is signed.

Claims are submitted after the follow-up sessions.

Pharmacists must use their Pharmacist ID as the prescriber ID when submitting a claim for the Pharmacy Smoking Cessation Program.

Point of Contact	PIN	Reimbursement
Readiness Assessment (May only be claimed once per year)	93899941	$40
Primary Follow-up Sessions (May be claimed three times per year)	93899942	$15
Secondary Follow-up Session (May be claimed four times per year)	93899943	$10

Program Evaluation Tracking

A claim for evaluation is made using the appropriate PIN after documentation is complete and the pharmacist is made aware of the program quit status of the patient. The program evaluation PIN should be submitted on the date the pharmacist is made aware of the program quit status. Once a program evaluation PIN is claimed, no further meetings are billable for the program period.

Only one of the three program evaluation PINs is claimed per patient per year:

Outcome	PIN	Reimbursement
Patient succeeded in quitting smoking (may be claimed once per year if applicable)	93899944	$0
Patient did not succeed in quitting smoking (may be claimed once per year if applicable)	93899945	$0
Patient quit smoking status is unknown (may be claimed once per year if applicable)	93899946	$0

Claim Validation
Each point of contact and/or meeting between the pharmacist and the patient must be documented to ensure program continuity and for the purposes of counselling, support, data analysis, evaluation and claims adjudication.
Using the Ministry template forms as a minimum standard, full documentation is required of all pharmacist/patient engagement including patient readiness, patient consent and agreement terms, first consultation meeting, follow-up counselling sessions and any incidence of program withdrawal.
Follow-up meetings may be in-person, by telephone, electronic messaging or other agreed upon method of communication. The method and location of these meetings must be included in the documentation.
Smoking cessation documents and associated patient records including any written referrals and patient consent documentation; drug therapy information and desired outcomes / action plans; and specifics on quit smoking plans and advice offered to the patient must be retained by the pharmacist in a readily retrievable format for inspection purposes.
Please note, in accordance with O. Reg. 264/16 made under the Drug and Pharmacies Regulation Act (“DPRA”), all pharmacies are required to keep patient records for a period of at least 10 years or until 10 years after the day on which the patient reaches or would have reached the age of 18 years, whichever is longer.
A copy of the completed smoking cessation training program by the pharmacist should also be readily retrievable at the pharmacy for purposes of an inspection.
Pharmacy records that are associated with the claims submission of professional services using the ODB HNS PIN mechanism are subject to inspection and must be maintained in the pharmacy.
The Ministry may recover funds for claims lacking documentation meeting mandatory requirements.

7.4 Ontario Naloxone Program for Pharmacies

On June 24, 2016, the National Association of Pharmacy Regulatory Authorities (NAPRA) finalized the scheduling change for naloxone hydrochloride injection (naloxone). Naloxone, when indicated for emergency use for opioid overdose outside hospital settings, is now classified as a Schedule II drug in the NAPRA’s National Drug Schedule (NDS).

As a result, effective June 24, 2016, naloxone **no longer requires a prescription** to be sold in Ontario pharmacies if indicated for emergency use for opioid overdose outside hospital settings. All pharmacies receive reimbursement for providing naloxone emergency kits by submitting claims through the HNS. Effective March 27, 2018, intra-nasal naloxone spray (INNS) (Narcan® Nasal Spray) is publicly funded allowing eligible recipients a choice between injectable naloxone and INNS kits.

If you have any questions, please contact the Ministry by email at PublicDrugPrgrms.moh@ontario.ca or the ODB Help Desk at 1-800-668-6641.

Pharmacy Compliance

A notice from the Executive Officer and the accompanying FAQs constitute a Ministry policy that pharmacy operators must comply with when submitting claims through the HNS for providing naloxone kits. Compliance with the Ministry policy is required under the HNS Subscription Agreement for Pharmacy Operators.

Eligibility:

All pharmacies are eligible to provide naloxone injectable or INNS emergency kits, through the Ontario Naloxone Program for Pharmacies (ONPP), at no cost to eligible persons, if certain terms and conditions are met. Criteria for an 'eligible person' include:

- A person who is either currently using opioids or is a past opioid user who is at risk of returning to opioid use, or
- A family member, friend or other person in a position to assist a person at risk of overdose from opioids.

Eligible recipients have the choice between injectable naloxone and INNS kits.

Also, effective March 27, 2018, in limited circumstances, pharmacists may:

- Provide naloxone kits to Ontarians who do not have an Ontario Health number or to those who do not wish to provide identification; and
- Provide two naloxone kits to an eligible recipient at one time.

Procedures for Providing and Billing

The Ontario Pharmacists Association (OPA) has developed an online education module and a guidance document for the providing or selling of naloxone available on their website. There may be other resources available to pharmacists. The pharmacist who provides the publicly funded naloxone kit must be identified in the pharmacist field on the claim submitted for

payment through the HNS using the appropriate PIN that was provided. Pharmacists, where possible, must ensure that the quarterly report-back form (available at: www.health.gov.on.ca/en/pro/programs/drugs/opdp_eo/eo_communiq.aspx) relating to outcomes for individuals who were provided a naloxone kit, is completed and returned to the Ministry by 30 days after end of each quarter in a fiscal year. Please refer to the FAQs for details on the reporting schedule.

The Ministry does not provide pre-made kits. Pharmacies may procure pre-made naloxone kits or the required supplies to assemble the injectable and INNS kits through usual and/or other local suppliers. All kits shall be assembled by a pharmacist, or a person under the supervision of a pharmacist.

Each injectable naloxone kit must include:

- One hard case;
- Two 1 mL ampoules or vials of naloxone hydrochloride 0.4 mg/mL injection;
- Two safety engineered syringes with 25 g one-inch needles attached;
- Two safe ampoules opening devices (also known as 'breakers', 'snappers', or 'openers');
- One rescue breathing barrier;
- One pair of non-latex gloves;
- One card that identifies the person trained to give the naloxone; and
- One updated instructional insert (English and French).

Each intra-nasal naloxone spray (INNS) kit must include:

- One hard case (preferred zippered hard black case with red 'naloxone' cross);
- Two doses of 4mg/0.1mL naloxone hydrochloride intra nasal spray;
- One rescue breathing barrier;
- One pair of non-latex gloves;
- One card that identifies the person trained to give the naloxone; and
- One updated instructional insert (English and French).

The list of items for both kits can be found at: www.opatoday.com/professional/naloxone_kit_tools.

Pharmacies are encouraged to seek out local suppliers for obtaining components required for pharmacy-assembled naloxone kits. Local suppliers are the usual manufacturers, distributors or wholesalers that pharmacies go to to procure medications for their pharmacy. For more information, please refer to the Ontario Pharmacists Association website at: https://www.opatoday.com/professional/naloxone_kit_tools. Additionally, pharmacies must

print the instructional insert for replacement in existing naloxone kits. (Available at: www.health.gov.on.ca/en/pro/programs/drugs/opdp_eo/eo_communiq.aspx)

Pharmacy Eligibility

All pharmacies that comply with the requirements of this Ministry policy are able to provide emergency naloxone kits, and bill the cost of those kits to the Ministry through the HNS.

Prior to providing naloxone kits to eligible persons, pharmacies must ensure that their pharmacists are trained to provide the necessary training to eligible persons who are to receive the naloxone kits.

Pharmacy Record Requirements

Standard record keeping requirements under current standards of practice apply. Pharmacies must keep a record when the naloxone kit (see table below) is provided to the eligible recipient. Pharmacists must keep records consistent with their obligations under the *Pharmacy Act, 1991*, the *Drug and Pharmacies Regulation Act* and any guidance (i.e., Documentation Guidelines) provided by the Ontario College of Pharmacists or the Ministry.

For billing purposes, pharmacy records must be maintained in a readily available format for claim validation for a minimum of 2 years.

In accordance with O. Reg. 264/16 made under the Drug and Pharmacies Regulation Act ("DPRA"), all pharmacies are required to keep patient records for a period of at least 10 years or until 10 years after the day on which the patient reaches or would have reached the age of 18 years, whichever is longer.

Pharmacy Billing Procedure

Naloxone emergency kits are reimbursed by the Ontario government in accordance with Ministry policy. The PINs listed below are to be used whenever an emergency naloxone kit is supplied to an eligible person, regardless of the person's eligibility under the ODB program.

PINs to support reimbursement of Naloxone emergency kits:

PIN	Description	Dosage Form	Total Amount Reimbursed

93877255	Intra-Nasal Naloxone Kit ▪ $110 – naloxone kit ▪ $10 – professional fee	Intra-Nasal	$120.00
93877251	Initial Injectable Naloxone Kit ▪ $35 – naloxone kit ▪ $10 – professional fee ▪ $25 – training fee	Injectable	$70.00
93877252	Replacement Injectable Naloxone Kit (or initial kit with no training) ▪ $35 – naloxone kit ▪ $10 – professional fee	Injectable	$45.00
93877256	Two Intra-Nasal Naloxone Kits (one professional fee only) ▪ $220 – two naloxone kits ▪ $10 – professional fee	Intra-Nasal	$230.00
93877257	Two Injectable Naloxone Kits (one initial and one replacement kit with one professional fee only) ▪ $70 – two naloxone kits ▪ $10 – professional fee ▪ $25 – training fee	Injectable	$105.00
93877258	Two Injectable Naloxone Kits (two replacement kits with one professional fee only) ▪ $70 – two naloxone kits ▪ $10 – professional fee	Injectable	$80.00

Claims must be submitted using the Ministry assigned PIN associated with the naloxone emergency kit and service provided. **Do <u>not</u>** use the DIN of the naloxone that is contained in the naloxone kit.

For Ontario Drug Benefit eligible recipients:

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

- Intervention code **"PS"** = Professional Care Services

- PIN: see table above for list of PINs
- Valid Pharmacist ID
- Professional Fee: see table above for 'Maximum Reimbursed Amount' for each kit

For non- Ontario Drug Benefit eligible recipients WITH an Ontario Health number:

When submitting a claim for an eligible person who does not have ODB coverage, pharmacists must submit the following information:

- Person's Gender: **"F"** = female; **"M"** = male
- Person's Date of Birth: Valid YYYYMMDD
- Person's Ontario Health number
- Intervention codes:
    - **"PS"** = Professional Care Services
    - **"ML"**: Established eligibility coverage (i.e., 1 day of the Plan 'S' coverage)
- Carrier ID: **"S"**
- PIN: see table above for list of PINs
- Valid Pharmacist ID
- Professional Fee: see table above for 'Maximum Reimbursed Amount' for each kit

For non- Ontario Drug Benefit eligible recipients WITHOUT an Ontario Health number:

When submitting a claim for an eligible person who does not have an Ontario Health number, pharmacists must submit the following information:

- First Name: HARM
- Last Name: REDUCTION
- Person's Gender: 'F' = female; 'M' = male; (or) Blank
- Person's Date of Birth: Valid YYYYMMDD (if known) or 20000101
- Proxy patient ID: 89999 999 91
- Intervention codes: PS (Professional Care Services)
- Product Identification Number (PIN)
- Valid Pharmacist ID
- Maximum Reimbursement Amount

Restrictions:

In addition to the maximum of two naloxone kits, the recipient must be an eligible person. An eligible person includes:

- A person currently using opioids; and
- Past opioid user at risk of returning to opioid use; and

- Family member, friend or other person in a position to assist at-risk person.

For further information please refer to the following:
http://www.health.gov.on.ca/en/pro/programs/drugs/naloxone/

For further information on naloxone and the ONPP, please refer to the EO Notice and FAQs on naloxone posted on the Ministry's website in August 2016:
http://www.health.gov.on.ca/en/pro/programs/drugs/opdp_eo/eo_communiq.aspx

Pharmacy Compliance

As of March 27, 2018, all pharmacies are eligible to provide naloxone kits with intra-nasal naloxone at no cost to eligible persons, if certain terms and conditions are met.

The Executive Officer's notice and the accompanying updated FAQs constitute a Ministry policy that pharmacy operators must comply with when submitting claims through the HNS. Compliance with the Ministry policy is required under section 3.2 of the HNS Subscription Agreement for Pharmacy Operators.

7.5 Reimbursement and Claims Submission using the Health Network System relating to Drugs for Medical Assistance in Dying

Overview

The Executive Officer has issued a notice that provides information to pharmacies regarding reimbursement and claim submissions for drugs used for Medical Assistance in Dying (MAID) using the HNS. This notice is available on the Ministry's website.

In addition, the CPSO, the College of Nurses of Ontario (CNO), and the OCP have each established MAID policies for their members.

Pharmacists and other dispensers must be familiar with the policies provided by their respective professional colleges. The colleges' policies can be found on their respective websites:

- Ontario College of Pharmacists: www.ocpinfo.com

- College of Physicians and Surgeons of Ontario: www.cpso.on.ca
- College of Nurses of Ontario: www.cno.org

You can also access the Ministry's website for more information: www.ontario.ca/page/medical-assistance-dying-and-end-life-decisions or email at endoflifedecisions@ontario.ca.

Pharmacy Compliance

The Executive Officer's notice and the accompanying FAQs constitute a Ministry policy that pharmacy operators must comply with when submitting claims through the HNS for dispensing drugs used in MAID. Compliance with the Ministry policy is required under section 3.2 of the HNS Subscription Agreement for pharmacy operators.

MAID Drug Protocols

Pharmacists should work with prescribers and patients to determine the appropriate MAID drug regimen for individual cases.

Prescribers should refer to their regulatory college for guidance regarding the drug protocols for the provision of MAID.

- CPSO: www.cpso.on.ca
- CNO: www.cno.org
- OCP: www.ocpinfo.com

Patient Eligibility

Federal legislation on MAID came into force on June 17, 2016. The legislation establishes eligibility requirements and requires that certain safeguards be met in the provision of MAID.

Providers are encouraged to contact their respective regulatory college for more information and guidance.

Procedures for Dispensing and Billing

Pharmacists must ensure that the eligible person's correct date of birth, Ontario Health number (or ODB eligibility number) and name (as it appears on the Ontario Health card or ODB eligibility documentation) are entered accurately as part of the HNS claims submission, as applicable. Failure to do so, especially for non-ODB individuals, may impact the ability to submit future claims for these individuals.

Pharmacies will purchase drug(s) and the required supplies to assemble the MAID kits in accordance with the table below.

Drugs for MAID provided to patients (based on the regimen prescribed) will be reimbursed by the Ministry. The PINs are used for both ODB-eligible recipients as well as non-ODB patients for the purposes of billing the value of the drugs.

Pharmacy Documentation Requirements for MAID drugs

Standard documentation requirements for prescriptions apply. Pharmacists shall keep records consistent with their obligations under the *Pharmacy Act, 1991*, DPRA, NSAA and any instructions provided by the OCP or the Ministry.

For billing purposes, pharmacy documentation must be maintained in a readily available format for the purpose of the Ministry inspection for a minimum of 2 years.

In accordance with O. Reg. 264/16 made under the Drug and Pharmacies Regulation Act ("DPRA"), all pharmacies are required to keep patient records for a period of at least 10 years or until 10 years after the day on which the patient reaches or would have reached the age of 18 years, whichever is longer.

PINs to support reimbursement of MAID kits

PIN	Description	Contents in MAID Kit*	Total Amount Reimbursed
93877101	MAID intravenous (IV) Kit with Supplies	Midazolam 1mg/mL Lidocaine 2% (without epinephrine) Magnesium sulfate 500mg/mL Propofol 10mg/mL Cisatracurium besylate 2mg/mL Rocuronium bromide 10mg/mL Sodium chloride (NaCl 0.9%) Syringes and tubes	$325.00

PIN	Description	Contents in MAID Kit*	Total Amount Reimbursed
93877102	MAID IV Kit (backup) with Supplies	Same as above	$325.00
93877103	MAID IV Kit with Phenobarbital and Supplies	Midazolam 1mg/mL Lidocaine 2% (without epinephrine) Magnesium sulfate 500mg/mL Propofol 10mg/mL Phenobarbital 120mg/mL Cisatracurium besylate 2mg/mL Rocuronium bromide 10mg/mL Sodium chloride (NaCl 0.9%) Syringes and tubes	$999.00
93877104	MAID IV Kit (backup) with Phenobarbital and Supplies	Same as above	$999.00
93877105	MAID Self-Administration Kit (Hydromorphone/Morphine)	Metoclopramide 10 mg Ondansetron 8 mg Propranolol 40 mg Morphine sulfate (liquid) Morphine sulfate 30 mg Hydromorphone 1 mg/mL liquid	$110.00

PIN	Description	Contents in MAID Kit*	Total Amount Reimbursed
		Hydromorphone 8 mg	
93877106	MAID Self-Administration Kit (Phenobarbital)	Metoclopramide 10 mg Ondansetron 8 mg Phenobarbital 20 g Chloral hydrate 20 g Morphine sulfate 3 g Haloperiodol 5mg/mL	$250.00

**Dispensers need to ensure that they select the appropriate quantities, package sizes, and brand of the product from the applicable guidelines and protocols.*

Claims must be submitted using the Ministry-assigned PIN associated with the appropriate MAID kit dispensed. Do not use DINs of the products in each MAID kit.

Note: For MAID kits, a primary kit and a back-up kit are to be dispensed at the same time for a patient. For MAID intravenous (IV) Kits, the back-up kit will have the same drugs as the primary kit. For example, primary is PIN 93877101 and the backup is PIN 93877102. For MAID Self-Administered kit, one of the MAID IV (backup) kits may be used (i.e., PIN 93877102, PIN 93877104). Unused drugs are to be returned to the pharmacy for appropriate disposal.

The PINs listed in the table are to be used by all Ontarians, regardless of eligibility for the ODB program.

For ODB-eligible recipients

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

- Intervention code **'PS'**: (Professional Care Services)
- PIN: see table above for list of PINs
- Valid Pharmacist ID
- Professional Fee: The actual Acquisition Cost of the MAID kit

For Non-ODB eligible recipients

When submitting a claim for a person who does not have ODB coverage, pharmacists must submit the following information:

- Patient Gender: **"F"** = female; **"M"** = male
- Patient Date of Birth: Valid YYYYMMDD
- Patient's Ontario Health number
- Intervention codes:
- **"PS"**: Professional Care Services
- **"ML"**: Established eligibility coverage (i.e., 1 day of the Plan 'S' coverage)

Note: for MAID IV kits ((i.e., PIN 93877103 and PIN 93877104) by manual (paper) claims:

- **"PS"**: Professional Care Services
- **"ML"**: Established eligibility coverage (i.e., 1 day of the Plan 'S' coverage)
- **"MO"**: Valid Claim - value $500.00 to $999.99
- Carrier ID: **"S"**
- Product Identification Number (PIN): see table above for list of PINs
- Valid Pharmacist ID
- Professional Fee: The actual Acquisition Cost of the MAID kit

Restrictions

Only the drugs provided in the MAID kits will be reimbursed.

7.6 Reimbursement and Claim Submissions for Mifepristone / Misoprostol (Mifegymiso)

Ontario publicly funds the drug Mifegymiso (combination mifepristone/misoprostol) for eligible patients.

Overview

On January 10, 2017, Mifepristone/misoprostol (Mifegymiso) was approved for use in Canada to achieve a medical abortion in early pregnancy (i.e., with a gestational age up to 63 days or within 63 days of last menstrual period).

The medication induces a miscarriage-like process and no surgical intervention is required.

Mifepristone/misoprostol (Mifegymiso) is recognized as a positive step in supporting autonomy for reproductive health, provides an alternative to surgical abortions, and expands access to care.

Mifepristone/misoprostol (Mifegymiso) is manufactured by Linepharma International Limited, and is distributed in Canada by Celopharma Inc.

The OCP has established a guidance document for its members at www.ocpinfo.com/library/practice-related/download/Dispensing_Mifegymiso.pdf.

In addition, CPSO also has issued a guidance document for its members at www.cpso.on.ca/Policies-Publications/Positions-Initiatives/Mifegymiso.

Similarly, CNO has issued information for its members at www.cno.org/en/news/2017/july-2017/what-nps-should-know-about-mifegymiso

On May 18, 2017, Health Canada issued a Dear Healthcare Professional Letter to clarify the different requirements and steps to follow in order to prescribe, order, stock, and/or dispense Mifepristone/misoprostol (Mifegymiso). The letter is available at: http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2017/63330a-eng.php

Pharmacy Compliance

The Executive Officer's notice on Mifepristone/misoprostol (Mifegymiso), available on the Ministry's website, and the accompanying FAQ constitute a Ministry policy that pharmacy operators must comply with when submitting claims through the HNS for dispensing Mifepristone/misoprostol (Mifegymiso). Compliance with the Ministry policy is required under the HNS Subscription Agreement for Pharmacy Operators.

Regulatory Guidance

Pharmacists should work with prescribers and patients to determine the appropriateness of prescribing Mifepristone/misoprostol (Mifegymiso) for individual patients.

Prescribers should refer to their respective regulatory college (i.e., CPSO, CNO) for any guidance and policies regarding the appropriate prescribing and patient monitoring related to Mifepristone/misoprostol (Mifegymiso).

Patient Eligibility

All Ontarians with a valid Ontario Health number and a valid prescription are eligible for Mifepristone/misoprostol (Mifegymiso).

This includes ODB recipients and non-ODB recipients.

Procedures for Dispensing and Billing

Pharmacists must ensure the eligible person's correct date of birth, Health number and name (as it appears on the Ontario Health Card) are entered accurately as part of the HNS claims submission.

Pharmacy Documentation Requirements

Standard documentation requirements for prescriptions apply. Pharmacists shall keep records consistent with their obligations under the *Pharmacy Act, 1991*, the *Drug and Pharmacies Regulation Act*, and any further instructions provided by the OCP and the Ministry.

For billing purposes, pharmacy documentation must be maintained in a readily available format for the purpose of Ministry inspections for a minimum of 2 years.

In accordance with O. Reg. 264/16 made under the Drug and Pharmacies Regulation Act ("DPRA"), all pharmacies are required to keep patient records for a period of at least 10 years or until 10 years after the day on which the patient reaches or would have reached the age of 18 years, whichever is longer.

Pharmacy Billing Procedure

Mifepristone/misoprostol (Mifegymiso) supplied to patients with a valid Ontario Health number and a valid prescription will be reimbursed by the Ministry. The DIN is to be used for both ODB-eligible recipients and non-ODB eligible patients for billing purposes.

Pharmacies will be reimbursed for supplying Mifepristone/misoprostol (Mifegymiso) in accordance with the table below.

DIN	Description	Total Amount Reimbursed (includes mark-up and dispensing fee)
02444038	Mifepristone/misoprostol (Mifegymiso)	$337.25

Ontario Drug Benefit Eligible Recipients

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

- Intervention code '**PS**': (Professional Care Services)
- DIN: 02444038
- Valid Pharmacist ID
- Professional Fee: $337.2500 (includes mark-up and dispensing fee)

Non-Ontario Drug Benefit Eligible Recipients

When submitting a claim for a person who does not have ODB coverage, pharmacists must submit the following information:

- Patient Gender: '**F**' = female; **"M"** = male
- Patient Date of Birth: Valid YYYYMMDD
- Patient's Ontario Health number
- Intervention codes:
- PS: Professional Care Services
- ML: Established eligibility coverage (i.e., 1 day of the Plan 'S' coverage)
- Carrier ID: '**S**'
- DIN: 02444038
- Valid Pharmacist ID
- Professional Fee: $337.2500 (includes mark-up and dispensing fee)

Restrictions

Only Mifepristone/misoprostol (Mifegymiso) supplied to an eligible patient with a valid prescription will be reimbursed.

7.7 Valved Holding Chambers

Effective January 1, 2018, Ontario publicly funds select Valved Holding Chambers (VHC) through the ODB program for eligible recipients (see Restrictions below)

Overview

Valved holding chambers are used in conjunction with metered-dose inhalers to deliver inhaled asthma medications. A VHC 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.

Pharmacy Billing Procedure

This is the list of the funded VHCs and the amount reimbursed by the Ministry (subject to change and communicated to pharmacies via email to the pharmacy's ONE® Mail account). You can select "Valved Holding Chambers" from the Coverage Status drop down menu at: https://www.formulary.health.gov.on.ca/formulary/

PIN	PIN Description	Manufacturer	Amount MOHLTC Pays
09858012	AeroChamber Plus Flow-Vu Anti-Static Valved Holding Chamber Infant Small Mask	Trudell Medical International	$37.6700
09858013	AeroChamber Plus Flow-Vu Anti-Static Valved Holding Chamber Child Medium Mask	Trudell Medical International	$37.6700
09858014	AeroChamber Plus Flow-Vu Anti-Static Valved Holding Chamber Youth Mouthpiece	Trudell Medical International	$23.5500
09858015	AeroChamber Plus Flow-Vu Anti-Static Valved Holding Chamber Girls Mouthpiece	Trudell Medical International	$23.5500
09858016	AeroChamber Plus Flow-Vu Anti-Static Valved Holding Chamber Adult Mouthpiece	Trudell Medical International	$23.5500
09858017	AeroChamber Plus Flow-Vu Anti-Static Valved Holding Chamber Adult Small Mask	Trudell Medical International	$39.8600
09858018	AeroChamber Plus Flow-Vu Anti-Static Valved Holding Chamber Adult Large Mask	Trudell Medical International	$39.8600
09858005	A2A Aerosol to Airways Spacer	Clement Clarke International Limited	$9.0000
09858006	A2A Spacer with Small Mask	Clement Clarke International Limited	$12.0000
09858007	A2A Spacer with Medium Mask	Clement Clarke International Limited	$12.0000
09858001	InspiraChamber	INSPIRX INC.	$23.5500
09858002	InspiraChamber + Mask Small	INSPIRX INC.	$37.6700
09858003	InspiraChamber + Mask Medium	INSPIRX INC.	$37.6700
09858004	InspiraChamber + Mask Large	INSPIRX INC.	$39.8600

09858008	Optichamber Diamond Valved Holding Chamber	Respironics Respiratory Drug Delivery (UK) LTD.	$16.3400
09858009	Optichamber Diamond Valved Holding Chamber + Small Mask	Respironics Respiratory Drug Delivery (UK) LTD.	$27.9300
09858010	Optichamber Diamond Valved Holding Chamber + Medium Mask	Respironics Respiratory Drug Delivery (UK) LTD.	$27.9300
09858011	Optichamber Diamond Chamber + Large Mask	Respironics Respiratory Drug Delivery (UK) LTD.	$30.7800

The Ministry will reimburse pharmacies the amount identified in the column "Amount MOHLTC Pays" in the Formulary plus a mark-up of 8% and the applicable ODB dispensing fee. There is no cost to the recipient.

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

In accordance with O. Reg. 264/16 made under the Drug and Pharmacies Regulation Act ("DPRA"), all pharmacies are required to keep patient records for a period of at least 10 years or until 10 years after the day on which the patient reaches or would have reached the age of 18 years, whichever is longer.

ODB-eligible Recipients

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

- Product Identification Number (PIN): Select the appropriate PIN from the table above or Formulary
- Quantity: Submit the value as "1"
- Days' Supply: Submit the value as "1" (or any other value up to 100)

Restrictions

Only ODB-funded VHCs supplied to an ODB eligible recipient with a valid prescription from a physician or nurse practitioner will be reimbursed. ODB eligible recipients aged 12 years and younger are entitled to receive one (1) valved holding chamber (with or without mask/mouthpiece) per 365-day period. ODB recipients aged 13 years and older are not eligible for ODB-funded valved holding chambers.

If a VHC claim is submitted for an ODB recipient aged 13 years and above, the claim will be rejected with the following response code:

Response Code	Message Description	Explanation of condition generating response code
"CD"	Patient Not Entitled to Drug Claimed	VHC is not a benefit based on the information provided on the claim (i.e., recipient is 13 years of age or over).

If a VHC claim is submitted that exceeds the claim count limit of one per 365-day period, the claim will be rejected with the following response code:

Response Code	Message Description	Explanation of condition generating response code
"LO"	Maximum Benefit Exceeded	This response code indicates that the recipient has exceeded his/her maximum benefit and cannot receive another VHC. A message data line* will be included to indicate the date of when the next VHC can be claimed.

HNS Response Message Data Line for VHC Claims

Example: "Remaining Qty: 0 until OCT 15, 2019"

Section 8: Paper Drug Benefit Claim Submissions and Drug Benefit Claim Reversals

Overview

The HNS is designed to process online transactions for prescriptions dispensed on any the most recent seven calendar days, including the current date.

If more than seven calendar days have elapsed, the pharmacy must submit their claim for payment or claim reversal manually with a paper-based submission, provided that the claim for payment/claim reversal meets one of the conditions for submission set out in Section 24 of O. Reg. 201/96 made under ODBA.

Please note, the Ministry is proposing to extend the submission window for electronic drug claim reversals from seven days to 90 days. If the proposed changes are approved, pharmacies would be notified by an EO Notice and via email to the pharmacy's ONE® Mail account.

This section outlines specific instructions for submission of a paper claim/reversal transaction:

Conditions that require the use of paper Drug Benefit Claim Submission and Drug Benefit Claim Reversal forms (*see Section 8.1*)

Features of the Drug Benefit Claim Submission and Drug Benefit Claim Reversal forms (*see Section 8.2*)

How to complete the Drug Benefit Claim Submission and Drug Benefit Claim Reversal forms (*see Section 8.3*)

Supporting documentation required (*see Section 8.4*)

8.1 When to Submit a Paper Drug Benefit Claim Submission and Drug Benefit Claim Reversal Forms

Subsection 24(2) of the O. Reg. 201/96 under the ODBA sets out the circumstances under which claim reversals (i.e., claim cancellations) and claims for payment may be submitted on paper to the Ministry.

The following claims may be submitted on paper:

- A claim for payment submitted to the Ministry more than seven days after the drug is supplied because proof that the drug is for an eligible person was not provided to the operator of the pharmacy or physician who supplied the until that time.
- A claim for payment that requires more than two intervention codes as set out in this Reference Manual.
- A claim for payment where the amount claimed is $10,000 or more (see *Section 6.4*).
- A claim for payment for an extemporaneous preparation where the claimed compounding time is 100 minutes or more.
- A claim reversal that is made more than seven days after the day the original claim to which the claim reversal relates was submitted.
- A claim for payment that is determined by the Ministry to be eligible for submission following a review by the Ministry or an inspection.
- A claim for payment that is submitted in accordance with subsection 26(3) of O. Reg. 201/96.

If more than seven days have passed since the original online or paper claim was processed, a paper claim reversal (i.e., claim cancellation) must be submitted for the following reasons:

- Overpayment has occurred
- A prescription was not picked up
- A claim was submitted in error
- A cancellation is required for another reason

Paper claim reversals must be submitted as soon as possible after the pharmacy becomes aware of one of these occurrences.

Note: Most paper claims for payment must be submitted within six months of the day on which the service giving rise to the claim was provided.

8.2 Paper Drug Benefit Claim Submission and Drug Benefit Claim Reversal Forms

To submit a paper drug benefit claim or drug benefit claim reversal, the pharmacy must complete a Drug Benefit Claim Submission form or Drug Benefit Claim Reversal form and forward it to:

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

The Drug Benefit Claim Submission and Drug Benefit Reversal forms are available on the Ontario Drug Benefits Forms website.

Drug Benefit Claim Submission and Drug Benefit Claim Reversal Forms Fields

The following table provides detailed descriptions of Drug Benefit Claim Submission and Drug Benefit Claim Reversal forms fields:

The asterisk (*) indicates optional fields required in certain situations.

Fields	Explanation
Resubmission Number*	Number assigned to rejected claims, as shown on the *Reject Report for Paper Submissions* (see *Section 11.2*) Must be provided (together with the Original Client ID/Code) when resubmitting a previously rejected claim.[1]
Provider Transaction Date*	Date (YYYYMMDD) of service
Pharmacy ID*	Unique identification number assigned to the pharmacy (*see Section 2.1*)
Client ID/Code (ODB Eligibility/ Health No.), Version*	Recipient identification number. Note: If Eligibility Number is different, the Health number must be provided. (*See Section 4 for more details*.)
Reason for Submission*	Select one or more of the following:

Fields	Explanation
	More than seven days have elapsed from the date of service, because proof that the drug is for an ODB-eligible person was not available before Amount being claimed exceeds $9,999.99

[1]Note: Additional data requirements include Provider Transaction Date, Pharmacy ID, and only the information needed to correct the previously rejected claim.

Claim Reversal Information (pertains to the original paid claim)

Fields	Explanation
Pharmacy I.D.*	Unique identification number assigned to the pharmacy (*see Section 2.1*)
Date Range of Clams to be Reversed	The start of transaction date and end of transaction date on the batch of reversals.
Total Reversal Amount*	Total amount of "Amount Billed to ODB"
Number of Pages Submitted (Including this form)	Total number of Drug Benefit Reversal Form pages being submitted.
Transaction Date	Date (YYYYMMDD) of service
Client ID/Code (ODB Eligibility/ Health No.)	Recipient identification number. Note: If Eligibility Number is different, the Health number must be provided. (See Section 4 for more details.)
Current Prescription Number	Prescription number of the claim to be reversed.
DIN/PIN	Drug Identification Number or Product Identification Number
Amount Billed to ODB	Amount paid for the claim to be reversed.
Claim Reversal Intervention/Exception Codes*	Select the applicable intervention/exception code(s) for the claim to be reversed.
Authorized Signature	Original signature of an individual who has been included in the List of Parties with Signing Authority section on the OPDP Application.

Claim Submission Information

Beneficiary Information:

Fields	Explanation
Patient First Name*	First name of patient
Patient Last Name*	Last name of patient
Middle Initial	Initial of patient's middle name
Patient Date of Birth*	Birthdate (YYYYMMDD) of patient Must be provided when a photocopy of the Eligibility Card is attached or when Carrier ID = H or E is specified, (*see Eligibility Establishment Summary Chart in Section 4.2*.)
Sex*	Must be provided when a photocopy of the Eligibility Card is attached or when a Carrier ID=H or E is specified, (*see Eligibility Establishment Summary Chart*.)
Carrier ID (Plan Code)*	Identifies the appropriate plan code, (*see Eligibility Establishment Summary Chart*.)
Group No./Code* (LTC home ID or HSC ID)	LTC or HSC home number (see *LTC and HSC list*) must be provided when services are rendered to recipients from LTC homes or HSC.
Ontario Health number * If different from ODB Eligibility No	**Note**: If ODB Eligibility number is different, the Health number must be provided. (*See Section 4 for more details*.)
Version	Ontario Health number version

Prescription Service Information:

Fields	Explanation
DIN/PIN*	Drug Identification Number or Product Identification Number
Current Prescription Number*	Unique prescription number
Quantity*	Quantity dispensed. Field allows one decimal place (e.g., 6 ½ tablets = 00006.5)
Day(s) Supply*	Number of days supplied by the prescription

Fields	Explanation
Prescriber ID*	Prescriber license number
Prescriber ID Ref.*	Reference number for prescriber, (*see Prescriber ID Reference Chart* in *Section 5.1*)
Drug Cost/Product Value*	Total drug cost
Cost upcharge*	Enter the mark-up amount, 8% when the total drug cost is less than $1,000.00 or 6% when the total drug cost is greater than or equal to $1,000.00. Can be equal to 0.
Professional Fee*	Pharmacist's fee for professional services (i.e., the lesser of the pharmacist's usual/customary fee or the current ODB fee). Can be equal to 0.
SSC	Enter "U" if submitting a claim for a child/youth 24 years of age and under who does not have a private plan (i.e., OHIP+ eligible). Otherwise, leave blank.
Compounding Time	Actual time required to mix the ingredients. This does not include weighing, measuring and other dispensing activities.
Compounding Charge	Total amount billed for compounding the prescription (equal to Compounding Rate x Compounding Time).
Medical Reason Ref.*	Use "B" (i.e., ODB reason for use codes), when: a prescriber has completed and signed the Canada vigilance side effect reporting form for a medically necessary "No Substitution" claim, or a claim is for a LU prescription for a drug listed as a LU product in the ODBF/CDI.
Medical Condition - Reason for Use*	Use "901" to indicate that a Canada Vigilance Adverse Reaction Reporting Form has been completed and signed by the prescriber. (*Refer to Section 6.2, Medically Necessary "No Substitution" Claims.)* For Limited Use claims, use the prescriber's designation for the applicable RFU code if a LU prescription (copy of prescription with LU documentation) is provided. (*Refer to Section 6.3, Limited Use Products*)

Fields	Explanation
	(*Refer to ODBF/CDI for RFU codes.*)
Previously Paid*	Not applicable.
Special Authorization Number (SAN)/Code*	Select the appropriate SAN corresponding to the hospital. *Refer to the Ministry's website for a listing of SAN codes.*
Claim Submission Intervention/Exception Codes*	Select the applicable intervention/exception code(s) for the submitted claim from the list of available codes, if necessary. (*Refer to Section 10.2, Intervention/Exception Code Table*)
Pharmacist ID*	Pharmacist license number. Must be provided, when the Claims Submission Intervention/ Exception Code is supplied.
Authorized Signature	Original signature of an individual who has been included in the List of Parties with Signing Authority section on the Application for OPDP Application.

8.3 Instructions for Completion of Paper Drug Benefit Claim Submission and Drug Benefit Claim Reversal Forms

When submitting the details for paper claims, complete the Drug Benefit Claim Submission or Drug Benefit Claim Reversal form based on the following instructions/guidelines:

- Fields marked with an asterisk (*)
  - Identify the required fields
  - Refer to Section 5 and Section 6 for detailed explanation of the required fields
- Unshaded areas
  - Identify the optional fields that may be required for certain situations (e.g., non-standard claims)
  - Refer to Section 6 for detailed claim requirements

Resubmission Number & Original Client ID/Code (Ontario Drug Benefit Eligibility/Health Number)

When resubmitting a previously rejected claim:

- Use the Resubmission Number from the Reject Report for Paper Submission
- Provide only the Provider Transaction Date, your Pharmacy ID, and the corrected information

When a reversed claim resulting from an inspection is eligible for resubmission:

- Use the Resubmission Number from the Summary Remittance Advice (see Section 11.2) to resubmit the previously reversed claim
- Provide all the required fields, including the corrected information

Reason for Submission

- The applicable Reason for Submission must be indicated
- This information is optional if the Resubmission Number is provided to correct a previously rejected or reversed claim

Intervention/Exception Codes

- This form includes two groups of intervention/exception codes:
  - Use Claim Reversal intervention/exception codes when reversing a claim
  - Use Claim Submission intervention/exception codes when submitting a claim
- Check or select the box corresponding to the applicable intervention/exception code
- This information is required to request special consideration based on special coverage and payment rules (*as described in this Reference Manual*)

Authorized Signature

- The form must be signed by an individual who has been included in the *List of Parties with Signing Authority* section on the original Application for OPDP Application submitted.

Submit completed Drug Benefit Claim Submission Form and Drug Benefit Claim Reversal Form to the address shown on the forms.

8.4 Supporting Documentation for Paper Drug Benefit Claim and Drug Benefit Claim Reversal Forms

The supporting documentation required for a paper Drug Benefit Claim form or Drug Benefit Claim Reversal form is the same as that for a claim submitted through the HNS and includes.

- provide a photocopy of the Drug Benefit Eligibility Card; or
- provide the SAV Portal eligibility result information and SAV helpline confirmation number in the comment section of the form for patients who present their Ontario Health Card or Ontario Health number *(see Section 4.2)* to establish eligibility for ODSP and OW program recipients; or
- provide a photocopy of a faxed notification provided by a LHIN for Home Care recipients; or
- provide a copy of the Ontario Health Card, or other proof of OHIP eligibility (e.g., a copy of the detachable portion of the Ontario Health Coverage Infant Registration Form) for eligible children and youth who do not have a private plan; or
- provide documentation that eligibility has been confirmed with the Ministry's Financial Management Branch (FMB) for residents of Homes for Special Care/Community Homes for Opportunity.

- The Carrier ID (Plan Code) is a required field to establish eligibility.
- The Patient Date of Birth and Sex are required fields.

Note: Eligibility will be established for the date of service only.

Comments

- Where possible, provide additional information or clarification.

Standard Claims:

All submitted paper claims to establish eligibility for payment for Home Care, ODSP or OW recipients must include a photocopy of the Drug Benefit Eligibility Card *(see Section 4.2)*. the patient's plan code and SAV helpline confirmation number or the faxed notification provided by a LHIN in the comment section of the form for patients who present their Health number.

Non-Standard Claims:

Refer to Section 12 for inspections' documentation requirements.

Section 9: Prospective Drug Utilization Review

Overview

The prospective Drug Utilization Review (DUR) process is a part of the online claims adjudication system. Its primary objective is to monitor new medication/prescription orders for potential drug related problems. It is intended to enhance, not replace, the current principles of pharmacy practice by making supplementary information available to health care professionals.

Prospective DUR involves the analysis of previous prescription/claims data and current prescription data to identify potential drug related problems. Health care professionals may evaluate this information, in consultation with appropriate resources (prescriber, recipient, literature, etc.), to address and resolve the potential drug related problem.

The Ministry does not warrant the accuracy and completeness of the DUR information supplied by the HNS. The information is advisory only and is intended to supplement the current information available to health care professionals. It is not intended to replace professional judgement or individualized patient care and consultation in the delivery of health care services.

This section provides/describes:

- The prospective DUR system design, including its different modules (*see Section 9.1*)
- DUR response codes (*see Section 9.2*)
- Applicable intervention codes for DUR response codes (*see Section 9.3*)
- How prospective DUR operates for:
- Claim submissions (*see Section 9.4*)
- Claim resubmissions (*see Section 9.5*)
- Claim rejections (*see Section 9.6*)
- Claim reversals (*see Section 9.7*)
- Phone support for prospective DUR inquiries (*see Section 9.8*)
- Confidentiality requirements on DUR information (*see Section 9.9*)

9.1 Overall System Description

When a claim transaction is transmitted to the HNS, the prospective DUR process is initiated upon the validation of recipient eligibility, DIN/PIN and Pharmacy ID.

Through analysis and retrieval of historical and current prescription claims data, the prospective DUR will warn of potential problems with the current prescription. All potential problems are identified by DUR response codes.

The DUR response codes are based on patient medication information submitted on a claim. It is essential that accurate information is provided so that a useful patient profile database can be developed. The patient history is limited to those prescriptions submitted for eligible recipients and drug products eligible under the ODB program.

Four prospective DUR modules are currently available, namely:

- Drug/Drug Interactions
- Double Doctoring
- Multiple Pharmacies (Poly-Pharmacy)
- Fill too soon/Fill too late

Drug/Drug Interactions

This module is designed to detect potential drug interactions between the prescription claim being adjudicated and other prescriptions that are considered "active" in the recipient's historical claims. The module can identify potential interactions for single ingredients and combination products. An "active" drug is determined by the service date of the claim and the days' supply end date.

System Description

When a claim is submitted for adjudication, the DIN/PIN is compared to the recipient's historical claims to determine whether there are any interactions. If any interactions are noted, the pharmacy will be advised of the potential problem(s) by the display of DUR Response Codes on the HNS.

Like most drug interaction databases, the DUR system includes a classification system that rates drug/drug interactions based on clinical significance.

The Ministry information is supplied by First DataBank and has been adapted for Canadian content. This database uses three reference sources (Hansten's *Drug Interactions, Facts & Comparisons*, and the *United States Pharmacopeia - Drug Information* (USP DI) and a panel of

clinical experts to classify the clinical significance of an interaction. The drug/drug interaction information is kept current through monthly updates.

The clinical significance rating used by First DataBank comprises three levels of significance (or severity). These are shown in the Drug/Drug Interaction Potential table below.

Level	Level 1	Level 2	Level 3
Severity	Contraindicated Drug Combination	Severe Interaction	Moderate Interaction
Action	This drug combination is clearly contraindicated in all cases and should not be dispensed or administered to the same patient.	Action to reduce risk of adverse interaction usually required. Assess risk to patient and take action as needed.	Assess risk to patient and take action as needed.
All interactions (for this level) detected for online claims will be communicated as…	*Reject Message* *(with the ability to override)*	*Reject Message* *(with the ability to override)*	*Information Message*

The priority for transmitting and reporting drug/drug interactions is such that all Severity Level 1 interactions will be transmitted first followed by all Severity Level 2 interactions, and then all Severity Level 3 interactions.

Multiple Prescribers (Double Doctoring)

This module is designed to advise of the possibility of a patient obtaining specific drugs that have the potential for abuse (e.g., narcotic analgesics, psychotherapeutic agents, sedatives/ hypnotics) through multiple prescribers.

System Description

When a claim is submitted for adjudication, the DIN/PIN is compared to each of the recipient's historical prescriptions. The check is based on the identification of prescriptions for drugs which have the potential for abuse prescribed by a specific number of prescribers over a specific period.

Multiple Pharmacies (Poly-Pharmacy)

This module is designed to advise of the possibility of a patient obtaining specific drugs that have the potential for abuse (e.g., narcotic analgesics, psychotherapeutic agents, sedatives and hypnotics) through multiple pharmacies.

System Description

When a claim is submitted for adjudication, the DIN/PIN is compared to each of the recipient's historical prescriptions. The check is based on the identification of prescriptions for drugs which have the potential for abuse dispensed by a specific number of pharmacies over a specific period.

Fill Too Soon/Too Late

This module is designed to detect non-compliance consisting of:

- Possible overuse by prescription renewal intervals that show the patient may be taking excessive doses [Fill Too Soon]; or
- Possible underuse by prescription renewal intervals that show the patient may be taking inadequate doses [Fill Too Late].

System Description

When a claim is submitted for adjudication, the DIN/PIN is compared to each of the recipient's historical prescriptions to determine the elapsed days since the previously submitted claim for the same product and any instances of "Fill Too Soon/Fill Too Late". The check is based on the assumption that the predicted duration of therapy of the recipient's historical prescriptions is accurate.

There are limitations on the accuracy of the number of days supplied. In addition, there may be other valid reasons for a change in the predicted duration of therapy (e.g., an adjustment in the dose by the prescriber, inconsistent standard dosage measurements that may arise with oral liquids or topical creams).
The HNS will detect instances wherein prescriptions are filled more than 10 days too soon or more than 10 days too late based on the days' supply of the previously submitted claim for the same product.

9.2 Drug Utilization Review Response Codes

When a potential problem is identified by the HNS, the pharmacy is notified by a DUR response code.

For prospective DUR, a response code may cause the prescription claim to be:

- Rejected with the ability to override the warning with the appropriate intervention code; or
- Approved for payment with information messages.

Response Code/ Message	Potential DUR Problem	Response Status
ME	Drug/drug interaction potential	Severity Level 1 - Reject Message (with the ability to override) Severity Level 2 - Reject Message (with the ability to override) Severity Level 3 - Information Message
MH	May be double doctoring	Information Message
MI	Poly-pharmacy use indicated	Information Message
D7	Refill too soon	Information Message
DE	Fill/refill too late	Information Message

Supplementary information related to the drug/drug interactions may be displayed in three message data lines.

Response code **"DD"** indicates that there are more than 3 drug interactions and there is insufficient space to display the supplementary information for all drug interactions. Information about these drug interactions may be obtained by phoning the ODB Help Desk (*see Section 14, Help Desk*).

Reject Message:
When a Reject Message appears, the claim has not been approved for payment because a potential DUR problem has been detected. This type of message can be overridden.
The pharmacist must investigate the problem and use the applicable intervention code (see Section 9.3) with the Pharmacist ID if resubmitting the claim.

Information Message
When an Information Message appears, the claim has been approved for payment but there is a cautionary message that advises that the potential DUR problem should be investigated.

The pharmacist must reverse the claim if the drug product is not dispensed to the recipient. (*Refer to Section 5.2, To Reverse a Standard (or Non-Standard Claim)*.

Drug/Drug Interaction

If a drug/drug interaction is found, the pharmacy will receive the DUR response code **"ME"**, meaning Drug/Drug Interaction potential.

In addition, a DUR response message will also be transmitted. This message will identify the severity level of the interaction, the DIN/PIN and the corresponding brand name for each interacting drug on the patient's profile.

The priority for transmitting and reporting Drug/Drug Interactions is such that all Severity Level 1 interactions will be transmitted first followed by all Severity Level 2 interactions and then all Severity Level 3 interactions.

For Drug/Drug Interactions, a single message data line will be used for each potential interaction.

The message data line contains:

- Severity code for the potential interaction
- DIN/PIN of historical drug
- Brand name of historical drug (up to the maximum for one message data line).

For example: ***1~~00609013~SOMOPHYLLIN-12***

This message text means that a ***Severity Level 1*** *(Contraindicated Drug Combination) potential interaction has been identified between the current prescription being claimed and a drug that is on the patient/ recipient's current profile. The interacting drug is identified through the DIN number "****00609013****" and the brand name of the drug* ***Somophyllin - 12****.*

The amount of space in a message data line is limited. Therefore, it may not always be possible to transmit the full name of the drug, based on the length of the drug name. In this case, the full name of the interacting drug may be verified by referring to the ODBF/CDI.

After receiving the above information, the pharmacist should select an appropriate course of action. This may include, but not be limited to:

Discussion with the patient to confirm that the patient is still receiving the historical interacting drug, because the drug may have been discontinued or the entry of number of days supplied did not match the actual days supplied. In addition, the pharmacy may verify the dosing regimen and the name of the prescriber. This information may not be available if the interacting drug was dispensed from another pharmacy;

Reviewing the effect and proposed mechanism of the interaction, clinical documentation substantiating the interaction, and suggested management in a drug interaction reference book;

Taking steps to intervene in drug therapy when, in the pharmacist's professional opinion, the therapy prescribed is not in the patient's best interest. These steps may include contacting the prescriber about the therapy, consulting other health care professionals and/or refusing to fill the prescription.

Multiple Prescribers (Double Doctoring)

A multiple prescribers encounter is communicated to the pharmacy with the DUR response code **"MH"**, meaning the patient may be double doctoring.

Upon receipt of this DUR information, the pharmacist would then assess the specific information to select an appropriate course of action. This may include, but not be limited to:

- Entering into discussion with the patient to confirm the dosing regimen, directions for use, or other possible reasons for the "Double Doctoring" encounter;
- Establishing that the prescription is not being obtained through fraudulent means or for abuse purposes;
- Taking steps to intervene in drug therapy when, in the pharmacist’s professional opinion, the therapy prescribed is not in the patient's or the public's best interest. These steps may include contacting the prescribers regarding the therapy, consulting other health care professionals, and/or refusing to fill the prescription. If the prescription is not filled, reverse the claim using the appropriate intervention code.

Multiple Pharmacies (Poly-Pharmacy)

A Multiple Pharmacy encounter is communicated to the pharmacy with the DUR response code **"MI"**, meaning poly-pharmacy use indicated.

Upon receipt of this DUR information, the pharmacist would then assess the specific information to decide an appropriate course of action. This may include, but not be limited to:

- Discussion with the patient to confirm the dosing regimen, directions for use, or other possible reasons for the Multiple Pharmacy encounter;

- Establishing that the prescription is not being obtained through fraudulent means or for abuse purposes;
- Taking steps to intervene in drug therapy when, in the pharmacist's professional opinion, the therapy prescribed is not in the patient's or the public's best interest. These steps may include contacting the prescriber regarding the therapy, consulting with other health care professionals and/or refusing to fill the prescription. If the prescription is not filled, reverse the claim using the appropriate intervention code.

Fill Too Soon/Too Late

A "Fill too soon" encounter is communicated to the pharmacy with the DUR response code **"D7"** and a "Fill too late" with the DUR response code **"DE"**.

Upon receipt of this DUR information, the pharmacy would assess the specific information to decide upon an appropriate course of action. This may include, but not be limited to:

- Discussion with the patient to confirm the dosing regimen, directions for use, etc.
- Taking steps to intervene in drug therapy when, in the pharmacist's professional opinion, the therapy prescribed is not in the patient's best interest. These steps may include contacting the prescriber regarding the therapy, consulting other health care professionals, and/or refusing to fill the prescription. If the prescription is not filled, reverse the claim using the appropriate intervention code.

9.3 Drug Utilization Review Intervention Codes

Specific intervention codes can be used in response to DUR response codes.

An intervention code is required for:

- Reject Messages; or
- Information Messages requiring the reversal of a claim approved for payment.

The pharmacist (based on previous experience with the patient) may sometimes submit a claim with an acceptable intervention code and Pharmacist ID, prior to seeing the DUR response code.
Although this may eliminate the need to respond to a Reject Message, this practice is not encouraged as this could result in other response codes being overlooked or possible claim rejections.

The table on the following page lists the DUR response codes, response status and intervention codes for the DUR modules.

Code	Description	Response Status	Condition Generating Response Code	Intervention Code/Description
D7	Refill too soon	Information Message	Indicates a refill should not be required at this time. **The claim has been approved for payment**. The pharmacist may want to ensure that the medication has been taken appropriately and verify if there have been changes to the therapy (e.g., changed dose or directions). However, if the prescription is not filled, reverse the claim using the appropriate intervention code.	**UD*** = consulted prescriber and changed drug **UE*** = consulted prescriber and changed quantity **UL*** = prescription not filled - pharmacist decision **UH*** = counselled patient. Prescription not filled

Code	Description	Response Status	Condition Generating Response Code	Intervention Code/Description
DE	Fill/refill too late	Information Message	Indicates that a refill is overdue at this time. **The claim has been approved for payment**. The pharmacist may want to ensure that the recipient is compliant and taking adequate doses. However, if the prescription is not filled, reverse the claim using the appropriate intervention code.	**UD*** = consulted prescriber and changed drug **UE*** = consulted prescriber and changed quantity **UL*** = prescription not filled - pharmacist decision
ME	Drug/drug interaction potential	**Severity Level 3** Information Message	Indicates a potential drug/drug interaction between the prescription being filled and one which the recipient is already receiving. **The claim has been approved for payment**. However, if the prescription is not filled, reverse the claim using the appropriate intervention code.	**UD*** = consulted prescriber and changed drug **UL*** = prescription not filled - pharmacist decision

Code	Description	Response Status	Condition Generating Response Code	Intervention Code/Description
ME	Drug/drug interaction potential	**Severity Level 1 or 2** Reject Message (with the ability to override)	Indicates a potential drug/drug interaction between the prescription being filled and one which the recipient is already receiving. **The claim has been rejected.** However, if the pharmacist should ascertain that the prescription is required, the claim may be processed using the appropriate intervention code.	**UA** = consulted prescriber and filled prescription as written **UB** = consulted prescriber and changed dose **UC =** consulted prescriber and changed instructions for use **UF** = patient gave adequate explanation. Prescription filled as written **UG** = cautioned patient. Prescription filled as written **UI** = consulted other source. Prescription filled as written
MH	May be double doctoring	Information Message	Indicates that the recipient may be visiting multiple prescribers to obtain drugs which have the potential to be abused. **The claim has been approved for payment**. However, if the prescription is not filled, reverse the claim using the appropriate intervention code.	**UD*** = consulted prescriber and changed drug **UE*** = consulted prescriber and changed quantity **UL*** = prescription not filled - pharmacist decision **UH*** = counselled patient. Prescription not filled

Code	Description	Response Status	Condition Generating Response Code	Intervention Code/Description
MI	Poly-pharmacy use indicated	Information Message	Indicates that the recipient may be visiting multiple pharmacies to obtain drugs which have the potential to be abused. **The claim has been approved for payment**. However, if the prescription is not filled, reverse the claim using the appropriate intervention code.	**UD*** = consulted prescriber and changed drug **UE*** = consulted prescriber and changed quantity **UL*** = prescription not filled - pharmacist decision **UH*** = counselled patient. Prescription not filled

The asterisk (*) indicates intervention code is applicable during claim reversal processing only.

It is important for pharmacists to familiarize themselves with these intervention codes. If an incorrect intervention code is used, the transaction will be rejected and must be resubmitted.

9.4 Claim Submissions

Once the initial adjudication checks are made, the HNS conducts prospective DUR on every claim.

Based on the previous experience with the patient, the claim may be submitted with an acceptable intervention code and Pharmacist ID before seeing the DUR response.

The system will then verify if the intervention code is acceptable for the prospective DUR Override-able Warning.

This may eliminate the need to respond to an Override-able Reject Message, but this practice is not encouraged as this could result in other DUR response codes being overlooked or possible claim rejections.

9.5 Claim Resubmissions

For all claim transactions with a potential Override-able Warning, the HNS will check for the presence of an acceptable intervention code and Pharmacist ID.

Claims with unacceptable intervention codes and/or missing Pharmacist ID will be rejected.

9.6 Claim Rejections

If a claim is rejected because of an unacceptable intervention code and/or a missing Pharmacist ID, the claim must be resubmitted.

9.7 Claim Reversals

Interventions that require a change in the prescription (e.g., discontinuation or change of drug) will require a claim reversal (*refer to Section 5.2*). The pharmacy may reverse the claim with an appropriate Claim Reversal intervention code following an Information Message.

9.8 Help Desk Assistance

Please refer to Section 14.2 for the ODB Help Desk hours of operation to help pharmacies with inquiries about DUR response codes or intervention codes.

ODB Help Desk operators are not pharmacists and are not permitted to enter into any clinical discussions or to recommend an appropriate course of action to be taken.

9.9 Confidentiality

Under the *Freedom of Information and Protection of Privacy Act* (FIPPA) and *PHIPA*, all patient information is considered personal.

Therefore, pharmacists are reminded to take all reasonable precautions to ensure this information is treated with the greatest sensitivity and to respect the patient's privacy when discussing this information with the patient and/or other health care professionals. (Refer to Section 3.1, Privacy of Patient Information).

Section 10: Response and Intervention Codes

Overview

Claim transactions submitted will be validated and processed to determine eligibility. Claim transactions may be approved with information messages or rejected.

This section contains two "**Quick Reference" Guides for:**

Interpretation of Response Codes (*see Section 10.1*)

Interpretation of the Intervention/Exception Codes (*see Section 10.2*)

Refer to Section 9, Prospective DUR for more details on how DUR response codes are generated and the use of intervention codes.

10.1 Response Codes Table

Response Code

This column lists the code assigned by the system in response to a particular transaction that may warrant attention.

Message Description

This column provides a brief explanation of the response code.

Field Requirement or Explanation of Condition Generating Response Code

This column identifies the field requirements when the response code shows a field error (i.e., the response code is often an indication that the field requirements have not been met).

Intervention Code/Description

This column displays all applicable intervention codes for response codes that can be overridden. ODB program payment rules provide the opportunity to override the system decision.

Table of Response Codes

Response Code	Message Description	Field Requirement or Explanation of Condition Generating Response Code	Intervention Code/ Description
01	BIN error	Bank ID Number # 610054 required	N/A
02	Version number error	Current CPhA Version required	N/A
03	Transaction code error	Transaction code (01, 11, 30, 31, 32, or 33) required	N/A
04	Provider software ID error	Pharmacy's Provider Software ID required	N/A
05	Provider software version error	Pharmacy's Provider Software Version required	N/A
21	Pharmacy ID code error	Pharmacy ID Code required	N/A
22	Provider transaction date error	Date (YYMMDD) of service required	N/A
23	Trace number error	A numeric value greater than 0	N/A
30	Carrier ID error	If Carrier ID is entered, must be a valid Plan Code. Only mandatory if intervention code "**MK"** or "**ML"** is applied.	N/A
31	Group number error	Group Number is mandatory for services provided to an LTC and to override the dispensing fees restriction when dispensed to a resident of an HSC. *Refer to* http://www.health.gov.on.ca/en/pro/programs/drugs/	N/A
32	Client ID # error	Invalid format. For intervention code "**MJ"**, Client ID # will be blank.	**"MK"** = eligibility established - emergency coverage

Response Code	Message Description	Field Requirement or Explanation of Condition Generating Response Code	Intervention Code/ Description
34	Patient date of birth error	YYYYMMDD format. Only mandatory if intervention code “**MK”** or “**ML”** is applied.	N/A
37	Patient first name error	Must match the first initial of the patient on file.	**“PB”** = name entered is consistent with card
38	Patient last name error	Must match the last name of the patient on file.	**“PB”** = name entered is consistent with card
39	Provincial Health number error	Invalid Health number format	N/A
40	Patient gender error	May be "M”, "F", "U", or blank. "M" or "F" is mandatory if intervention code “**ML”** or “**MK”** is applied.	N/A
50	Medical reason reference error	The Medical Reason Reference field should be blank. If the drug dispensed is a LU product or a medically necessary “No Substitution” prescription claim, this field should contain "B" (i.e., ODB reason for use codes).	N/A
51	Medical condition/ reason code error	The Medical Condition/Reason for Use field should be blank unless the drug dispensed is a LU product or a medically necessary “No Substitution” prescription claim (No Sub). When a claim is both LU and No Sub, the LU Reason for Use code supersedes the No Sub code of 901. This Response Code will not be generated if the drug dispensed is an ODB recognized AIDS treatment drug or an EAP approved benefit.	N/A

Response Code	Message Description	Field Requirement or Explanation of Condition Generating Response Code	Intervention Code/ Description
55	Current Rx # error	Must be numeric value greater than 0.	N/A
56	DIN/GP#/PIN error	Must be a valid DIN/PIN.	N/A
57	SSC error	SSC code was submitted inappropriately. Must be blank or U.	N/A
58	Quantity error	Must be a numeric value greater than 0. May not exceed maximum allowed for DIN.	**"MQ"** = valid claim - quantity over limit
59	Days' supply error	Must be a numeric value greater than 0	N/A
60	Invalid Prescriber ID Reference code	The Prescriber ID Reference field must be "01", "02", "03", "05", "08", "09", "43", "44", "N0" or "99" *(See Prescriber ID Reference Chart in Section 5.1)*	N/A
61	Prescriber ID error	This field should not be blank. May be entered as "99999" along with Prescriber ID Reference field = "99" (**where all attempts to locate Prescriber ID have failed**)	**"MH"** = override - prescriber ID (Note: Do not apply override if prescriber privileges have been suspended or restricted)
62	Product selection code error	The claim has been rejected because the required information in the Medical Condition/Reason for Use field is missing or incorrect. If the Product Selection code is "1", the Medical Condition/Reason for Use must be "901".	N/A

Response Code	Message Description	Field Requirement or Explanation of Condition Generating Response Code	Intervention Code/ Description
		In the case of medically necessary "No Substitution" for a Limited Use Product, use the RFU code *(as listed in the Formulary/CDI which is appropriate for the product)* instead of "901".	
63	Unlisted compound code error	May be blank, or value between 0 and 9 *(Refer to Compound Type Codes in Appendix A)*	N/A
64	Special authorization number/ code error	Must be supplied on initial claims for Vfend.	N/A
65	Intervention/ exception code error	Must be a valid and appropriately used intervention/exception code. *(Refer to Section 10.2, Intervention/ Exception Code Table)*	N/A
66	Drug cost/product value error	Numeric value greater than or equal to 0	N/A
67	Cost mark-up error	Numeric value greater than or equal to 0	N/A
68	Professional fee error	Numeric value greater than or equal to 0	N/A
70	Compounding charge error	Numeric value greater than or equal to 0	N/A
71	Compounding time error	Numeric value greater than or equal to 0	N/A
75	Previously paid error	Numeric value greater than or equal to 0	N/A
76	Pharmacist ID code error/ missing	A valid Pharmacist ID is required when intervention/exception code is used; otherwise may be blank	N/A

Response Code	Message Description	Field Requirement or Explanation of Condition Generating Response Code	Intervention Code/ Description
87	Exceeds max. # of prof. fees for this drug	Payment of a dispensing fee is limited to a maximum five fees per 365 days for certain chronic-use medications for some ODB recipients. Please refer to "Conditions for Payment of a Dispensing Fee" on the Ministry website.	**"UN"** = Assessed patient. Therapy is appropriate
88	Zero dispensing fee 28-Day limit exceeded	Payment of a dispensing fee is limited to a maximum of two dispensing fees per 28-days for some medications for some ODB recipients. Please refer to "Conditions for Payment of a Dispensing Fee" on the Ministry website.	N/A
90	Adjudication date error	Must be a numeric value (YYMMDD format)	N/A
91	Beginning record error	Numeric value greater than or equal to 0	N/A
92	Ending record error	Must be numeric value greater than 0 and greater than beginning record number	N/A
A1	Claim too old	Transaction date must be less than seven calendar days from current date (e.g., if the current date is October 21, a claim with a transaction date of October 14 will be rejected (response code "**A1**"); a transaction date of October 15 will be accepted). Transaction date must be less than seven calendar days from claim adjudication date for OLTP. Claims with transaction dates more than seven calendar days and less than six months from the current date may be submitted as a paper claim or claim reversal. *(See Section 8.1, When to Submit a Paper Claim or Paper Claim reversal)*	N/A
A2	Claim is post-dated	Transaction date future dated	N/A

Response Code	Message Description	Field Requirement or Explanation of Condition Generating Response Code	Intervention Code/ Description
A3	Identical claim processed	Prior claim exists for: same patient same DIN/PIN or interchangeable product same date of service same pharmacy or a compound for: same patient same prescription number (for unlisted compounds only) same DIN or interchangeable product same date of service same pharmacy same unlisted compound type code	**"UA"** = consulted prescriber and filled Rx as written **"UB"** = consulted prescriber, changed dose **"UC"** = consulted prescriber, changed instructions for use **"UE"*** = consulted prescriber, changed quantity **UF** = patient gave adequate explanation, Rx filled as written **"MM"** = replacement claim, drug cost only **"MN"** = replacement claim due to

Response Code	Message Description	Field Requirement or Explanation of Condition Generating Response Code	Intervention Code/ Description
			dosage change **"MR"** = replacement claim, item lost or broken **"MV"** = vacation supply
A7	Submit manual reversal	Reversal transaction submitted more than seven days from adjudication date must be submitted manually	N/A
A8	No reversal made/ original claim missing	No claim on file that matches submitted information	N/A
A9	Reversal processed previously	Claim previously reversed	N/A
B1	Pharmacy not authorized to submit claims	Pharmacy ID is required. Pharmacy must be registered with MOH for claim submission on date of service.	N/A
C2	Service provided before effective date	The patient must have effective coverage in the program. This response code is set if the patient's program effective date is later than the claim's date of service. *(Refer to Section 4, Eligibility)*	**"MK"** = eligibility established emergency coverage **"ML"** = eligibility established standard coverage
C3	Coverage expired before service	The patient must have effective coverage in the program. This response code is set if the	**"MK"** = eligibility established

Response Code	Message Description	Field Requirement or Explanation of Condition Generating Response Code	Intervention Code/ Description
		patient's program expiration date is before the claim's date of service. *(Refer to Section 4, Eligibility)*	emergency coverage **"ML"** = eligibility established standard coverage
C8	No record of this beneficiary	This response code is set when the Client ID # is not found on the patient file. *(Refer to Section 4, Eligibility)*	**"ML"** = eligibility established standard coverage
CD	Patient not entitled to drug claimed	Health care item claimed is not a benefit based on the information provided on the claim.	N/A
CF	Quantity exceeds maximum days of treatment	Quantity dispensed exceeds the allowable number of days for the course of treatment.	N/A
CG	Drug not eligible for LTC home	Patients in an LTC home are not normally eligible for benefits supplied by the Ontario Government Pharmaceutical and Medical Supply Service.	N/A
CI	Program not eligible for established eligibility	An eligibility establishment intervention code has been submitted (e.g., "**ML", "MK"**) but the patient's plan is not eligible under eligibility establishment.	N/A
CJ	Patient not covered by this plan	A Plan Code has been provided in the Carrier ID for a program that has no current active record for this patient.	**"MK"** = eligibility established emergency coverage **"ML"** = eligibility established

Response Code	Message Description	Field Requirement or Explanation of Condition Generating Response Code	Intervention Code/ Description
			standard coverage
CK	Health Card version code error	**Information Message only.** A valid Health number is submitted but the Version Code does not match for the date of service.	N/A
CL	Exceeds established eligibility limit	The number of claims eligible under eligibility establishment has been exceeded.	**"MW"** = valid reason to exceed eligibility limit
D2	DIN/GP#/ PIN is discontinued	Health care item no longer available as a benefit.	N/A
D3	Prescriber is not authorized	Prescriber ID must be valid and active for date of service. Prescriber ID must not be suspended. (Note: Do not apply override if prescriber privileges have been suspended or restricted)	**"MH"** = override prescriber ID
D6	Maximum cost is exceeded	Claim exceeds $499.99	**"MO"** = valid claim value $500 to $999.99 **"MP"** = valid claim value $1,000 to $9,999.99
D7	Fill/Refill too soon	**Information Message only.**	**"UD"*** = consulted

Response Code	Message Description	Field Requirement or Explanation of Condition Generating Response Code	Intervention Code/ Description
		Indicates a refill should not be required at this time. The claim has been approved for payment. The pharmacist may want to ensure that the medication is being taken appropriately and verify if there have been any changes to the therapy (e.g., changed dose or directions). However, if the Rx is not filled, reverse the claim using the appropriate intervention code. *(Refer to Section 9, Prospective DUR)*	prescriber changed drug **"UE"*** = consulted prescriber changed quantity **"UL"*** = prescription not filled, pharmacist decision **"UH"*** = counselled patient. Rx not filled
D8	Reduced to generic cost	**Information Message only.** Drug cost reduced (e.g., reduced to the cost for generic drug and/or ODB list price).	N/A
DD	Insufficient space for all DUR warnings	**Information Message only.** There is insufficient space for all DUR messages. Additional messages are available by calling the ODB Help Desk within days of the transaction.	N/A

Response Code	Message Description	Field Requirement or Explanation of Condition Generating Response Code	Intervention Code/ Description
DE	Fill/refill too late non-compliant	**Information Message only.** Indicates that a refill is overdue at this time. The claim has been approved for payment. The pharmacist may want to ensure that the recipient is compliant and taking adequate doses. However, if the Rx is not filled, reverse the claim using the appropriate intervention code. *(Refer to Section 9, Prospective DUR)*	**"UD"*** = consulted prescriber and changed drug **"UE"*** = consulted prescriber and changed quantity "**UL"*** = prescription not filled, pharmacist decision
DF	Insufficient space for all warnings	**Information Message only.** There is insufficient space for all response codes. Additional response codes are available by calling the ODB Help Desk within days of the transaction.	N/A
DG	Duplicate prescription number	Prior claim exists for: same pharmacy same date of service same prescription number Prescription number must be unique for each dispensing.	N/A
DZ	Days' supply limited due to benefit year end	The claim has been rejected because the days' supply has been exceeded for a recipient of the Trillium Drug Program. Trillium recipients are entitled to the lesser of a 100-day supply or a quantity sufficient to extend up to 30 days after the end of the	N/A

Response Code	Message Description	Field Requirement or Explanation of Condition Generating Response Code	Intervention Code/ Description
		Trillium eligibility period (e.g., in July, a quantity sufficient to last until August 30 will be covered). This response code is accompanied by a message indicating the maximum allowed days' supply for the date of service indicated on the claim.	
E1	Host processing error	System Error. Contact the ODB Help Desk. *(Refer to Section 14, Help Desk)*	N/A
E8	Patient must remit cash receipt to Trillium	The claim has been rejected because the Trillium recipient has previously indicated to the Ministry that he/she has private insurance coverage in effect on the date of service indicated on the claim. The recipient must submit the receipt to their private insurer and then submit the insurance statement from the private insurer along with a copy of the receipt to the Trillium Drug Program. A receipt which indicates the amount previously paid by a private insurer through electronic claims submission is also acceptable.	N/A
EG	No Record of Trying 1st Line Therapy	The claim has been rejected because the required smoking cessation program first consultation assessment or primary follow up counselling is missing	N/A
EL	Prior to pro-rated start date	The claim has been rejected because the date of service is earlier than the enrolment start date indicated by the household on the Trillium Drug Program application form.	N/A
EM	ODB pricing - TDP deductible reached	**Information Message only.** The claim caused a Trillium quarterly or annual deductible to be reached, therefore, the reimbursement amount has been reduced according to ODB payment rules.	N/A

Response Code	Message Description	Field Requirement or Explanation of Condition Generating Response Code	Intervention Code/ Description
KG	Authorization refills exceeded	This claim has been rejected because it exceeds claim count limits over period. Note: currently used for Xarelto and Eliquis to limit reimbursement to 1 claim in a 120-day period.	**"VE"** = treatment of acute condition Note: Only for use under RFU code 433 or 434 (e.g., for surgery of opposite knee/hip)
KT	Assess Recipient SDP eligibility	As per the "Special Drugs Program", if the recipient does not have coverage established yet, this informs the dispensing pharmacy. Note: There are only a small set of pharmacies authorized to submit claims through the Special Drugs Program.	**"NC"** = patient SDP eligibility confirmed
LN	Check potential benefit criteria	Initial claim for Vfend drug products must establish a Limited Use Authorization.	**"LU"** = start new LU authorization
LO	Benefits maximum exceeded	This claim has been rejected because benefits maximum exceeded. For example, when a second annual MedsCheck claim is received within 12 months.	N/A
ME	Drug/drug interaction potential	**Severity Level 1 or 2** **Overrideable Warning.** Indicates a potential drug/drug interaction between the prescription being filled and one which the recipient is already receiving. The claim has been rejected.	**"UA"** = consulted prescriber and filled Rx as written **"UB"** = consulted prescriber

Response Code	Message Description	Field Requirement or Explanation of Condition Generating Response Code	Intervention Code/ Description
		However, if the pharmacist should ascertain that the prescription is required, the claim may be processed using the appropriate intervention code.	and changed dose **"UC"** = consulted prescriber and changed instructions for use **"UF"** = patient gave adequate explanation. Rx filled as written **"UG"** = cautioned patient. Rx filled as written **"UI"** = consulted other source. Rx filled as written
ME	Drug/drug interaction potential	**Severity Level 3** **Information Message only.** Indicates a potential drug/drug interaction between the prescription being filled and one which the recipient is already receiving. **The claim has been approved for payment.**	**"UD"*** = consulted prescriber and changed drug **"UL"*** = prescription not filled - pharmacist decision

Response Code	Message Description	Field Requirement or Explanation of Condition Generating Response Code	Intervention Code/ Description
		However, if the prescription is not filled, reverse the claim using the appropriate intervention code.	
MH	May be double doctoring	**Information Message only**. Indicates that the recipient may be visiting multiple prescribers to obtain drugs which have a potential to be abused. **The claim has been approved for payment.** However, if the prescription is not filled, reverse the claim using the appropriate intervention code.	**"UD"*** = consulted prescriber and changed drug **"UE'*** = consulted prescriber and changed quantity "**UL"*** = prescription not filled - pharmacist decision **"UH"*** = counselled patient. Rx not filled
MI	Poly-pharmacy use indicated	**Information Message only.**	**"UD"*** = consulted prescriber and changed drug

Response Code	Message Description	Field Requirement or Explanation of Condition Generating Response Code	Intervention Code/ Description
		Indicates that the recipient may be visiting multiple pharmacies to obtain drugs which have a potential to be abused. **The claim has been approved for payment.** However, if the prescription is not filled, reverse the claim using the appropriate intervention code.	**"UE"*** = consulted prescriber and changed quantity **"UL"*** = prescription not filled - pharmacist decision **"UH"*** = counselled patient. Rx not filled
MY	Duplicate drug other pharmacy	Prior claim exists for: same patient same DIN/PIN or interchangeable product same date of service different pharmacy	**"UA"** = consulted prescriber. Rx filled as written **"UB"** = consulted prescriber and changed dose **"UC"** = consulted prescriber and changed instructions for use **"UE"*** = consulted prescriber

Response Code	Message Description	Field Requirement or Explanation of Condition Generating Response Code	Intervention Code/ Description
			and changed quantity **"UF"** = patient gave adequate explanation. Rx filled as written **"MM"** = replacement claim, drug cost only **"MN"** = replacement claim, due to dosage change **"MR"** = replacement, item lost or broken **"MV"** = vacation supply
OC	Quantity Reduction Required	An initial prescription that previously was rejected with response code (OF = Initial Rx Days' Supply exceeded) was resubmitted with a reduced Days' supply, but the corresponding quantity was not reduced accordingly.	**"NF"** = Override - Quantity Appropriate
OF	Initial Rx Days' Supply Exceeded	An initial prescription for a drug product must not exceed 30 days' supply.	**"NH"** = Initial Rx Program Declined
OI	Claim precedes start of current period	The dispense date of the claim precedes the start of an already recorded treatment period.	N/A

Response Code	Message Description	Field Requirement or Explanation of Condition Generating Response Code	Intervention Code/ Description
PC	Not a benefit for this prescriber type	This claim has been rejected because the drug product is not an ODB benefit for this prescriber type.	N/A
PM	No Private Insurance Attestation Missing	The claim has been rejected for a child/youth 24 years of age and under as the Special Service Code (SSC) "U" is missing. Confirm that the recipient does not have a private plan and resubmit with SSC "U". If the recipient has a private plan, do not submit claim to the HNS.	N/A
QM	No record of required prior therapy	N/A	N/A
QN	Agency restriction for this drug	Special Drugs can only be dispensed by an authorized pharmacy.	N/A
ZR	Submit receipt to TDP or Attest to No PI	The claim has been rejected for a child/youth 24 years of age and under because the recipient has TDP coverage. Verify private plan status. If the recipient does not have a private plan, resubmit the claim with SSC "U". Or if the recipient has a private plan, submit the claim to the private plan and advise recipient to submit private plan information and receipts for out-of-pocket expenses to TDP.	N/A

The asterisk (*) indicates intervention code is applicable during claim reversal processing only.

10.2 Intervention/Exception Codes Table

Intervention/exception codes are required to be submitted on some claims to facilitate proper adjudication and payment. Generally, they indicate that some assessment or additional review has been performed, and a claim that would otherwise be rejected, should be paid. Rules

applicable to the use of intervention/exception codes are described in other sections of the Manual, as follows:

- *Section 4.2, Policy for Establishing Eligibility for Payment*,
- *Section 6, Submit Non-Standard Online Claims*
- *Section 9.3, DUR Intervention Codes*

Note: The Pharmacist ID is mandatory (unless the dispenser is a physician) when intervention/exception codes are applied. An intervention/exception code error will be generated if the system determines that the code applied was not necessary.

Only two intervention/exception codes will be accepted against a single transaction. If more than two intervention/exception codes are necessary, then claims must be submitted manually. *See Section 8, Paper Drug Benefit Claim Submission and Drug Benefit Claim Reversals.*

The following table lists all of the intervention/exception codes. See Section 9.3 for full descriptions.

Table of All Intervention/Exception Codes

Code	Description
LU	Start new LU authorization
MG	Override - Clinical Reasons - Clinical various reasons
MH	Override - Prescriber ID (Note: If practitioner prescribing privileges have been suspended or restricted, the override should not be applied.)
MI	No interchangeable available at less than or equal to Drug Benefit Price plus allowable mark-up (i.e., copies of supplier invoices which demonstrate that the lowest-priced interchangeable product had been ordered and unavailable during the appropriate time period must be kept on file for claim validation)
MJ	Government pharmacy authorized claim
MK	Eligibility established - Emergency coverage
ML	Eligibility established - Standard coverage
MM	Replacement claim, drug cost only
MN	Replacement claim due to dosage change
MO	Valid claim - value of $500.00 to $999.99
MP	Valid claim - value of $1,000.00 to $9,999.99
MQ	Valid claim - quantity over limit
MR	Replacement, item lost or broken

Code	Description
MV	Vacation supply
MW	Valid reason to exceed established eligibility limit
NC	Patient SDP eligibility confirmed
NF	Override - Quantity Appropriate
NH	Initial Rx Program Declined
PB	Name entered is consistent with card
PS	Professional Care Service
UA	Consulted prescriber and filled Rx as written
UB	Consulted prescriber and changed dose
UC	Consulted prescriber and changed instructions for use
UD*	Consulted prescriber and changed drug
UE*	Consulted prescriber and changed quantity
UF	Patient gave adequate explanation. Rx filled as written
UG	Cautioned patient. Rx filled as written
UH*	Counseled patient. Rx not filled
UI	Consulted other source. Rx filled as written
UL*	Prescription not filled - pharmacist decision
UN	Assessed patient, therapy is appropriate
VE	Treatment of acute condition

**Used during claim reversal processing only.*

Section 11: Reconciliation/Payment

Overview

This section explains:

Payment procedures for online claims/reversals processed by pharmacies (*see Section 11.1*)

Payment procedures for paper claims/reversals processed by the Ministry (*see Section 11.2)*

Reconciliation of remittance statements by the Ministry (*see Section 11.3*)

Payment scheduling (*see Section 11.4*)

Registering for direct deposit (*see Section 11.5*)

11.1 Payment Information for Online Claims/Reversals

Pharmacies should extract payment information for online claims/reversals daily.

Procedures for requesting this payment information are described within Section 5, Submit Standard Online Claims

The following payment information is available for any one of the most current seven days:

Payment Information	Description
Daily Totals*	Accumulated payment amount for a specific day (*see Section 5.4, To Request Daily Totals*)
Claim Details	Details of claims processed for a specific day (*see Section 5.5, To Request Claim Details*)
Same Day Reversal Details, or Prior Day Reversal Details	Details of claims reversed for the specified day (*see Section 5.6, To Request Same Day Reversal Details or Section 5.7, To Request Prior Day Reversal Details*)

**Pharmacies must request and reconcile claim totals on a daily basis.*

Note: After seven days, this payment information will not be available.

Keep records of this information to reconcile with ODB program payments (issued twice a month).

No Summary Remittance Advice is produced for online claims/reversals. Only when the Ministry processes paper claims/reversals or adjustments for a pharmacy or a pharmacy begins a payment period with a negative balance, a Summary Remittance Advice will be produced for the payment period and will be delivered to the pharmacy's ONE® Mail account.

11.2 Payment & Drug Utilization Review Information for Paper Drug Benefit Claim Submissions and Drug Benefit Claim Reversals

For paper claims for payment or claim reversals adjudicated by the Ministry, the following payment information will be sent directly via email to the pharmacy's ONE® Mail account:

Payment Information	Description
Summary Remittance Advice	Approved paper claims and claim reversals, and adjustments for a payment period
Reject Report for Paper Submissions	Rejected paper claims and claim reversals
DUR Responses for Paper Submissions	Prospective DUR responses

Refer to Section 13, Electronic Mail, for specific instructions on how to retrieve email messages from the HNS.

When a pharmacy ceases to operate, the payment method will revert to cheque. The Summary Remittance Advice will be mailed with the final cheque payment(s). Any remaining Reject Reports for Paper Submissions will be mailed separately.

Summary Remittance Advice

Note: The Summary Remittance Advice will only be produced when one or more of the following occur during the payment period:

- Paper drug benefit claims and drug benefit claim reversals are processed by the Ministry;
- The Ministry posts an adjustment to the pharmacy's account (e.g., due to an inspection);
- The pharmacy's account is at a negative balance at the beginning or end of the payment period.

The Summary Remittance Advice is produced twice a month and delivered to pharmacies via their ONE® Mail account. Pharmacies are reminded that under the terms of the HNS Subscription Agreement, they are required to log on to the ONE® Mail email system at least once per week.

The Summary Remittance Advice may include the following information, if applicable:

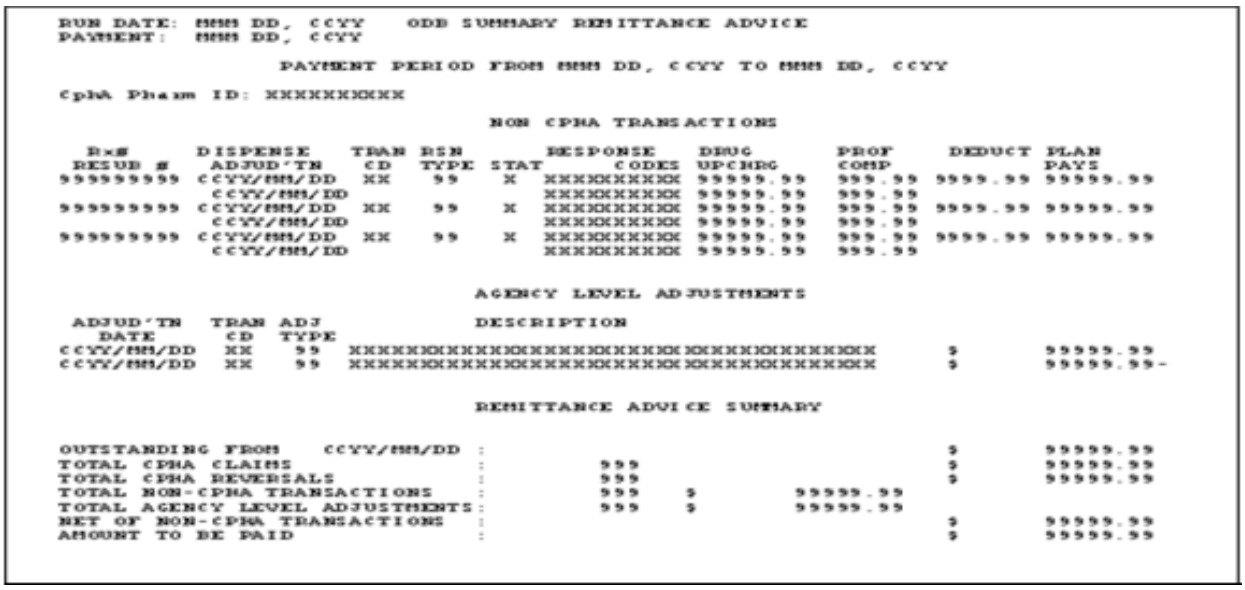
- Totals for online transactions for the same payment cycle
- Details of approved paper drug benefit claim submissions and drug benefit claim reversals processed by the Ministry
- Adjustments against previously paid claims and recoveries, as well as the Adjustment/Reason Type Code (*see table below*)
- Transaction Codes (*see Transaction Code table below*)
- Response status of the claim transaction such as:
    - A = accepted as submitted, no price adjustment(s)
    - B = accepted with price adjustment(s)
    - V = reversal accepted

If the Summary Remittance Advice shows that the pharmacy has been in a negative balance for a period of more than 30 days, a notification letter will be sent to the pharmacy requesting payment for the balance owing.

The pharmacy will be required to send a cheque payable to the "Minister of Finance" for the outstanding amount to:

Ministry of Health
Financial Management Branch
49 Place d'Armes, 2nd Floor
Kingston, ON
K7L 5J3

Summary Remittance Advice Sample



```
RUN DATE:  MMM DD, CCYY     ODB SUMMARY REMITTANCE ADVICE
PAYMENT:   MMM DD, CCYY

                PAYMENT PERIOD FROM MMM DD, CCYY TO MMM DD, CCYY

CphA Pharm ID: XXXXXXXXXX

                                NON CPHA TRANSACTIONS

  Rx#       DISPENSE    TRAN RSN        RESPONSE    DRUG        PROF      DEDUCT PLAN
 RESUB #     ADJUD'TN    CD   TYPE STAT     CODES  UPCHRG      COMP             PAYS
999999999 CCYY/MM/DD   XX    99    X   XXXXXXXXXX 99999.99    999.99  9999.99 99999.99
            CCYY/MM/DD                 XXXXXXXXXX 99999.99    999.99
999999999 CCYY/MM/DD   XX    99    X   XXXXXXXXXX 99999.99    999.99  9999.99 99999.99
            CCYY/MM/DD                 XXXXXXXXXX 99999.99    999.99
999999999 CCYY/MM/DD   XX    99    X   XXXXXXXXXX 99999.99    999.99  9999.99 99999.99
            CCYY/MM/DD                 XXXXXXXXXX 99999.99    999.99

                               AGENCY LEVEL ADJUSTMENTS

 ADJUD'TN   TRAN ADJ                DESCRIPTION
   DATE      CD  TYPE
CCYY/MM/DD   XX    99  XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX      $       99999.99
CCYY/MM/DD   XX    99  XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX      $       99999.99-

                               REMITTANCE ADVICE SUMMARY

OUTSTANDING FROM    CCYY/MM/DD :                                              $       99999.99
TOTAL CPHA CLAIMS              :          999                                 $       99999.99
TOTAL CPHA REVERSALS           :          999                                 $       99999.99
TOTAL NON-CPHA TRANSACTIONS    :          999    $       99999.99
TOTAL AGENCY LEVEL ADJUSTMENTS :          999    $       99999.99
NET OF NON-CPHA TRANSACTIONS   :                                             $       99999.99
AMOUNT TO BE PAID              :                                             $       99999.99
```

Adjustment/Reason Type Codes

Reason/ Adjustment Type Code	Description	Explanation
02	Supporting Documentation	The payment of certain claims, such as medically necessary "No Substitution", Limited Use, Nutrition Products and establishing eligibility, is conditional upon the pharmacy producing the required supporting documentation at the Ministry's request.
03	Inspection Recovery	Payments are recoverable by the Ministry when inspection results reveal a violation of a specific section of the ODBA, O. Reg. 201/96 or the pharmacy's HNS Subscription Agreement. Claim has been adjusted or reversed.
04	Retroactive Drug Cost	The Ministry may from time to time modify drug costs which may require adjustment at the agency or claim levels.
05	Negative Balance Recovery	Credits will be applied to pharmacies in negative balance situations when they make a direct payment to the Ministry.

Reason/ Adjustment Type Code	Description	Explanation
06	Retroactive Fee	The Ministry may from time to time modify dispensing fees which may require adjustment at the agency or claim levels.
07	Miscellaneous Adjustment	This code is used in exceptional circumstances where an adjustment is not directly attributable to one of the other existing Adjustment/Reason Type Codes.
08	Ministry Correction	This code indicates the reversal of an earlier incorrect Agency Adjustment transaction.
10	Subject to Ministry Review	The Ministry reserves the right to adjust claim amounts, pending further review.
11	Pharmacy Initiated Reversal	This code denotes a pharmacy-initiated On-Line Transaction Processing (OLTP) claim reversal or a paper claim reversal.
12	Ministry Correction	This code is used to correct a paper claim that was inadvertently reversed or adjudicated.
13	Methadone Capitation Payment	This code is used to identify methadone capitation payments to pharmacies that have entered into a Capitation Agreement with the Ministry for the supply of methadone to ODB-eligible recipients.
15	Eligible for Resubmission	A Drug Benefit Claim or Drug Benefit Claim Reversal form may be submitted, indicating the Resubmission Number, the original ODB number (in the Original Client ID/Code field), and the appropriate changes. The Patient First Name, Patient Last Name, Client ID/Code and Version, Provider Transaction Date, Patient Date of Birth, Sex, and Pharmacy ID cannot be altered. In order for the resubmission to be accepted, the amount payable must be less than the original claim.
16	Not Eligible for Resubmission	This claim is not eligible for resubmission.
17	Eligible for New Claim Submission	A Drug Benefit Claim or Drug Benefit Claim Reversal form may be submitted, indicating the Resubmission Number, the original ODB number (in the Original Client ID/Code field), and the appropriate changes.

Reason/ Adjustment Type Code	Description	Explanation
		Either the ODB number (in the Client ID/Code field) or date of service (in the Provider Transaction Date) must be altered.
22	Transition payment	Additional dispensing fee over and above standard dispensing fee.

Rejected Claims

Rejected paper claims for payment and claim reversals will be recorded on a 'Reject Report for Paper Submissions' and will be delivered to the pharmacy via email on the next business day.

Transaction Codes

Transaction Code	Purpose of Transaction
A2	Ministry-initiated Batch Adjustment
A4	Ministry-initiated Agency Adjustment
D1	Claim level adjustment - Online claim
D2	Claim level adjustment - Paper claim
M1	Paper claim submission
M2	Paper claim reversal submission

Reject Report for Paper Submissions

The Reject Report for Paper Submissions will:

- List claim transactions that have been rejected
- State the reason for the rejection

Note: The Reject Report for Paper Submissions will be generated nightly by the Health Network System. It will be available to pharmacies via email on the day following the date the paper claim was adjudicated by the Ministry (*refer to Section 13*, Electronic Mail).

Pharmacies can use this report to reconcile accounts and correct paper claim submissions and claim reversals. The resubmission of rejected paper claims may be expedited by using the Resubmission Number shown on the Reject Report for Paper Submission (*refer to Section 8.2, Paper Drug Benefit Claim Submission and Drug Benefit Claim Reversal Forms).*

Sample Reject Report for Paper Submissions

Run Date: DEC 13, 2014 ODB - REJECT REPORT
Adj Date: DEC 12, 2014 FOR PAPER SUBMISSIONS

Dispense Dt: YYYY-MM-DD Pharm ID: ON12345678 Resub No: 123456789 Client ID/Ver: XXXXXXXXXX XX
First Name: XXXXXXXXXXXX Last Name: XXXXXXXXXXXXXXX

Birth: XXXX-XX-XX
Sex: X Carrier ID: Group No:

Health No: XXXXXXXXXXXXX DIN/GP #: Curr RX: 1234567

Quantity: Days Supp:

Presc ID: XXXXXXXXXX Presc Ref: XX

Drug Cost: Cost Upchg: Prof Fee:

SSC: Prod Sel: Unl Comp:

Comp Tm: Comp Chg: Med Reas:

Med Cond: Prev Pd: Rvsl Amt: 10.00

Phmcist ID: Int/Excpt Codes:

Response Codes:

A8 No Reversal Made/Orig Claim Missing

Message Line:

END OF REPORT

Drug Utilization Review Responses

Prospective DUR responses identified in the processing of paper claims will be reported on a DUR Responses for Paper Submissions report and will be delivered to the pharmacy via email on the next business day.

Drug Utilization Review Responses for Paper Submissions

The DUR Responses for Paper Submissions will list details for DUR responses identified while processing paper claims.

The DUR Responses for Paper Submissions will be generated nightly by the HNS. It will be available to pharmacies via email on the day following the date the paper claim was adjudicated by the Ministry.

Sample Drug Utilization Review Responses for Paper Submissions

Run Date: DEC 20, 2014 ODB - DUR RESPONSES

Adj Date: DEC 19, 2014 FOR PAPER SUBMISSIONS

CPhA Pharmacy ID: ODP1234567

Client ID: XXXXXXXXXX XX First Name: XXXXXXXXXXXX Last Name: XXXXXXXXXXXXXXX
DIN / PIN: 09850724 Drug Name: Allergen extracts

Dispense Dt: YYYY-MM-DD Current Rx: 123456

Prescriber: XX XXXXXXXXXX XXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXX

D7 Fill Too Soon

****

Client ID: XXXXXXXXXX XX First Name: XXXXXXXXXXXX Last Name: XXXXXXXXXXXXXXX
DIN / PIN: 09850724 Drug Name: Allergen extracts

Dispense Dt: YYYY-MM-DD Current Rx: 234567

Prescriber: XX XXXXXXXXXX XXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXX

D7 Fill Too Soon

END OF REPORT

11.3 Reconciliation of Remittance Statements

There are two ways of reconciling drug benefit payments deposited to your bank account by the Ministry:

Note: Remittance advice reports will only be received if there were paper drug benefit claims or drug benefit claim reversals processed or a Ministry adjustment in any given payment period.

Using the Summary Remittance Advice:

- From the ONE® Mail system, retrieve the Summary Remittance Advice for the same (payment) date as the "deposit date"
- Check for the payment amount (in the "Amount to be paid" column)
- Compare this payment amount to the amount deposited by the Ministry

If there is no Summary Remittance Advice:

- Gather all daily totals (previously requested online and kept on file) within that particular payment period that is covered by the "deposit date" (See Section 11.4, Payment Schedule)
- Based on the information collected, calculate the payment amount
- Compare this payment amount to the amount deposited by the Ministry

Payment Discrepancies
If there is an unresolved payment discrepancy, contact the ODB Help Desk (see Section 14, Help Desk). Be prepared to provide your pharmacy name, Pharmacy ID and payment date.

11.4 Payment Schedule

The Ministry issues two payments per month:

- At the middle of each month
- At the end of each month.

Approved online claims/reversals will be processed by the Ministry for payment according to the following Online Payment Periods schedule:

Online Payment Periods

Cut-off Date	Covers this period	For payment
By 9th of each month (up to 3:30 a.m. Eastern Time)	23rd of previous month (after 3:30 a.m. Eastern Time) to 9th of current month (up to 3:30 a.m. Eastern Time)	End of month payments
By 23rd of each month (up to 3:30 a.m. Eastern Time)	9th of current month (after 3:30 a.m. Eastern Time) to 23rd of current month (up to 3:30 a.m. Eastern Time)	Middle of following month payments

11.5 Direct Deposit

To register for direct deposit or change direct deposit information, complete the Notification of Change form (see Section 2.2) and send it by fax to (613) 548-6614 or by email to: HNS-Registration.MOH@ontario.ca or by mail to:

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

Note: A blank cheque marked “VOID” will be required with the direct deposit application.

When changing direct deposit information, existing bank accounts should be kept open for at least one month.

Section 12: Inspection

Overview

Under the authority of Section 14 of the ODBA, the minister appoints inspectors to conduct inspections of pharmacies.

This section explains policies and procedures that pharmacies must observe and explains how compliance with the policies and procedures will be assessed during an inspection.

Use of Intervention/Exception Codes

The pharmacy must adhere to the rules applicable to the use of intervention/exception codes as described in this manual. It is essential that the appropriate intervention/exception codes are used.

Inspectors in the Ministry's Pharmaceutical Strategy Unit will closely monitor the use of these codes.

Policy for Establishing Eligibility

The pharmacy must ensure that proof of eligibility is kept on file. Failure to do so will result in recovery of payments.

Acceptable Supporting Documentation

Many claims require supporting documentation, as indicated in the chart below. Documentation must be kept on file at the pharmacy in a readily retrievable format for a minimum of two years from the date of the last claim for claim validation purposes under the ODB program. Documentation must be complete and accurate, and may be in the form of original paper documents, unaltered electronic scanned images of original documents, or electronic records.

Type of submission	Supporting Documentation Required
All claims	Prescriptions and all supplier invoices (wholesalers and manufacturers) as directed in Section 5 of Regulation 936 under DIDFA. This includes any invoices and documentation related to transfers of drugs to/from other pharmacies from additional sources.

Type of submission	Supporting Documentation Required
Claims for Home Care recipients	Drug Benefit Eligibility Card (or written/fax notification from a Local Health Integration Network) valid for the date of service. *See Section 4.2, Policy For Establishing Eligibility for Payment.*
Claims for OW and ODSP	For claims validated using a paper drug card, the paper drug card must be retained on file. For claims validated successfully in the HNS using the patient's valid Ontario Health number, where no intervention codes are required, no further documentation is required. For claims validated through the SAV Portal or SAV Helpline when the patient's Ontario Health number information is rejected by the HNS indicating that eligibility cannot be established on the HNS network: 1) A print out of the SAV Portal search results or documentation of the following: • Reference number • Date of search ('Eligibility Result as of') • Type of Coverage ('Plan Code C or Plan Code D) • Results of the search (e.g., eligible or ineligible) OR 2) The SAV Helpline upon completion of the call will provide the pharmacy information for eligible results based on the following: • The confirmation number • Date and time of call • Eligibility Coverage period • Type of Coverage (Plan Code C or D) • Results of the search (e.g., eligible or ineligible) *See Section 4.2, Policy For Establishing Eligibility for Payment.*
Claims for Home for Special Care / Community Home for Special Opportunity	Patient eligibility (i.e., residents of Homes for Special Care/Community Homes for Opportunity) can be confirmed by contacting the MOH's Financial Management Branch (FMB) at: 416-326-9842. Documentation that eligibility has been confirmed is needed.

Type of submission	Supporting Documentation Required
Claims for children and youth when the pharmacist has established eligibility	A copy of the Ontario Health Card, or other proof of OHIP eligibility (e.g., a copy of the **detachable portion of the Ontario Health Coverage Infant Registration Form).**
Extemporaneous preparations claim	The formula of the preparation, set out in a manner that clearly indicates all the ingredients and the quantities of those ingredients, the cost of each ingredient (i.e., copy of the manufacturer's or wholesaler's invoice(s) which demonstrate the Acquisition Cost of the ingredients) and the compounding time.
Medically necessary "No Substitution" claim	Health Canada Side Effect Reporting form(s) completed and signed by the prescriber where a patient has experienced significant adverse reactions with two lower cost interchangeable drug products (where available), the prescription on which the prescriber has prescribed the higher cost interchangeable product, and the prescriber has directed that there be "No Substitution" or "No Sub".
LU product claim	Prescription with LU documentation, including an RFU code. RFU codes may be communicated in writing, electronically or verbally. RFU code must be documented on the prescription.
Emergency Authorization claim	Copy of the authorization to dispense items usually provided to LTC homes by the Ontario Government Pharmaceutical and Medical Supply Service.
Allergen claim	Valid SAA form (completed and signed by the prescriber). Manufacturer or wholesaler invoices must be readily retrievable for claim validation.
Cost-to-Operator claim	Copy of the manufacturer's or wholesaler's invoice(s) which demonstrate the Acquisition Cost claimed, as well as invoices which show that the lowest priced interchangeable product was ordered and not available at the time of the cost-to-operator claim.
Vacation Supply claim	Copy of a letter signed and dated by the recipient indicating dates of travel, or a copy of the recipient's travel insurance, confirming that the recipient is leaving the province for between 100 and 200 days.
EAP claim	When Acquisition Cost is being claimed, a copy of the supplier's invoice and a detailed calculation of the cost of purchasing the drug product. Reminder: Reimbursement is subject to lowest cost OFI products.

Type of submission	Supporting Documentation Required
Nutritional Product claim	Valid nutrition product form(s) (completed and signed by the prescriber and the dispenser).
Diabetic Testing Agent claim	If intervention codes are entered to override the test strip limit, reasons for the override must be documented on the prescription.
30-Day Prescription Program claim	If intervention codes are used to override the 30-day limitation, reasons for the override must be documented on the prescription hard copy.
SDP claim	Supplier invoices (wholesalers and manufacturers) may be required to validate claims.
MedsCheck claim	MedsCheck documentation records including assessment summaries must be retained by the pharmacist in a readily retrievable format. Please refer to the Professional Pharmacy Services Guidebook 3.0 for program details.
Claims dispensed that are less than the maximum quantity	A written record of the reasons for the dispenser's opinion. A copy of the notification to the prescriber about the determination. The agreement of the eligible recipient or the person presenting the prescription.
POP (Pharmaceutical Opinion Program) claims	Original prescription or a copy, whether verbal or written, along with the documentation criteria set out in the Professional Pharmacy Services Guidebook 3.0 must be retained by the pharmacist in a readily retrievable format.
Smoking Cessation	Smoking cessation documents and associated patient records including any written referrals and patient consent documentation; drug therapy information and desired outcomes / action plans; and specifics on quit smoking plans and advice offered to the patient must be retained by the pharmacist in a readily retrievable format.
Universal Influenza Immunization Program claim	A record of every dose of publicly funded influenza vaccine administered must be retained by the pharmacist in a readily retrievable format. In addition, in cases where epinephrine auto-injection was administered for emergency use following pharmacist-administered influenza injection, a record must be retained by the pharmacist in a readily retrievable format.

During an on-site inspection, the above records must be readily available. If filing is such that the documents are not readily retrievable, it is the responsibility of the pharmacy owner/manager to

provide the required documents. Failure to do so will result in recovery of amounts paid for claims for which the required documents are not supplied.

The Ministry may periodically select a sample of claims for which a pharmacy must supply supporting documentation.

Failure to provide supporting documentation for a select sample of claims will prompt one or more of the following actions:

- Request for expanded sample of documentation;
- Recovery of funds for claims not supported by documentation;
- An inspection.

Retention of Records

Section 29 of O. Reg 201/96 made under the ODBA specifies a number of records which must be retained by the pharmacy for a particular period of time (please see the regulation for details):

A copy of a statement of daily transaction totals prepared each day

A copy of each summary remittance statement or reject statement received from the Executive Officer

A copy of each paper claim for payment or claim reversal submitted to the Ministry, together with a record of the date on which the claim was submitted

The monthly Drug Benefit Eligibility card or a copy of the card with respect to each eligible person for whom a drug is dispensed (or, a record log or print out of eligibility verification results where social assistance recipients' eligibility for coverage is confirmed through the SAV Portal or SAV Helpline)

Each prescription received that contains a direction that there be no substitution, as well as a copy of the Health Canada Side Effect Reporting Form(s) received with the prescription

Each prescription received that contains a Reason for Use Code, as set out in the Formulary, which shall be deemed to be confirmation by the prescriber that the applicable clinical criteria for Limited Use have been met

For each extemporaneous preparation supplied to ODB program recipients, the formula of the preparation set out in a manner that clearly indicates all the ingredients, the quantities of those ingredients, the cost of each ingredient (i.e., manufacturer or wholesaler invoice) and the compounding time

In all cases where the Acquisition Cost of a drug is claimed, a copy of the supplier's invoice and a detailed calculation (in accordance with section 14 of O. Reg 201/96) of the cost of purchasing the drug product

Where the dispenser has made a determination that the quantity of a drug supplied should be less than the maximum quantity under section 18 of O. Reg 201/96 or less than the amount prescribed, the dispenser shall make and retain written reasons for his or her opinion, obtain and retain the patient's (or agent's) written agreement to the dispensed quantity, and obtain and retain a copy of the notification the dispenser gave to the prescriber about the determination.

In accordance with O. Reg. 264/16 under the DPRA, all pharmacies are required to keep documents relating to the care of a patient for a period of at least 10 years from the last recorded pharmacy service provided to the patient or until 10 years after the day on which the patient reaches or would have reached the age of 18 years, whichever is longer.

Examples of records and documents included but are not limited to:

- MedsCheck documentation
- Pharmacist refill authorization information
- Pharmaceutical opinion
- Medication management
- Identified drug related problems
- Consent forms
- Dialogue with patients
- Any other information essential for continuity of care
- Any future record keeping requirements under the new expanded scope of practice

Please refer to OCP's Guideline on Record Retention, Disclosure and Disposal for more information.

Control of Network Access

The pharmacist owner/manager is responsible for authorizing and delegating network access to the HNS. They are also responsible for maintaining security on their systems and keeping confidential any information received from the Ministry. *Refer to Section 3, Confidentiality and Security*.

Recoveries

The Ministry may recover amounts paid for claims which are submitted contrary to the provisions of the ODBA, O. Reg 201/96 or the HNS Subscription Agreement or which relate to dispensing

activities that are contrary to accepted standards of professional practice. This includes, **but is not limited to**, amounts paid for:

- Claims for prescriptions improperly cancelled or not dispensed
- Claims paid in error
- Claims for quantities in excess of the maximum number of days' supply
- Claims resulting from failure to monitor dosages
- Claims associated with improper use of intervention codes
- Claims for which required supporting documentation is expired or not supplied upon request
- Claims that do not satisfy Program or documentation criteria
- Claims submitted for amounts in excess of what is allowed by the ODBA, O. Reg 201/96, and the HNS Subscription Agreement
- Claims associated with improper number of days' supply
- Claims for MedsCheck services for which MedsCheck documentation records, including assessment summaries signed and dated by the patient and the pharmacist, are not available for review
- Claims for Expanded Services for which the original prescription, whether verbal or written, along with the documentation criteria are not available in a readily retrievable format. When verbal prescription is in question, the rules set out by the college apply.
- Claims for dispensing fees submitted in violation of the "Conditions for Payment of Dispensing Fees" (see Section 5).

Recovery Letters (outlining the amount of overpayment identified from an inspection) will be sent to the pharmacy.

Penalties

Penalties for violation of certain provisions of the ODBA are set out in Section 15 of the Act. Inappropriate use of the HNS can result in revocation of network access (as specified in the terms and conditions of the HNS Subscription Agreement).

Pursuant to Sections 11.1 and 11.2 of the ODBA, breach of a condition prescribed by the regulations or agreed to by the pharmacy operator or physician can result in suspension from entitlement to receive payment from the Ministry.

Section 13: Electronic Mail

Overview

eHealth Ontario's ONE® Mail email system is a secure email accessible via the internet. The ONE® Mail email system is used to advise pharmacies of drug benefit changes, program changes, and

payment information. A **single** ONE® Mail email account is provided to each pharmacy upon approval of a new HNS account for accessing Ministry messages. Any changes to the accreditation number of a pharmacy will require a new HNS account number and new corresponding ONE® Mail account.

The Ministry will address the communication directly to registered account users. ONE® Mail email messages will include important Executive Officer Communication, Summary Remittance Advice statements, Formulary Updates, Monitored Drugs Updates, CPSO Notices, and Prescription Forgery alerts for pharmacies.

Pharmacies should:

- Check for the Ministry messages preferably on a daily basis and at a minimum once per week.
- Delete old messages that are no longer required from the ONE® Mail email account on a regular basis.

This section outlines the process involved with:

- ONE® Mail Registration
- ONE® Mail Account Activation
- Registration Information Change Request Form for ONE® Mail Account
- Troubleshooting

Pharmacies are reminded that under the terms of the HNS Subscription Agreement, they are required to log on to the ONE® Mail email system at least once per week.

ONE® Mail Registration

The ONE® Mail Registration form is provided as part of the HNS registration process. The pharmacy owner/pharmacist with signing authority will be the owner of the ONE® Mail account. The pharmacy must submit the completed ONE® Mail Registration form to the ODB registration desk. Please refer to the form for terms and conditions governing the use of the ONE® Mail email system.

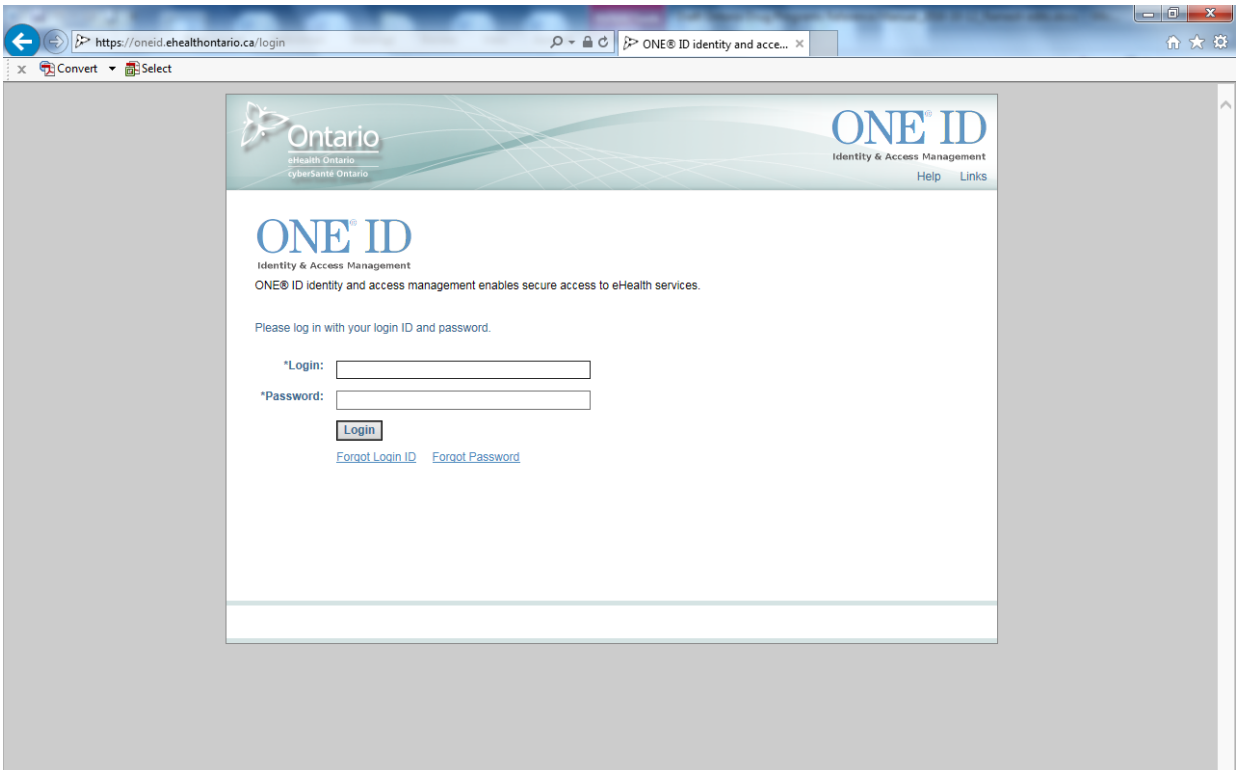
ONE® Mail Account Activation

Upon registration, eHealth Ontario will notify the pharmacy to confirm that the ONE® Mail account registration is complete. This confirmation email will be sent to the pharmacy's personal or corporate email address (provided by the pharmacy on the ONE® Mail registration form) and provides instructions for ONE® Mail account activation, including ONE® Mail account ID and user name of the account owner. In order to activate the ONE® Mail account, the account owner will need a temporary password, which can be obtained by calling the eHealth Ontario service desk

at 1-866-250-1554. After obtaining a temporary password, the user will be required to use eHealth Ontario's ONE® ID (Identity and Access Management) system to login for the first time by using the ONE® Mail user name and temporary password provided. The web link to access ONE® ID system is: https://oneid.ehealthontario.ca/login

ONE® ID is an authentication service used to manage access to eHealth Ontario's ONE® Mail email service.

The screenshot for ONE® ID system is provided below:



Once the user has logged into ONE® ID self-management, the user will need to agree to eHealth Ontario's acceptable use policy. Select three secret questions and provide answers to these questions and select a new password (specifying your temporary password as the old password).

These secret questions and answers will be used by the user for re-setting the password in future.

ONE® Mail Direct User Guide

Visit eHealth Ontario's website for accessing ONE® Mail Direct user guide:

http://www.ehealthontario.on.ca/images/uploads/services/resources/ONE_Mail_Direct_Web_Browser_Guide.pdf

Generic Email Account Information Change Request Form (for ONE® Mail Account)

The Generic Email Account Information Change Request Form can be obtained by contacting the ODB Help Desk or email to MOH.G.HNS.ONE.MAIL@ontario.ca for ONE® Mail account changes including:

- Change of ONE® Mail account ownership
- Changes to ONE® Mail registrant information, such as name and/or phone number
- Change of pharmacy trade name
- Forgotten secret questions and answers
- Forgotten logins or passwords

Pharmacies must forward the signed and completed Generic Email Account Information Change Request Form by mail, fax or email to:

Ministry of Health
Claims Services Branch
Provider Registry
P.O. Box 68
Kingston ON K7L 5K1
Fax: (613) 548-6614
MOH.G.HNS.ONE.MAIL@ontario.ca

Troubleshooting

For ONE® Mail account login issues, including password resetting, call the eHealth Ontario service desk at 1-866-250-1554.

For ONE® Mail registration issues, call the ODB Help Desk at 1-800-668-6641.

Section 14: Help Desk

Overview

The ODB Help Desk was established by the Ministry to provide both technical and business support to users of the HNS. The ODB Help Desk provides a central point of contact for prompt response to pharmacies' inquiries. The toll-free number provided to pharmacies is for pharmacy use only.

ODB recipients should call ServiceOntario INFOline at 1-866-532-3161 for inquiries or assistance.

This section explains:

- Procedures to deal with issues or problems that may be resolved prior to contacting the ODB Help Desk (*see Section 14.1*)
- The two types of issues/inquiries with which the ODB Help Desk is prepared to provide assistance (*see Section 14.2*)
- How the phone call will be handled by the ODB Help Desk (*see Section 14.3*)

14.1 Troubleshooting

Before you call the ODB Help Desk:

- Check all computer connections
- Contact your Pharmacy Software Vendor to ensure that all software packages are error free
- Refer to the applicable section of this Manual (for problems that you may be able to resolve) as shown on the following table:

Type of Problem	What to do before you call….
Adjudication of a Claim	Consult this Reference Manual
Reject / Response Error	Consult this Reference Manual (*Refer to Section 10.1, Response Code Table)*

Type of Problem	What to do before you call….
Cannot Complete Call or Time out Messages or Network Error or System Not Available or Process Error/ Host Processing Error	Consult your Pharmacy Software Vendor's manual; then Contact your Pharmacy Software Vendor and/or your Corporate Internal Helpdesk Then, if the issue cannot be resolved, contact your Acquirer Host.

14.2 Types of Inquiries & Hours of Service

Pharmacy inquiries can be classified into two categories:

- Business
- Technical

Business inquiries are questions or problems relating to ODB program eligibility, claims processing, policy and procedures.

Hours of service: 8 a.m. to 5 p.m. Mon to Fri (except Statutory Holidays) (Regular Ministry business hours)

Technical inquiries/service calls are for questions or problems relating to the HNS and its operation.

Hours of service: 24/7 (i.e., 24 hours a day, 7 days a week, 365 days a year)

Note: Technical Help Desk agents are available to receive emergency technical inquiries outside of regular business inquiry hours (i.e., 5 p.m. to 8 a.m.); resolution of business inquiries will not be addressed until the next business day.

14.3 How Your Call is Handled

Be prepared to provide your Pharmacy ID Code (see *Section 2.1*) and patient ODB Eligibility Number when calling the ODB Help Desk.

Once a call is established:

- ODB Help Desk agent identifies the nature of the inquiry/problem
- ODB Help Desk agent logs inquiry/problem and assigns the inquiry/problem to a particular owner responsible for its resolution
- ODB Help Desk agent determines severity level
- A Problem Ticket Number is assigned
- If the inquiry/problem is resolved, the Problem Ticket is closed
- If the inquiry/problem cannot be resolved immediately, the affected pharmacy will be advised immediately, while steps are taken to address/resolve the inquiry/problem (within defined escalation standards)

When calling back to the ODB Help Desk regarding an existing inquiry/problem, please provide the Problem Ticket Number.

Glossary of Terms

Term	Definition
ACSD	Assistance for Children with Severe Disabilities
Acquirer Host	Independent (third-party) system which accepts real-time transactions from pharmacies and routes them to the Health Network System
Acquisition Cost	Same as CTO. (*Refer to Acquisition Cost Calculations in Section 6.7)*
Adjudication	Processing of a claim by the HNS that includes the following: • validate submission date • determine recipient eligibility for claimed benefit • determine payment amount • conduct prospective DUR • validate claim detail, and • provide claim response.
AIDS	Acquired Immune Deficiency Syndrome
ANPD	Approved Non-Prescription Drug
BGTS	Blood Glucose Test Strips
BIN	Bank Identification No. (identifying Ministry of Health)
CBCRP	Case-by-Case Review Program
CCO	Cancer Care Ontario
CDI	Comparative Drug Index
CMQ	Collège des Médecins du Québec
CNO	College of Nurses of Ontario
Co-payment	Recipient share of the professional service fee for an ODB-eligible prescription, as set out in O. Reg 201/96 under the ODBA.
CPhA	Canadian Pharmacists Association
CPhA Standard	Pharmacy Claim Standard, published by the Canadian Pharmacists' Association
CPhA Version	Number assigned to a version of the CPhA Standard
CPR	Cardiopulmonary Resuscitation
CPSM	College of Physicians and Surgeons of Manitoba
CPSO	College of Physicians and Surgeons of Ontario
CRA	Canada Revenue Agency
CTO	Cost to Operator

Term	Definition
DBP	Drug Benefit Price
Deductible	Amount an individual or household must spend on prescription drugs before becoming eligible for coverage
DHDR	Digital Health Drug Repository
DIDFA	Drug Interchangeability and Dispensing Fee Act
DIN	Drug Identification Number
DPP	Designated Pharmaceutical Product
DPRA	Drug and Pharmacies Regulation Act
DPV	Drug Profile Viewer
DUR	Drug Utilization Review
EAP	Exceptional Access Program
EFT	Electronic Funds Transfer
Electronic Mail	Electronic messaging system
EO	Executive Officer
Establish eligibility	Policy which permits dispensing of prescriptions for recipients not yet registered as eligible on the HNS
Exception Code	Code used with online transactions to identify special situations (same meaning as Intervention Code)
FAQ	Frequently Asked Question
FIPPA	Freedom of Information and Protection of Privacy Act
FMB	Financial Management Branch
GP#	General Product Number
HIA	Health Insurance Act
HIV	Human Immunodeficiency Virus
HNS	Health Network System
HSC	Homes for Special Care
HSCA	Homes for Special Care Act
ID	Identification
Intervention Code	Code used with online transactions to override specific situations (same meaning as Exception Code)
IV	Intravenous
LHIN	Local Health Integration Network
LTC	Long-Term Care

Term	Definition
	LTC home is a place that is licensed as a long-term care home under the LTCHA, and includes a municipal home, joint home or First Nations home approved under Part VIII of the LTCHA.
LTCHA	Long-Term Care Homes Act, 2007
LU	Limited Use
MAID	Medical Assistance In Dying
Mandatory Field	Required data on claim submission
MAR	Maximum Allowable Reimbursement
MCCSS	Ministry of Children, Community and Social Services
MDL	Monitored Drugs List
MMT	Methadone Maintenance Treatment
MOH	Ministry of Health
NAPRA	National Association of Pharmacy Regulatory Authorities
NDS	National Drug Schedule
NMS	Narcotics Monitoring System
NOC	Notice of Compliance
NSAA	Narcotics Safety and Awareness Act, 2010
Non-Standard Claims	Claims which require special claim instructions, including input to data fields other than those listed under *Section 5.1*
OCP	Ontario College of Pharmacists
ODB	Ontario Drug Benefit
ODB Eligibility Number	Ontario Health number (or other number) that identifies a recipient of ODB program benefits
ODBA	Ontario Drug Benefit Act, R.S.O. 1990, c.O.10
ODBF	Ontario Drug Benefit Formulary
ODP	Ontario Drug Programs
ODSP	Ontario Disability Support Program
OFI	Off-Formulary Interchangeability
OGPMSS	Ontario Government Pharmaceutical and Medical Supply Service
OHIP	Ontario Health Insurance Program
OHIP+	ODB eligibility category for children and youth aged 24 and under, who do not have a private plan
OLTP	On-Line Transaction Processing

Term	Definition
Online	Submitted electronically via the network
Ontario Health number	10-digit number that identifies a recipient of health care benefits provided by the Ministry of Health Note: In some cases, a one or two-character Version Code forms part of the Health number
OPDP	Ontario Public Drug Programs
OW	Ontario Works
Override	Intervention and Exception Code
Password	User-assigned code which must be entered before access can be gained
PBDP	Provincial Borders Drug Program
Pharmacist ID	Pharmacist's registration number with OCP
Pharmacy	The term 'pharmacy' is used in this manual for consistency and ease of reading, however, all pharmacy requirements refer equally to Dispensing Physician accounts as well
Pharmacy ID	Unique identification code used to identify the pharmacy
PHIPA	Personal Health Information Protection Act, 2004
PIN	Product Identification Number In certain situations, a listed drug product on the Formulary (or a drug approved through the EAP) may be assigned a product PIN instead of a DIN (e.g., if there are two different package sizes, a PIN may be assigned to one of the pack sizes). PINs are also used for listed substances - nutritional products and diabetic test strips. Other service PINs are used to bill claims for MedsCheck, Pharmaceutical Opinion Program, other expanded scope of practice activities, etc.
POP	Pharmaceutical Opinion Program
Professional service fee	The dispensing fee payable by the Ministry to pharmacies for supplying an ODB-eligible prescription, in accordance with the O. Reg 201/96 under the ODBA.
PSV	Pharmacy Software Vendor Person or organization which develops and maintains the pharmacy management software
Prospective DUR	Drug Utilization Review conducted at time of dispensing

Term	Definition
Recipient	Person eligible for benefits provided by the ODB program
Response Code	Code assigned to error or information messages some of which may cause a claim to be rejected
Reversal	Transaction that reverses a previous claim submission
RFU	Reason for Use
RHPA	Regulated Health Professions Act, 1991
SAA	Special Authorization Allergen
SAN	Special Authorization Number
SAP	Special Access Program
SAV	Social Assistance Verification
SCP	Senior's Co-payment Program
SDP	Special Drugs Program
SSC	Special Service Code
Standard Claims	Claims which do not require special claim instructions
TCA	Temporary Care Assistance
Third-Party Host	See Acquirer Host
TDP	Trillium Drug Program
Transaction	Submission of a claim, claim reversal or request for information
Transaction Code	Unique code assigned to each type of transaction or system response
TRS	Telephone Request Service
UIIP	Universal Influenza Immunization Program
USPDI	United States Pharmacopeia - Drug Information
User ID	Unique code used to identify an authorized person or organization accessing the network
Version Code	One- or two-character code assigned to a replacement Health Card

Appendix A: Extemporaneous Preparations Table

Category	Compound Type Code[1]	Compounding PIN[2]
1. Methadone preparation (using methadone powder). Exceptional Access Program approval is required for methadone compounding from powder.	N/A	09857499
2. Preparation is for oral consumption and contains a solid oral dosage form of a listed drug product compounded into a liquid or capsule and no other medicinally active substance.	**3** or **5** Note: Enter the DIN/PIN of the listed drug product with the highest cost in all cases	N/A
3. Preparation is for injection and contains an ODB benefit that is approved by Health Canada for injectable administration and meets the requirements of the Extemporaneous Preparation Reimbursement Policy for injectable preparations outlined in section 6.1 of this manual. **Claim each prepared unit (bag or vial) as a quantity of 1.** ***For example:*** *claimed quantity for three 50mL bags is 3* *claimed quantity for one 250mL bag is 1* ***Note: This should be used for the preparation of ALL IV bags for infusion***	**6** (when using the DIN/PIN of a listed drug product)	09850627
4. Preparation is for dermatological/topical use and contains a single ODB listed drug product used for dermatological/topical purposes and no other medicinally active substances other than one or more of the following: camphor, compound benzoin tincture, hydrocortisone powder, liquor carbonis detergens, menthol, salicylic acid, sulfur or tar distillate.	**0**, **1** or **2** Note: Enter the DIN/PIN of the listed drug product with the	N/A

Category	Compound Type Code[1]	Compounding PIN[2]
	highest cost in all cases	
5. A dermatological/topical nitrogen mustard preparation.	N/A	09850635
6. A dermatological/topical preparation consisting of liquor carbonis detergens, salicylic acid, sulfur or tar distillate, but no other active substance, compounded in petrolatum jelly or lanolin.	N/A	09850643
7. An ophthalmic solution containing amikacin, cefazolin or vancomycin.	**7** (when using the DIN/PIN of a listed drug product)	09850651
8. An ophthalmic solution containing gentamycin or tobramycin in a concentration greater than three milligrams per millilitre.	**7** (when using the DIN/PIN of a listed drug product)	09850678
9. An Extemporaneous Total Parenteral Nutrition (TPN) Preparation.	N/A	09850686
10. IV Cassette preparation 50mL size. **Claim each prepared unit as a quantity of 1**.	N/A	09850694
11. IV Cassette preparation 100mL size. **Claim each prepared unit as a quantity of 1**.	N/A	09850708
12. Other IV Infusion Device* up to 100mL. **Claim each prepared unit as a quantity of 1.**	N/A	09857134
13. Other IV Infusion Device* 101mL to 250mL. **Claim each prepared unit as a quantity of 1**.	N/A	09857135
14. Other IV Infusion Device* greater than 250mL. **Claim each prepared unit as a quantity of 1.**	N/A	09857136

*Note: All regular IV infusion bags, regardless of volume (e.g., NS 250mL) should be claimed under Compounding PIN 09850627 or Compound Code Type 6 (if using the DIN/PIN of a listed drug product).

[1] Compound Type Code

This code identifies the type of compound. It is entered in the Unlisted Compound field and indicates that the claim is for an extemporaneous preparation (compound) for a formulary benefit product (or an EAP approved drug) with a DIN/PIN. Please note that the Compounding PIN should not be used in these cases.

Code	Type of Compound
0	compounded topical cream
1	compounded topical ointment
2	compounded external lotion
3	compounded internal use liquid
5	compounded internal powder
6	compounded injection or infusion
7	compounded ear/eye drop

[2]Compounding PIN

Compounding PINs should only be used for preparing a compound with an unlisted drug product (as its highest cost) that meets the Extemporaneous Preparations guidelines (*see Section 6.1*). In addition, certain compounding PINs are assigned to allow billing of approved extemporaneous preparations that are compound specific.

Infusion sets, tubings, empty bags, syringes, adaptacaps, etc. are not eligible for reimbursement under the Extemporaneous program and therefore should not be added to the drug cost.

Appendix B: Approved Non-Prescription Drug Products

The Pharmacy and LTC Home Requisition forms for ODB ANPDs can be accessed from the Central Forms Repository website.

PIN	Product
9857143	Acetaminophen 325mg Tab
9857144	Acetaminophen 500mg Tab
9857145	Acetylsalicylic Acid 325mg Ent Tab
9857147	Acetylsalicylic Acid 650mg Ent Tab
9857238	Ascorbic acid 500mg Tab
9857149	Bisacodyl 5mg Ent Tab
9850783	Chlorpheniramine Maleate 4mg Tab
9850775	Cyproheptadine HCl 4mg Tab
9850848	Dimenhydrinate 50mg Tab
9850791	Diphenhydramine 25mg Tab or Caplet
9850805	Diphenhydramine 50mg Tab or Caplet
9857153	Docusate Sodium 100mg Cap
9857154	Ferrous Gluconate 300mg Tab
9851267	Ferrous Sulfate 300mg Tab
9851178	Multivitamin Tab
9854347	Potassium Chloride 8mEq LA Cap
9857239	Potassium Chloride 8mEq LA Tab
9857164	Sennosides A & B 8.6mg Tab
9851194	Vitamin B Compound & C Cap or Tab

Appendix C: Approved Non-Prescription Drug Products - Emergency Authorization

If the Ontario Government Pharmaceutical and Medical Supply Service (OGPMSS) is unable to supply ANPD directly to the LTC Home and Emergency Authorization has been granted, the pharmacy may submit claims with the following PINs.

The Pharmacy and LTC Home Requisition forms for ODB ANPDs can be accessed from the Central Forms Repository website.

PIN	Product
9857143	Acetaminophen 325mg Tab
9857144	Acetaminophen 500mg Tab
9857145	Acetylsalicylic Acid 325mg Ent Tab
9857147	Acetylsalicylic Acid 650mg Ent Tab
9850759	Aluminum Hydroxide & Magnesium Hydroxide & Dimethylpolysiloxane 40mg & 40mg & 5mg O/L
9854320	Aluminum Hydroxide & Magnesium Hydroxide 40mg & 40mg/mL O/L
9854312	Aluminum Hydroxide 64mg/mL O/L
9850732	Analgesic Rub
9857238	Ascorbic acid 500mg Tab
9857148	Bisacodyl 10mg Sup
9857149	Bisacodyl 5mg Ent Tab
9850953	Body Lotion
9850961	Calamine Lotion
9850929	Cascara Sagrada O/L
9850813	Chlorhexidine Gluconate 0.05% w/v Sterile Aqueous Antiseptic Sol
9850783	Chlorpheniramine Maleate 4mg Tab
9857151	Cyanocobalamin 1mg/mL Inj Sol

PIN	Product
9850775	Cyproheptadine HCl 4mg Tab
9857152	Dextromethorphan HBR 3mg/mL O/L
9850856	Dimenhydrinate 100mg Sup
9850872	Dimenhydrinate 3mg/mL O/L
9850864	Dimenhydrinate 50mg Sup
9850848	Dimenhydrinate 50mg Tab
9850996	Dimethylpolysiloxane 20% Cr
9850791	Diphenhydramine 25mg Tab or Caplet
9850805	Diphenhydramine 50mg Tab or Caplet
9857153	Docusate Sodium 100mg Cap
9857154	Ferrous Gluconate 300mg Tab
9851267	Ferrous Sulfate 300mg Tab
9854339	Glycerin 2.7g Adult Sup
9850945	Guaifenesin 20mg/mL O/L
9850821	Hydrogen Peroxide 3% Sol
9851011	Isopropyl Rubbing Alcohol
9857156	Magnesium Hydroxide 80mg/mL O/L
9857157	Methylcellulose 0.5% Oph Sol
9857158	Methylcellulose 1% Oph Sol
9851178	Multivitamin Tab
9857160	Nitroglycerin 0.6mg SL Tab
9857161	Potassium Chloride 1.33mEq/mL O/L
9854347	Potassium Chloride 8mEq LA Cap
9857239	Potassium Chloride 8mEq LA Tab
9854355	Povidone-Iodine 10% Top Sol

PIN	Product
9857163	Psyllium Mucilloid Oral Pwd
9857164	Sennosides A & B 8.6mg Tab
9857165	Sodium Biphosphate & Sodium Phosphate 160mg & 60mg/mL Enema
9851259	Sodium Chloride 0.9% Sol for Irrigation
9851119	Sterile Water for Irrigation
9851208	Vitamin A & D & C & B Complex Ped O/L
9851194	Vitamin B Compound & C Cap or Tab
9851135	Water for Injection
9851046	White Petroleum Oint
9854394	Zinc Oxide 15% Oint
9857167	Zinc Sulfate 0.5% Oint

Appendix D: Allergen Products

DIN/PIN	Product
09850724	Allergen Extracts
00509558	Epipen 1/1000
00578657	Epipen Jr. 0.5mg/mL
00464988	Pollinex R

Catalogue No. 300121 ISBN 978-1-4868-4017-5 (PDF) January 2020