Ontario Drug Programs Reference Manual

Delivery and Eligibility Review Branch
Health Programs and Delivery Division
Ministry of Health

November 27, 2019 Revision #10 – December 27, 2023

© Queen's Printer for Ontario





*COVID-19 Notice

The Ministry of Health has made some changes to the Ontario Drug Benefit Program and may continue to make changes related to COVID-19. The changes related to COVID-19 are not reflected in this Manual. Please refer to the Executive Officer Notices and Qs & As posted on the Ministry's website for the following:

- Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies
- Publicly Funded COVID-19 Testing Services in Ontario Pharmacies
- Supplying of Publicly Funded Evusheld[™] for Pre-Exposure Prophylaxis of COVID-19 in Ontario Pharmacies
- Prescribing & Dispensing Publicly Funded Paxlovid™ in Ontario Pharmacies
- Executive Officer Notice: Dispensing Publicly Funded Remdesivir (Veklury™) in Ontario Pharmacies

The Executive Officer Notices can be found on the <u>Ontario Public Drug Programs</u> <u>– Executive Officer Communications</u> website.

Pharmacies are reminded to check their Microsoft Office 365 (O365) email account (replacement of the ONE® Mail email account) for regular updates to these policies and others that apply during this period.

Reminder to pharmacies

Due to the COVID-19 pandemic, **most** Ontarians with expiring and expired Ontario Health cards will continue to have access to insured health services. Pharmacy staff are reminded to encourage patients to update their Ontario Health card if applicable.

For more information, please access the <u>ministry announcements</u> on extended coverage.



Revision #10 Updates

The following updates are reflected in this Revision (Revision #10), effective December 27, 2023:

Section	Description of update
Section 4.1	Updated language on ODB access for recipients of social assistance from First Nations ODSP & OW offices on reserve
Section 6.20	Updated eligibility of Compensation for Pharmacists under the Biosimilar Policy



Table of Contents

*COVID-19 Notice	2
Reminder to pharmacies	2
Revision #9 Updates	3
Introduction	11
Purpose	11
Background	12
Health Network System (HNS)	12
Narcotics Monitoring System	13
Digital Health Drug Repository	13
Ontario Public Drug Programs Forms	15
Section 1: Updates	16
Overview	16
Section 2: Registration and Notice of Changes	17
Overview	17
2.1 Program Registration	17
2.2 Notification of Change(s)	21
2.3 Closure or Sale of Pharmacy	22
Section 3: Confidentiality and Security	23
Overview	23



3.1	Privacy of Patient Information	23
3.2	Security	24
Secti	on 4: Eligibility	25
Ov	erview	25
4.1	Program Eligibility	25
4.2	Policy for Establishing Payment Eligibility	48
Secti	on 5: Standard Online Claims	54
Ov	erview	54
5.1	To Submit a Standard Online Claim	59
5.2	To Reverse a Standard (or Non-Standard) Online Claim	64
5.3	Reconciliation of Online Claims and Reversals	66
5.4	To Request Daily Totals	67
5.5	To Request Claim Details	70
5.6	To Request Same Day Reversal Details	72
5.7	To Request Prior Day Reversal Details	74
Secti	on 6: Submit Non-Standard Online Claims	77
Ov	erview	77
6.1	Extemporaneous Preparations	78
6.2	Medically Necessary "No Substitution" Claims	84
6.3	Limited Use Products	87
6.4	Claim Submission for Prescription with Drug Costs \$10,000 or Over	97



	6.5	Approved Non-Prescription Drugs	98
	6.6	Allergen Program	.102
	6.7	Cost-to-Operator Claims	104
	6.8	Duplicate Claim Submission Including Vacation Supply and Methadone	
		Claims	106
	6.9	Exceptional Access Program	119
	6.10	Compassionate Review Policy	.127
	6.11	Nutrition Products	129
	6.12	Diabetic Testing Agents	132
	6.13	30-Day Prescription Program	142
	6.14	Special Drugs Program	144
	6.15	Universal Influenza Immunization Program	148
	6.16	Policy for Pharmacy Payments under the Long-Term Care Home Capita	itior
		Funding Model, 2020	158
	6.17	Valved Holding Chambers	165
	6.18	Flash Glucose Monitoring Systems	170
	6.19	Temporary Benefit Listing	173
	6.20	Biosimilar Policy	174
S	ectio	n 7: Professional Pharmacy Services	180
	Ove	rview	.180
	7.1	MedsCheck Program	. 181



	7.2	Pharmaceutical Opinion Program	19C
	7.3	Pharmacy Smoking Cessation Program	200
	7.4	Ontario Naloxone Program for Pharmacies	215
	7.5	Reimbursement and Claims Submission using the Health Network Syste	em
		relating to Drugs for Medical Assistance in Dying	. 222
	7.6	Reimbursement and Claim Submissions for Mifepristone / Misoprostol	
		(Mifegymiso)	. 229
	7.7	Funding for Minor Ailment Services in Ontario Pharmacies	. 233
S	ectio	on 8: Paper Drug Benefit Claim Submissions and Drug Benefit Claim	
		Reversals	.246
	Ove	erview	. 246
	8.1	When to Submit Manual Benefit Claim Submission and Drug Benefit Cla	aim
		Reversal Forms	247
	8.2	Paper Drug Benefit Claim Submission and Drug Benefit Claim Reversal	
		Forms	. 248
	8.3	Instructions for Completion of Manual Drug Benefit Claim Submission a	nd
		Drug Benefit Claim Reversal Forms	254
	8.4	Supporting Documentation for Manual Drug Benefit Claim and Drug Ben	nefit
		Claim Reversal Forms	. 256
S	ectio	on 9: Prospective Drug Utilization Review	.258
	Ove	erview	258
	9.1	Overall System Description	. 259



9.2 Drug Utilization Review Response Codes	262
9.3 Drug Utilization Review Intervention Codes	267
9.4 Claim Submissions	271
9.5 Claim Resubmissions	272
9.6 Claim Rejections	272
9.7 Claim Reversals	272
9.8 Help Desk Assistance	272
9.9 Confidentiality	273
Section 10: Response and Intervention Codes	274
Overview	274
10.1 Response Codes Table	274
10.2 Intervention/Exception Codes Table	296
Section 11: Reconciliation/Payment	299
Overview	299
11.1 Payment Information for Online Claims/Reversals	299
11.2 Payment & Drug Utilization Review Information for Manual	Drug Benefit
Claim Submissions and Drug Benefit Claim Reversals	300
11.3 Reconciliation of Remittance Statements	308
11.4 Payment Schedule	309
11.5 Direct Deposit	310
Section 12: Inspection	311



Overview	311
Use of Intervention/Exception Codes	311
Policy for Establishing Eligibility	311
Acceptable Supporting Documentation	311
Other Rules Regarding Retention of Records	319
Control of Network Access	320
Recoveries	320
Penalties	321
Section 13: Prescription Forgery	322
Section 14: Electronic Mail	323
Overview	323
Section 15: Narcotic Monitoring System	326
Overview	326
15.1 NMS Requirements	328
15.2 Monitored Drugs List	330
15.3 Identifying Numbers	331
15.4 NMS On-line Dispense Transaction	341
15.5 NMS On-line Inquiry Transaction	344
15.6 NMS On-line Reversal Transaction	345
15.7 NMS Data Validation Response Codes and Messages	347
15.8 Drug Utilization Review (DUR) Warning Response Codes	353



Section 16: Help Desk	357
Overview	357
16.1 Troubleshooting	357
16.2 Types of Inquiries & Hours of Service	358
16.3 How Your Call is Handled	359
Glossary of Terms	360
Appendix A: Extemporaneous Preparations Table	367
Appendix B: Approved Non-Prescription Drug Products PINs	371
Appendix C: Allergen Products	374
Appendix D: Attestation / Notice of Change in LTC Home Primary Phare	macy
Service Provider Form	375
Appendix E: Templates for the Pharmacy Smoking Cessation Program	378
Readiness Assessment	378
Pharmacy Smoking Cessation Program Patient Agreement to Enrol & Pa	atient
Consent Form	379
FIRST QUIT CONSULTATION MEETING	380



Introduction

The Health Programs and Delivery Division (HPDD) 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 manual 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, dated November 27, 2019 (revised on December 27, 2023), is an update to the previous Reference Manual revised on October 10, 2023.



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 <u>Section 2</u>.

As part of the HNS registration process, pharmacies must also register for access to the Microsoft Office 365 (O365) email 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 O365 email at least once per week. Further information on the O365 email registration process can be found in <u>Section 14</u>.

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 <u>Narcotics Monitoring System (NMS)</u> 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 requirements outlined in Section 15. Note that the former Narcotics Monitoring System (NMS) Pharmacy Reference Manual is now incorporated into Section 15 of this Manual.

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. Applicants are encouraged to use the <u>Ontario Drug Benefit Program Online Applications and Forms</u> website or the <u>Ontario central forms repository</u>. 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 O365 email 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 O365 email 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 O365 email at least once per week (see Section 14).

This section outlines specific instructions for:

- ODP registration (see <u>Section 2.1</u>)
- Notification of ODP registration changes (see <u>Section 2.2</u>)
- Closure or sale of a pharmacy (see <u>Section 2.3</u>)

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: <u>HNS-Registration.MOH@ontario.ca</u> 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
- O365 email 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.mohantario.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 O365 email 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 O365 email.

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 O365 email.

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 O365 email 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 O365 email 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 is compliant 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 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: <u>HNS-Registration.MOH@ontario.ca</u>, 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 O365 email 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: https://doi.org/10.1001/journal.com, 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 <u>Personal Health Information Protection Act, 2004 ("PHIPA")</u>. 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 <u>Section 3.1</u>)
- On-site physical security and password (network access) security (see <u>Section</u> 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 <u>Section 4.1</u>)
- 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 <u>Section 4.2</u>)

4.1 Program Eligibility

The ODB program provides community-based drug benefits to:

- Individuals entitled to receive drug benefits under the <u>Ontario Disability</u> <u>Support Program Act, 1997 ("ODSPA")</u> including Assistance for Children with Severe Disabilities (ACSD), and the <u>Ontario Works Act, 1997 ("OWA")</u> including Temporary Care Assistance (TCA); and
- **2.** Individuals who are insured persons under the <u>Health Insurance Act ("HIA")</u> 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. residents of Long-Term Care (LTC) homes
 - d. residents of Homes for Special Care (HSC) or Community Homes for Opportunity (CHO)
 - e. enrolled in the Trillium Drug Program (TDP)



- 3. Individuals who are receiving:
 - a professional service (other than training) under O. Reg 187/22 (Home and Community Care Services) made under the Connecting Care Act, 2019 that is provided by a health service provider or Ontario Health Team; or
 - a substantially equivalent service that is provided by an Indigenous organization that has entered into an agreement with the Ministry of Health.

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

Seniors

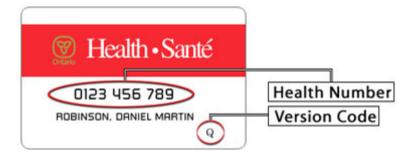
All residents of Ontario (including permanent residents) who are eligible for coverage under OHIP will qualify for drug benefits under the ODB program on the first day of the month following their 65th birthday. For example, if a resident's 65th birthday is April 15th, he/she will become eligible for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

Policy for establishing eligibility for payment does not apply (see <u>Section 4.2</u>).

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:

A single senior who has an annual net income greater than the Senior Co-payment Program (SCP) individual threshold or a senior with a spouse who (along with their spouse) has a combined annual net income greater than the SCP couple threshold is 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. The 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 copayment.

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.

Seniors Co-payment Thresholds:

SCP individual threshold	As of August 1, 2021: \$22,200
SCP couple threshold	As of August 1, 2021: \$37,100

Lower-income co-payment:

A single senior who has an annual net income equal to or less than the SCP individual threshold or a senior with a spouse who (with their spouse) has a combined annual net income equal to or less than the SCP couple threshold can apply to be 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, seniors must apply to the Seniors Co-Payment Program. To avoid unnecessary delays and ensure timely processing, applicants can complete the <u>Seniors Co-Payment Program Application</u> available on the <u>Ontario Drug Benefit Program Online Applications and Forms</u> website. The online form will guide the applicant through the process to ensure all the information required for enrolment is provided before submission.



Applicants may also refer to the SCP Guide to help them complete the application.

If the applicant does not have access to a computer, they can also ask for the form to be mailed to them. Applicants can request a paper copy of the SCP form and guide by contacting the SCP.

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

Tel: 416-503-4586

Toll-free: 1-888-405-0405

Email: seniors@ontariodrugbenefit.ca

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 belongs to one of these other eligibility categories, then only a \$2 co-payment may be charged.

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

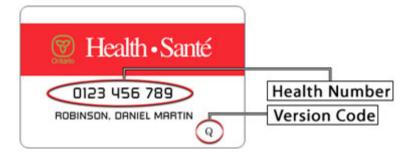


Private plan definition:

"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 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 <u>Section 12</u>, Inspection)
- 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.

Pharmacies who do not have access must register online to gain access to the portal. For registration and login related issues, help is available by contacting support by e-mail at SAVPortalSupport@accerta.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 during regular business days.

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.

The majority of clients can be verified using the Ontario health card number. If eligibility cannot be verified through the SAV Portal using the health card number, Pharmacies should remove the Ontario health card number and use the person's name and date of birth combination to verify eligibility.



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 maintained on file and be readily available for two years following the last claim date. If a printed copy of the search results is not maintained, documentation must be maintained 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, Clients receiving assistance from a First Nations Ontario Works administrator or First Nations ODSP office on-reserve will continue to receive a paper drug card to access the ODB, unless the client's eligibility can be confirmed through the SAV portal.

For these social assistance clients who continue to receive paper drug cards as proof of eligibility, pharmacies must continue to retain copies of the paper drug cards on file. For claim validation purposes, and in accordance with O Reg 264/16 under the DPRA if applicable, copies of the paper drug cards must be maintained for the Retention Period. Discarding copies of paper drug cards prior to the end of the Retention Period may result in claim recoveries.

Further details can be accessed through the <u>Executive Officer Communications</u> <u>website</u>.

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

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



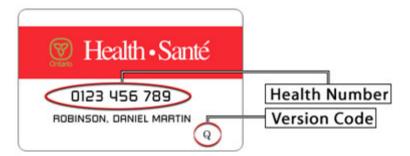
Policy for establishing eligibility for payment applies (see Section 4.2).

See <u>Acceptable Supporting Documentation</u> 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. For claim validation, and in accordance with O Reg 264/16 under the DPRA if applicable, documentation of the eligibility verification results must be recorded and maintained in a readily-accessible format for the Retention Period.

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. For claim validation purposes, and in accordance with O Reg 264/16 under the DPRA if applicable, ensure documentation required prior to submitting a claim for



payment is maintained in a readily-accessible format for the Retention Period [see <u>Section 12</u>, 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:
 - o Enter the Health number in the Provincial Health Care ID Code field
 - o Include the version code if embossed on the Health Card
- Ensure the Drug Eligibility Card or a copy of the card is maintained in a readily-accessible format. For claim validation purposes, and in accordance with O Reg 264/16 under the DPRA if applicable, this record must be maintained for the Retention Period.

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 a professional service (other than training) under O. Reg 187/22 (Home and Community Care Services Regulation) made under the Connecting Care Act, 2019 are eligible to receive benefits under the ODB program. Individuals receiving a substantially equivalent service that is provided by an Indigenous organization that has entered into an agreement with the Ministry of Health are also eligible to receive benefits under the ODB Program. The health service provided (HSP) or Ontario Health Teams (OHT) determine eligibility for coverage.

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

See <u>Acceptable Supporting Documentation</u> requirements.



How recipients are identified:

 Recipients may present a Drug Benefit Eligibility Card valid for the date of service or the HSP/OHT 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 Notific	ation
20-Sep-2018 8:41 AM E	DT
Shoppers Drug Mart - Ti	hunder 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 or fax notification in the Client ID # field (omit any preceding letters).
- If the HSP/OHT has provided other written/fax notification to establish eligibility:
 - o enter the Health / eligibility number in the Client ID # field
 - o include the version code if embossed on the Health Card.
- If the recipient recently moved from another province/territory, does not have OHIP coverage and is receiving end-of-life professional home care services:
 - Enter the temporary eligibility number (begins with '08') from the Drug Benefit Eligibility Card or notification in the Client ID # field
- If the recipient is receiving professional home care services from an Indigenous organization:
 - For recipients who do not have a Health Card, enter the eligibility number (begins with '08') from the Drug Benefit Eligibility Card or notification in the Client ID # field: OR
 - For recipients with a Health Card, enter the Health Card number in the Client ID # field and 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 or other notification, 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 or other notification is valid only during the time the recipient is receiving certain professional. 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 or a new notification is faxed.

• If the pharmacy receives a notification fax from the HSP/OHT 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 HSP/OHT included a later end date for coverage.

Long-Term Care Home Residents

Residents of an LTC home licensed under the <u>Long-Term Care Homes Act, 2007</u> (<u>"LTCHA"</u>) 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 <u>LTC home identification number</u> (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 <u>Section 4.2</u>).

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:

• There is no co-payment for all LTC home residents for eligible ODB claims.

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

The reimbursement model for pharmacies that provide pharmacy services, including prescription dispensing and MedsCheck / Pharmaceutical Opinion programs, to residents of Long-Term Care Homes has changed effective January 1, 2020 from a fee-for-service model to a per-bed-fee capitation model. Please refer to <u>Section 6.16</u> for the full Policy.

Homes for Special Care / Community Homes for Opportunity

Residents of HSC licensed under the <u>Homes for Special Care Act ("HSCA")</u> 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 <u>Acceptable Supporting Documentation</u> 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 <u>HSC/CHO identification number</u> (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 <u>Section 4.2</u> for further details) once eligibility has been confirmed by FMB. Documentation of the call (including ODB Help Desk ticket # if it was contacted) must be recorded and maintained for the Retention Period for claim validation purposes, and in accordance with O Reg 264/16 under the DPRA if applicable.

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 <u>Trillium Drug Program (TDP)</u> 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 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 the TDP, applicants must complete a <u>Trillium Drug Program Application</u> form. To ensure timely processing and avoid unnecessary delays, applicants can complete the Trillium Drug Program Application available on the <u>Ontario Drug Benefit Program Online Applications and Forms</u> website. The online form will guide the applicant through the process to ensure all the information required for enrolment is provided before submission.

Applicants may also refer to the <u>TDP Guide</u> to help them complete the application.

If applicants do not have access to a computer, they can also ask for the form to be mailed to them. Applicants can request a paper copy of any of the TDP forms and guide, by **contacting** the TDP.

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

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 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:

- Consent for the Ministry to access any household member income information from Canada Revenue Agency (CRA) is missing.
- Any household member is turning 18 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 <u>ODBF/CDI</u> (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 <u>ODBF/CDI</u> (e.g., nutrition products, diabetic testing agents, and valved holding chambers if applicable eligibility criteria are met, see <u>section 6</u>).
- Extemporaneous preparations designated as pharmaceutical products under the ODBA.
- Products approved under the EAP.
- Products listed in Schedule 2 to <u>O. Reg. 201/96</u> (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 <u>ServiceOntario</u> 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.

For claim validation purposes and in accordance with O Reg 264/16 under the DPRA if applicable, pharmacies and dispensing physicians are required to maintain supporting documentation that verifies a patient's eligibility on file for the Retention Period. The supporting documentation that must be obtained and maintained is specific to the type of eligible person. Please see Acceptable Supporting
Documentation requirements or Section 4.1 for further details.

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 or other written notification



- 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 / fax notification 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, ServiceOntario, etc.).

For Home Care recipients with an eligibility number that begins with '08' that is rejected, the pharmacy may establish eligibility by entering the following:

- Carrier ID / Plan Code "P"
- Date of Birth
- Gender
- "ML" in the Intervention/Exception code field*
- Pharmacist ID

*Note: Do not use the "MK" intervention code for recipients with an eligibility number that begins with '08'. Using "MK" will result in the claim being rejected with the response codes "C8" (no record of beneficiary) and "65" (intervention/exception code error).



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
"」"	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 <u>section 4.1</u>

**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 <u>Section 5.2</u>)
- Reconcile online claim and reversal transactions (see Section 5.3)
- Request payment information for any of the most current seven days
 - o Daily Totals (see <u>Section 5.4)</u>
 - o Claim Details (see Section 5.5)
 - o Same Day Reversal Details (see <u>Section 5.6</u>)
 - o Prior Day Reversal Details (see <u>Section 5.7</u>)

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 residential facility, other than a long-term care home, 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".*
- 2. 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 **
- **3.** 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 and 2, 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 2, 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 3, the dispenser must perform of all the following:

- The dispenser must make a written record of the reasons for his or her opinion. The nature of the physical, cognitive or sensory impairment must be clearly documented;
- 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 for the reduced quantity (i.e., patient / agent's signature on the record of authorization;
- Upon request, the dispenser must provide the Ministry with copies of the written record, agreement and notification to the prescriber; and
- Assessment and documentation records are only valid for 365 days and must be re-evaluated annually. The following must be re-assessed and updated annually, and maintained as part of the ODB recipient's permanent pharmacy health record:
 - A dispenser's assessment that a patient requires more frequent dispensing;
 - Notification to the prescriber, and:
 - o record of the authorization received from the ODB recipient (or person presenting the prescription) for dispensing in reduced quantities (i.e., patient or agent's signature for the reduced quantity).

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:

- **1.** The ODB recipient is a resident of a residential facility, other than a long-term care home, 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".
- 2. 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,
 - 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.
- 3. 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 residential facility, other than a long-term care home, 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").
- 2. The listed drug product dispensed is an extemporaneous preparation.
- **3.** 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. **
- **4.** 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 or the person presenting the prescription has consented to obtaining the lesser quantity. **

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

**Note: In the case of Exception 3 and 4, the dispenser must perform all of the following:

- The dispenser must make a written record of the reasons for his or her opinion. The nature of the physical, cognitive or sensory impairment or complex medication regimen must be clearly documented, including clinical or safety risks to the patient if larger quantities were dispensed;
- 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 for the reduced quantity (i.e., patient / agent's signature on the record of authorization);
- Upon request, the dispenser must provide the Ministry with copies of the written record, agreement and notification to the prescriber; and
- Exceptions 3 and 4 are only valid for a period of 365 days. A dispenser's assessment that a patient requires more frequent dispensing, notification to the prescriber and record of the authorization received from the ODB recipient



(or person presenting the prescription) for dispensing in reduced quantities, (i.e., patient or agent's signature for the reduced quantity) must be reassessed, and updated annually, and 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.

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.

Please refer to Section 12: Inspection for more information about recordkeeping requirements for the records relating to dispensing fees described above.

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	"O1"
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 <u>Section 2.1</u>)



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 <u>Section 4</u>)
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 <u>Appendix A</u> for Extemporaneous Mixture DIN/PINs and <u>Appendix C</u> 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 <u>prescriber ID</u> <u>reference chart</u> noted below)
Prescriber ID	Prescriber license number
Drug Cost/Product Value	Total drug cost or product value



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 <u>Section 6</u>) and claim transactions where eligibility is established (see <u>Section 4.2</u>).

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
College of Midwives of Ontario	08
Ontario College of Pharmacists	09
College of Optometrists of Ontario	43
College of Nurses of Ontario	44
College of Naturopaths of Ontario	NO



Other (where all attempts to locate Prescriber ID,	99
including contacting the ODB Help Desk, have failed)	

*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 <u>Section 10.1</u> 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	Detailed response information
Number 3	

*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 90 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 <u>Section 9.3</u>) (if applicable)
Pharmacy ID Code	CPhA number or Ministry-assigned number of the pharmacy, (see <u>Section 2.1</u>)
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
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 90 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 <u>Section 8</u>).



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 <u>Section 10.1</u> 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 <u>Section 5.4</u>).

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 <u>Section 5.5</u>, <u>Section</u>



<u>5.6</u> and <u>Section 5.7</u>). 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 <u>Section 5.5</u>)
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 <u>Section</u> <u>5.7</u>)

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 <u>Section 2.1</u>)
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 Code	(See <u>Section 10.1</u> 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 <u>Section 11.4, Payment Schedule</u>)



*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)
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 <u>Section 2.1</u>)
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 <u>Section 10.1</u> for valid response codes)
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 O3)
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 <u>Section 2.1</u>)



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 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 <u>Section 10.1</u> 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	PSV-assigned code, identifying the version of the	
Version	pharmacy software currently used	
	, ,	
Pharmacy ID Code	CPhA number or Ministry-assigned number of the	
	pharmacy, (see <u>Section 2.1</u>)	
Provider Transaction	Date (YYMMDD) on which the pharmacy sends the	
Date	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.	
Designing of Deserd*	Dy number of the last prescription that prescription	
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	
2.13 31 1133313	request	
	request	
l .	ı	

^{*}This will enable you to narrow down the range/volume of reversal details by specifying these fields. If the value is zero (O). 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 <u>Section 10.1</u> 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 <u>Section 5.1</u>):

- Extemporaneous Preparations (see <u>Section 6.1</u>)
- Medically Necessary "No Substitution" Claim (see <u>Section 6.2</u>)
- Limited Use Products (see Section 6.3)
- Claim Submission for Prescription with Drug Costs over \$10,000 (see <u>Section</u> 6.4)
- Approved Non-Prescription Drug Products and Emergency Authorization Drugs to Long-Term Care Homes (see <u>Section 6.5</u>)
- Allergen Claims (see <u>Section 6.6</u>)
- Cost-to-Operator Claims (see <u>Section 6.7</u>)
- Duplicate Claim Submission including Vacation Supply and Methadone Claims (see Section 6.8)
- Exceptional Access Program (see <u>Section 6.9</u>)
- Compassionate Review Policy (see <u>Section 6.10</u>)
- Nutrition Products (see <u>Section 6.11</u>)
- Diabetic Testing Agents (see <u>Section 6.12</u>)
- Thirty-Day Prescription Program (see Section 6.13)
- Special Drugs Programs (see <u>Section 6.14</u>)
- Universal Influenza Immunization Program (see <u>Section 6.15</u>)



- Policy for Pharmacy Payments under the Long-Term Care Home Capitation Funding Model (see <u>Section 6.16</u>)
- Valved Holding Chambers (See <u>Section 6.17</u>)
- Flash Glucose Monitoring Systems (See <u>Section 6.18</u>)
- Temporary Benefit Listing (see <u>Section 6.19</u>)

6.1 Extemporaneous Preparations

This policy effective on January 1, 2020 replaces the previous extemporaneous preparation policy. Please also refer to the updated EO Notice of Interim Change to Extemporaneous Preparation Policy for Anti-Infectives dated April 16, 2021 and May 31, 2022 found on the Ontario Public Drug Programs - Executive Officer Communications website.

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 <u>O. Reg 201/96</u> 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 Program¹

¹It 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
 - Gentamicin or tobramycin in a concentration greater than three milligrams per milliliter.
- **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:



- i. Injectable vitamins, minerals, amino acids, lipids, botanicals and other natural health products (NHPs)
- ii. Vaccines
- iii. Alprostadil injection
- iv. Ketorolac injection
- v. 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 <u>Section 5.1</u>, 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	Υ	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 <u>Appendix</u> <u>A, Extemporaneous Preparation Table</u>) if applicable.	
Quantity	Υ	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 lation (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 <u>Appendix A, Extemporaneous Preparation</u> <u>Table</u>)
Drug Cost/Product	Y	Enter the total cost of all ingredients used, based on the following:
Value	alue	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 <u>Drug</u> <u>Benefit Prices (DBPs) for products reimbursed under the EAP</u> on the Ministry's website.
		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 or wholesaler's invoice amount minus discounts). Do not include mark-ups and/or HST in this field.
		(Refer to <u>Acquisition Cost in Section 6.7</u>)
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:

- Fax, <u>submit online</u> 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, the pharmacy must maintain 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.

For claim validation purposes, and in accordance with O Reg 264/16 under the DPRA, the pharmacy or dispensing physician must maintain 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 the Retention Period.

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 the case where only one product has been designated as interchangeable with the drug product supplied and is generally available for sale in Ontario, if one (1) completed and signed Side Effect Reporting Form is not available at the pharmacy during an inspection, the claim will be subject to recovery.



The pharmacist must fax, <u>submit online</u> or mail the completed <u>Side Effect Reporting</u> <u>Form(s)</u> 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 <u>Canada Vigilance Program</u> can be accessed online or by calling 1-866-234-2345.

Claim Requirements

Aside from including the fields indicated in <u>Section 5.1</u>, 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*	Υ	Enter " B " (i.e., ODB reason for use codes)
Medical Condition/Reason for Use*	Υ	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	Υ	Enter the Drug Benefit Price or Unit Cost
Cost Mark-up	Υ	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 <u>ODBF/CDI</u> 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 <u>ODB e-Formulary</u>.

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 prescribers 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 OPDD 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/maintained in the pharmacy.
- 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 maintained by the pharmacy for claim validation purposes, and in accordance with <u>O. Reg. 264/16</u> made under the **DPRA if applicable**, for the Retention Period.

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 prescribers 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 maintain LU documentation on file for the purposes of claim validation, and in accordance with O. Reg. 264/16 made under the DPRA if applicable, for the Retention Period. Documentation must be complete at the time of claim submission.

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 <u>Section 5.1</u>, 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*	Υ	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	Υ	Enter the Drug Benefit Price
Cost Mark-up	Υ	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

OPDD 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.



Promoting Compliance with the Existing Limited Use Criteria for Specified Drug Products

Effective April 1, 2021, new network rules were implemented in the HNS to promote the safe and effective use of specified drug products with age-related and gender-related/sex-related restrictions by promoting compliance with the LU criteria for these medications. The LU criteria for all related products were already in place (i.e., there were no criteria changes) and are aligned with Health Canada-authorized product labelling indications and/or drug expert advisory committee recommendations.

These changes reflect a Ministry policy that must be complied with, in accordance with the HNS Subscription Agreement for Pharmacy Operators.

Reimbursement Criteria and Restrictions

The drug products affected by the new HNS network rules, as well as related LU codes, a summary of current LU criteria, and associated age-related and gender-related/sex-related restrictions being implemented, are summarized in the table below.

Drug product(s)	Reimbursement criteria	Restriction
(LU code)	summary	
Age-based restrictions		
Abobotulinum toxin A, Botulinum toxin type A, Clostridium botulinum neurotoxin type A (130)	To reduce the symptoms and signs of cervical dystonia (spasmodic torticollis) in adults	Age ≥18 years
Abobotulinum toxin A, Botulinum toxin type A, Clostridium botulinum neurotoxin type A (412)	For the management of focal spasticity, due to stroke or spinal cord injury, in adults	



Adalimumab (417) Ustekinumab (419)	Treatment of severe plaque psoriasis in patients 18 years of age or older who have experienced failure, intolerance, or have a contraindication to adequate trials of several standard therapies	
Clostridium botulinum neurotoxin type A (421)	Treatment of blepharospasm associated with dystonia in adults	
Botulinum toxin type A (440)	For adult patients with urinary incontinence due to neurogenic detrusor overactivity who have failed other therapies	
Botulinum toxin type A (460)	For adult patients with urinary frequency, urgency or urge incontinence due to overactive bladder who have failed other therapies	
Filgrastim (specific vial format only) (500)	For pediatric patients (less than 18 years age) who are unable to achieve the appropriate dose of granulocyte colonystimulating factor with the formulary listed formats of pre-filled syringes	Age ≤17 years
Gender-based/sex-based restricti	ons	
Alfuzosin, Silodosin (351)	Management of benign prostatic hyperplasia where other formulary alpha	Male gender/sex



	blockers have been ineffective
Alfuzosin, Silodosin (352)	Management of benign prostatic hyperplasia where other formulary alpha blockers produced intolerable side effects
Dutasteride, Finasteride (384)	For use in combination with an alpha blocker for the treatment of men with symptomatic benign prostatic hyperplasia
Dutasteride, Finasteride (385)	For use as second-line monotherapy (after failure/intolerance to an alpha blocker) for the treatment of men with symptomatic benign prostatic hyperplasia
Testosterone (397)	For male patients with confirmed low morning serum testosterone levels

Please refer to the Ministry's online e-Formulary (<u>Formulary Search</u>) to find a listing of all affected DINs/PINs.

In some cases, requests not meeting the above criteria may be considered on a case-by-case basis through the <u>Exceptional Access Program</u>.

Pharmacy Procedures

There are no changes to the claim submission process. The current process for submitting claims for LU products still applies.



HNS Response Codes

The new network rules utilize the HNS database as the source for ODB recipients' date of birth and gender/sex.

Automated adjudication will ensure current LU criteria for the identified drug products are met and there will be a rejection response to submitted claims where the age or gender/sex criteria are not met.

- If a claim is submitted for an identified drug product restricted to use in patients of a certain age group (i.e., adults or pediatrics as per the LU criteria) and the patient does not meet the age requirement specified in the LU criteria, the claim will be rejected with the response code "CD - Patient Not Entitled to Drug Claimed".
- If a claim is submitted for an identified drug product restricted to use in
 patients of a certain gender/sex (i.e., male patients as per the LU criteria) and
 the patient does not meet the gender/sex requirement specified in the LU
 criteria, the claim will be rejected with the response code "CD Patient Not
 Entitled to Drug Claimed".

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 manual claims process.

Claims can only be split for the purpose of online claim submission. There are no changes to the manual 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 <u>frequently asked questions (FAQ) document</u>.

6.5 Approved Non-Prescription Drugs

Effective October 1, 2023, the Ontario Government Pharmaceutical and Medical Supply Service (OGPMSS) no longer distributes Approved Non-Prescription Drugs (ANPD) products to Long-Term Care (LTC) home Pharmacy Service Providers (PSPs). As a result, the process of obtaining ANPD emergency authorizations from OGPMSS by PSPs has been discontinued.

Starting October 1, 2023, PSPs acquire all ANPD products directly from their suppliers (e.g., wholesaler), dispense ANPD products for residents of LTC homes at no cost to residents or their LTC homes, and submit claims for payment (claims) to the HNS. PSPs dispense ANPDs for individual residents of LTC homes as directed by a prescriber as well as dispense bulk bottles of specific ANPDs to LTC homes, as requested by the LTC homes.

Pharmacies will be paid up to the maximum reimbursable cost of the ANPD product and up to an 8% mark up (see Tables 1 and 2 below for details). No amount can be charged to or paid by the LTC home or a resident of the LTC home for the supply of an ANPD.

ANPDs can only be dispensed by a PSP that has a contract with a LTC home. Claims submitted to the HNS in respect of supplying an ANPD for a LTC home resident can be submitted as follows:

• by submitting a claim through the HNS for each ANPD product dispensed for a LTC home resident (i.e., an individual claim) OR



- by submitting a claim through the HNS for each ANPD product dispensed for a LTC home as stock for that LTC home's subsequent supplying of the product to residents of the home (i.e., a bulk claim).
 - A claim for dispensing ANPD product(s) in bulk must be submitted as a bulk claim and cannot be duplicated in an individual claim. Similarly, a claim for dispensing an ANPD product for an individual resident of a LTC home must be submitted as an individual claim and cannot be duplicated in a bulk claim. Duplicate claims cannot be submitted through the HNS and are subject to recovery if paid.

The Product Identification Numbers (PINs) must be used for all claim submissions. These PINs are listed in Appendix B of the current Ontario Drug Programs (ODP) Reference Manual.

Approved Non-Prescription Drug Claim Requirements for Individual Claims

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

Table 1:

Fields	Required (Y/N)	Explanation
Intervention/ Exception Code	N	Leave blank
Group Number or Code	Υ	LTC home number (see for a <u>list of LTC homes</u>)
Client ID # or Code	Υ	Enter ODB eligibility number
Patient First Name	Υ	ODB recipient's first name
Patient Last Name	Υ	ODB recipient's last name

Drug Cost/Product Value	Y	Enter the actual Cost (equal to manufacturer or wholesaler's invoice amount minus discounts). Do not include mark-ups here.
Cost Mark-up	Υ	Note: Up to 8% of the drug cost mark-up is payable
Professional Fee	Υ	Enter "O" for allowed professional fee.
DIN/GP#/PIN	Υ	Enter the ANPD PIN (Refer to Appendix B)
Quantity**	Υ	Enter the quantity to be billed

^{**}Note that the quantity field must be populated with a value greater than zero. If the product quantity field is zero, left blank, or completed with an invalid value, the claim will be rejected with the response code "58 – Quantity Error".

Approved Non-Prescription Drug Claim Requirements for Bulk Claims

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

Table 2:

Fields	Required (Y/N)	Explanation
Intervention/ Exception Code*	Υ	Enter "MJ"
Group Number or Code	Υ	Enter the number for the LTC home receiving services. (See a <u>list of LTC homes and/or HSC</u>)



Client ID # or Code	N	Leave blank
Patient First Name	N	Leave blank
Patient Last Name	N	Leave blank
Pharmacist ID*	Υ	Enter the Pharmacist ID
Drug Cost/Product Value	Υ	Enter the actual Cost (equal to manufacturer or wholesaler's invoice amount minus discounts). Do not include mark-ups here.
Cost Mark-up	Υ	Enter the mark-up amount Note: Up to 8% of the drug cost mark-up is payable
Professional Fee	Υ	Enter "O" for allowed professional fee
DIN/GP#/PIN	Υ	Enter the PIN of the product authorized (Refer to Appendix B)
Quantity	Υ	Enter the quantity to be billed

The asterisk (*) indicates additional fields.

^{**}Note that the quantity field must be populated with a value greater than zero. If the product quantity field is zero, left blank, or completed with an invalid value, the claim will be rejected with the response code "58 – Quantity Error".



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 C.

Special Authorization Allergen Form

Except for epinephrine products listed in <u>Appendix C</u>, 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 cannot 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 maintained on file for claim validation purposes, and in accordance with O Reg 264/16 under the DPRA if applicable, for the Retention Period.

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 <u>Section 5.1</u>, 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	Υ	Enter the DIN/PIN of the product authorized, (refer to Appendix C)
Drug Cost	Υ	Enter the actual Acquisition Cost (equal to manufacturer or wholesaler's invoice amount minus discounts)
		Do not include mark-ups and/or HST in this field (refer to <u>Acquisition Cost in Section 6.7</u>)
Mark-up	Υ	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) and 2) A valid prescription for the allergen product(s) dispensed must be maintained on file for claim validation purposes, and in accordance with O Reg 264/16 under the DPRA if applicable, for the Retention Period.

3) For claim validation purposes and in accordance with Regulation 936 under the DIDFA, a copy of the manufacturer/wholesaler's invoice or purchase record must be maintained on file for at least two years from the day the invoice or record was received.

Deductible and co-payment rules in <u>O. Reg. 201/96</u> 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 <u>O. Reg. 201/96</u> 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. For claim validation purposes and in accordance with Regulation 936 under the DIDFA if applicable, supporting documentation (manufacturer or wholesaler's invoice), which clearly indicates that the generic product had been ordered and was unavailable during the appropriate time period, and a detailed calculation in accordance with s. 14 of O Reg 201/96 must be maintained on file for at least two years from the day the invoice was received. 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 <u>Section 5.1</u>, 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*	Υ	Enter " MI " (e.g., pharmacy unable to acquire the lowest DBP product)
Pharmacist ID*	Υ	Enter the Pharmacist ID
Drug Cost/Product Value	Υ	Enter the actual or net Acquisition Cost (equal to manufacturer or wholesaler's invoice amount minus discounts). Mark-ups and HST are not applicable
Cost Mark-up	Υ	Must be equal to 0

The asterisk (*) indicates additional fields.

Claim Validation

Supporting documentation may be requested. The dispenser must obtain and retain a copy of:

(a) The manufacturer 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 <u>O. Reg. 201/96</u> under the Ontario Drug Benefit Act).

These records must be maintained on file for at least two years from the day the invoice was 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 copayments 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. For claim validation purposes, and in accordance with O Reg 264/16 under the DPRA if applicable, the letter, or copy of travel documentation, must be maintained on file for a period of the Retention Period. 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.

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 maintained on file in a readily retrievable location for the Retention Period for claim validation purposes, and in accordance with O Reg 264/16 under the DPRA if applicable.

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*	Υ	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.

¹Duplicate 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 Methadone Maintenance Treatment Reimbursement Policy, 2022 replaced the Methadone Maintenance Treatment Reimbursement Policy, 2020 to reflect additional methadone 10mg/mL oral concentrate product options that are listed on the Ontario Drug Benefit Formulary (Formulary).

The Methadone Maintenance Treatment Reimbursement Policy, 2022 was effective on **August 31, 2022** and replaced the 2020 policy as of that date.



Methadone Maintenance Treatment Reimbursement Policy, 2022

As a precondition to obtaining billing privileges under the *Ontario Drug Benefit Act* (*ODBA*), all pharmacy operators are required to enter into a Health Network System (HNS) Subscription Agreement with the Executive Officer. Under section 3.2 of this Agreement, pharmacy operators are required to comply with all Applicable Law, Ontario College of Pharmacists Rules, and Ministry Policies.¹

The Executive Officer of the Ontario Public Drug Programs of the Ministry of Health (the "Ministry") hereby establishes a policy for the reimbursement of methadone for all pharmacy operators in Ontario that supply methadone to Ontario Drug Benefit (ODB) eligible persons requiring methadone maintenance treatment (MMT) for opioid use disorder (hereinafter, referred to as the "Policy"). The Policy is comprised of this notice and the accompanying Questions & Answers document available on the ministry's website.

The Policy is made in accordance with section 5(2) of the ODBA and subsection 20(1) of O. Reg. 201/96 under the ODBA and applies to claims submitted through the HNS for ODB eligible recipients.

Under this Policy the Ministry will reimburse all pharmacy claims for the Formulary listed methadone 10mg/mL oral concentrate products that are dispensed to ODB eligible persons receiving MMT in the manner outlined in the next page.

Table 1: Publicly funded methadone hydrochloride 10mg/mL oral concentrate

Product	DIN	Manufacturer	Colour/flavour/	Interchangeable
Name			sweetener	
			Blue/unflavoured/	Υ
Jamp	02495783	Jamp Pharma	sugar-free,	
Methadone*		Corporation	sweetened with	
			sorbitol	
NA - tla - al - a -	00004010	Mallinckrodt	Clear/unflavoured	Υ
Methadose	02394618	Canada ULC	/unsweetened	

¹ The terms 'pharmacy' and 'pharmacy operators' are used in this Policy for consistency and ease of reading, however, all pharmacy requirements refer equally to 'dispensing physicians' as well. The term 'dispensing physician' refers to a physician who has a valid HNS Subscription Agreement with the ministry and is connected to the HNS.



Odan- Methadone*	02495880	Odan Laboratories Ltd.	Clear/unflavoured /unsweetened	Y
Methadose**	02394596	Mallinckrodt	Red/cherry	Z
Methadose	02394390	Canada ULC	flavour/sucrose	
Metadol-D**	02244290	Paladin Labs	Clear/unflavoured	Z
Metadot-D	02244290	Inc.	/unsweetened	

^{*}The generic methadone hydrochloride 10mg/mL oral concentrate formulations, Jamp Methadone DIN 02495783 and Odan-methadone DIN 02495880 are interchangeable with Methadose (unflavoured) DIN 02394618.

Payment of Drug Cost

A transition period was provided (from August 31, 2022 to September 28, 2022), during which the Ministry continued to reimburse Methadose (unflavoured) DIN 02394618 at its Formulary Drug Benefit Price (DBP). The lowest cost interchangeable product payment rule was not applied during this transition period.

Effective September 29, 2022, the usual lowest cost interchangeable payment rule was implemented. Where a methadone 10mg/mL oral concentrate product in an interchangeable category is dispensed, the Ministry only pays the lowest Drug Benefit Price of the interchangeable products in the category. A patient wishing to receive a higher-priced interchangeable product at their request or pursuant to a "no sub" prescription must pay the difference in price, unless the patient has a "no sub" prescription and has experienced an adverse reaction to at least two of the lower priced interchangeable products, if available, as documented by their prescriber in a Health Canada Side Effect Reporting Form. Please refer to the Ontario Drug Programs Reference Manual s. 6.2 for requirements and details on how to submit a "no substitution" claim.

For a methadone 10mg/mL oral concentrate product that is not in an interchangeable category (e.g., Methadose (cherry flavour) DIN 02394596 and Metadol-D DIN 02244290), the drug cost paid is the Drug Benefit Price of the product on the Formulary.

^{**}The Formulary listings of Methadose (cherry flavour) DIN 02394596 and Metadol-D DIN 02244290 are not designated as interchangeable with any drug products.



Health Canada Safety Information

- Pharmacists are reminded of the two Health Canada "Dear Healthcare Professional" letters posted in <u>March 2020</u> and <u>July 2020</u> regarding switching of methadone hydrochloride oral concentrate products.
- Pharmacists are encouraged to discuss switching products with patients and prescribers. The following excerpt is taken from the product monograph of methadone hydrochloride oral concentrate solutions:

General Disorders and Administration Site Conditions: drug ineffective

Isolated reports have been received for drug ineffectiveness following a switch between different methadone products. The current data are insufficient to support an estimate of the incidence or to establish causation. Patients presenting with symptoms of withdrawal following formulation change should be clinically monitored and dose titrated as needed.

• When switching from Methadose to a generic formulation, patients should be monitored as per the precautions noted above.

Ministry requirements for reimbursement of methadone claims under the Policy for Pharmacy Operators:

The Ministry will pay pharmacies, via the HNS, one ODB dispensing fee per daily supply (i.e., the pharmacy's applicable ODB dispensing fee) for dispensing methadone 10mg/mL oral concentrate, as listed on the Formulary, to an ODB eligible person for MMT.

For example, for a prescription written to witness one dose on Monday and dispense 6 carry doses for Tuesday to Sunday, the ministry pays one dispensing fee for one witnessed dose on Monday and one dispensing fee for each daily supply carry dose labelled for Tuesday through Sunday; all 7 prescription claims would be submitted on the Monday, the day of the witnessed dose, and all 7 claims are eligible for a dispensing fee.

Please note:



- persons whose household has not yet reached its quarterly Trillium Drug
 Program deductible are not eligible for ODB benefits, and as such, their MMT claims do not fall under this Policy.
- the Policy does not apply to the Primary Pharmacy Service Providers (PSP) that dispense MMT to residents of Long-Term Care (LTC) homes as dispensing fees submitted for LTC home residents are included as part of the capitation payment to Primary PSPs effective January 1, 2020. However, the Policy does apply to the dispensing of methadone to a LTC home resident for MMT by a Secondary PSP. Secondary PSPs that dispense to residents of LTC homes on an emergency basis, will follow the protocol outlined under the Policy for Pharmacy Payments under the LTC Home Capitation Funding Model, 2020 that was posted on the ministry's website on December 16, 2019 and can be accessed on the Ontario Public Drug Programs Executive Officer Communications website.

Payment of mark up

The Ministry will reimburse the pharmacy for the applicable drug cost in respect of each claim for methadone 10mg/mL oral concentrate plus the applicable % mark-up on that amount. See above section on "Payment of Drug Cost" for more information.

No co payment

No co payment may be charged to the ODB eligible person or a private third party with respect to the supply of methadone for maintenance treatment. However, the amount of the co-payment that would apply to the ODB recipient for other drug claims (i.e., \$0, \$2.00 or \$6.11 depending on their class of eligibility) will still be deducted from the dispensing fee paid for the methadone claim.

Additional Requirements

 A separate claim must be submitted on-line for each day's supply of methadone for ODB eligible persons receiving MMT (i.e., one claim for each day's supply) using the appropriate Drug Identification Number (DIN) and the quantity of methadone 10mg/mL oral concentrate dispensed.



- The quantity must reflect only the amount of methadone 10mg/mL oral concentrate dispensed, and must not include any amount of drink mix (e.g., Tang®) also included in the bottle dispensed.
 - o one claim is submitted for each witness dose and one claim is submitted for **each** daily supply carry dose that is provided to the ODB recipient
 - claims for witness doses and individual carry doses must be submitted on the date that the witness dose and/or carry doses are dispensed
 - a maximum of one dispensing fee may be claimed per ODB recipient per daily dose
- For example, if you have a prescription for one witnessed dose on Monday and 6 carry doses for Tuesday through Sunday, on Monday the claims appear as follows:
 - o one claim is submitted for the Monday witnessed dose
 - o one claim is submitted for the Tuesday carry dose
 - o one claim is submitted for the Wednesday carry dose; and so on for Thursday, Friday, Saturday and Sunday
 - each claim for the carry doses is submitted on the day that the carry doses were dispensed (i.e., Monday in this example)
- In other words, on Monday when all of the doses were dispensed, a total of 7 claims with 7 dispensing fees would have been submitted to the Ministry for payment through the HNS.
 - O When more than one claim is submitted for the same DIN on the same day for the same patient, the HNS will reject the second (and subsequent) claim(s) with response code "A3" – identical claim processed which can be overridden with an appropriate intervention code. Please refer to the Ontario Drug Programs Reference Manual for intervention codes.
 - o If replacement claims are required because of dose changes after carry doses have already been dispensed, the replacement claims are not eligible for additional dispensing fees as this would exceed the maximum number of dispensing fees allowed. Similarly, additional



doses to supplement the carry doses already dispensed are not eligible for additional dispensing fees.

- All labels must adhere to all Ontario College of Pharmacists policies and guidelines including the dose and date of ingestion on each labelled bottle.
- No co-payment amount may be collected from ODB eligible persons or a
 private third party for ODB eligible persons receiving methadone for MMT.
 However, additional charges such as ODB deductible amounts and out-ofpocket charges for patients who request a higher priced interchangeable
 product but do not meet the medically necessary "no substitution"
 requirements are eligible to be collected.
- No compounding time or charge is permitted for the dispensing of methadone 10mg/mL oral liquid. For example, when methadone 10mg/mL oral concentrate is diluted prior to dispensing, this practice is not considered compounding.
- No other ingredient costs may be added to the amount billed to the ministry (i.e., cost of distilled water or drink mix (e.g., Tang®) may not be billed to the ministry in addition to the cost of methadone amount already being reimbursed).
- If an ODB recipient's dose is changed by their prescriber after the ODB recipient's carry doses have already been dispensed (i.e., the dispensing fee from that day's dose has already been billed with the original carries), the replacement claim must not include a dispensing fee.
- The quantity of methadone 10mg/mL oral concentrate used in dispensing the final prescribed methadone dose must be entered as milliliters (mLs) of drug dispensed. The milligrams of methadone prescribed must be converted to mLs of methadone 10mg/mL oral concentrate dispensed and entered as a single dose for the submission to the HNS and the Narcotics Monitoring System (NMS). For example, if the physician prescribed methadone 100 mg each day, the claim submission to the HNS and the NMS record must indicate a quantity of 10 mLs of methadone 10mg/mL oral concentrate.
- The pharmacy-generated prescription label must comply with the appropriate Ontario College of Pharmacists policies and guidelines.



- The drug cost, plus the applicable % mark-up and the applicable dispensing fee are to be submitted on-line via the HNS. The prescription receipt must indicate a zero co-payment amount.
- Methadone used for the treatment of chronic pain is not eligible for reimbursement under this Policy. An application for funding consideration must be submitted by an authorized prescriber to the Exceptional Access Program for any ODB eligible patient who is prescribed methadone for chronic pain.

Use of extemporaneous compounded methadone liquid:

- Effective September 1, 2014, the extemporaneously compounded methadone solution prepared using methadone powder is no longer funded under the ODB program for MMT.
- However, compounded methadone (using methadone powder) under the Policy may only be dispensed to patients who have had an allergic reaction to all manufactured methadone products listed on the Formulary. Exceptional Access Program approval is required.

Amendments and Updates

The Ministry may make changes to this Policy at any time upon giving at least 30 days' notice to Ontario pharmacy operators.

Buprenorphine / Naloxone (Suboxone® and generics) Reimbursement

Reminder under the Ontario Drug Benefit Program

Buprenorphine/Naloxone is used for the treatment of opioid use disorder and is listed on the Ontario Drug Benefit (ODB) Formulary as a general benefit. As a narcotic drug, Buprenorphine/Naloxone requires a written or faxed prescription from a prescriber who is expected to have undergone appropriate training / education on Buprenorphine/Naloxone treatment and addiction medicine.

Best practice guidelines direct that Buprenorphine/Naloxone be prescribed similar to methadone maintenance treatment including:



- Start and stop dates
- Days for supervised administration (witness doses)
- Days for take home doses

Please note: Buprenorphine/Naloxone is not included in the Methadone Maintenance Treatment (MMT) Reimbursement Policy for all pharmacies that dispense methadone maintenance treatment for opioid use disorder under the ODB Program. Therefore, pharmacies are not entitled to submit separate claims for each take-home dose of Buprenorphine/Naloxone as is the practice for methadone maintenance treatment claims dispensed under the MMT Reimbursement Policy.

Buprenorphine/Naloxone Claims Submission for ODB eligible recipients:

Prescriptions for Buprenorphine/Naloxone will vary depending on the clinical assessment of the patient. Pharmacists may receive prescriptions that indicate:

- daily dosing for a period of time
- take home supplies and/or
- supplemental dosing.

As a narcotic, Buprenorphine/Naloxone is one of the drugs that is exempted by the Executive Officer from the two-dispensing-fees-per-28-days rule set out in subsection 18(10) of Ontario Regulation 201/96 under the *Ontario Drug Benefit Act*. For more information on the exempted medication lists please visit the ministry website.

Pharmacists must bear in mind the requirements regarding narcotic prescription dispensing in general, as well as recordkeeping and data disclosure procedures for opioids and monitored drugs under the *Narcotics Safety and Awareness Act, 2010*. Pharmacists should ensure accurate prescriptions in all cases. For possible prescription scenarios refer to the table below.

 Pharmacies may claim one dispensing fee per day per patient for each supervised / witnessed Buprenorphine/Naloxone dose on the day the dose is witnessed by the pharmacist.



- If a prescription directs a take home supply in addition to one witnessed dose, one extra fee may be submitted on the same day for the take home "carry" doses.
- If a prescription directs a supplemental supply of Buprenorphine/Naloxone in addition to the take home supply of doses, only one dispensing fee for the total supplemental and take-home supply may be claimed on the same day.
- When two fees are charged in one day, pursuant to the conditions above, the "UA" intervention code will be required.
- A pharmacy may only bill one fee per day for patients if the patient attends the pharmacy daily for witnessed doses.
- Buprenorphine/Naloxone prescriptions that are dispensed by pharmacies for transferred patient care via batch shipping to physician offices or to off-site care facilities (i.e., addiction treatment centers) are eligible for one dispensing fee per patient prescription that could encompass both witness and carry doses, since they are dispensed from the pharmacy at one time.

Table 1: Possible Buprenorphine/Naloxone prescription scenarios:

Prescription direction	Dispensing fee
7 witness doses	1 fee allowed each day
1 witness dose & 6 carry doses	2 fees allowed; 2 claims submitted on the day the dose was witnessed in the pharmacy and the take home doses were provided
1 witness dose each day Mon – Fri; 2 carry doses	1 fee allowed per day from Mon-Thurs with each witnessed dose; 2 fees allowed on Friday – one for the witnessed dose, one for the weekend carry doses
7 carry doses	1 fee for all carry doses combined
Any combination of witness and carry doses where care has been transferred	1 fee for all doses combined



to a physician, clinic or other care	
to a prhysician, curile of other care	
facility.	
raciuty.	

In summary, the Ministry pays the sum of:

- Drug cost as per the ODB Formulary listing;
- Current mark-up on the ODB drug cost, and
- ODB dispensing fee up to a maximum of one fee per witness dose and one fee for all take-home doses that are dispensed at one time.
- Co-payments may be charged to the eligible recipient; however, pharmacies may choose to waive the co-payment amount.

For more information refer to the Notice from the Executive Officer from March 13, 2019 on the <u>Ontario Public Drug Programs – Executive Officer Communications</u> website.

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 (Special Authorization Digital Information Exchange) portal is available 24x7 to authorized prescribers (Ontario physicians and nurse practitioners) and their delegates and designates (e.g., nurses, pharmacists, reimbursement coordinators) enabling the creation and submission of webbased electronic requests directly to the Exceptional Access Program.



To help prescribers make decisions about submitting requests, the clinical criteria associated with most EAP products can be found within the SADIE portal.

Authorized prescribers who are Manitoba and Quebec physicians and nurses with the authority to prescribe drugs cannot submit EAP requests through SADIE. EAP requests should be faxed to 1-833-905-4260. This number is for the use of Manitoba and Quebec physicians and nurses only.

More information about SADIE can be found at www.ontario.ca/SADIE.

- 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).
 - Authorized prescribers in Manitoba and Quebec may fax EAP requests to 1-833-905-4260.
- **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 hospitalized patients who are imminently awaiting hospital discharge may be submitted electronically through <u>SADIE</u> or on the hospital discharge form and faxed toll-free to 1-844-829-6807 or 416-314-3857 (Toronto area).
- **5.** 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 authorized prescribers within the meaning of the ODBA may submit an EAP request. Under the ODBA, authorized prescribers include Ontario physicians and



nurse practitioners, and physicians and nurses in the provinces of Manitoba and Quebec who have the authority to prescribe drugs.

Note: Effective June 14, 2021, a new regulation was made under the to the ODBA to expand the definition of "authorized prescribers" who can submit EAP requests on behalf of an ODB recipient to include Manitoba and Quebec physicians and nurses who have authority to prescribe (see <u>Ontario Regulation 470/21</u>). This regulation replaces the former Provincial Borders Drug Program, a policy-based pilot program which enabled consideration of EAP requests from physician prescribers in the provinces of Manitoba and Quebec.

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 can be found on the SADIE (<u>Special Authorization Digital Information Exchange</u>) portal or on the <u>Exceptional Access Program website</u>.

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).

Exceptional Access Program Application Process

To apply through the EAP, the patient's authorized prescriber 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. Authorized prescribers who are Ontario physicians and nurse



practitioners, and physicians and nurses in the provinces of Manitoba and Quebec who have the authority to prescribe drugs may submit an EAP request.

For more information on how to submit a request to the Exceptional Access Program, see section above: Submitting Exceptional Access Program Requests

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 can be found on the SADIE (<u>Special Authorization Digital Information Exchange</u>) portal or on the <u>Exceptional Access Program website</u>.

Authorized prescribers are encouraged to utilize the Reimbursement criteria for EAP Frequently Request Drugs resource on the Ministry's website to ensure that they provide the adequate clinical information necessary for the EAP to assess the requested drug(s). Note: authorized prescribers who have access to SADIE can also find such information on the SADIE portal.

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 MOH 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 reissuance 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.

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 <u>TRS</u> 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 <u>Section 5.1</u>, 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	Υ	Enter the DIN/PIN of the product authorized
Quantity	Y	Enter the quantity to be billed (in units)



Drug Cost/Product Value	Υ	Enter the DBP (if available in the Formulary/CDI or posted on the M) or the actual Acquisition Cost (equal to manufacturer 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	Υ	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 from the day the invoice was received a copy of: (a) the supplier's invoice which demonstrate the Acquisition Cost claimed, (b) invoices which show that the lowest price interchangeable product was ordered and not available at the time of the cost-to-operator claim, and (c) a detailed calculation of the cost of purchasing the drug product (in accordance with section 14 of the O. Reg. 201/96 under 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 maintained on file for claim validation purposes, and in accordance with O Reg 264/16 under the DPRA if applicable, for the Retention Period.

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 <u>Section 5.1</u>, 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	Υ	Enter the PIN of the product, as listed in the ODBF/CDI
Quantity	Υ	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 or wholesaler's invoice amount minus discounts). Mark-ups and HST are not applicable, refer to pricing information in ODBF/CDI
Cost Mark-up	Υ	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 maintained on file for the Retention Period for the purposes of claim validation, and in accordance with <u>O. Reg. 264/16</u> made under DPRA if applicable.

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 (an Ontario physician or nurse practitioner) in order to be eligible for reimbursement under the ODB program. Prescriptions and prescription extensions by pharmacists for BGTS are not 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. The PIN must match the brand of test strips that is prescribed and dispensed. Dispensing a brand of test strips that has not been prescribed or dispensing one brand of test strips and billing another brand, will result in invalid claims for payment that are subject to recovery. When billing test strips, the package size (e.g., one box) cannot be used since reimbursement is based on the number of units (i.e., strips) of each product dispensed. Test strip allotments for ODB recipients take into account diabetic test strip products that contain for example, 51 and 102 test strips per package.



Blood Glucose Test Strips Reimbursement Maximums

The limits noted below are aligned with the <u>Canadian Diabetes Association (CDA)</u> <u>recommendations</u> to encourage proper testing practices for optimal patient outcomes and to test according to the current medication profile. HNS will track and determine appropriate levels of reimbursement of BGTS based on the current diabetes therapy used by eligible ODB program recipients. The HNS determines the treatment category for an ODB recipient based upon claims for insulin products or other anti-diabetes medications available on the ODB Formulary.

When a claim is submitted for BGTS for eligible ODB program recipients, the HNS will automatically review the insulin and anti-diabetes medications claims or prescription receipts within the **previous 180 days** to identify claims or receipts for insulin products and other anti-diabetes medications. The HNS will then apply a maximum number of self-monitoring BGTS that may be reimbursed for the recipient, based on both online and manual claims submitted by pharmacies and prescription receipts submitted by ODB-eligible recipients to the ministry for reimbursement or to satisfy a TDP deductible 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*	400
Patients managing diabetes using anti- diabetes medication with low risk of causing hypoglycemia**	200
Patients managing diabetes through diet/lifestyle therapy only (no insulin or anti-diabetes medications)	200

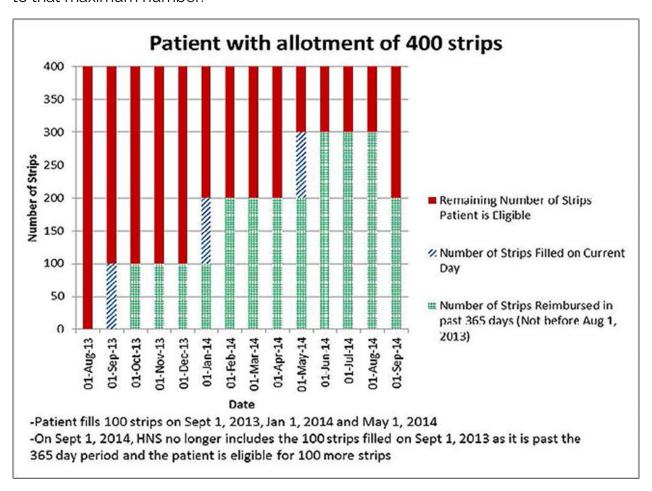
^{*}Including but not limited to glyburide, gliclazide, chlorpropamide, tolbutamide, repaglinide, nateglinide, or glimepiride



**Including but not limited to metformin, sitagliptin phosphate monohydrate, saxagliptin, acarbose, rosiglitazone, pioglitazone, linagliptin, liraglutide, canagliflozin 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 manual claims submitted by pharmacies as well as prescription receipts submitted by ODB-eligible recipients to the ministry for reimbursement or to satisfy a TDP deductible.

When a claim is submitted, HNS calculates whether the recipient has met their allotted maximum for the year by reviewing BGTS claims and receipts history in the last 365-day period. The allotment is recalculated each time the HNS reviews the 365-day period prior to every BGTS claim. If the recipient has not reached their maximum number of allotted test strips, they will be eligible to receive test strips up to that maximum number.

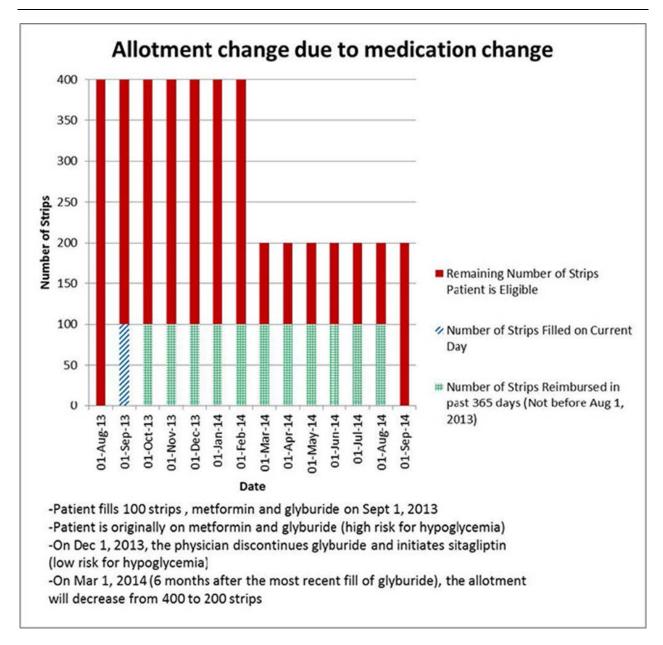




The test strip allotment is based on a patient's current treatment method, as based on their claims and prescription receipts history in the HNS in the previous 180 days and may change during this period based on changes to anti-diabetic medications (e.g., if a patient originally uses a medication with a high risk of hypoglycemia, but then only uses medications with a low risk of hypoglycemia or vice versa).

For example, a physician discontinues glyburide, a medication with a high risk of hypoglycemia, and the patient remains on medications with a low risk of hypoglycemia. The patient's allotment was originally 400 annual test strips, but will change to 200 annual test strips 180 days after the last fill of glyburide. The total number of strips reimbursed within a 365-day period is still calculated in the same manner. Education of the patient's monitoring frequency is important when there are changes with the patient's medications.





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 for more information, including supporting documentation requirements.

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.



See override codes below for more information, including supporting documentation requirements.

Note: When submitting a claim for insulin or anti-diabetes medication along with a claim for BGTS, pharmacists must **submit the claims for insulin or anti-diabetes medications prior to submitting 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 manual claims must be submitted by the pharmacy for processing as soon as possible. Finally, where an ODB-eligible person pays for the BGTS, insulin or anti-diabetes medication out-of-pocket and intends to submit their prescription receipt to the ministry for reimbursement or to satisfy their TDP deductible, then the pharmacy should advise the person to submit their prescription receipt to the ministry as soon as possible to ensure the prompt updating of their claims history.

Diabetic Testing Agents Claim Requirements

Pharmacies may not charge eligible ODB recipients any amount other than the copayment for supplying BGTS under the ODB program. The Ministry will reimburse pharmacies the amount identified in the column "Amount MOH 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 <u>Section 5.1</u>, 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	Υ	Enter the PIN of the specific brand of test strips that is dispensed, as listed in the ODBF/CDI
Quantity	Υ	Enter the quantity to be billed, in terms of number of units (not as package size) dispensed For example, one box of 50 test strips must be billed as units = 50



Drug Cost/Product Value	Υ	Enter the actual Acquisition Cost (equal to manufacturer 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	Υ	Must be equal to zero

The reconciliation adjustment process described in the most recent version of EO Notice: Reconciliation Adjustment Percentages to Improve the Value of Pharmacy Payments applies to BGTS claims and is posted on the <u>Ontario Public Drug Programs</u> – <u>Executive Officer Communications website</u>.

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 their 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 before they reach their limit.
"LO"	Maximum Benefit Exceeded	This response code indicates that the recipient has exceeded their 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.

In addition, patients should be encouraged to have their prescriptions filled at one pharmacy to ensure that they have a complete history of all the medications and test strips that they have received in the past especially if they want to track the remaining number of strips available for reimbursement.

Override Codes

There may be exceptional clinical circumstances where patients may require additional test strips. When a patient has reached their 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. Dispensers must maintain this information on file for claim validation purposes, and in accordance with O Reg 264/16 under the DPRA if applicable, for the Retention Period.

Intervention	Message	Explanation of condition generating response
Code	Description	code
"NF"	Override- Quantity Appropriate	This intervention code may be used for patients who require more than 200 or 400 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 180 days, that were not reimbursed under the ODB program



		or not recorded in the HNS. The identified anti- diabetes medications that were reimbursed by private drug insurance plans or paid by the patient and not recorded in the HNS 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 non-insulin dependent 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 beyond the prescribed annual limit for a given 365-day period, 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, specific testing frequency (if not indicated on the prescription) and the name of the referring healthcare professional and the dispensing pharmacist's OCP license number. The additional test strips distributed to patients for exceptional clinical circumstances will not have an impact on the allotment of test strips for the patient within the next 365-day period.

*Clinical reasons for which an individual may require more frequent testing may include the following:

- Patient has experienced acute illness or infection that affected blood glucose control over a sustained period of time
- Issues related to drug interactions which have impacted blood glucose control
- Patient has gestational diabetes



- Patient has an occupation that requires strict avoidance of hypoglycemia (e.g., pilots, air-traffic controllers, critical positions in railways)
- Patient is not meeting glycemic targets for 3 months or greater

If a patient provides information that differs from what is being indicated in the HNS, the patient medication profile may be out of date or incomplete.

If there is a discrepancy, the pharmacist should:

- Reconfirm the patient's allotment based on the patient history to ensure that
 the limit indicated in the HNS is correct. All prescription information should be
 confirmed as up-to-date.
- Review what order prescriptions were entered if a prescription was entered
 into the system after the claim for the test strips, the limit indicated for the
 patient may not be accurate.
- Inquire to see if the patient has received any medications outside of the ODB program within the past 180 days that would entitle them to a higher allotment.

If it is determined that the patient is wrong about their allotment (change in medication profile, etc.), an override is not allowed.

Note: Changing to a new device does not qualify as a clinical reason for additional test strips. If the patient has not reached their allotment, they can receive test strips for their new device, but the total allocation includes the test strips from their previous device. It is recommended that the patient use a device that will be compatible with their current test strips to ensure the patient does not exceed their allocated maximum number of test strips for the year. If there are malfunctions with their current device, it is recommended that the patient use a new device that remains compatible with their test strips.

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 the purposes of claim validation, and in



accordance with <u>O. Reg. 264/16</u> made under DPRA if applicable, for the Retention Period.

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.

code description response code Override C An initial prescription that previously	rvention/ rride Code
rejected with response code "OF" (=	= Override antity

30-Day Prescription Program Claim Requirements

Fields	Required (Y/N)	Explanation
Pharmacist ID*	Υ	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 and maintained for the Retention Period for the purposes of claim validation and in accordance with <u>O. Reg. 264/16</u> made under the DPRA if applicable.



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 <u>hospital group</u> class under the <u>Public Hospitals Act</u>.

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 reenrolled 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 <u>Section 5.1</u>, 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	Υ	Enter the PIN of the SDP product authorized
Pharmacist ID	Υ	Enter the Pharmacist ID of the pharmacist involved in the intervention
Intervention/	Y (annually	"NC" = Patient SDP Eligibility Confirmed



Exception Code	for each recipient)	
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	Υ	Maximum of 180 days.
Intervention/ Exception Code	Υ	Claims up to \$9,999.99 may be billed online without an intervention code
for high cost claims		Claims of \$10,000 or more, can be submitted by splitting the claim (see <u>Section 6.4</u>) 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 and must be maintained on file for at least two years from the day the invoice was received for purposes of claim validation, and in accordance with Regulation 936 under the DIDFA if applicable. Utilization may be periodically reviewed.

6.15 Universal Influenza Immunization Program

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

For more information, pharmacies must access the <u>Executive Officer Notice</u> for detailed information including submitting claims for pharmacy-administration of the influenza vaccine using HNS for the current influenza season.

Under the UIIP, trained pharmacy staff are authorized to administer publicly funded influenza vaccines by injection to people aged two years and older who live, work or go to school in Ontario.

Only Part A pharmacists and trained pharmacy staff (defined as pharmacy technicians, pharmacy students and pharmacy interns) 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. In addition, trained pharmacy staff must administer the vaccine under the direct supervision of an injection-trained pharmacist (Part A pharmacist or pharmacist [emergency assignment]).

Only pharmacies that are approved by the Ministry via a User Agreement can provide the publicly funded influenza vaccine to the public. In order for a pharmacy to be approved to administer the publicly funded influenza vaccine, pharmacy managers must complete the Ministry's User Agreement for Pharmacies with a Licensed Injection-Trained Pharmacist Requesting Publicly Funded Influenza Vaccines for the UIIP each year.

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



Restrictions

Please refer to the Executive Officer Notice, accompanying Questions & Answers, and the UIIP User Agreement for the applicable terms and conditions governing the UIIP.

Claim Requirements for Pharmacists Administering Influenza Vaccine

The claim for payment for administration of the publicly funded influenza vaccine must be submitted through HNS after administering the influenza vaccine to the patient on the same day of administration. Manual claims are not eligible for payment unless there is a need to use 3 intervention codes.

Pharmacies will be reimbursed \$8.50 per injectable vaccine and \$5.00 per nasal spray vaccine per eligible claim (if the nasal spray is available for the flu season) 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.

Influenza products that are publicly funded under the UIIP may differ from year to year and changes occur throughout the seasons. Please refer to the Ministry's website for more specific and the most recent information on the publicly funded influenza vaccines available for the current Influenza Immunization Season.

The pharmacist who administers or directly supervises the administration of the publicly funded influenza vaccine must use their Pharmacist ID as the Prescriber ID when submitting a claim for the influenza vaccine. The claim must be submitted on the day of the vaccine administration, subject to the exception below.

Exception: if the influenza vaccine was administered off-site in accordance with applicable terms and conditions, then 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 <u>Section 5.1</u>, there are additional fields required (or certain exceptions applicable to specific fields) when submitting a claim for an influenza vaccine administered by the pharmacist or trained pharmacy staff, 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	Υ	"PS" = Professional Care Service
DIN/GP#/PIN	Υ	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 EO Notice on 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	Υ	Pharmacist Licence #
Professional Fee	Y	\$8.50 (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	Υ	"PS" = Professional Care Service
		"ML" = Eligibility established-Standard coverage



Patient Gender	Υ	"F" = female, "M" = male
Patient Date of Birth	Υ	YYYYMMDD
Client ID # or Code	Y	Health number
Carrier ID	Υ	"S"

Additional fields required for patients without an Ontario health number:

Fields	Required (Y/N)	Explanation
Intervention Code	Υ	"PS" = Professional Care Service"PB" = Name entered is consistent with card
Patient Gender	Y	"F" = female, "M" = male, "U" = unknown
Patient Date of Birth	Υ	YYYYMMDD
Proxy ID # or Code	Υ	6999 999 995



Claim Validation for Influenza Vaccine

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

- Name of patient, date of birth and patient's address
- Name of vaccine administered, strength/dose (if applicable), Lot # and expiry
 date of the publicly funded influenza vaccine that was administered as well as
 route and site of administration
- Time and date the vaccine was administered; Location of the immunization
- Name and signature of the trained pharmacist (or trained pharmacy staff) who administered the vaccine; name and address of the pharmacy
- Signed and dated patient consent form completed by the patient or patient's substitute decision-maker as applicable
- A record of influenza immunization record provided to the patient
- A record of any adverse events following immunization (AEFIs) that may or may not result in the administration of epinephrine, and the circumstances relating to the administration of the substance.
- Pharmacists are required by law to report AEFIs. Reports should be made using the <u>Ontario Adverse Events Following Immunization Reporting Form</u> and sent to the local public health unit (PHU). A copy of the Reporting Form sent to the PHU must be retained by the pharmacy.

Pharmacists, trained pharmacy staff and pharmacies shall keep records consistent with their obligations under the Pharmacy Act, 1991, the Drug and Pharmacies Regulation Act, as applicable, and any instructions or guidelines provided by the OCP or the ministry.

For purposes of post-payment verification, pharmacy records related to claims for administering a publicly funded influenza vaccine must be maintained in a readily available format for the Retention Period.



Reimbursement of Epinephrine Auto-Injector for Emergency Treatment

In a situation of an adverse event resulting immediately after the administration of:

 the publicly funded influenza vaccine to an eligible person aged two or older;

or

ii. publicly funded COVID-19 vaccine,

the Ministry will reimburse pharmacies the Acquisition Cost of the epinephrine autoinjector when used for emergency treatment in the pharmacy or at the immunization location.

Note: The reimbursement procedure set out in this Section 6.15 applies to submitting claims for the Acquisition Cost of epinephrine auto-injectors used for emergency treatment of adverse events resulting from administering publicly funded influenza vaccines to eligible persons and public funded COVID-19 vaccines to eligible persons.

Under the Regulated Health Professions Act, 1991, pharmacy staff 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 by pharmacy staff will **not** be reimbursed in the following situations (other examples may apply):

- Providing the epinephrine auto-injector 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)
- Emergency injection of epinephrine auto-injector that is not due to an adverse drug reaction resulting from the administration of the publicly funded influenza or COVID-19 vaccine
- Emergency injection of epinephrine auto-injector at a nurse-led pharmacy clinic



• Emergency injection after providing any injection or inhalation for the purpose of demonstration or education.

The Ministry does not accept manual claims for epinephrine auto-injection claims submitted for this purpose unless there is a need to use 3 intervention codes.

Claim Requirements for Epinephrine Auto-Injector for Emergency Treatment

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

If administering for emergency use, the epinephrine auto-injector PIN must be billed as a second claim following the publicly funded vaccine claim on the same day of service. Please note the cost of the epinephrine auto-injector 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.**

Epinephrine products and reimbursement for emergency treatment after administering a publicly funded vaccine

PIN	Epinephrine Product	Total Amount Reimbursed
09857423	Epipen 1/1000 (1mg/1mL) DIN 00509558	\$94.44
09857424	Epipen Jr. 0.5mg/mL DIN 00578657	\$94.44
09857439	Allerject 0.15mg/0.15mL DIN 02382059	\$94.44
09857440	Allerject 0.3mg/0.3mL DIN 02382067	\$94.44



09858129	Emerade 0.3mg/0.3mL Inj DIN 02458446	\$85.54
09858130	Emerade 0.5mg/0.5mL Inj DIN 02458454	\$85.54

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

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

Fields	Required (Y/N)	Explanation
Intervention Code	Υ	"PS" = Professional Care Service
DIN/GP#/PIN	Υ	Enter the appropriate PIN as per the epinephrine auto-injector administered.
		Please refer to the above table for the current list of epinephrine auto-injector products that will be funded for this purpose.
Pharmacist's ID code	Υ	Pharmacist Licence #
Professional Fee	Υ	Please note that the cost of the epinephrine auto- injector will appear in the Dispensing Fee field of the claim.



Additional fields required for non-ODB recipients:

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

Additional fields required for patients without an Ontario health number:

Fields	Required (Y/N)	Explanation
Intervention Code	Υ	"PS" = Professional Care Service"PB" = Name entered is consistent with card
Patient Gender	Υ	"F" = female, "M" = male, "U" = unknown
Patient Date of Birth	Y	YYYYMMDD
Proxy ID # or Code	Υ	6999 999 995



<u>Claim Validation for Epinephrine Auto-injector Administration</u>

Pharmacies are required to keep a record of when an epinephrine auto-injector was administered for emergency use following an influenza or COVID-19 injection administered by a pharmacist or trained pharmacy staff. Required documentation includes:

- Name and signature of the pharmacist (or trained pharmacy staff) who administered the epinephrine auto-injector;
- The name and address of the pharmacy
- Name, strength/dose (if applicable) of the epinephrine auto-injector that was administered
- Name of Patient, date of birth and patient's address
- Time and date the epinephrine auto-injector was administered; place of administration if not at the pharmacy
- Cross-reference to the Vaccine Administration claim for the patient receiving epinephrine auto-injector

Pharmacists, trained pharmacy staff and pharmacies shall keep records consistent with their obligations under the Pharmacy Act, 1991, as applicable, the Drug and Pharmacies Regulation Act, and any instructions or guidelines provided by the OCP or the ministry.

For purposes of post-payment verification, pharmacy records related to claims for administering a publicly funded epinephrine auto-injector must be maintained in a readily available format for the purpose of ministry inspection for the Retention Period.

- Time and date the epinephrine auto-injector was administered; place of administration if not at the pharmacy
- Cross-reference to the Vaccine Administration claim for the patient receiving epinephrine auto-injector

Pharmacists, trained pharmacy staff and pharmacies shall keep records consistent with their obligations under the Pharmacy Act, 1991, as applicable,



the Drug and Pharmacies Regulation Act, and any instructions or guidelines provided by the OCP or the ministry.

For purposes of post-payment verification, pharmacy records related to claims for administering a publicly funded epinephrine auto-injector must be maintained in a readily available format for the purpose of ministry inspection for the Retention Period.

6.16 Policy for Pharmacy Payments under the Long-Term Care Home Capitation Funding Model, 2020

Overview

Effective January 1, 2020, the Executive Officer of the Ontario Public Drug Programs of the Ministry of Health (the "Ministry") established this Policy regarding payments made to pharmacies for supplying listed drug products or listed substances and providing professional services to residents of long-term care (LTC) homes.

As a precondition to obtaining billing privileges under the Ontario Drug Benefit Act (ODBA), all pharmacy operators are required to enter into a Health Network System (HNS) Subscription Agreement with the Executive Officer. Under section 3.2 of the HNS Subscription Agreement, pharmacy operators are required to comply with all Applicable Law, Ontario College of Pharmacists Rules, and Ministry Policies.

This Policy governs payments made to LTC home primary pharmacy service providers under a capitation funding model, as well as payments made to secondary pharmacy service providers under a fee-for-service funding model.

- A primary pharmacy service provider is defined as the pharmacy that is under contract with a LTC home to provide pharmacy services to residents of the LTC home.
- A secondary pharmacy service provider is defined as a community pharmacy that may dispense a prescription for a LTC home resident through an arrangement with the primary pharmacy service provider (as defined above) for emergency prescriptions. On rare occasions, it could be a pharmacy that



the resident attends for emergency purposes, for example, while on a visit with family outside the LTC home.

This Policy also clarifies that no co-payment may be charged to a resident of a LTC home for dispensing a listed drug product or listed substance.

How the LTC capitation funding model works

Effective January 1, 2020, the ministry replaced the fee-for service model for paying primary pharmacy service providers that provide medication dispensing and professional pharmacy services for residents of LTC homes with a fee-per-bed capitation model.

The primary pharmacy service provider is paid an annual fee-per-bed (on a monthly schedule) for all medication dispensing and professional pharmacy services based on the number of licensed LTC home beds serviced. The annual fees were initially set as follows:

- \$1,500 in 2019/20 (\$125/month)
- \$1.500 in 2020/21 (\$125/month)
- \$1,400 in 2021/22 (\$116.67/month)
- \$1,300 in 2022/23 (\$108.33/month)
- \$1,200 in 2023/24 (\$100/month)

The schedule reductions to the annual fee-per-bed in the Policy were delayed twice due to the COVID-19 pandemic on:

- April 1, 2021 (see EO Notice and accompanying materials posted on January 15, 2021 here); and
- April 1, 2022 (see EO Notice and accompanying materials posted on February 18, 2022 <u>here</u>).

The scheduled fee reduction is being put ON HOLD for one more year until 2024 and the \$1,500 payment per bed per year will be maintained for Fiscal Year (FY) 2023/24.



The Ministry amended the Policy to provide for revised annual fees-per-bed for FY 2024/24 to FY 2026/27. Primary pharmacy service providers will be paid an annual fee-per-bed (in monthly allotments), in accordance with the amended Policy, over the next four FYs as follows:

- \$1,500 in FY2023-2024 (\$125/month)
- \$1,400 in FY2024-2025 (\$116.67/month)
- \$1,300 in FY2025-2026 (\$108,33/month)
- \$1,200 in FY2026-2027 (\$100/month)

There continues to be no co-payment for all LTC home residents for eligible Ontario Drug Benefit (ODB) claims submitted through the Health Network System (HNS).

The fee-per-bed reimburses pharmacies for all pharmacy services provided for LTC home residents including medication dispensing services for eligible ODB products and all professional pharmacy services.

To receive the fee-per-bed, primary pharmacy service providers are expected to continue to provide medication management services, including medication reviews (such as MedsCheck LTC annual and quarterly medication reviews), medication assessments (e.g., as with the Pharmaceutical Opinion Program [POP]), and smoking cessation counselling (e.g., as with the Smoking Cessation Program), as appropriate.

- Claims for providing POP and Smoking Cessation services to LTC home residents should not be submitted through the HNS for reimbursement; overpayments due to inappropriate claim submissions are subject to recovery.
- MedsCheck LTC annual and quarterly medication review PINs were discontinued in the HNS.

How pharmacies receive the capitation payment

Primary pharmacy service providers must notify the ministry of the name(s) of the long-term care home(s) (including the LTC Agency IDs) with whom they have entered pharmacy services contracts in order to receive the monthly capitation payment. (Note: This was initially confirmed via an attestation process in December 2019.)



If the contract between a LTC home and the pharmacy service provider ends, the previous and new pharmacy service provider that ends or enters into a contract with the LTC home must notify the ministry in writing by the 15th of the previous month before the effective date of the change to ensure payments are processed in a timely manner (i.e., only attestation / notice of change forms that are received by the 15th will be processed for the following month's capitation payment). The capitation payment will be pro-rated based on the effective date of the change in pharmacy service provider once the ministry has been notified. Note that this may not be reflected in the monthly capitation payment until the following month.

Pharmacies that have entered into new pharmacy service contracts with LTC homes (not listed on their original Attestation Form in December 2019) must complete an "Attestation / Notice of Change in LTC Home Primary Pharmacy Service Provider Form"; see <u>Appendix D</u>.

Attestation / Notice of Change in LTC Home Primary Pharmacy Service Provider Form must be emailed to ODBLTCcap@ontario.ca. The ministry requires the following information:

- Pharmacy name
- Pharmacy address
- Pharmacy ID #
- Pharmacy fax
- Pharmacy O365 email address
- Effective date of the contract change
- Name of the LTC home
- Address of the LTC home
- LTC Agency ID #
- Attestation that the above information is accurate

The monthly capitation payment is based on the number of licensed LTC home beds on the last day of the previous month. For example, for the January 2020 payment,



the number of licensed beds at the LTC home as of December 31, 2019 was used to determine payment.

The primary pharmacy service provider on file at the ministry on the last day of the previous month will receive the capitation payment for that LTC home at the end of the current month.

The monthly capitation payment is based on the following formula:

(# of licensed LTC home beds on the last day of the previous month) X (annual bed fee / 12 months) = \$ amount paid to the pharmacy service provider for the LTC home for the current month; paid on the date of the second bi-weekly HNS payment for the current month.

For example, in January 2020 for a LTC home with 100 beds:

100 X (\$1500 / 12) = \$12,500 for Jan 2020; payment on January 31, 2020.

The monthly LTC capitation payment is included on the regular HNS payment date at the end of the month and will appear as a single line adjustment under the heading "Agency Level Adjustments" on the pharmacy's ODB Summary Remittance Advice (RA) report:

- Adjustment Type: "14 Long Term Care Capitation Payment"
- Transaction Code: "A2 Ministry Initiated Batch Adjustment"

Capitation payment dates follow the HNS payment schedule. The monthly capitation payment is reflected on the second HNS payment date of the month (i.e., the end of the month).

Recovery of capitation payments

The ministry's payment of capitation fees to primary pharmacy service providers is based on ODB claims data, an attestation from the primary pharmacy service provider, and notices of change to the attestation submitted by a primary pharmacy service provider. These data sources identify a pharmacy as a primary pharmacy service provider and the LTC home(s) for whom a pharmacy is the primary pharmacy service provider.

Errors in any of the above data sources may result in a pharmacy operator receiving a capitation payment for which they are not entitled – i.e., a capitation payment in



respect of a LTC home for which the pharmacy is not contracted as the primary pharmacy service provider. The ministry will recover such capitation payments so that they can be paid to the actual contracted primary pharmacy service provider for the LTC home.

In accordance with section 8.1 of the Health Network System Subscription Agreement for Pharmacy Operators, the following additional conditions are imposed on all pharmacy operators that submit claims in respect of long-term care home residents, effective January 1, 2020.

A9.0 RECOVERY OF OVERPAYMENTS

A9.1 Where the Executive Officer has reasonable grounds to believe that the Executive Officer has paid an amount to the Operator that is based on the number of beds in a Long-Term Care Home for which the Operator is not the Primary Pharmacy Service Provider for the relevant time period used to calculate the payment, that amount will be deemed to be a debt due and owing by the Operator to Her Majesty the Queen in right of Ontario.

A9.2 The Executive Officer may obtain or recover a debt that arises under section

A9.1 by way of set off against any amount payable to the Operator under the ODBA.

A9.3 Prior to initiating any recovery under section A9.2, the Executive Officer will provide the Operator with not less than twenty (20) Days written notice together with reasons for the recovery.

A9.4. In section A9.1, the following terms have the following meanings:

"Long-Term Care Home" means a long-term care home within the meaning of the Long-Term Care Homes Act, 2007; and

"Primary Pharmacy Service Provider" means the operator of a pharmacy that has been retained by the licensee of a Long-Term Care Home in accordance with section 119 of Ontario Regulation 79/10 (General) made under the Long-Term Care Homes Act, 2007.



Claims submission

A valid LTC agency ID number (ODP number) must be included as part of the claim submission for LTC home residents. Failure to do so could result in a rejection by HNS with response code "31" - Group Number Error

All pharmacies submitting claims for LTC home residents are reimbursed for the ODB allowable drug cost, applicable mark-up and compounding fee (if applicable). The dispensing fee is zero.

Secondary pharmacy service providers that provide additional and/or emergency prescription claims to residents of LTC homes that they do not have a contract with receive a dispensing fee (\$5.57 for most retail locations and a range from \$6.67 to \$9.99 for rural pharmacies) by submitting the claim with the intervention code "LT – LTCH Disp. Fee Payment for Emergency Rx" in order to be paid their corresponding ODB dispensing fee. The PINs previously used by secondary pharmacy service providers to submit the second claim for a dispensing fee have been discontinued. Any claim using these PINs will be rejected with the response code "D2 – DIN/PIN/GP # is discontinued". The patient copay is zero.

Primary pharmacy service providers must submit ODB-eligible claims through the HNS as per the normal process for claim submissions. No dispensing fee is paid.

The claim submission for secondary pharmacy service providers who provide emergency prescriptions for residents of LTC homes follows the normal process for submitting LTC claims on the Health Network System with the following additional information:

- Intervention code 'LT': (LTCH Disp. Fee Payment for Emergency Rx)
- Valid Pharmacist ID

No co-pay is to be collected from the LTC home resident. The HNS is set up to deduct the \$2.00 co-pay as part of the claims adjudication process. To ensure secondary pharmacy service providers are reimbursed for their appropriate ODB dispensing fee, they must submit claim values to account for the HNS adjudication process (i.e., adding the \$2.00 co-pay value to the dispensing fee amount they are entitled to receive).



Restrictions and Exemptions

Pharmacies can no longer submit claims through the HNS for MedsCheck LTC (both annual and quarterly medication reviews). The PINs have been discontinued. Primary pharmacy service providers are expected to continue to provide professional pharmacy services including medication reviews/reconciliation and assessments to residents of the LTC homes as part of their capitation payment and in accordance with their contracts with LTC homes.

Claims for LTC home residents submitted by the primary pharmacy service provider cannot be submitted with the intervention code "LT".

Claims for the Pharmaceutical Opinion Program by secondary pharmacy service provider if required, are eligible for reimbursement and can be submitted with the intervention code "LT". For clarity, payment eligibility rules for the Pharmaceutical Opinion Program apply to these claims.

Claims for LTC home residents submitted by secondary pharmacy service providers are exempt from the dispensing fee rules 2 fees/28 days and 5 fees/365 days. In other words, a dispensing fee for each ODB-eligible prescription dispensed will be paid if the applicable dispensing fee PIN is submitted by the secondary pharmacy service provider in accordance with this Policy.

Claims for LTC home residents, including those submitted by secondary pharmacy service providers, are also exempt from the Reconciliation Adjustment process implemented on January 1, 2020 that impacts all other ODB claims submitted for reimbursement.

All other HNS rules and Ministry Policies remain the same.

6.17 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

VHCs 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 O365 email account). You can select "Valved Holding Chambers" from the Coverage Status drop down menu on the <u>Formulary website</u>.

PIN	PIN Description	Manufacturer	Amount MOH 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 MOH Pays" in the Formulary plus a mark-up of 8% and the applicable ODB dispensing fee. There is no cost to the recipient.

For the purpose of claim validation and in accordance with <u>O. Reg. 264/16</u> made under the DPRA if applicable, documentation must be maintained for the Retention Period. Overpayments due to inappropriate claim submissions are subject to recovery.

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 eligible ODB 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) VHC (with or without mask/mouthpiece) per 365-day period. ODB recipients aged 13 years and older are not eligible for ODB-funded VHCs.

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"



6.18 Flash Glucose Monitoring Systems

Overview - FreeStyle Libre 14-day sensors and reader

Effective September 16, 2019, Ontario began funding FreeStyle Libre 14-day sensors and readers through the Ontario Drug Benefit (ODB) program. The FreeStyle Libre system belongs to a class of glucose monitoring systems called Flash Glucose Monitoring (FGM) Systems. Each FreeStyle Libre sensor measures glucose for 14 days and does not require the use of test strips for calibration purposes.

It has two components:

- Disposable sensor worn on the back of the upper arm, and;
- Reader (or via phone app) used to scan the sensor and review glucose data.

Reimbursement Criteria

All ODB eligible recipients receiving insulin therapy who also have a valid prescription from a physician or nurse practitioner for FreeStyle Libre sensors and readers are eligible to receive ODB-funded FreeStyle Libre sensors and readers.

Restrictions

Patients managing their diabetes with insulin are eligible for a maximum quantity of sensors over the course of a 365-day period as outlined in the table below:

Diabetes treatment	Maximum number of sensors per 365 days
Patients managing diabetes with insulin	33 (one sensor lasts up to 14 days)

Pharmacists must adhere to the quantity restriction as noted above. Effective March 21, 2021, the HNS includes quantity restrictions in place for the submission of FGM claims according to this policy announced in September 2019. For each claim submitted on or after March 21, 2021, the HNS will review the previous 365 days of



claims and ensure that the permitted maximum of 33 sensors per 365-day period is not exceeded.

In addition, the conditions and restrictions respecting the payment of a dispensing fee in O. Reg. 201/96 under the Ontario Drug Benefit Act apply to the dispensing of FGM systems as if they are listed drug products. More information is available in Section 5 and Ministry website.

Pharmacy Billing Procedure

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

- Product Identification Number (PIN)
- Valid Pharmacist ID

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

PIN	PIN Description	Manufacturer	Reimbursable Amount
09857632	FreeStyle Libre 14- day Sensor	Abbott Laboratories Limited	\$89.0000
09857633	FreeStyle Libre Reader	Abbott Laboratories Limited	\$49.0000

Pharmacies are eligible to be reimbursed in accordance with the following formula:

Reimbursable amount + mark-up + applicable ODB dispensing fee*

*The payment of dispensing fee is subject to the restrictions and conditions in section 18 of O. Reg. 201/96 under the ODBA. See note above.



HNS Response Codes and Messages

- If an FGM claim is submitted for an ODB recipient whose past 180 day claim history recorded in the Health Network System (HNS) does not include a claim for insulin, the claim will be rejected with a response code "QM- No Record of Required Prior Therapy". FGMs are only eligible for ODB recipients who are also receiving insulin therapy.
- If the pharmacist has confirmed that the patient is currently receiving insulin therapy which has not been recorded in the HNS (for example, insulin that is paid for by cash or through private insurance), intervention code "MZ Required Prior Therapy Documented" can be submitted to override the QM response code rejection. Pharmacists must properly document the required prior therapy.
- If an FGM claim is submitted and the dispensed quantities summed in the qualifying historical claims exceeds the limit of 33 sensors per 365-day period, the claim will be rejected with a response code "LO – Benefit Maximum Exceeded".
- The HNS will send a message line "Remaining Qty: xxxx until MMM DD, YYYY" when a claim is approved or rejected due to the quantity restriction, for example:

Remaining Qty: 0 until APR 01, 2021

- If an FGM claim is submitted and the dispensed quantities summed in the qualifying historical claims **plus the quantity in the current claim** exceeds the limit of 33 sensors per 365-day period, the claim will be rejected with a response code **"OC Quantity Reduction Required"**.
- The HNS will send a message line "Remaining Qty: xxxx until MMM DD, YYYY" when a claim is approved or rejected due to the quantity restriction, for example:

Remaining Qty: 2 until APR 01, 2021

When an OC response code is received, the dispensed quantity can be reduced to align with the remaining quantity as indicated in the message line, and the claim can be resubmitted for the lower quantity.



No interventions codes are permitted to override LO or OC response codes.

For billing purposes, pharmacy documentation must be maintained in a readily available format for the purpose of post-payment verification for a period of at least 10 years from the last recorded pharmacy service provided to the ODB recipient, or 10 years after the day on which the ODB recipient reached or would have reached the age of 18 years, whichever is longer. Overpayments due to inappropriate claim submissions are subject to recovery.

Message Format

For machine readability, the remaining quantity and date appear at fixed positions in the message line:

- the quantity appears right justified at positions 16-19
- the date appears at positions 27-38

Example message lines for various quantities:

```
Remaining Qty: 1000 until DEC 01, 2016
Remaining Qty: 100 until DEC 01, 2016
Remaining Qty: 10 until DEC 01, 2016
Remaining Qty: 10 until DEC 01, 2016
Remaining Qty: 1 until DEC 01, 2016
```

6.19 Temporary Benefit Listing

Temporary Benefits

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

Claim Submission Process

Billing procedures for Temporary Benefit listings are the same as the billing procedures for other listed drug products on the ODB Formulary.



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

Reimbursement Policy

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

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

The ministry will monitor the supply and shortage status of the original listed product. Once resolved and if the listing of the Temporary Benefit is no longer in the public interest, the removal of the Temporary Benefit from the Formulary will be communicated to pharmacies.

Please call the ODB Pharmacy Help Desk at 1-800-668-6641 for additional information on Temporary Benefits.

6.20 Biosimilar Policy

The Ontario government is expanding its biologic drug coverage policy to further promote the use of biosimilars funded through the Ontario Drug Benefit (ODB) program. As a key health system partner, the Ministry of Health ("the ministry") is seeking support from pharmacists in the implementation of this policy. These changes support the ministry's objectives of creating a modern and sustainable drug system that continues to offer high-quality treatment, while allowing the government to fund more new drug therapies, bring innovation to the health care system and continue its work to deliver better, connected patient care.



In general, effective March 31, 2023, the ODB program will start transitioning coverage for Copaxone^{®2}, Enbrel[®], Humalog^{®3}, Humira[®], Lantus[®], NovoRapid[®], Remicade[®], and Rituxan[®] to their biosimilar versions. As new biosimilars enter the Canadian market, these biosimilars and their corresponding originator biologic drugs may be included as part of this policy change.

Effective December 29, 2023, coverage for these originator biologic drugs through the ODB program will not be available for patients and the ODB program will only provide coverage for the biosimilar version of these drugs for all ODB program recipients, with limited exemptions (see below). In general, for ODB program recipients who are already on these biologic drugs, there is up to a 9-month transition period (see below for more information).

This biosimilars policy does not apply to coverage outside of the ODB program, including private drug plans and prescriptions paid out-of-pocket. However, the biosimilar policy will apply to patients transitioning from other coverage types to the ODB program; such patients who are on originator biologic drugs subject to the biosimilar policy will need to transition to a biosimilar version to receive coverage for these biologic drugs under the ODB program, with exemptions.

Transition period

ODB program recipients on any of the drugs listed above will be required to transition to a biosimilar version to continue receiving coverage for their medication under the ODB program, unless they meet a medically necessary exemption. A transition period of up to nine months, beginning March 31, 2023, will be granted for ODB program recipients (including existing Exceptional Access Program (EAP) recipients) to provide an opportunity for patients and their health care professionals to discuss biosimilar transition.

EAP approvals for Copaxone®, Enbrel®, Humira®, Remicade® or Rituxan® expiring between March 31, 2023, and June 29, 2023, will be extended to June 30, 2023. The purpose of this extension is to give prescribers adequate time to contact their

² Glatect® and Copaxone® are non-biologic complex drugs (NBCDs), however, the biosimilars policy will apply to their funding. As a result, in this document, references to an originator biologic include Copaxone® and references to a biosimilar include Glatect®.

³ Humalog® 200 units/mL KwikPen® 200U/mL Inj Sol-Pref Pen 5x3mL Pk (DIN 02439611) is excluded from the biosimilar policy. No biosimilar is available for this strength.



patients and discuss the transition to the biosimilar version or to determine if the patient may require a medically necessary exemption.

Patients with EAP approvals for Copaxone®, Enbrel®, Humira®, Remicade® or Rituxan® expiring *after* June 29, 2023, will be required to transition to a biosimilar by the expiry date of their EAP approval OR December 28, 2023, whichever is earlier, in order to continue receiving ODB program coverage for these biologics.

Prescribers are being asked to contact their patients to discuss transitioning to a biosimilar version of their medication and will need to write a new prescription. Prescribers should access the biosimilar for their patients on the ODB Formulary by using an eligible Limited Use (LU) code as applicable.

Medically Necessary Exemptions for Formulary Biologics

Medically necessary exemptions to this policy may be granted on a case-by-case basis through the EAP. Note that patients are generally expected to trial at least two⁴ biosimilars of the originator biologic before a request to the EAP will be considered to resume funding of the originator product.

During the transition period of March 31, 2023 to December 28, 2023, prescribers with patients requiring medically necessary exemptions to this policy for Lantus®, NovoRapid®, and Humalog® may include the corresponding temporary LU codes on their prescriptions, but only if the patient is currently established on the originator. These temporary LU codes will be available for medically necessary exemptions until the effective date of the December 2024 Formulary update, and any medically necessary exemptions for Lantus®, NovoRapid®, and Humalog® will need to be submitted to the EAP for case-by-case consideration. Physicians are encouraged to submit EAP requests as soon as possible during the transition period to avoid a gap in coverage.

As of December 29, 2023, access to Enbrel® and Humira® for plaque psoriasis will be discontinued and that indication will be removed from the ODB Formulary. Requests for patients requiring medically necessary exemptions to this policy for Enbrel® or Humira® for plaque psoriasis will need to be submitted to the EAP.

⁴ Where an originator biologic only has one biosimilar, a patient would only be required to trial one biosimilar before an EAP request for the originator biologic would be considered.



Compensation for Pharmacists

The Biosimilar Support Fee is paid to pharmacists who provide assistance to ODB program recipients in their transition from an originator biologic to a biosimilar under the Biosimilar Policy. Previously, pharmacists could only submit a claim for the Biosimilar Support Fee when filling the first prescription for a biosimilar included in the Biosimilar Policy for a transitioning ODB program recipient. Pharmacists now have the flexibility to submit a claim for a Biosimilar Support Fee when they undertake activities to support a patient to transition to a biosimilar, such as contacting a prescriber to obtain the ODB program recipient's first prescription for a biosimilar as part of their transition from the originator biologic, subject to any terms and conditions set out in this EO Notice. Where an ODB program recipient obtains their first prescription for the biosimilar directly from the prescriber without pharmacy involvement, the pharmacy may continue to submit a claim for the Biosimilar Support Fee when filling the prescription for the first time. The purpose of the Biosimilar Support Fee is to help ensure a smooth and timely transition for ODB program recipients to biosimilar products before the end of December 2023.

The fee can be claimed **once per patient per drug transitioned to a biosimilar product**. Claims for the support fee will only be paid during the transition period for eligible patients.

Note that the fee can only be claimed for transitioning ODB recipients between March 31, 2023 and December 28, 2023. It is not eligible to be claimed for:

- Recipients who are new to ODB on or after March 31, 2023;
- Prescriptions for biosimilars that were dispensed prior to March 31, 2023 or after December 28, 2023;
- Subsequent prescriptions for a biosimilar product, after the patient's initial transition to that drug product;
- Recipients who are not enrolled in the ODB program and pay out-of-pocket or are reimbursed by a third-party insurer; or
- Treatment-naïve recipients.

In order to be reimbursed for the Biosimilar Support Fee, pharmacies must follow the normal process for submitting claims to the Health Network System (HNS) (See



Section 5 of the Ontario Drug Programs Reference Manual ("Manual")), with the following additional information:

- Intervention code 'PS': (Professional Care Services)
- PIN: see Table below for list of PINs
- Valid Pharmacist ID

New PINs will be added if the policy is expanded to include new biosimilars. All other HNS rules and Ministry Policies remain the same.

For purposes of post-payment verification, pharmacy records related to claims for the Biosimilar Support Fee must be maintained in a readily available format for the purpose of ministry inspection for the Retention Period.

Overpayments due to inappropriate claim submissions are subject to recovery.

Pharmacy records must include the following:

- Signed and dated documentation, that includes but is not limited to the following:
 - Cross-referencing to the biosimilar claim to which the support fee relates;
 and
 - o Confirmation of the originator biologic that the patient was taking; and
 - When the originator biologic was last dispensed, if available; and
 - Summary of the pharmacist-patient interaction.

Drug Product	Biosimilar Patient Support Fee PINs
Adalimumab	09858133
Etanercept	09858104
Glatiramer acetate	09858107
Infliximab	09858105



Insulin aspart	09858238
Insulin glargine	09858108
Insulin lispro	09858132
Rituximab	09858106

Compliance with all ministry policies is required under <u>section 3.2</u> of the Health Network System (HNS) Subscription Agreement for Pharmacy Operators.



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 <u>Section 7.1</u>)
 - o MedsCheck Annual Medication Review and Follow-Up
 - MedsCheck Diabetes
 - MedsCheck at Home
 - MedsCheck LTC (Note: Funding parameters for MedsCheck for Long Term Care residents have changed effective January 1, 2020. For more information, see <u>Section 6.16</u>)
- Pharmaceutical Opinion Program (see <u>Section 7.2</u>)
- Pharmacy Smoking Cessation Program (see <u>Section 7.3</u>)
- Ontario Naloxone Program for Pharmacies (see <u>Section 7.4</u>)
- Reimbursement and Claims Submission using the Health Network System relating to Drugs for Medical Assistance in Dying (see <u>Section 7.5</u>)
- Reimbursement and Claim Submissions for Mifepristone/Misoprostol (Mifegymiso) (see <u>Section 7.6</u>)
- Reimbursement and Claims Submissions for Minor Ailment Services (see Section 7.7)

Please refer to the <u>Professional Pharmacy Services Guidebook</u> 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. The program also includes MedsCheck Follow-up, MedsCheck for Diabetes and MedsCheck at Home.

The MedsCheck program is voluntary and requires the patient's signed acknowledgment of the services each year. This process builds patient awareness and a better understanding of the MedsCheck services offered at community pharmacies.

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.

Pharmacists are required to follow up on potential drug-related problems resulting from all MedsCheck reviews (see <u>Section 7.2</u> 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 <u>Professional Pharmacy Services Guidebook</u> contains further details on the program including:

• eligibility Criteria



- location for service provision (where applicable)
- mandatory requirements, including the completion of the new <u>MedsCheck</u> 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 <u>Professional Pharmacy Services Guidebook</u>:

- MedsCheck Annual
- MedsCheck Follow-up
- MedsCheck for Diabetes
- MedsCheck At Home

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 provider, are available in the <u>Professional Pharmacy Services</u> Guidebook.

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 <u>MedsCheck Diabetes</u> 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

Effective January 1, 2020, funding for MedsCheck LTC has changed. All professional pharmacy services including dispensing fees and Professional Pharmacy Services (e.g., MedsCheck LTC, Pharmaceutical Opinion Program) provided to residents of long-term care homes are now reimbursed through a per-bed-fee capitation model.

To receive the fee-per-bed, pharmacists are expected to continue to provide medication management services, including medication reviews (e.g., MedsCheck LTC annual and quarterly medication reviews) and medication assessments (e.g., as with the Pharmaceutical Opinion Program) as appropriate to residents of LTC homes.

Pharmacies are no longer required to submit claims through the Health Network System (HNS) for MedsCheck LTC (both annual and quarterly medication reviews). The PINs have been discontinued.

For more information, please see <u>Section 6.16</u> or the Policy for Pharmacy Payments under the Long-Term Care Home Capitation Funding Model, 2020 on the <u>Ontario Public Drug Programs – Executive Officer Communications website</u>.



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 <u>Section 3.1</u>, 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 <u>Professional Pharmacy Services Guidebook</u> 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.



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 at Home, where 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 <u>Section 5.1</u>, 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	Υ	"PS" = Professional Care Service
DIN/GP# /PIN	Υ	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	Υ	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	Υ	"PS" = Professional Care Service
DIN/GP#/PIN	Y	Enter the appropriate Professional Care Service PIN: 93899988 = MedsCheck Diabetes Annual Assessment Summary 93899989 = Diabetes Education Follow-up
Pharmacist's ID code	Υ	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	Υ	"PS" = Professional Care Service
DIN/GP#/PIN	Y	Enter the appropriate Professional Care Service PIN: 93899987 = MedsCheck Home Assessment Summary
Pharmacist's ID code	Υ	Pharmacist License #
Professional Fee	Υ	MedsCheck Home Assessment Summary: \$150 per year/patient

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

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

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 for the Retention Period for claim validation purposes, and in accordance with O Reg 264/16 if applicable.



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 Meds Checks 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.

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 – a clinical intervention - during the course of dispensing a new or repeat prescription, or when conducting a MedsCheck medication review for a recipient of the ODB program (excluding a LTC home resident; for more information, see Section 6.16).

To be eligible for a professional intervention fee, the pharmacist must document and make a recommendation to the prescriber regarding the medication with the intent to achieve optimum patient health outcomes.

While the POP is only billable for ODB program recipients (with the exception of LTC Home residents), there is an expectation as per the Standards of Practice that pharmacists aim to resolve or prevent any drug therapy problems for all patients.

Outcomes

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.

Types of Prescription Interventions in a Pharmaceutical Opinion

In situations not already captured by the Health Network System (HNS) such as a Drug Utilization Response (DUR) code, the pharmacist may implement a pharmaceutical opinion based on one of the following prescription intervention criteria or drug therapy problems:

- i. Therapeutic Duplication; drug may not be necessary
- ii. Requires drug; patient needs additional drug therapy
- iii. Sub-optimal response to a drug; drug is not working as well as needed
- iv. Dosage too low
- v. Adverse drug reaction; possibly related to an allergy or a conflict with another medication or food, or a side effect
- vi. Dangerously high dose; patient may, either accidentally or on purpose, be taking too much of the medication
- vii. Non-compliance; patient is refusing to take the drug, or not taking it properly
- viii. Prescription has been confirmed false or has been altered

Identification of the Drug Therapy Problem

In the course of filling a prescription or when conducting a MedsCheck medication review, a pharmacist may identify a problem or potential problem that they feel should be discussed with the patient's prescriber. An intern or a registered pharmacy



student may conduct a POP service as long as the intern or student is under the supervision of a licensed pharmacist.

Contacting the Prescriber

- On identifying the potential drug therapy problem, the pharmacist must contact/consult with the prescriber to discuss the drug therapy problem or concern.
- The pharmacist provides the prescriber with a recommendation and documents the intervention on the prescription or worksheet (i.e., the drug therapy problem and recommendation). If a recommendation is not provided and documented, a claim for a POP cannot be billed.
- The pharmacist must document the outcome on the prescription or worksheet based on the interaction with the prescriber:
 - Not filled
 - No change to prescription therapy; filled as prescribed; therapy continued
 - Change to prescription therapy; filled as per change(s) (includes adding new drug therapy and discontinuing drug therapy)
- The main elements of discussion between the pharmacist and the prescriber must also be documented.

Communication with the Patient

- The pharmacist must inform the patient (or caregiver) why the prescription will
 not be dispensed as written/prescribed and what the potential drug therapy
 problem is.
- The pharmacist must also discuss any alternative therapeutic plan (if applicable) and convey such information to the patient and the prescriber.



 The pharmacist will provide the patient with an updated MedsCheck Personal Medication Record based on the outcome of the drug therapy problem if the intervention resulted from a MedsCheck.

What is NOT Eligible for Payment under the Pharmaceutical Opinion Program

- **1.** 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.
- 2. Contacting the prescriber without a clinical intervention when a patient missed a methadone dose (or a dose of any other drug).
- **3.** A one-way fax communication to the prescriber without a documented resolution to the problem as discussed with the prescriber.
- **4.** Recommendations to the prescriber for medical device therapy (including but not limited to blood glucose test strips, blood glucose meters, flash glucose meters, valved holding chambers).
- 5. Recommendation for the Smoking Cessation program.
- **6.** Recommendation for an influenza or COVID-19 vaccine (or other routine vaccines).
- **7.** Contacting the prescriber for a clinical intervention related to a drug recall, shortage or backorder.
- **8.** Contacting the prescriber for an early release of medication for interval restricted drugs (e.g., narcotic prescription) without a clinical recommendation.
- **9.** Referral to go see their primary care provider, a specialist, other health care provider or to go to the hospital.
- **10.** Pharmaceutical opinion conducted in conjunction with medical clinics or other health care facilities (e.g., cancer clinic pharmacies).
- 11. Drug therapy monitoring (e.g., INR monitoring).



- **12.** Recommendation to prescriber for patient to take over-the-counter or Schedule II medications (including naloxone).
- **13.** Recommending that a patient already enrolled in a methadone maintenance treatment (MMT) program requires drug therapy relating to the MMT.
- 14. Making a recommendation relating to Paxlovid™ prescribing and dispensing that is not eligible to be billed as a pharmaceutical opinion in the circumstances set out in the Executive Officer Notice on Prescribing and Dispensing of Paxlovid™ in Ontario Pharmacies on the ministry website.
- **15.** Making a recommendation in relation to a pharmacist prescribing allowable medications for minor ailments as set out in Section 7.7 of this manual.

Invalid Pharmaceutical Opinion Scenarios

Scenario #1 - Therapeutic Duplication

The patient presents a prescription for a Flovent (fluticasone propionate) inhaler. On checking the profile, the pharmacist sees that the patient is already taking Breo Ellipta (fluticasone furoate & vilanterol). The pharmacist contacts the prescriber and mentions that the patient has two prescriptions for the same therapy; they ask the prescriber which inhaler should be used? The physician / prescriber responds back to indicate that the patient requires both.

- The above scenario is not an acceptable POP claim as the pharmacist failed to make a recommendation to the prescriber.
- While the documentation indicated therapeutic duplication, it did not outline a recommendation to the prescriber by the pharmacist.
- A valid claim would have seen documentation that the pharmacist recommended one of the inhalers be discontinued and the rationale.

Scenario #2 - Adverse Drug Reaction

A patient with a penicillin allergy was prescribed cefuroxime. The pharmacist contacts the prescriber to ask for an alternate drug to be prescribed. The prescriber changes the prescription to azithromycin.



- The above scenario is not an acceptable POP claim as the pharmacist failed to make a recommendation to the prescriber.
- While the documentation indicated the allergy and potential for an adverse reaction, it did not outline a recommendation to the prescriber.
- A valid claim would have seen documentation that the pharmacist recommended azithromycin or another drug that a patient with a penicillin allergy could take.

Scenario #3 - Adverse Drug Reaction

A pharmacist received a prescription for cimetidine for a patient taking methadone for maintenance treatment (MMT). The pharmacist contacted the prescriber to indicate that cimetidine may increase the levels of methadone and therefore the dose should be adjusted or alternatively another drug should be prescribed. The prescriber discontinued the prescription for cimetidine and prescribed pantoprazole instead.

- The above scenario is not an acceptable POP claim as the pharmacist failed to make a recommendation to the prescriber.
- While the documentation indicated that the cimetidine dose should be adjusted, the pharmacist did not provide a recommended dose. In addition, while the pharmacist indicated that an alternate drug be prescribed, they did not recommend an alternative to the prescriber.
- A valid claim would have seen documentation that the pharmacist recommended the adjusted dose for cimetidine or an alternate drug treatment such as pantoprazole be prescribed.

Definitions of Prescription Intervention Terms or Drug Therapy Problems

1. Therapeutic Duplication; drug may not be necessary

The prescribed medication or a medication from the same therapeutic class is being taken by the patient. The addition of the prescribed medication may provide no clinical benefit beyond the medication already being taken or it may harm the patient.



2. Requires drug; patient needs additional drug therapy

Additional prescription drug therapy is required to treat or to prevent a medical condition in the patient.

3. Sub-optimal response to a drug; drug is not working as well as needed

The drug is not the most effective or is not effective for the medical problem. This may include situations in which:

- the dosage form for the drug product is not appropriate
- the medical condition is refractory to the drug product (not yielding to drug therapy)
- the prescribed medication has been previously taken by the patient and the patient did not experience the intended benefit of the medication

This would also include refill prescriptions or a second fill to the Trial Prescription Program in which it is determined by the pharmacist that the patient is not receiving the intended benefit of the medication.

4. Dosage too low

The total daily dose is below the usual recommendation and it is of little clinical value for the patient to take the medication in the dose that is prescribed.

5. Adverse drug reaction; possibly related to allergy or conflict with another medication or food

The prescribed medication may result in a potential drug interaction between it and the current medication therapy, the prescribed medication and a medical condition or the medication is contraindicated for use during pregnancy or breastfeeding or another condition.

The drug interaction is such that it has the potential to cause significant harm to the patient.

The prescribed medication has been previously taken and resulted in an adverse reaction, allergy or side effect that resulted in the medication being



discontinued. The adverse reaction was such that in the pharmacist's judgement the medication should not be received again by the patient.

This would also include refill prescriptions where the patient is having side effects with a prescribed medication, and because of the actions of the pharmacist in identifying the problem the medication is discontinued.

6. Dangerously high dose; patient may, either accidentally or on purpose, be taking too much of the medication

The total daily dose prescribed is above the maximum recommended daily dose and would harm the patient.

7. Non-compliance; patient is refusing to take the drug, or not taking it properly

The patient does not understand the instructions.

The patient prefers not to take the medication or forgets to take the medication.

The patient cannot swallow or self-administer the drug product appropriately.

The frequency that the patient is taking the medication does not align with the frequency prescribed.

8. Prescription has been confirmed false or has been altered

The pharmacist or pharmacy technician must confirm the validity of the prescription with the prescriber or the appropriate references including the respective prescriber's regulatory authority.

A copy of the forgery is maintained for the record and cross-referenced with the Pharmaceutical Opinion claim; documentation includes findings regarding the confirmed forgery.

In the majority of cases, recommendations to prescribers regarding forgeries do not apply due to the nature of this prescription intervention.

Pharmacists are expected to report the prescription forgery to the appropriate authority.

Note: Only ODB program recipients (excluding residents of LTC homes) are eligible for the POP (see <u>Section 4.1</u> for ODB Patient Eligibility). All claims will be monitored



by the Ministry. Claims submitted for non-ODB program recipients or residents of LTC homes will be subject to recovery. Also, see page 2 of the Executive Officer Notice for the POP as it relates to Prescribing & Dispensing Publicly Funded Paxlovid™ in Ontario Pharmacies. Separate POP PINs and criteria are used for the Paxlovid program.

Claim Requirements for Pharmaceutical Opinion Program

POP claims for payment may only be submitted for ODB program recipients (excluding residents of LTC homes). Claims submitted for pharmaceutical opinion for residents of long-term care homes will be subject to recovery as reimbursement parameters for LTC residents have changed effective January 1, 2020. For more information, please see Section 6.16 or the Policy for Pharmacy Payments under the Long-Term Care Home Capitation Funding Model, 2020 on the Ontario Public Drug Programs – Executive Officer Communications website.

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 <u>Section 5.1</u>, 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	Υ	"PS" = Professional Care Service
DIN/GP#/PIN	Υ	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	Υ	Pharmacist License #
Professional Fee	Υ	\$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. As a minimum to include:

- Details of the drug therapy problem (there are 8 reasons for not dispensing the prescription as written/prescribed).
- Medication(s) involved.
- Recommendation to the prescriber
- The date and the name of the prescriber who was contacted.



- Action plan / discussion with the patient (caregiver)
- The outcome: 1) Not filled due to a confirmed forgery / clinical concern; 2)
 Prescription filled as prescribed/therapy continued as prescribed; 3) Prescription therapy changed.
- The date of the transaction and the pharmacist's signature.
- Other comments required to substantiate the decision
- In the case of MedsCheck, the POP is documented on the pharmacist's worksheet and un updated MedsCheck Personal Medication Record is provided to the patient and the primary care provider as per MedsCheck standards.

Please note the documentation must be maintained for the Retention Period for purposes of claim validation, and in accordance with <u>O. Reg. 264/16</u> made under the DPRA if applicable. 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 provides an opportunity for community pharmacists to provide a one-to-one support service and advice to people eligible to receive ODB benefits 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 combined with a first consultation as well as a number of follow-up counselling sessions over a one-year period.

The pharmacist helps to facilitate access to, and where appropriate, supply suitable stop-smoking drugs and aids. For example, if a patient could benefit from prescription therapy to stop smoking, a pharmacist may independently prescribe as per their scope of practice.



Patient eligibility

The program is available to recipients of benefits under the ODB program (with the exception of LTC Home residents; for more information, see <u>Section 6.16</u>) who smoke and demonstrate a willingness or readiness to quit.

ODB recipients may enrol in the program once per year from the date of the patient's first meeting with the pharmacist at which time they have agreed to work together on a stop-smoking strategy.

A patient who smokes may self-identify their interest in the smoking cessation program. As pharmacists are in dialogue with their patients and caregivers daily for MedsCheck appointments, for questions related to over-the-counter medications and in fulfilling their dispensing services, there are many opportune times to talk about smoking cessation.

While pharmacists already provide advice to their patients on the risks of smoking during these interactions, the opportunity may also arise when patients are indeed ready to quit smoking and decide to enrol in the smoking cessation program.

The Process

Using the 5 As algorithm⁵ (Ask, Advise, Assess, Assist, Arrange) the pharmacist will guide the patient through a smoking cessation program (refer to <u>5 A's Algorithm</u> below).

As with all professional pharmacy services, pharmacists will provide the smoking cessation service in an area of the pharmacy that provides a sufficient level of privacy and safety for the patient.

All meetings with the patient must be documented to ensure program continuity. Follow-up meetings may be in person, via telephone, electronic messaging or other agreed-upon methods of communication.

⁵ The 5 As algorithm of Ask, Advise, Assess, Assist and Arrange is a smoking cessation algorithm that is commonly used by health care providers. For more information refer to the Smoking Cessation resource tools on the Ontario Pharmacists Association website: https://opatoday.com/product/smoking-cessation/



Standardized template forms are provided as minimum standards of care to assist pharmacists with the mandatory documentation at each patient point of contact. (Refer to <u>Appendix E</u>). While pharmacists may develop their own forms, the standardized template forms from the ministry must be adapted to maintain consistency of the program protocol.

While one pharmacist may be the initial contact with the patient, any pharmacist at the same pharmacy who has the appropriate training may meet with the patient over the course of the program. It is important, however, that there is a trusting relationship between the patient and the pharmacist(s) for the duration of the program. A one-to-one relationship between the patient and the counselling pharmacist may support a more successful quit attempt.

Duration of Program

The program includes nine points of contact over 365 days, including the readiness assessment whereby the patient agrees to the requirements to enrol, the first consultation meeting and the follow-up counselling sessions.

Readiness Assessment

The outcome of the Readiness Assessment is that the patient agrees to enrol in the smoking cessation program and establish a quit date.

- The pharmacist provides information that fosters program awareness for the patient and asks of their willingness to quit smoking. Generally, this is an inperson interaction and may result from the MedsCheck appointment, a patient enquiry about over-the-counter nicotine replacement therapy or as a result of another interaction where the opportunity to discuss the patient's desire to quit in the next month occurs.
- The Readiness Assessment includes a questionnaire to determine the level (rating) of the desire to quit smoking. A patient may not be ready to quit and may require more time to reflect before finally deciding to enrol.
- When the patient agrees to move forward and work with the pharmacist, the initial consultation will be arranged.



- A pharmacist and the patient may engage in a quit smoking discussion many times before a patient agrees to enrol and indicates a willingness to set a quit date.
- The readiness assessment process requires the pharmacist to document the patient's name, contact information and date of the discussion in which the patient agrees to enroll in the program.
- Documentation should also outline the questions asked, the level of desire to quit smoking and the pharmacist's name. Patients may request a copy of this record.

Patient's Signature

Patients who enrol in the Smoking Cessation program are required to establish a quit date and provide consent to the service including the method of communication whether in person, by phone or other means, and the time(s) for the consultations.

Patients also provide consent for sharing the readiness assessment or first consultation summary or other documentation within the circle of care.⁶

First Consultation Meeting

The outcome of the first consultation is to engage the patient in a dialogue about their smoking history, and to ensure the patient understands the goals and objectives of the program including their responsibilities towards success. The first consultation occurs after the pharmacist has conducted the readiness assessment and obtained the patient's consent to enroll in the program enrolment and share their health information within their circle of care.

The pharmacist meets with the patient in-person for the first consultation to discuss tobacco use and medication history, health risks, triggers/strategies; a quit date and consideration of pharmacotherapy.

⁶ Circle of Care is a commonly used term in the health care community that refers to the health care providers who share patient health information; for more information regarding patient consent refer to the OCP website (www.ocpinfo.com) and the Information and Privacy Commissioner website at www.ipc.on.ca



- Patient enrolment and consent forms should be signed prior to the first consultation meeting.
- An in-person appointment should be scheduled for the first consultation to ensure adequate time to discuss the patient's history and pharmacotherapy options.
- Patients should be provided with supporting printed education material relating to the benefits of quitting smoking and/or information pertaining to internet resources, peer groups and contact information such as the <u>Smokers</u> <u>Help Line</u>, other health care professionals and programs to reinforce their quit smoking goals.
- The first consultation includes developing a plan or an agreement on the chosen treatment pathway, ensuring that the patient understands the ongoing support and monitoring arrangements. Patients will use a quit smoking plan, which the pharmacist is required to provide. It is a personal plan for preparing to quit smoking and what to expect regarding their process. Other quit smoking management tools including brochures, referral information to support groups and other tools and/or strategies to promote positive results should also be provided.
- The first consultation also includes the appropriate advice and documentation that it may be necessary for the pharmacist to discuss and share the patient's health information with other health care professionals (physicians, nurse practitioners) in the process of assisting with the quit smoking program. While patients have signed consent forms, they should be informed if the pharmacist provides a copy of the readiness assessment and/or first consultation or follow-up session(s) information to the physician or other health care professionals.
- Follow-up counselling sessions for the purpose of patient progress, evaluation and monitoring smoking status, addressing any concerns or issues and providing support are outlined and tentatively scheduled at the time of the first consultation.

A billing code (<u>noted below</u>) through the ODB Health Network System is used by the pharmacist to claim payment after the first consultation. The claim for payment is processed once documentation of the first consultation meeting is complete and the patient has signed the appropriate agreements (Readiness Assessment).



Follow-up Counselling Sessions

All follow-up counselling sessions must be documented to ensure continuity of the program and evaluation of it and for the purpose of ministry inspection.

There are a total of seven follow-up counselling sessions that are billable by the pharmacist through the ministry's Health Network System. Pharmacists may meet with their patient more often if required such as prior to the targeted quit date or other times that require support strategies and pharmacotherapy intervention; however, the program limits payment to defined parameters.

The first three or primary follow-up counselling sessions should take place within three weeks of the first consultation, and the latter four or secondary follow-up sessions are expected to take place at intervals as agreed by the pharmacist and the patient between one and two months; between three and four months; between six and seven months; and between eight and twelve months.

Suggested timelines for follow-up counselling sessions:

Primary Follow-up sessions

- Day 3–5 (10 minutes)
- Day 7–10 (10 minutes)
- Day 14–21 (10 minutes)

Secondary Follow-up sessions

- Day 30–60 (3–5 minutes)
- Day 90–120 (3–5 minutes)
- Day 180–210 (3–5 minutes)
- Day 240–365 (3–5 minutes)

Primary Follow-up Counselling Sessions 1 - 3

 The first three follow-up counselling sessions should take approximately ten minutes and should occur within the first three weeks of the program being initiated.



• The sessions include a dialogue with the patient on their success with the strategy chosen including identifying any potential drug therapy issues. It is a time to discuss what is working or not working and ways in which the patient can overcome triggers, cravings or withdrawal symptoms. Pharmacists will optimize on the program successes and encourage continuation of those favourable outcomes. In addition, a review of biological incidents including personal, psychological or social issues, if any, that prevented the patient from reaching their goal are part of the discussion.

Secondary Follow-up Counselling Sessions 4 - 7

- The four secondary follow-up counselling sessions are approximately five minutes in duration and occur at the suggested intervals following the first month.
- The sessions continue to build on the program success history and review incidents including drug therapy issues and biological incidents, if any, that prevented the patient from reaching their goal.

A billing code (<u>noted below</u>) for the ODB Health Network System is used by the pharmacist to claim payment for each of the primary and secondary follow-up counselling sessions. The claim for payment is processed once documentation of the session is complete.

Program Evaluation

Pharmacists are asked to document smoking cessation program results for the purpose of program evaluation.

The following results are claimed using the ODB HNS PINs for the purpose of establishing patient success in the Ontario government's quit smoking program. The three PINs used for program evaluation provide no remuneration. Only one of the three program evaluation PINs is claimed per patient.

Once a program evaluation PIN is claimed, no further meetings are billable for that program period.



Successful Quit

 The successful quit is claimed when a patient indicates at any time during the program that they have successfully quit smoking. Once the PIN is claimed, no further meetings are scheduled or billable.

Unsuccessful Quit

- The unsuccessful quit is claimed when a patient indicates at any time during the program that they have not succeeded in quitting smoking. Once the PIN is claimed, no further meetings are scheduled.
- Pharmacist should inform patients who withdraw from the program of their eligibility to re-enrol at a later date (one year from the date of their first consultation with the pharmacist).

Unknown Status/Program Withdrawal

 The unknown status is claimed when a patient cannot be reached to continue with their program or when a patient withdraws from the program without indicating their success in quitting smoking.

Location of Meetings

In recognition of providing professional services by community pharmacists, the Smoking Cessation program meetings are ideally conducted in the community pharmacy, in person with the patient. The first consultation meeting should take place in the pharmacy, in person. Follow-up sessions are more flexible.

A sufficient level of privacy and safety for the patient must be ensured by the pharmacist.

The Ontario government recognizes that not all interactions between the pharmacist and the patient for the smoking cessation program can be conducted in person at the pharmacy. Should a meeting occur outside the community pharmacy or by another mechanism including telephone, email or other means as arranged and agreed upon by both parties, the location and method used must be documented.



Pharmacist Education Requirements

The Smoking Cessation program is considered to be within the scope of practice of a pharmacist licensed to practise direct patient care (Part A of the Register, Ontario College of Pharmacists). An intern or a registered pharmacy student may conduct a Pharmacy Smoking Cessation service as long as the intern or student is under the supervision of a licensed pharmacist.

In addition, pharmacists are required to take a smoking cessation training program to ensure they have a basic level of training including motivational interviewing strategies, a familiarity with more involved smoking cessation counselling and quit smoking planning.

The training program must support the Smoking Cessation Algorithm (5 As) of Ask, Advise, Assess, Assist, Arrange. Smoking cessation programs are obtainable in Ontario through the Ontario Pharmacists Association, the Canadian Pharmacists' Association and the Centre for Addiction and Mental Health.

Additional Requirements

- The designated manager of a pharmacy that provides a smoking cessation program must be trained in smoking cessation within six months from the time the pharmacy provides the smoking cessation service.
- A pharmacist who is trained in smoking cessation must be available during hours of operation at the pharmacy that offers a smoking cessation program.
- Training for smoking cessation must be updated at a minimum of every five years.
- A copy of the completed smoking cessation training program should be readily retrievable at the pharmacy for purposes of audit.

Quit Smoking Information and Resources

Information on the <u>Ontario Government's Support to Quit Smoking</u>⁷

⁷Refer to Ontario Government's <u>Support to quit smoking | ontario.ca</u>



- Canadian Cancer Society⁸
- Ontario Lung Association⁹
- Centre for Addiction and Mental Health¹⁰

Quit Smoking Helplines

- Smoke-Free Ontario Smokers Helpline 1-877-513-5333
- Canadian Cancer Society Smokers' Helpline 1-877-513-5333
- Ontario Lung Association 1-888-344-LUNG (5864)
- Centre for Addiction and Mental Health (CAMH) Information Centre 1-800-463-6273

Pharmacists may develop their own smoking cessation materials for patients. However, standardized template forms are provided by the Ontario Government as minimum mandatory standards of care to assist pharmacists document each patient point of contact. While pharmacists may develop their own forms, the standardized templates from the ministry need to be adapted to maintain a consistency of the program protocol.

Refer to the <u>ministry templates</u> for the Pharmacy Smoking Cessation Program (<u>Appendix E</u>).

⁸ Refer to Smoking and Tobacco references on the Canadian Cancer Society website: https://www.cancer.ca/en/support-and-services/support-services/quit-smoking/?region=on

⁹ Smoking and Tobacco references on the Ontario Lung Association website: https://lunghealth.ca/tobacco/

¹⁰ Refer to Tobacco and Smoking references on the Centre for Addiction and Mental Health website: https://www.camh.ca/en/health-info/mental-illness-and-addiction-index



Templates for pharmacist's materials are also available from the <u>Ontario Pharmacists</u>
<u>Association¹¹</u>

Documentation and Record Keeping

Each point of contact 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.

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.

All documents and records relating to the Smoking Cessation program may be stored electronically or as a hard copy when completed and be readily available for retrieval at a later date.

Refer to <u>Section 12</u> for requirements on supporting documentation.

Results

Patients are entitled to a copy of their readiness assessment, consent forms and any documentation from the first consultation and follow-up counselling sessions.

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.

¹¹ Refer to Smoking Cessation resource tools on the Ontario Pharmacists Association website: https://www.opatoday.com/smoking-cessation/



The 5 As Algorithm

Point of Contact	Description	Outcomes
Readiness Assessment	ASK client if they smoke ADVISE smokers to quit ASSESS patient readiness to make a quit attempt now	If client is NOT ready to make a quit attempt: Provide client with an information sheet to encourage self-reflection. No signature will be required If the client is ready to make a quit attempt and set a quit date: Client's agreement to enrol, to receive counselling and that health information may be shared within the circle of care will be sought through a signature
First Consultation (~ 20 mins in duration)	ASSIST the client in making a quit attempt	Using the standardized template as a minimum guide, the pharmacist and patient will: • Set a quit date • Create a quit plan • Provide practical counselling • Offer pharmacologic therapy, handouts and refer to community supports
Follow-up Counselling Sessions 1–3 (~10 mins in duration)	ARRANGE for follow-up contact, either in person or via telephone Contact client according to agreed-upon intervals. For example:	Using the standardized template as a minimum guide, the pharmacist and patient will: • Determine quit status • Assess pharmacotherapy use



	Between days 3–5 Between days 7–10 Between days 14–21	Discuss triggers and strategies to overcome them
Follow-up Counselling Sessions 4–7 (~3–5 mins in duration)	ARRANGE for follow-up contact, either in person or via telephone	Using the standardized template as a minimum guide, the pharmacist and patient will:
	Contact client according to agreed-upon intervals. For example:	Determine quit statusAssess pharmacotherapy use
	Between days 30–60 Between days 90–120 Between days 180–210	
	Between days 240–365	
Successful QuitUnsuccessful Quit	To determine patient's success status with the program	Using the standardized template, the pharmacist will indicate one of the following outcomes:
Unknown Quit Status		Patient succeeded in quitting smoking
		Patient did not succeed in quitting
		Patient did not indicate whether they quit smoking

Claim Requirements for Pharmacy Smoking Cessation Program

Smoking cessation claims for payment may only be submitted for ODB program recipients (excluding residents of LTC homes). Claims submitted for smoking cessation for residents of long-term care homes will be subject to recovery as reimbursement parameters for LTC residents have changed effective January 1, 2020. For more information, please see <u>Section 6.16</u> or the Policy for Pharmacy Payments under the Long-Term Care Home Capitation Funding Model, 2020 on the <u>Ontario Public Drug Programs – Executive Officer Communications website</u>.



A claim for payment is made after documentation is complete and the respective smoking cessation meeting/session has occurred using the appropriate PIN; claim to be submitted on the date of service.

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	93899941	\$40
(May only be claimed once per year)		·
Primary Follow-up Sessions		
(May be claimed three times per year)	93899942	\$15
Secondary Follow-up Session	93899943	\$10
(May be claimed four times per year)	33033343	\$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	\$O
Patient did not succeed in quitting smoking (may be claimed once per year if applicable)	93899945	\$O
Patient quit smoking status is unknown (may be claimed once per year if applicable)	93899946	\$O

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 (refer to <u>Appendix E</u>) 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 maintained by the pharmacist in a readily retrievable format for inspection purposes.



Please note for claim validation purposes, in accordance with <u>O. Reg. 264/16</u> made under the <u>Drug and Pharmacies Regulation Act ("DPRA")</u> if applicable, the documentation must be maintained for the Retention Period.

A copy of the completed smoking cessation training program by the pharmacist must 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 <u>notice from the Executive Officer</u> and the accompanying <u>FAQs</u> 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.

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 (preferred zippered hard black case with red 'naloxone' cross);
- 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: https://opatoday.com/naloxone/

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 procure medications for their pharmacy. For more information, please refer to the Ontario Pharmacists Association website at: https://opatoday.com/naloxone/. Additionally, pharmacies must print the instructional insert for replacement in existing naloxone kits available on the Ontario Public Drug Programs - Executive Officer Communications website.



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 the purposes of claim validation, and in accordance with <u>O. Reg. 264/16</u> made under the **DPRA if applicable**, all records must be maintained for the Retention Period.

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	Intra-Nasal	\$120.00



	\$10 – professional fee		
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 \$45.0		\$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 **not** 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:
 - o "PS" = Professional Care Services
 - o "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 Ministry website.

For further information on naloxone and the ONPP, please refer to the EO Notice and FAQs on naloxone posted on the <u>Ontario Public Drug Programs – Executive Officer Communications website</u> in August 2016.



Pharmacy Compliance

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

The <u>Executive Officer's notice</u> and the accompanying updated <u>FAQs</u> 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.

Updated Quarterly Report Back Form (QRBF)

Effective December 12, 2022, the Quarterly Report Back Form (QRBF) is no longer required to be submitted by participating pharmacies to the ministry under the Ontario Naloxone Program for Pharmacies (ONPP).

Pharmacies participating in the ONPP can email the ministry at PublicDrugPrgrms.moh@ontario.ca if they have any comments or concerns about the program.

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 <u>notice</u> 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 and the OCP have each established MAID policies for their members.

Pharmacists and dispensing physicians¹ 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: <u>www.ocpinfo.com</u>
- College of Physicians and Surgeons of Ontario: www.cpso.on.ca

¹ The term "dispensing physician" refers to a physician who has a valid Health Network System (HNS) Subscription Agreement with the ministry and is connected to the HNS.

You can also access the Ministry's website for more information.

Compliance

The Executive Officer's notice and the accompanying <u>Frequently Asked Questions</u> constitute a Ministry policy that pharmacy operators and dispensing physicians 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 and dispensing physicians ("HNS Agreement").

Patient Eligibility

Federal legislation governs the provision of MAID. Providers are encouraged to contact their respective regulatory college for more information and guidance about who is eligible to receive MAID.

Individuals in Ontario who are insured persons under the Health Insurance Act and able to receive MAID under federal law are eligible to receive publicly funded drugs for MAID ("eligible persons").

Procedures for Dispensing and Billing

Pharmacists and dispensing physicians 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 eligible persons, may impact the ability to submit future claims for these individuals.



Pharmacies and dispensing physicians will purchase drug(s) and the required supplies to assemble the MAID kits in accordance with Table 1 below.

Documentation Requirements for MAID drugs

Standard documentation requirements for prescriptions apply. Pharmacists and dispensing physicians shall keep records consistent with their obligations under, as applicable, the Pharmacy Act, 1991, DPRA, NSAA, *the Medicine Act, 1991*, their HNS Agreement, and any instructions provided by the OCP, the CPSO or the Ministry.

For the purposes of claim validation and in accordance with <u>O. Reg. 264/16</u> made under **DPRA if applicable**, records must be maintained for the Retention Period. Within the context of the definition of Retention Period, dispensing by a dispensing physician is considered a pharmacy service. The definition of Retention Period also applies with modification to non-ODB eligible persons who receive MAID drugs.

Billing procedure for MAID drugs

Drugs for MAID provided to eligible persons (based on the regimen prescribed) will be reimbursed by the Ministry. The product identification numbers (PINs) are used for both ODB-eligible and non-ODB eligible persons for the purposes of billing the value of the drugs in Ontario.

Funded MAID Drug Protocols

Pharmacists and dispensing physicians should work with prescribers and eligible persons 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: <u>www.cpso.on.ca</u>

OCP: <u>www.ocpinfo.com</u>



Table 1: 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	\$325.00
		Lidocaine 2% (without epinephrine)	
		Magnesium sulfate 500mg/mL	
		Propofol 10mg/mL	
		Citraturia besylate 2mg/mL	
		Rocuronium bromide 10mg/mL	
		Sodium chloride (NaCl 0.9%)	
		Syringes and tubes	
93877102	MAID IV Kit (backup) with Supplies	Same as above	\$325.00
93877103	MAID IV Kit with Phenobarbital and Supplies	Midazolam 1mg/mL	\$999.00



		Lidocaine 2% (without epinephrine)	
		Magnesium sulfate 500mg/mL	
		Propofol 10mg/mL	
		Phenobarbital 120mg/mL	
		Citraturia besylate 2mg/mL	
		Rocuronium bromide 10mg/mL	
		Sodium chloride (NaCl 0.9%)	
		Syringes and tubes	
93877104	MAID IV Kit (backup) with Phenobarbital and Supplies	Same as above	\$999.00
93877105	MAID Self-Administration Kit (Hydromorphone/Morphine)	Metoclopramide 10 mg	\$110.00
		Ondansetron 8 mg	
		Propranolol 40 mg	
		Morphine sulfate (liquid)	



		Morphine sulfate 30 mg Hydromorphone 1 mg/mL liquid Hydromorphone 8 mg	
93877110	MAID Self-Administration Kit (Secobarbital)	Secobarbital 15 g (mixture) Metoclopramide 10 mg Dexamethasone 8 mg Ondansetron 8mg	\$665.00

^{*}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, it is best practice for a primary kit and a back-up kit 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.

For ODB-eligible persons

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 1 above for list of PINs
- Valid Pharmacist ID
- Professional Fee: Up to the Total Amount Reimbursed

Note: The Total Amount Reimbursed listed in Table 1 refers to the maximum amount for that MAID kit. Where appropriate, a lower total amount must be claimed in situations where a prescription does not require one (or more) of the drugs or components in a kit. The lower amount claimed is the acquisition cost of the drugs within the kit that are dispensed.

For Non-ODB eligible persons

When submitting a claim for a person who does not have ODB coverage, pharmacists and dispensing physicians 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
 - o "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 claims:

- "PS": Professional Care Services
- o "ML": Established eligibility coverage (i.e., 1 day of the Plan 'S' coverage)
- o "MO": Valid Claim value \$500.00 to \$999.99
- Carrier ID: "S"
- PIN: see Table 1 above for list of PINs



- Valid Pharmacist ID
- Professional Fee: Up to the Total Amount Reimbursed

Note: The Total Amount Reimbursed listed in Table 1 refers to the maximum amount for that MAID kit. Where appropriate, a lower total amount must be claimed in situations where a prescription does not require one (or more) of the drugs or components in the kit. The lower amount claimed is the acquisition cost of the drugs within the kit that are dispensed.

Restrictions

Only the drugs provided in the MAID kits will be reimbursed, as well as other components such as the syringes and tubes for IV MAID kits (according to Table 1).

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/Physicians/Policies-Guidance/Statements-Positions/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 on the Government of Canada website.

Pharmacy Compliance

The Executive Officer's notice on Mifepristone/misoprostol (Mifegymiso), available on the Ministry's <u>website</u>, and the accompanying <u>FAQ</u> 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 the purposes of claim validation and in accordance with <u>O. Reg. 264/16</u> made under the **DPRA if applicable**, records must be maintained for the Retention Period.

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:
 - o PS: Professional Care Services
 - o 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 Funding for Minor Ailment Services in Ontario Pharmacies

As of January 1, 2023, Ontario pharmacists¹² are authorized to prescribe certain medications for the 13 minor ailments listed below ("minor ailments"), in accordance with the *Pharmacy Act, 1991* and Ontario Regulation 202/94 under that Act.

List of Minor Ailments¹³

- Allergic rhinitis
- Candidal stomatitis (oral thrush)
- Conjunctivitis (bacterial, allergic or viral)
- Dermatitis (atopic, eczema, allergic or contact)
- Dysmenorrhea
- Gastroesophageal reflux disease (GERD)
- Hemorrhoids
- Herpes labialis (cold sores)
- Impetigo
- Insect bites and urticaria (hives)
- Tick bites, post-exposure prophylaxis to prevent Lyme disease
- Musculoskeletal sprains and strains
- Urinary tract infections (uncomplicated)

¹² For the purposes of this section, where the term "pharmacist" is used it is inclusive of pharmacy interns and registered pharmacy students, and subject to any terms, conditions, and limitations on their certificates of registration. Where this is not the case, it will be clearly identified.

¹³ The Ontario College of Pharmacists describe minor ailments as health conditions that can be managed with minimal treatment and/or self-care strategies that are usually a short-term condition, where lab results are not usually required, there is a low risk of treatment masking underlying conditions, no medication/medical history red flags that could suggest a more serious condition and only minimal or short-term follow-up required.



As of October 1, 2023, pharmacists are authorized to prescribe certain medications for an additional 6 minor ailments, in accordance with the Pharmacy Act, 1991 and Ontario Regulation 202/94 under that Act:

- Acne (mild to moderate)
- Canker sores (oral aphthae)
- Diaper dermatitis
- Nausea and vomiting in pregnancy
- Pinworms and threadworms
- Vulvovaginal candidiasis (yeast infection)

The medications that may be prescribed by a pharmacist for the above minor ailments are set out in Schedule 4 to Ontario Regulation 202/94 under the *Pharmacy Act, 1991* ("allowable medication").

This section and the accompanying Questions and Answers document on the ministry's website (the Qs & As) set out the terms and conditions for an eligible pharmacy's submission of claims for payment (claims) for providing a therapeutic assessment regarding the appropriateness of an allowable medication to treat a minor ailment for an eligible person (the "minor ailment services").

Eligible pharmacies that decide to participate in this publicly funded program must comply with all of the terms and conditions set out in this section and the Qs & As.

General Description

- There is no cost to eligible persons (see definition in section below) who receive a minor ailment service from an eligible pharmacy (see definition in section below).
- The minor ailment service must be provided in-person at an eligible pharmacy or virtually (including by phone) from the location of the pharmacy. Note that claims for virtual care must follow the requirements provided by the Ontario College of Pharmacists <u>Virtual Care Policy</u>.



- Prescriptions provided by the pharmacist must adhere to Ontario Regulation 202/94 under the *Pharmacy Act, 1991*, as well as the guidelines and requirements provided by the Ontario College of Pharmacists, including the guideline on <u>Initiating, Adapting and Renewing Prescriptions</u>.
- For each valid claim submitted for minor ailment services using one of the Product Identification Numbers (PINs) in Table 1 below, a pharmacy will receive \$19 as payment for services provided in-person or \$15 for services provided virtually regardless of whether a prescription is issued. The minor ailment services include the following:
 - Obtaining informed consent from the eligible person or the eligible person's substitute decision maker to provide the minor ailment services (consent may be given verbally or in writing).
 - o Collecting and reviewing all relevant information about the eligible person to evaluate them and the situation (e.g., history of presenting complaint, person's health and medication history, etc.).
 - Assessing the eligible person to verify the person's self-diagnosis and identifying the best course of action.
 - Determining through a shared decision-making process the appropriate care plan.
 - o Implementing the care plan which may include issuing a prescription (if applicable) or referring the eligible person to their primary care provider (if any), providing education for the eligible person, documentation, and notification of the eligible person's primary care provider if an allowable medication is prescribed.
 - o If applicable, prescription requirements including:
 - Date prescribed
 - Eligible person's name, address, and date of birth
 - Drug name and strength, directions for use, quantity authorized
 - Pharmacist's signature / authorization (including registration #)



- Following-up with the eligible person (or their substitute decisionmaker) to establish monitoring parameters, evaluate safety and efficacy of the care plan, and additional next steps as required.
- Table 1 lists the PINs to submit claims for providing minor ailment services to eligible persons, including a description of each PIN and any restrictions.
- If a prescription for an allowable medication is issued, the eligible person must be informed that they are permitted to take the prescription to any pharmacy of their choice for dispensing. Where the eligible person decides to have their prescription filled at another pharmacy, the pharmacy/pharmacist that provided the minor ailment services must follow-up with the eligible person as part of the care plan.

Eligible pharmacies

Pharmacies that meet the following criteria ("eligible pharmacies") are eligible to submit claims for providing minor ailment services for eligible persons:

- Have a valid HNS Subscription Agreement with the ministry
- Ensure that only pharmacists (see definition on page 1) who have completed the Ontario College of Pharmacists' <u>Mandatory Orientation for Minor Ailments</u> <u>Module and who comply with applicable legislative and OCP requirements</u> provide the minor ailment services.

Eligible pharmacies are strongly encouraged to enrol in one of the provincial clinical viewers (<u>ConnectingOntario</u> or <u>ClinicalConnect</u>) at no cost through <u>Ontario Health</u>. The viewers provide health information about eligible persons, including laboratory test results and dispensed medications that could enhance clinical decision-making and help improve health outcomes. It also provides a history of publicly funded professional services.

Eligible persons

A person who meets the following criteria ("eligible person") is eligible to receive publicly funded minor ailment services from an eligible pharmacy:



- Has a valid Ontario health number¹⁴
- Presents with one of the minor ailments listed in Table 1 below; and
- Is not precluded from receiving minor ailment services based on the claim maximums listed in Table 1 (next page).

Table 1: PINs to Support Payment of Publicly Funded Minor Ailment Services¹⁵

The Table below includes claim maximums. When a claim for a minor ailment service fee is submitted, the HNS will look back 365 days from the claim's date of service to determine whether the maximum number of claims for that particular minor ailment has been exceeded. For example, if a patient receives a minor ailment service at one pharmacy and the pharmacy submits the PIN for "No Rx Issued (In Person)" and the next day, receives another minor ailment service (for the same minor ailment) at another pharmacy and that pharmacy submits the PIN for "Rx Issued (In Person)", this will count as 2 claims against the maximum number of claims.

If a claim is submitted to the HNS for a minor ailment service fee that exceeds
the maximum number of claims allowed for a particular minor ailment, the
claim will be rejected with the response code "LO – Benefit Maximum
Exceeded". No intervention code can be used to override the claim.

Pharmacists must also adhere to the OCP guidelines, appropriate clinical guidance and applicable algorithms for a particular condition when determining whether minor ailment services can be provided and billed to the ministry. This includes identifying situations (also known as "red flags") where an individual may not have a

¹⁴ "Ontario health number" means Ontario Health Insurance Plan (OHIP) Card Number or Ontario Drug Benefit (ODB) eligibility number issued by the Ministry of Children, Community and Social Services or by a Home and Community Care Support Service organization for some ODB eligible recipients.

¹⁵ Primary pharmacy service providers of long-term care (LTC) homes are paid for providing minor ailment services for residents of LTC homes through the LTC home capitation model and will not be paid a minor ailment service fee. Except in emergency situations, secondary pharmacy service providers (i.e., those that do not have a contract with a LTC home) are also not eligible for a service fee for providing minor ailment services for LTC home residents. Pharmacies ineligible to receive a service fee must submit claims for minor ailment services with a zero dollar fee.



minor ailment or has signs or symptoms that may not be solely attributed to a minor ailment. Where such "red flags" occur, the individual should be referred to another health care provider. See OCP's <u>Infographic</u> for an overview for treating minor ailments, including identifying and responding to red flags.

The red flags are also reflected in the claim maximums established for each PIN. The claim maximums are intended to identify situations where an individual may not have a minor ailment or has signs or symptoms that may not be solely attributed to a minor ailment, based on the frequency in which the individual is self-reporting a minor ailment and receiving minor ailment services from a pharmacy in a year. Where the claim maximum has been met, the pharmacy cannot submit a claim to the HNS for reimbursement for minor ailment services and the pharmacist must exercise their professional judgment in deciding whether to refer the individual to another health care provider, such as a physician or nurse practitioner.

Minor Ailment	Maximum number of claims per year ¹⁶	Rx Issued (In-Person)* Total Amount Paid \$19	No Rx Issued (In- Person)** Total Amount Paid \$19	Rx Issued (Virtual)*** Total Amount Paid \$15	No Rx Issued (Virtual)**** Total Amount Paid \$15
Allergic Rhinitis	4	9858181	9858182	9858183	9858184
Candidal Stomatitis	4	9858185	9858186	9858187	9858188
Conjunctivitis	3	9858189	9858190	9858191	9858192
Dermatitis	4	9858193	9858194	9858195	9858196
Dysmenorrhea	2	9858197	9858198	9858199	9858200
GERD	3	9858201	9858202	9858203	9858204
Hemorrhoids	3	9858205	9858206	9858207	9858208
Herpes Labialis	8	9858209	9858210	9858211	9858212

¹⁶ The maximum number of claims per year will be based the individual's claim history in the last 365-day period.

Ontario Drug Programs Reference Manual



Minor Ailment	Maximum number of claims per year ¹⁶	Rx Issued (In-Person)* Total Amount Paid \$19	No Rx Issued (In- Person)** Total Amount Paid \$19	Rx Issued (Virtual)*** Total Amount Paid \$15	No Rx Issued (Virtual)**** Total Amount Paid \$15
Impetigo	2	9858213	9858214	9858215	9858216
Insect Bites/Urticaria (cannot be combined with PINs for tick bites on the same day)	8	9858217	9858218	9858219	9858220
Musculoskeletal Sprains & Strains	4	9858221	9858222	9858223	9858224
Tick Bites (cannot be combined with PINs for insect bites on the same day)	4	9858225	9858226	9858227	9858228
Urinary Tract Infections (uncomplicated ¹⁷)	3	9858229	9858230	9858231	9858232
Acne (mild to moderate)	4	9858248	9858250	9858251	9858252
Canker Sores (Oral aphthae)	4	9858253	9858254	9858255	9858256
Diaper Dermatitis	4	9858257	9858258	9858259	9858260

_

 $^{^{17}}$ Refer to OCP's Assessment and Prescribing Algorithm for Uncomplicated Urinary Tract Infection (Cystitis) for complicating factors (e.g., male sex, pregnancy, age < 12 years, etc.) that may require referral to a physician or nurse practitioner.



Minor Ailment	Maximum number of claims per year ¹⁶	Rx Issued (In-Person)* Total Amount Paid \$19	No Rx Issued (In- Person)** Total Amount Paid \$19	Rx Issued (Virtual)*** Total Amount Paid \$15	No Rx Issued (Virtual)**** Total Amount Paid \$15
Nausea and Vomiting in Pregnancy	3	9858261	9858262	9858263	9858264
Pinworms and Threadworms	3	9858265	9858266	9858267	9858268
Vulvovaginal Candidiasis	4	9858269	9858270	9858271	9858272

^{*} Rx Issued (In-Person) refers to minor ailment services provided in-person at the pharmacy for an eligible person that result in a prescription for an allowable medication being issued for the eligible person.

^{**} No Rx Issued (In-Person) refers to minor ailment services provided in-person at the pharmacy for an eligible person that do NOT result in a prescription being issued (e.g., individual needs to be seen by a physician or nurse; or there is a recommendation to provide alternative treatments like non-pharmacological therapies and/or over-the-counter medications).

^{***} Rx Issued (Virtual) refers to minor ailment services conducted virtually (including by telephone) from the location of the pharmacy for an eligible person that result in a prescription for an allowable medication being issued for the eligible person.

^{****} No Rx Issued (Virtual) refers to minor ailment services conducted virtually (including by telephone) from the location of the pharmacy for an eligible person that do NOT result in a prescription being issued (e.g., individual needs to be seen by a physician or nurse practitioner; or there is a recommendation to provide alternative treatments like non-pharmacological therapies and/or over-the-counter medications).



Billing Procedures - Summary

- Claims for providing minor ailment services can only be submitted electronically using the HNS (see "Billing Procedures - Detailed" below). No manual paper claims will be accepted unless 3 intervention codes are required in order to process the claim.
- The Part A pharmacist who provides the minor ailment services or who is supervising a registered pharmacy student or an intern who is providing the service must be identified in the prescriber field on the claim.
 - Prescriber ID Reference must be entered as '09' (not '01' or '99'). Any other
 Prescriber ID Reference code will be rejected with response code "60 –
 Prescriber License Code Error".
- Each claim must include the PIN corresponding to the service provided to the eligible recipient (see Table 1 above).
- For clarity, a claim can be submitted for minor ailment services that do not result in the issuance of a prescription for an allowable medication. Please choose the appropriate PIN in Table 1 for this scenario.
- The person submitting the claim on behalf of the pharmacy operator must ensure that the eligible person's date of birth, Ontario health number and name (as it appears on the health card / document) are included in the claim.
 Failure to do so – especially for non-Ontario Drug Benefit (ODB) Program recipients – may impact the ability to submit future claims for these persons.

Pharmacy Documentation Requirements

Eligible pharmacies must keep a record of their provision of minor ailment services that result in a claims submission.

Pharmacists shall keep records consistent with their obligations under the *Pharmacy Act*, 1991, the *Drug and Pharmacies Regulation Act*, and any instructions or guidelines provided by the OCP or the ministry.

For purposes of post-payment verification, pharmacy records related to claims for minor ailment services must be maintained in a readily available format for the purpose of ministry inspection for a minimum of 10 years from the last recorded



pharmacy service provided to the individual, or until 10 years after the day on which the individual reached or would have reached the age of 18 years, whichever is longer.

Overpayments due to inappropriate claim submissions are subject to recovery.

Pharmacy documentation must be maintained in a readily retrievable format and recordkeeping requirements include the following records:

- Record of name, address, date of birth and Ontario health number of eligible person.
- Record confirming the consent of the eligible person or their substitute decision maker to the minor ailment services (whether such consent was provided verbally or in writing)
- Record of:
 - The minor ailment service including whether a prescription for an allowable medication was issued:
 - If a prescription was issued a copy of the prescription including but not limited to: date prescribed; eligible person's name, address and date of birth; name, strength (where applicable) and quantity of drug prescribed; directions for use including dose, frequency, route of administration; name, address, telephone number and OCP registration number of pharmacist issuing the prescription
 - If a prescription was not issued rationale must be provided including whether referral to another health care provider is warranted, that other non-pharmacological therapies and/or over-the-counter medications were recommended
 - The care plan including date and method of notification to the primary care provider (if any) if a prescription is issued
 - The follow-up with the individual including any monitoring parameters or next steps



Billing Procedures - Detailed

Claims submission requirements for minor ailment services are as follows:

For ODB-eligible recipients

The claim submission follows the usual process (See <u>Section 5</u> of the Ontario Drug Program Reference Manual) for submitting claims on the HNS with the following additional information:

- Intervention code 'PS': (Professional Care Services)
- Product Identification Number (PIN): for the applicable minor ailment services provided (see Table 1 above)
- Valid Pharmacist ID
- Professional Fee: see Table 1 above for 'Total Amount Paid'

For Non-ODB recipients

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

- Patient Gender: 'F' = female; 'M' = male; 'U' = unknown
- Patient Date of Birth: Valid YYYYMMDD
- Patient's Ontario Health Card number*
- Intervention codes:
 - o PS: Professional Care Services
 - o ML: Established eligibility coverage (i.e., 1 day of the Plan 'S' coverage)
- Carrier ID: 'S'
- Product Identification Number (PIN): for the applicable minor ailment services provided (see Table 1 above)
- Valid Pharmacist ID
- Professional Fee: see Table 1 above for 'Total Amount Paid'



Exclusions and Restrictions

- Individuals who do not have a valid Ontario health number are not eligible to receive publicly funded minor ailment services.
- Pharmacists cannot conduct minor ailment services for themselves or a family member. See OCP's policy on <u>Treating Self and Family Members</u>.
- Only one claim for minor aliment services can be submitted by a pharmacy
 per day per eligible person for a particular minor ailment (e.g., if a minor
 ailment service is provided and claimed for Urinary Tract Infections (UTIs) by
 one pharmacy that does not result in a prescription, another minor ailment
 service for UTI that results in a prescription by the same pharmacy cannot be
 conducted and claimed on the same day).
 - o If a second claim is submitted for the same patient, on the same day, from the *same* pharmacy, for the same minor ailment (using any one of the 4 PINs for that minor ailment), the claim will be rejected with the response code "A3 Identical Claim Processed". No intervention code can be used to override the claim.
 - o If a second claim is submitted for the same patient, on the same day, from a *different* pharmacy, for the same minor ailment (using any one of the 4 PINs for that minor ailment), the claim will be accepted with the warning response code "NU Too Soon After Previous Therapy". If the pharmacist chooses to provide another minor ailment service for the same condition, there must be proper documentation and rationale as to why it was provided so soon after the previous minor ailment service.
- Claims for the minor ailment service must be submitted electronically using the HNS on the day the service was provided.
- Pharmacies cannot claim a fee for a minor ailment service if the individual does not qualify and/or where they should automatically be referred to another health care provider (e.g., "red flags" like a UTI in pregnancy).
- Minor ailment services for an eligible person who is a resident of a LTC home are paid under the LTC capitation funding model and must be provided by the LTC home's contracted primary pharmacy service provider. A LTC home



primary pharmacy service provider is not eligible for the fee described in this Notice for providing minor ailment services for a LTC home resident.

- In emergency situations, secondary pharmacy service providers (i.e., those that do not have a contract with a LTC home) are eligible for the professional fee described in this Notice for providing minor ailment services for LTC home residents.
- O Pharmacies not eligible for a professional fee must submit claims for minor ailment services with a zero dollar fee. If a dollar amount is submitted as a professional fee on the claim, it will be rejected with the response code "68 – Professional Fee Error". Only secondary pharmacy service providers will be allowed to override the claim with intervention code "LT – LTCH Dispensing Fee Payment for Emergency Rx".
- A professional intervention fee for a Pharmaceutical Opinion Program (POP) service cannot be claimed in relation to a pharmacist prescribing allowable medications for minor ailments.
- A fee for a MedsCheck Follow-Up cannot be claimed in combination with minor ailment services that result in a prescription for an allowable medication.



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 of 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 manually, provided that the claim for payment meets one of the conditions for submission set out in Section 24 of <u>O. Reg. 201/96</u> made under ODBA.

For claim reversals, as of April 1, 2020, the submission window for electronic drug benefit claim reversals was extended from seven days to 90 days.

This section outlines specific instructions for submission of a manual claim for payment or claim reversal on paper ("manual claim" or "paper claim"):

- Conditions that require the use of paper Drug Benefit Claim Submission and Drug Benefit Claim Reversal forms (see <u>Section 8.1</u>)
- 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 <u>Section 8.4</u>)



8.1 When to Submit Manual Benefit Claim Submission and Drug Benefit Claim Reversal Forms

Subsection 24(2) of the <u>O. Reg. 201/96</u> under the ODBA sets out the circumstances under which claims for payment and claim reversals (i.e., claim cancellations) may be submitted to the Ministry via the Drug Benefit Claim Submission or Drug Benefit Claim Reversal forms.

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 prescriber who supplied the drug 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 90 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 <u>O. Reg. 201/96</u>.

Pharmacies are reminded that a manual claim submission due to accidental reversal is not within the allowable circumstances noted above.

If more than 90 days have passed since the original online or paper claim was submitted, 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 as per subsection 24(3) of the O.Reg. 201/96 under the ODBA.

8.2 Paper Drug Benefit Claim Submission and Drug Benefit Claim Reversal Forms

To submit a paper claim for payment or claim reversal, the pharmacy must complete a Drug Benefit Claim Submission form or Drug Benefit Claim Reversal form and forward it via fax to:

Ministry of Health Claims Services Branch

Fax: 1-613-237-3246

The <u>Drug Benefit Claim Submission and Drug Benefit Reversal forms</u> are available on the <u>Central Forms Repository</u> website.

Drug Benefit Claim Submission Forms Fields

The following tables provide 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
Reason for Submission	Select one or more of the following:
	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
	> 2 Intervention/Exception Codes
	>99 minutes compounding time
	Amount being claimed exceeds \$9,999.99
	Ministry Authorized Submission
Provider Transaction Date*	Date (YYYYMMDD) of service
Provider ID*	Unique identification number assigned to the pharmacy also referred to as "Pharmacy I.D." (see Section 2.1)
Client ID/Code (ODB Eligibility/ Health No.)*	Recipient identification number. Note: If Eligibility Number is different, the Health number must be provided. (See <u>Section 4</u> for more details.)
Version*	Ontario Health number version

¹Note: Additional data requirements include Provider Transaction Date, Pharmacy ID, and only the information needed to correct the previously rejected claim.

Claim Submission Information

Client Information:

Fields	Explanation
Patient Last Name*	Last name of patient



Patient First Name*	First 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 <u>Eligibility Establishment</u> <u>Summary Chart</u> in <u>Section 4.2</u>).
Sex*	Must be provided when a photocopy of the Eligibility Card is attached or when a Carrier ID=H or E is specified (see <u>Eligibility Establishment</u> <u>Summary Chart</u>).
Carrier ID (Plan Code)*	Identifies the appropriate plan code (see <u>Eligibility</u> <u>Establishment Summary Chart</u>).
Group No./Code* (Long Term Care Agency I.D.)	LTC or HSC home number (see <u>LTC and HSC list</u>) must be provided when services are rendered to recipients from LTC homes or HSC.

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
Prescriber ID*	Prescriber license number



Prescriber ID Ref.*	Reference number for prescriber, (see <u>Prescriber</u> <u>ID Reference Chart</u> in <u>Section 5.1</u>)
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.
Special Service Code/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.
Product Selection Code	Only required if submitting medically necessary "no substitution" claims. Enter reason code "1" to indicate prescriber directed medically necessary "No Substitution"
Unlisted Compound Type	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
	(see <u>Extemporaneous Preparations Claim</u> Requirements in <u>Section 6.1</u>)
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).



F	
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 <u>Section 6.2, Medically Necessary "No</u> <u>Substitution" Claims</u>)
	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 <u>Section 6.3, Limited Use Products</u>)
	(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 <u>listing</u> of SAN codes.
Intervention/Exception Codes	Select the applicable intervention/exception code(s) for the submitted claim from the list of available codes, if necessary.
	(Refer to <u>Section 10.2, Intervention/ Exception</u> <u>Code Table</u>)
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.
	Application.

Drug Benefit Claim Reversal Form Fields (pertains to the original paid claim)

The following table provides detailed descriptions of Drug Benefit Claim Reversal forms fields:

The asterisk (*) indicates optional fields required in certain situations.

Fields	Explanation
Provider I.D.*	Unique identification number assigned to the pharmacy also referred to as "Pharmacy I.D." (see Section 2.1)
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 <u>Section 4</u> for more details.)
Rx 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.
Total \$	Total amount of "Amount Billed to ODB" for all claims submitted for reversal.



included in the List of Parties with Signing Authority section on the OPDP Application.	in	riginal signature of an individual who has been cluded in the List of Parties with Signing uthority section on the OPDP Application.
--	----	--

The Drug Benefit Claim Reversal Form allows users to submit more than one claim reversal at a time, if required. The user may enter up to ten reversal claims on this form or submit a report generated from their pharmacy system for processing multiple reversals along with this form. The pharmacy-generated report must, at a minimum, include the same columns of data as listed on the form.

8.3 Instructions for Completion of Manual Drug Benefit Claim Submission and Drug Benefit Claim Reversal Forms

When submitting the details for manual 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 <u>Section 5</u> and <u>Section 6</u> for detailed explanations of the required fields

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

- The Drug Benefit Claim Submission Form may require 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.

Reconciliation of Manual Claim Submissions and Reversals

It is the responsibility of the pharmacy to track the status of a manual claim submission. The Ministry is not responsible for providing status updates on manual claims awaiting processing. Refer to Section 11, Reconciliation/Payment for further details regarding reconciliation of ODB payments.

 A Summary Remittance Advice for manual claim submissions/reversals or adjustments processed by the Ministry will be provided to the pharmacy for a payment period, via their O365 email account



Rejected manual claims for payment and reversals will be recorded on a
 "Reject Report for Paper Submissions", delivered to the pharmacy via O365
 email on the day following the date the paper claim was adjudicated by the
 Ministry. Pharmacies can use this report to reconcile accounts and correct
 manual claim submissions and reversals.

If a pharmacy receives confirmation of claim payment through their O365 email account and it does not match the manual submission, the following steps should be undertaken:

- Re-submit the original manual claim noting a keying error by the Ministry
- No reversal form is necessary

Note: All manual claim submissions are processed on a "first-in, first-out" basis, to maintain the same service standard for all stakeholders.

The pharmacy is advised to retain a copy of the confirmation record indicating a successful fax submission. Only in cases where the pharmacy receives a failed fax transmission notice, are they advised to resubmit the claim.

Unless advised to do so by the Ministry, re-submitting manual claims that have already previously been submitted to the Claims Services Branch (CSB) may result in delays in processing.

8.4 Supporting Documentation for Manual Drug Benefit Claim and Drug Benefit Claim Reversal Forms

The supporting documentation required for a manual 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 <u>Section 4.2</u>) to establish eligibility for ODSP and OW program recipients; or



- provide a photocopy of a faxed notification provided by an HSP/OHT 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 <u>Section 12</u> 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 <u>Section 9.2</u>)
- Applicable intervention codes for DUR response codes (see <u>Section 9.3</u>)
- How prospective DUR operates for:
 - o Claim submissions (see Section 9.4)
 - o Claim resubmissions (see <u>Section 9.5</u>)



- o Claim rejections (see <u>Section 9.6</u>)
- o Claim reversals (see <u>Section 9.7</u>)
- Phone support for prospective DUR inquiries (see <u>Section 9.8</u>)
- Confidentiality requirements on DUR information (see <u>Section 9.9</u>)

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			Information Message



will be	Reject Message	Reject Message	
communicated	(with the ability to	(with the ability to	
as	override)	override)	

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
		Severity Level 1 - Reject Message (with the ability to override)
ME	Drug/drug interaction potential	Severity Level 2 - Reject Message (with the ability to override)
		Severity Level 3 - Information Message
МН	May be double doctoring	Information Message
МІ	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 <u>Section 16 Help Desk</u>).

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 <u>Section 9.3</u>) 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 <u>Section 5.2, To Reverse a Standard (or Non-Standard Claim</u>).

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 "O0609013" 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.

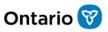


The table on the following page lists the DUR response codes, response status and intervention codes for the DUR modules.

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



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



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 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
МН	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	UD* = consulted prescriber and changed drug UE* = consulted prescriber and changed quantity UL* = prescription not filled - pharmacist decision



			appropriate intervention code.	UH* = counselled patient. Prescription not filled
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 <u>Section 5.2</u>). 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 <u>Section 16.2</u> 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 <u>Freedom of Information and Protection of Privacy Act (FIPPA)</u> 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 <u>Section 3.1</u>, 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 <u>Section 10.1</u>)
- Interpretation of the Intervention/Exception Codes (see <u>Section 10.2</u>)

Refer to <u>Section 9</u>, <u>Prospective DUR</u> 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.	N/A
		Refer to this <u>link</u> .	
32	Client ID # error	Invalid format. For intervention code "MJ" , Client ID # will be blank.	"MK" = eligibility established - emergency coverage
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
55	Current Rx # error	Must be numeric value greater than 0.	N/A
56	DIN/GP#/P IN error	Must be a valid DIN/PIN.	N/A



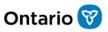
57	SSC error	SSC code was submitted inappropriately. Must be blank or U.	N/A
58	Quantity error	Must be a numeric value greater than 0. May not exceed maximum allowed for DIN.	"MQ" = valid claim - quantity over limit
59	Days' supply error	Must be a numeric value greater than 0	N/A
60	Invalid Prescriber 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 cannot be blank. For transactions in which the Prescriber ID relates to a prescriber who is retired or deceased or whose licence is suspended, the HNS will also return the following Message Line: • "Prescriber is not active" For transactions in which the Prescriber ID relates to a prescriber who has not been registered on the HNS, no Message Line is returned and	"MH" = override - prescriber ID. The use of the MH Intervention Code is based on the professional judgement of the pharmacist. Proper documentation to support the use of the MH Intervention Code must be maintained (e.g., documentation explaining why the prescription is still valid and being



only response code 61 will appear.	dispensed), and is subject to inspection and post-submission verification. Resources are available on the OCP website here.
	For prescribers (other than physicians licensed with the College of Physicians and Surgeons of Ontario [CPSO]) who are not registered on the HNS, no Message Line is returned. The claim can be resubmitted with an "MH" intervention code and the proper Prescriber ID and Prescriber ID Reference.
	For physicians licensed with the College of Physicians and Surgeons of Ontario (CPSO) who are not registered on the HNS, no intervention code



			can be used. Please contact the ODB Pharmacy Help Desk at 1- 800-668-6641, and the physician will be added to the HNS, as soon as possible.
		The claim has been rejected because the required information in the Medical Condition/Reason for Use field is missing or incorrect.	
62	Product selection code error	If the Product Selection code is "1", the Medical Condition/Reason for Use must be "901".	N/A
		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 authorizatio n 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/produ ct 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	Professiona I fee error	Numeric value greater than or equal to 0	N/A
70	Compoundi ng charge error	Numeric value greater than or equal to 0	N/A
71	Compoundi ng 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	This field cannot be blank. A valid Pharmacist ID is required for all ODB and NMS submissions. Response Code 76 will also be received for transactions that include a Pharmacist ID of a pharmacist whose licence is suspended.	N/A



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 chronicuse 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	Adjudicatio n 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).	N/A



		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 manual claim or claim reversal. (See Section 8.1, When to Submit a Manual Claim or Claim reversal)	
A2	Claim is post-dated	Transaction date future dated	N/A
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 dosage change
			"MR" = replacement claim, item lost or broken
			"MV" = vacation supply
A7	Submit manual reversal	Reversal transaction submitted more than 90 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)	<pre>"MK" = eligibility established emergency coverage "ML" = eligibility established standard coverage</pre>
C3	Coverage expired before service	The patient must have effective coverage in the program. This response code is set if the patient's program expiration date is before the claim's date of service. (Refer to Section 4, Eligibility)	<pre>"MK" = eligibility established emergency coverage "ML" = eligibility established standard coverage</pre>
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.	<pre>"MK" = eligibility established emergency coverage "ML" = eligibility established standard coverage</pre>
		Information Message only.	
CK	Health Card version code error	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 discontinue d	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
		Information Message only.	
D7	Fill/Refill too soon	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)	"UD"* = consulted prescriber changed drug "UE"* = consulted prescriber changed quantity "UL"* = prescription not filled, pharmacist decision "UH"* = counselled patient. Rx not filled
D.0	Reduced to	Information Message only.	N1 /A
D8	generic cost	Drug cost reduced (e.g., reduced to the cost for generic drug and/or ODB list price).	N/A
	Insufficient	Information Message only.	
DD	space for all DUR warnings	There is insufficient space for all DUR messages. Additional messages are available by	N/A



		calling the ODB Help Desk within days of the transaction.	
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	The claim has been rejected because the days' supply has been exceeded for a recipient of the Trillium Drug Program.	N/A

	to benefit year end	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 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 <u>Section 16.</u> <u>Help Desk</u>)	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
FX	Possible Forgery- Check authenticity	Indicates that the ODB program has been made aware of alleged forgeries for specific drugs (mostly monitored drugs) and/or stolen prescription pads (Refer to Section 13)	N/A
KG	Authorizatio n 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	"UA" = consulted prescriber and filled Rx as written "UB" = consulted prescriber and changed dose "UC" = consulted
		rejected. However, if the pharmacist should ascertain that the prescription is required, the claim may be processed using	prescriber and changed instructions for use "UF" = patient gave adequate

		the appropriate intervention code.	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	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. 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
МН	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.	"UD"* = consulted prescriber and changed drug "UE'* = consulted prescriber and changed quantity "UL"* = prescription not filled - pharmacist decision



		However, if the prescription is not filled, reverse the claim using the appropriate intervention code.	"UH"* = counselled patient. Rx not filled
MI	Poly- pharmacy use indicated	Information Message only. 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.	"UD"* = consulted prescriber and changed drug "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 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
ОС	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
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	N/A



plan and advise recipient to submit private plan information and receipts for out-of-pocket	not have a private plan, resubmit the claim with SSC "U". Or if the recipient has a private plan,	
L EXDENSES TO TDP.	submit the claim to the private plan and advise recipient to submit private plan information	

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. <u>See Section 8, Manual Drug Benefit Claim Submission and Drug Benefit Claim Reversals</u>.

The following table lists all of the intervention/exception codes. See <u>Section 9.3</u> for full descriptions.



Table of All Intervention/Exception Codes

Code	Description
LT	Payment of dispensing fee for secondary pharmacy service provider for providing emergency/additional prescription to long-term care home recipient. Also used for submitting Pharmaceutical Opinion Program claim for long-term care home recipient by secondary pharmacy service provider.
LU	Start new LU authorization
MG	Override - Clinical Reasons - Clinical various reasons
МН	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
ММ	Replacement claim, drug cost only
MN	Replacement claim due to dosage change
МО	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
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
РВ	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 manual claims/reversals processed by the Ministry (see Section 11.2)
- Reconciliation of remittance statements by the Ministry (see <u>Section 11.3</u>)
- Payment scheduling (see <u>Section 11.4</u>)
- Registering for direct deposit (see <u>Section 11.5</u>)

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 <u>Section 5</u>, <u>Submit Standard Online Claims</u>.

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 <u>Section 5.4, To Request Daily Totals</u>)
Claim Details	Details of claims processed for a specific day (see Section 5.5, To Request Claim Details)



Same Day Reversal Details,	Details of claims reversed for the specified day (see
or	Section 5.6, To Request Same Day Reversal Details
Prior Day Reversal Details	or <u>Section 5.7, To Request Prior Day Reversal</u> <u>Details</u>)

^{*}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 manual 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 O365 email account.

11.2 Payment & Drug Utilization Review Information for Manual Drug Benefit Claim Submissions and Drug Benefit Claim Reversals

For manual claims for payment or claim reversals adjudicated by the Ministry, the following payment information will be sent directly via email to the pharmacy's O365 email account:

Payment Information	Description
Summary Remittance Advice	Approved manual claims and claim reversals, and adjustments for a payment period
Reject Report for Manual Submissions	Rejected manual claims and claim reversals
DUR Responses for Manual Submissions	Prospective DUR responses



Refer to <u>Section 14</u>, 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 Manual 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:

- Manual 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 O365 email account. Pharmacies are reminded that under the terms of the HNS Subscription Agreement, they are required to log on to the O365 email 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 manual 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 <u>Transaction Code</u> 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

PAYMENT:	eseses DD			ODB S	ZARSES	PER TTT	NCE A	DVICE				
		PAYES	NT P	ERI OD	FROM	enne DD,	c cyy	TO eseses	DD, cc	ex.		
Cpla Phan	n ID: X		MAK MAK									
			- Maria									
					N ON	CPHA TRAN	SACTI	ONS				
Fix#						RESPONSE		G		DEDUCT		
RESUD #				TYPE				B4 E8G	COMP		PAYS	
999999999				99	><	XXXXXXXX				9999.99	99999.	99
		eses/ DD				XXXXXXXX			999.99			
,,,,,,,,,,				9 9		XXXXXXXXX				9999.99	>>>>>.	99
		tests/ DD				XXXXXXXXX			999.99	2222.22		
,,,,,,,,,,,		6963 / DD		9.9		XXXXXXXXX			222.22	,,,,,,,,	,,,,,,	7.5
		13137 1010				AAAAAAAA	. ,,,,		222.33			
					/ CXXII C	Y LEVEL A	DJUST	69.XXXXTS				
ADJUD 'TN	TRAM	ADJ		,	onser	RIPTION						
	CD											
CCYY/MM/D	D 3030	9.9				иниоскии			XXXX		99999.	
CCYY/MM/D	D XX	9.9	XXXXX	CKKKKK	CHICK	XXXXXXXXX	XXXX	XXXXXX	XXXX	•	99999.	99-
					O WINST TO	TANCE ADV	. er =	THE A DV				
						INNEL ADV		OLE SALE I				
OUTSTANDI			YY/88	1/DD						9	99999.	
TOTAL CPR						999				9	99999.	
TOTAL CPH.						999	_			9	99999.	99
TOTAL NON						999	9		999.99			
TOTAL AGE						999	9	9 9	999.99			
MET OF NO.			ACTI	OWE						2	99999	
	DE PAI										22222.	



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.
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 manual claim reversa			
12	Ministry Correction	This code is used to correct a manual 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. 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 manual claims for payment and claim reversals will be recorded on a 'Reject Report for Manual 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 - Manual claim
M1	Manual claim submission
M2	Manual claim reversal submission



Reject Report for Manual Submissions

The Reject Report for Manual Submissions will:

- List claim transactions that have been rejected
- State the reason for the rejection

Note: The Reject Report for Manual 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 <u>Section 14</u>, Electronic Mail).

Pharmacies can use this report to reconcile accounts and correct manual claim submissions and claim reversals. The resubmission of rejected manual claims may be expedited by using the Resubmission Number shown on the Reject Report for Manual Submission (refer to <u>Section 8.2, Manual Drug Benefit Claim Submission and Drug Benefit Claim Reversal Forms</u>).

Sample Reject Report for Manual 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: XXXXXXXXXXXXXXXXX

Birth: XXXX-XX-XX

Sex: X Carrier ID: Group No:

Health No: XXXXXXXXXXXX DIN/GP #: Curr RX: 1234567

Quantity: Days Supp:

Presc ID: XXXXXXXXX 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 manual claims will be reported on a DUR Responses for Manual Submissions report and will be delivered to the pharmacy via email on the next business day.

Drug Utilization Review Responses for Manual Submissions

The DUR Responses for Manual Submissions will list details for DUR responses identified while processing manual claims.

The DUR Responses for Manual Submissions will be generated nightly by the HNS. It will be available to pharmacies via email on the day following the date the manual claim was adjudicated by the Ministry.

Sample Drug Utilization Review Responses for Manual Submissions

Run Date: DEC 20, 2014 ODB - DUR RESPONSES

Adj Date: DEC 19, 2014 FOR PAPER SUBMISSIONS

CPhA Pharmacy ID: ODP1234567

XXXXXXXXXXXXXXXXX

DIN / PIN: 09850724 Drug Name: Allergen extracts

Dispense Dt: YYYY-MM-DD Current Rx: 123456



D7 Fill Too Soon

XXXXXXXXXXXXXXXX

DIN / PIN: 09850724 Drug Name: Allergen extracts

Dispense Dt: YYYY-MM-DD Current Rx: 234567

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 manual 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 O365 email account, 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 <u>Section</u> <u>11.4, Payment Schedule</u>)
- 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 <u>Section 16, Help Desk</u>). 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.	9th of current month (after 3:30 a.m. Eastern Time)	Middle of following month payments
Eastern Time)	to	
	23rd of current month (up to 3:30 a.m. Eastern Time)	

11.5 Direct Deposit

To register for direct deposit or change direct deposit information, complete the Notification of Change form (see <u>Section 2.2</u>) and send it by fax to (613) 548-6614 or by email to <u>HNS-Registration.MOH@ontario.ca</u> 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.

For claim validation purposes under the ODB program, documentation must be kept in a readily retrievable format according to the appropriate retention schedule as outlined in the chart below and throughout the manual. In the case of the operator of a pharmacy, the documentation must be kept in or be readily available to the pharmacy or the dispensary of the pharmacy and, in the case of a dispensing physician, the documentation must be kept in or be readily available to the dispensary of the physician.



All 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	Retention Period
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.	Supplier Invoices - 2 years from day the invoice was received. Prescriptions – the Retention Period (see Glossary of Terms).
Claims for Home Care recipients	Drug Benefit Eligibility Card (or written/fax notification from an HSP/OHT valid for the date of service. See <u>Section 4.2</u> , <u>Policy For Establishing Eligibility for Payment</u> .	The Retention Period (see Glossary of Terms).
Claims for OW and ODSP	For claims validated using a paper drug card, the paper drug card must be maintained 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.	The Retention Period (see Glossary of Terms).
	For claims validated through the SAV Portal or SAV Helpline when the patient's eligibility cannot be established on the HNS network:	
	A printout of the SAV Portal search results or documentation of the following:	



		1
	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 <u>Section 4.2, Policy For Establishing</u> <u>Eligibility for Payment</u> .	
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.	The Retention Period (see Glossary of Terms).
Claims for children and youth when the pharmacist has	A copy of the Ontario Health Card, or other proof of OHIP eligibility (e.g., a copy of the	The Retention Period (see



established eligibility	detachable portion of the Ontario Health Coverage Infant Registration Form).	Glossary of Terms).
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 or wholesaler's invoice(s) which demonstrate the Acquisition Cost of the ingredients) and the compounding time.	Documents other than purchase records - the Retention Period (see Glossary of Terms). Invoices - 2 years from the day the invoice was received
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".	The Retention Period (see Glossary of Terms).
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.	The Retention Period (see Glossary of Terms).
Emergency Authorization claim	Copy of the authorization to dispense items usually provided to LTC homes by the Ontario Government Pharmaceutical and Medical Supply Service.	The Retention Period (see Glossary of Terms).
Allergen claim	Valid SAA form (completed and signed by the prescriber). Manufacturer or wholesaler	Invoices - 2 years from the day the



	invoices must be readily retrievable for claim validation.	invoice was received. Form - the Retention Period (see Glossary of Terms).
Cost-to- Operator claim	Copy of the manufacturer's or wholesaler's invoice(s) which demonstrate the Acquisition Cost claimed, invoices which show that the lowest priced interchangeable product was ordered and not available at the time of the cost-to-operator claim, and a detailed calculation in accordance with section 14 of O. Reg. 201/96 of the cost of purchasing the drug product.	2 years from day the invoice was received.
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.	The Retention Period (see Glossary of Terms).
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.	2 years from the day the invoice was received.
Nutritional Product claim	Valid nutrition product form(s) (completed and signed by the prescriber and the dispenser).	The Retention Period (see Glossary of Terms).
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.	The Retention Period (see



		Glossary of Terms).
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.	The Retention Period (see Glossary of Terms).
SDP claim	Supplier invoices (wholesalers and manufacturers) may be required to validate claims.	2 years from day the invoice was received.
MedsCheck claim	MedsCheck documentation records including assessment summaries must be maintained by the pharmacist in a readily retrievable format. Please refer to the Professional Pharmacy Services Guidebook for program details.	The Retention Period (see Glossary of Terms).
Claims dispensed that are less than the maximum quantity in accordance with s. 18(8)(c) of O. Reg. 201/96	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. Please refer to s. 18(9) of O. Reg. 201/96 and Section 5 of this Reference Manual.	The Retention Period (see Glossary of Terms).
Claims dispensed that are less than the maximum quantity in accordance with s. 18(8)(a) of O. Reg. 201/96	A written record of the reasons for the dispenser's opinion. A copy of the notification to the prescriber about the determination. Please refer to s. 18(8.1) of O Reg 201/96 and Section 5 of this Reference Manual.	The Retention Period (see Glossary of Terms).
Claims dispensed more	A written record of the reasons for the dispenser's opinion. A copy of the	The Retention Period (see



frequently than twice per 28-day period in the circumstances described in s. 18(8)(a) of O. Reg. 201/96	notification to the prescriber about the determination. Please refer to s. 18(8.1) of O Reg 201/96 and Section 5 of this Reference Manual.	Glossary of Terms).
Claims dispensed more frequently than five times per 365-day period in the circumstances described in s. 18(8)(c) of O. Reg. 201/96	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. Please refer to s. 18(9) and 18(11.1) of O Reg 201/96 and Section 5 of this Reference Manual.	The Retention Period (see Glossary of Terms).
Claims dispensed more frequently than five times per 365-day period in the circumstances described in s. 18(11.1)(c)	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. Please refer to Section 5 of this Reference Manual.	The Retention Period (see Glossary of Terms).
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 must be maintained by the pharmacist in a readily retrievable format.	The Retention Period (see Glossary of Terms).
Smoking Cessation	Smoking cessation documents and associated patient records including any written referrals and patient consent	The Retention Period (see



	documentation; drug therapy information and desired outcomes / action plans; and specifics on quit smoking plans and advice offered to the patient must be maintained by the pharmacist in a readily retrievable format.	Glossary of Terms).
Flu vaccine claims	See <u>Section 6.15</u> of Manual for documentation requirements.	The Retention Period (see Glossary of Terms)
Claims for epinephrine auto-injector administration for emergency use following flu vaccine	See <u>Section 6.15</u> of Manual for documentation requirements.	The Retention Period (see Glossary of Terms)
Manual claims for payment or manual claim reversals	A copy of each manual claim for payment or claim reversal submitted to the Ministry, together with a record of the date on which the claim was submitted	The Retention Period (see Glossary of Terms)
Claims relating to COVID-19 programs (testing, vaccine administration, Paxlovid, Evusheld)	See applicable Executive Officer notice on Ministry's website	The Retention Period (see Glossary of Terms)
Claims relating to Professional Pharmacy Services not described in the rows above (e.g.,	See applicable subsection in Section 7 of Manual for documentation requirements.	The Retention Period (see Glossary of Terms)



Naloxone, MAID,	İ
	İ
Minor Ailments)	

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.

Other Rules Regarding Retention of Records

In addition to the records to support the various submissions outlined in the table above, the following records must be maintained by the pharmacy:

- A copy of a statement of daily transaction totals prepared each day (must be maintained for a period of two years from the day on which the daily statement is prepared)
- A copy of each summary remittance statement or reject statement received from the Executive Officer (must be maintained for a period of two years from the day on which the statement is received)

In accordance with <u>O. Reg. 264/16</u> 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, <u>O. Reg 201/96</u> 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" (<u>see Section 5</u>).

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: Prescription Forgery

Effective November 23, 2020, the ministry implemented system changes to notify dispensers in real-time about reports of alleged forgeries and/or stolen prescription pads utilizing the ministry's online claim adjudication system - the Health Network System (HNS), which includes the Narcotics Monitoring System (NMS). Prescription Forgery Alert Notices being sent out to pharmacies via electronic mail have been discontinued effective November 23, 2020.

- Pharmacies will receive a Forgery Notification Alert (in 'real-time', as part of the adjudication response) that this prescription order contains attributes that relate them with a recorded Forgery Notification Alert issued under the prescriber's name.
- The system will display a warning response code "FX" and a message that is cautionary/informational in nature.
 - o For ODB Claims Adjudication: 'Possible Forgery-Check authenticity'
 - o For NMS Adjudication: 'NMS: Possible Forgery-Check authenticity'
- The dispenser should follow their established process to confirm the authenticity of the prescription and use their professional judgment to determine the appropriate course of action, including verifying authenticity by consulting with the prescriber. If the prescription is confirmed to be a forgery, the pharmacist should not proceed with dispensing the prescription drug and must submit a claim reversal if the drug is not dispensed.

The pharmacist and the associated prescriber should contact the Ontario Drug Benefit program at <u>drugprogramsdelivery@ontario.ca</u> to report the occurrence of a forgery. The following information is required when reporting a prescription forgery:

- The prescriber details on the forged prescription including prescriber name, address, phone/fax number;
- The name(s) of the drug(s) mentioned on the forgeries (if known); and
- Attach a copy of the prescription and any additional forged prescription pages you may have.



Section 14: Electronic Mail

Overview

As of January 15, 2022, the ministry will be replacing the ONE® Mail email service with Microsoft Office 365 (O365) email account for dispensers.

O365 is a secure email service developed and operated by Microsoft that is accessible via the internet (e.g., a web browser). It meets the high security requirements to exchange information between the ministry and stakeholders.

O365 email is used to advise pharmacies of drug benefit changes, program changes, and payment information. A **single O365** 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 O365 email account.

The ministry will address the communication directly to registered email account users. O365 email messages will include important Executive Officer Communication, Summary Remittance Advice statements, Formulary Updates, Monitored Drugs Updates, and CPSO Notices.

Pursuant to their HNS Subscription Agreements, pharmacies must check their O365 email accounts at least once per week.

In addition, pharmacies should delete old messages that are no longer required from the O365 email account on a regular basis.

This section outlines the process involved with:

O365 Email Account Registration

O365 Email Account Activation

O365 Email Account Forms

Troubleshooting



O365 Email Account Registration

The O365 email account registration form is provided as part of the HNS registration process. The pharmacy owner/pharmacist with signing authority for the operator will be the owner of the O365 email account. The pharmacy must submit the completed O365 email account registration form to the ODB registration desk.

O365 Email Account Activation

Upon registration, the ministry will notify the pharmacy that the O365 email account registration is complete. This automated confirmation email will be sent to the pharmacy's personal or corporate email address (provided by the pharmacy on the O365 email account registration form).

The confirmation email will contain the new username (e.g., **ON#@opddp.ca)**, a **unique temporary password** for the initial log-in, and a direct link for logging in.

You will be required to change the temporary password the first time you login.

To launch the email service, please log in to https://outlook.office.com to change the temporary password, then proceed to follow the on-screen setup process.

When changing the password, please follow the password complexity rules. It is recommended that a unique password be used that is not used with any other applications.

- Password must be 12 or more characters long.
- Password must contain characters from all the following four categories:
 - Uppercase characters A-Z (Latin alphabet).
 - o Lowercase characters a-z (Latin alphabet).
 - o Digits 0-9.
 - o Special characters (@, \$, #, %, etc.).

Type in the current (temporary) password and your new password based on the password complexity above. Follow the steps in your browser.



O365 Email Account Forms

Email Account Registration and Enrolment Request Form (for O365 email account)

2. Email Account Information Change Request Form

Complete this form for O365 email account changes including change of O365 email account ownership.

3. O365 Email Account Revocation Form

The O365 email Account Revoke Form is provided as part of the HNS account closing process. The pharmacy must submit the completed O365 email account revoke form to the ODB registration desk. The O365 email account will be cancelled as part of the HNS account closing process. Your E-mail account will remain active for three months after the closure date.

Pharmacies must forward the signed and completed form by email, fax, or mail to:

Email: HNS-Registration.MOH@ontario.ca

Fax: (613) 548-6614

Ministry of Health Claims Services Branch Provider Registry P.O. Box 68

Kingston ON K7L 5K1

Troubleshooting

For O365 email account login issues, including password resetting, call the ODB Help Desk at 1-800-668-6641.

For O365 email account registration, call the ODB Help Desk at 1-800-668-6641.



Section 15: Narcotic Monitoring System

Overview

This section replaces the Narcotic Monitoring System (NMS) Pharmacy Reference Manual Version 1.2 dated May 24, 2012.

The Narcotics Monitoring System (NMS) collects dispensing data from dispensaries in respect of all dispensed narcotics, controlled substances and other monitored drugs, irrespective of whether the prescription is paid for under a publicly funded drug program, through private insurance, or by cash. The collected data will be reviewed and analyzed by the Ministry of Health (the "ministry") for a variety of purposes including, but not limited to: educational and public health purposes, reporting possible professional misconduct to regulatory authorities, and reporting possible criminal conduct to law enforcement agencies.

The Narcotics Safety and Awareness Act, 2010, S.O. 2010, c.22 (the "Act" or "NSAA") and Ontario Regulation 381/11 (General) made under the NSAA (the "Regulation") govern the NMS. The NSAA and the Regulation require a dispenser to keep certain records for a period not less than 2 years. This retention period applies to all records described in this section.

The NSAA defines a "monitored drug" as: (i) a controlled substance as defined in the Controlled Drugs and Substances Act (Canada) (CDSA), unless the controlled substance has been excluded by the regulations under the NSAA; and (ii) any other drug designated by the regulations. Any drug product that is an opioid that is not listed under the CDSA has been designated under the Regulation as a monitored drug. No controlled substance under the CDSA has been excluded by the Regulation.

Section 8 of the NSAA confers authority on the Executive Officer of Ontario Public Drug Programs (the "Executive Officer") or the Minister to direct prescribers, dispensers and pharmacy operators to disclose certain information to the ministry about the monitored drugs they prescribe or dispense. By notice from the Executive Officer, dispensers and pharmacy operators have been directed to submit the required information about monitored drugs to the ministry electronically using the Narcotics Monitoring System (NMS).



Effective May 14, 2012, all dispensers in Ontario are required to submit the following information to the NMS when dispensing a monitored drug to a patient:

- Prescriber's registration number issued to the prescriber by the College of which he or she is a member
- Prescriber ID reference (identifying the professional college to which the prescriber belongs – e.g., CPSO, RCDSO)
- Identifying number of the patient and the identifying number type
- Name of the patient for whom the monitored drug is prescribed
- Date of birth and gender of the patient
- Date on which the monitored drug is dispensed
- Drug identification number
- Quantity of the monitored drug dispensed
- Length of therapy, in number of days, of the monitored drug
- Prescription number
- Pharmacist ID (registration number from the Ontario College of Pharmacists)
- Pharmacy ID

Pursuant to subsection 8(2) of the NSAA, prescribers, dispensers and pharmacy operators are required to disclose the information specified under the Act at the time and in the form and manner that the Minister of Executive Officer directs. The Executive Officer directs that the required dispensing information be submitted by dispensers and pharmacy operators to the NMS in accordance with this section of the Reference Manual.

Prescribers, dispensers and pharmacy operators may be inspected for the purpose of determining their compliance with the requirements of the NSAA (see section 13 of the Act).

This section of the Reference Manual outlines requirements for submission of NMS claims and also describes the various system responses:



- NMS Requirements (Section 15.1)
- Monitored Drugs List (<u>Section 15.2</u>)
- Identifying Numbers and Prescriber ID Reference Chart (Section 15.3)
- NMS On-Line Dispense Transaction and System Response (<u>Section 15.4</u>)
- NMS On-Line Inquiry Transaction and System Response (<u>Section 15.5</u>)
- NMS On-Line Reversal Transaction and System Response (<u>Section 15.6</u>)
- NMS Data Validation Response Codes and Messages (<u>Section 15.7</u>)
- NMS Drug Utilization Review (DUR) Warning Response Codes (<u>Section 15.8</u>)

15.1 NMS Requirements

General

To ensure that information in the NMS database is current and accurate, dispensers must submit the required dispensing information to the NMS at the time that a monitored drug is dispensed. Reversals must be submitted to the NMS as soon as the need for a reversal transaction is identified.

Dispensers and pharmacy operators are responsible for ensuring that the dispensing information submitted to the NMS is true, accurate and complete. Pursuant to section 14(1) of the NSAA, a dispenser or pharmacy operator may be found guilty of an offence if the person fails to maintain the records required under section 11 of the NSAA, fails to submit the required dispensing information to the NMS, or submits information to the NMS that the person knows to be false or misleading.

A dispenser or pharmacy operator may use the NMS only for the purpose of carrying out the dispenser's or pharmacy operator's duties and functions under the NSAA.

Prescriber Identification

The NSAA requires prescribers of all monitored drugs to record the registration number or certificate number issued to the prescriber by the college (i.e., the prescriber license number) on prescriptions for monitored drugs.



A valid prescriber ID and the appropriate corresponding prescriber ID reference are mandatory for submitting NMS transactions. Please refer to the prescriber ID reference chart (Section xx.4) for the prescriber ID references of those prescribers who can prescribe monitored drugs.

Transactions submitted to the NMS using the unknown prescriber ID reference "99" and the unknown prescriber ID "99999" are not valid. Failure to properly identify the prescriber in the NMS constitutes a breach of the dispenser's disclosure obligations under the NSAA.

Dispenser Identification

The registration number of the dispensing pharmacist is mandatory for transactions submitted to the NMS.

Non-application to Veterinary Prescriptions

Submission to the NMS is not required when dispensing prescriptions for monitored drugs written by veterinarians in the course of their practice. The NSAA does not apply to such prescriptions.

Exceptions

Submission to the NMS is not required when dispensing prescriptions for monitored drugs dispensed to prisoners or inmates. This includes prescriptions written for people confined to a correctional institution, penitentiary, prison or youth custody facility. The NSAA does not currently apply to these populations as they have been exempted by the Regulation.

Submission to the NMS is not required when dispensing prescriptions for monitored drugs to an in-patient of a public hospital as part of his or her treatment in a public hospital. The NSAA does not currently apply to in-patients of public hospitals as they have been exempted by the Regulation. The NSAA does apply, however, to outpatients of public hospitals and to in-patients of private hospitals or any other institution that is not a public hospital.



Prescriptions for Residents of Long-Term Care Homes

The NSAA applies to prescribing and dispensing prescriptions for monitored drugs to residents of long-term care homes.

NMS Transactions

Pharmacists can submit dispensing information to the NMS before or after the submission of a claim to the ministry's Health Network System (HNS) or to any other third-party claim adjudicator.

Prior to dispensing, pharmacists have an option to send an NMS inquiry transaction with an intervention code "DU". The NMS will perform all data integrity checks and Drug Utilization Review (DUR) checks, but will not store the drug information as a dispense transaction. If the pharmacist subsequently dispenses the drug, the ministry will require the submission of a dispense transaction to record the correct dispensing information. NMS inquiry transactions do not require a reversal transaction to be submitted.

While the NMS will accept electronic submission of monitored drug dispensing information and reversal transactions up to 365 days from the date of service, dispensers are required to submit NMS transactions at the time of dispensing.

The special service code "6" is mandatory for all NMS dispense transactions, NMS inquiry transactions and NMS reversal transactions.

Prescription (Rx) number is a mandatory field for NMS dispense transactions. The same Rx number submitted to the HNS for claim adjudication or to any other third-party claim adjudicator must also be sent to the NMS for recording dispense transactions.

15.2 Monitored Drugs List

The monitored drugs list (MDL) provides a list of products that the ministry has selected for monitoring. This list will be used as a reference to determine if a submission to the NMS is required for the product being dispensed. Pharmacy software vendors and pharmacies are required to update their software with the latest information when new versions are published.



The MDL will be reviewed on a regular basis and notification will be provided to pharmacies and pharmacy software vendors whenever an updated list is made available.

The MDL can be downloaded in Excel or XML format from the Ministry website.

Monitored drugs that are not on the MDL

If a pharmacist submits an NMS dispense or inquiry transaction for a monitored drug, which is not on the ministry's MDL, the NMS will reject the transaction with a response code "56" = DIN/GP#/PIN error. This may occur when a new monitored drug becomes available on the Canadian market and an update to the MDL has not yet been published.

If this situation is encountered, pharmacists are directed to notify the ministry by calling the ODB business helpdesk at 1-800-668-6641. Once notified, the ministry will verify the information and publish an updated MDL. Each DIN in the MDL will include an effective date indicating when it was added to the list and when the requirement for submission to the NMS became effective.

Although the NMS will allow electronic submission of dispensing information (and reversals) up to 365 days from the date of service, dispensers are required to make submissions to the NMS at the time of dispensing.

15.3 Identifying Numbers

Prescribers are required to legibly record an identifying number on all prescriptions for monitored drugs. Ministry-approved forms of identification are listed below.

- Ontario Health Card or other health card issued by a Province or Territory in Canada
- Valid Driver's License or Temporary Driver's License (issued by Ontario or other jurisdiction)
- Ontario Photo Card
- Birth Certificate from a Canadian province or territory
- Government-issued Employee Identification Card



- Ontario Outdoors Card
- BYID (age of majority card)
- Certificate of Indian Status
- Valid Passport Canadian or other country
- Certificate of Canadian Citizenship
- Canadian Immigration Identification Card
- Permanent Resident Card
- Old Age Security (OAS) Identification Card
- Canadian Armed Forces Identification Card
- Royal Canadian Mounted Police/Provincial/Municipal Police Identification
- Firearms Possession and Acquisition License (PAL)

Please note that the above list of approved forms of identification is subject to change based on direction received from the Minister. Pharmacists will be advised of changes to the approved list through the O365 email and an up-to-date list will be posted on the ministry's website.

Identifying Numbers Reference Chart

Province/Other	Client ID Number/Code Format/Value	Cardholder Identity Code	Comments
Alberta	9 digits	AB	Format will be validated
British Columbia	10 digits	ВС	Format will be validated
Manitoba	9 digits	МВ	Format will be validated
New Brunswick	9 digits	NB	Format will be validated
Newfoundland and Labrador	12 digits	NL	Format will be validated



Nova Scotia	10 digits	NS	Format will be validated
Nunavut	9 digits	NU	Format will be validated
Northwest Territories	1 letter+ 7 digits	NT	Format will be validated
Ontario	10 digits	ON	Must be valid Ontario Health number
PEI	8 digits or 9 digits	PE	Format will be validated
Québec	4 letters + 8 digits	QC	Format will be validated
Saskatchewan	9 digits	SK	Format will be validated
Yukon	9 digits	YT	Format will be validated
Canadian Forces	1 letter + 8 digits	CF	Format will be validated
Royal Canadian Mounted Police	5 or 6 digits	RCMP	Format will be validated
First Nations, Inuit, and Aboriginal Health	Between 8 and 10 digits in length	FNIAH	DIAND or other FNIA identification
Out of Country Residents with Approved Identification	0011984275	ONG	For out of country residents. DUR checks are not performed on these transactions
Residents of Canada with Other Approved Identification	0011984276	ONO	For residents of Canada for whom the prescriber has recorded another approved ID as the identifying number. DUR checks are not performed on these transactions



Residents of Canada with No Approved Identification	0011984277	ONX	For a person who meets the regulatory exemption requirements whereby the person is unable to produce any of the approved identification and for whom the prescriber has recorded on the prescription the reason why the person needs to receive the monitored drug before he or she can obtain the appropriate identification DUR checks are not performed on these transactions
Office Use Prescriptions	0011984283	ONOU	Used for dispensing prescriptions for monitored drugs to prescribers for office use. DUR checks are not performed on these transactions

Note: The cardholder identity code "ONO" and "ONG" must be used only when a patient provides one of the following ministry-approved forms of identification to the prescriber:

- Valid Driver's License or Temporary Driver's License (issued by Ontario or other jurisdiction)
- Ontario Photo Card
- Birth Certificate from a Canadian province or territory
- Government-issued Employee Identification Card



- Ontario Outdoors Card
- BYID (age of majority card)
- Valid Passport Canadian or other country
- Certificate of Canadian Citizenship
- Canadian Immigration Identification Card
- Permanent Resident Card
- Old Age Security (OAS) Identification Card
- Provincial/Municipal Police Identification
- Firearms Possession and Acquisition License (PAL)

Provincial Health Card

Dispensing information submitted to the NMS for which the identifying number is a provincial health card is to be entered as follows:

- Cardholder Identity: Provincial Identifier (please see table below)
- Client ID Number or Code: Patient health card number
- Quantity: Total drug quantity
- Days Supply: Total number of days supply
- DOB: Patient birth date
- Gender: M or F or U
- Last name: Patient last name
- First Name: Patient first name



Canadian Forces (CF)

Dispensing information submitted to the NMS for which the identifying number is a Canadian Forces ID is to be entered as follows:

• Cardholder Identity: CF

• Client ID Number or Code: ID number as issued by CF

Quantity: Total drug quantity

• Days Supply: Total number of days supply

• DOB: Patient birth date

• Gender: M or F or U

Last name: Patient last name

• First Name: Patient first name

Royal Canadian Mounted Police (RCMP)

Dispensing information submitted to the NMS for which the identifying number is a Royal Canadian Mounted Police ID is to be entered as follows:

• Cardholder Identity: RCMP

Client ID Number or Code: ID number as issued by RCMP

Quantity: Total drug quantity

• Days Supply: Total number of days supply

• DOB: Patient birth date

Gender: M or F or U

• Last name: Patient last name

First Name: Patient first name



First Nations, Inuit, and Aboriginal Health (FNIAH)

Dispensing information submitted to the NMS for which the identifying number is a First Nations, Inuit and Aboriginal Health ID is to be entered as follows:

• Cardholder Identity: FNIAH

• Client ID Number or Code: ID number as issued by FNIAH

Quantity: Total drug quantity

• Days Supply: Total number of days supply

• DOB: Patient birth date

• Gender: M or F or U

Last name: Patient last name

• First Name: Patient first name

Out-of-country Residents with Approved Identification (ONG)

Dispensing information submitted to the NMS for out-of-country residents are to be entered as follows:

Cardholder Identity: ONG

Client ID Number or Code: 0011984275

Quantity: Total drug quantity

• Days Supply: Total number of days supply

• DOB: Patient birth date

Gender: M or F or U

Last name: Patient last name

First Name: Patient first name



Residents of Canada with Other Approved Identification (ONO)

Dispensing information submitted to the NMS for residents of Canada for whom the prescriber has recorded another approved ID as the identifying number are to be entered as follows:

Cardholder Identity: ONO

• Client ID Number or Code: 0011984276

Quantity: Total drug quantity

Days Supply: Total number of days supply

• DOB: Patient birth date

• Gender: M or F or U

• Last name: Patient last name

• First Name: Patient first name

Residents of Canada with No Approved Identification (ONX)

Section 6 of the Regulation sets out the conditions under which a dispenser will be exempt from the NSAA requirement to maintain a record of a patient's identifying number:

- **1.** The patient is unable to present an identifying number to the prescriber of the prescription.
- 2. The prescriber records on the prescription the reason why the patient needs to receive the monitored drug before he or she can present an identifying number.
- **3.** The dispenser keeps a record of the reason why the patient needs to receive the monitored drug before he or she can present an identifying number.
- **4.** The dispenser provides the monitored drug directly to the patient, either at the dispenser's place of business or through the dispenser's delivery service, without any agent being used to receive the drug on the patient's behalf and



without a third-party mail or courier service being used to deliver the monitored drug.

In cases where all of the foregoing conditions have been met, the submission to the NMS must be entered as follows:

• Cardholder Identity: ONX

Client ID Number or Code: 0011984277

Quantity: Total drug quantity

Days Supply: Total number of days supply

DOB: Patient birth date

• Gender: M or F or U

• Last name: Patient last name

• First Name: Patient first name

Prescriber's Office Use Prescriptions (ONOU)

Dispensing information submitted to the NMS for prescriptions that are being filled for use in a prescriber's office are to be entered as follows:

Cardholder Identity: ONOU

Client ID Number or Code: 0011984283

• Quantity: Total drug quantity

Days Supply: 999

• DOB: 20010101

• Gender: M or F or U

Last name: Prescriber's last name

First Name: Prescriber's first name



Prescriber ID Reference Chart

Prescriber ID Reference	Prescriber ID Reference #
The College of Physicians & Surgeons of Ontario	01
Royal College of Dental Surgeons of Ontario	02
College of Chiropodists of Ontario	03
Out of Province	05
College of Midwives of Ontario	08
Ontario College of Pharmacists	09
College of Optometrists of Ontario	43
College of Nurses of Ontario	44

Prescriber ID for Out-of-province Prescribers

When the prescriber is known to be registered in a Canadian province or territory outside of Ontario, the Prescriber ID Reference 05 should be used, along with a Prescriber ID from the following table:

Prescriber ID	Province of Registration
10001	British Columbia
10002	Alberta
10003	Saskatchewan
10004	Manitoba
10005	Quebec
10006	Newfoundland and Labrador
10007	New Brunswick



10008	Nova Scotia
10009	Prince Edward Island
10010	Yukon Territory
10011	Northwest Territory
10012	Nunavut

Note: The above values must be used for the Prescriber ID or the submission will be rejected with Response Code "61".

15.4 NMS On-line Dispense Transaction

A standard NMS on-line dispense transaction must conform to the Canadian Pharmacists' Association (CPhA) Pharmacy Claim Standard Version 03.

- While the NMS will accept electronic submission up to 365 days from date of service, on-line dispense transactions must be submitted to the NMS at the time of dispensing
- The NMS will validate the information submitted
- For online dispense transactions, the NMS will verify if there is an existing 'forgery notification alert' set-up under the prescriber
- If a pharmacy's computer system is unable to make a submission to the NMS at the time that a monitored drug is dispensed, pharmacists are required to submit the required dispensing information to the NMS as soon as possible after their system becomes available
- The NMS will not perform DUR checks for dispense transactions submitted for Cardholder Identity codes ONG, ONO, ONX, and ONOU

The table below shows the required fields for submitting a standard NMS on-line dispense transaction:

(Please refer to your Pharmacy Software Vendor's (PSV) manual for specific instructions on how to use your pharmacy software for this type of transaction.)



Required Fields	Explanation
Bank ID Number (BIN)	610054
Version Number	CPhA Pharmacy Claim Standard Version currently used (i.e., Version 03)
Transaction Code	01
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 dispensary
Provider Transaction Date	Date (YYMMDD) of service
Trace Number	Pharmacy system-generated number, assigned to the transaction
Client ID Number or Code	Recipient identification number (See Section xx.3 "Identifying Numbers" for more details)
Patient Date of Birth	Must be in the format YYYYMMDD
Cardholder Identity	(See Section xx.3 "Identifying Numbers" for more details)
Patient First Name	First name of patient
Patient Last Name	Last name of patient
Patient Gender	Must be M-Male or F-Female or U-Unknown
Current Prescription Number	Unique prescription number (from the prescription label or record of service). Not mandatory for "NMS Inquiry Transaction"



DIN/GP#/PIN	DIN/PIN of product (See Monitored Drugs list for DIN/PINs)
Special Service Code (SSC)	Must be value of '6' for NMS
Quantity	Quantity dispensed (one assumed decimal place)
Days Supply	Estimated number of days of treatment (as accurate as possible) supplied by the prescription
Prescriber ID Reference	Reference number for prescriber (See Prescriber ID Reference Chart)
Prescriber ID	Prescriber license number must be entered
Unlisted Compound	Indicates the transaction is for an extemporaneous compound that has not been assigned a PIN that is included in the MDL. Code identifies the type of compound and is mandatory for all compounds not identified by a PIN
Pharmacist ID	Pharmacist Registration Number

System Response for NMS Dispense Transaction

The Narcotics Monitoring System will provide the following details:

Response Fields	Explanation
Adjudication Date*	Date (YYMMDD) assigned to the transaction by the Narcotics Monitoring System
Trace Number	Pharmacy system-generated number assigned to the transaction
Transaction Code	51



Reference Number	Internal reference number assigned by the Narcotics Monitoring System
Response Status	A=accepted as transmitted, no warnings B=accepted with warnings R= rejected, data integrity issues
Response Code	(See Section xx.7 for NMS data validation response codes and messages.)
Message Data Line Number 1	Detailed Forgery Notification Alert or DUR response information, Message will contain "NMS" even if no warnings.
Message Data Line Number 2	Detailed DUR response information
Message Data Line Number 3	Detailed DUR response information

Note: During early morning hours, the adjudication date will not be the same as the provider transaction date. Adjudication date begins at 3:30 a.m. (Eastern Time) and concludes 24 hours later.

15.5 NMS On-line Inquiry Transaction

Prior to dispensing, pharmacists have the option to send an NMS on-line inquiry transaction for DUR purposes. The NMS inquiry transaction will perform all data integrity checks and DUR checks but will not store the drug information as a dispense transaction. If the pharmacist subsequently dispenses the drug, the ministry will require the separate submission of a dispense transaction to record the required dispensing information in the NMS.

Dispense transactions and inquiry transactions that generate DUR responses do not refer to historical inquiry records when generating a response.

NMS inquiry transactions do not have to be reversed.



A standard NMS on-line inquiry transaction must conform to the Canadian Pharmacists' Association (CPhA) Pharmacy Claim Standard Version 03.

- The data fields required for submitting a standard NMS inquiry transaction are the same as an NMS dispense transaction, except an intervention code "DU" is required for each inquiry transaction.
- Prescription (Rx) number is optional for inquiry transactions.
- The NMS will not perform DUR checks for inquiry transactions submitted for Cardholder Identity codes ONG, ONO, ONX, and ONOU.
- The system response for NMS inquiry transactions is identical to NMS dispense transaction system response (See Section xx.4 above).

15.6 NMS On-line Reversal Transaction

In certain circumstances, pharmacists may be required to reverse a dispense transaction that has been submitted to the NMS.

- On-line reversal transactions are delivered in real-time to the NMS which will validate the information submitted
- NMS on-line reversal transactions must be processed as soon as the need for a reversal is identified. If it is not possible in the circumstances for a pharmacy to submit a reversal transaction immediately, then the transaction must be reversed as soon as possible to keep the NMS database accurate and up-todate.

The table below shows the required fields for submitting a standard NMS on-line reversal transaction.

Required Fields	Explanation
Bank ID Number (BIN)	Must be 610054
Version Number	CPhA Pharmacy Claim Standard Version currently used (i.e., Version 03)
Transaction Code	11



Provider Software ID	CPhA-assigned code, identifying pharmacy software currently used
Pharmacy ID Code	CPhA number or ministry-assigned number of the dispensary
Provider Transaction Date	Date (YYMMDD) of service of claim to be reversed
Trace Number	Pharmacy system-generated number, assigned to the transaction
Client ID Number or Code	Must match the original dispense transaction
Cardholder Identity	Must match the original dispense transaction
Current Prescription Number	Must match the original dispense transaction
DIN/GP#/PIN	Must match the original dispense transaction
Special Service Code (SSC)	Must be '6'
Adjudication Date	Date (YYMMDD) on which dispense transaction to be reversed was originally adjudicated

System Response for NMS Reversal Transaction

The system response will provide the following details:

Response Fields	Explanation
Adjudication Date	Date (YYMMDD) assigned to the transaction by the Narcotics Monitoring System
Trace Number	Pharmacy system-generated number assigned to the transaction
Transaction Code	61



Reference Number	Internal reference number assigned by the Narcotics Monitoring System
Response Status	R= rejected reversal V= reversal accepted
Response Code	(See Section xx.7 for NMS data validation response codes and messages.)

Note: The system response for NMS reversal transactions is identical to the system response for HNS claim reversals.

15.7 NMS Data Validation Response Codes and Messages

The table below shows the various response codes associated with the validation of data submitted on NMS transactions. The table shows 'Reject Response Codes' and 'Warning Response codes' separately.

Please note that all definitions indicated are based on the CPhA response code descriptions. In some cases, individual software vendor response code descriptions may be different from the CPhA definitions.

Reject Response Codes and Messages:

Response Code	Message Description	Field Requirement or Explanation of Condition Generating Response Code
01	BIN error	Bank ID Number # 610054 required
02	Version number error	Current CPhA Version required
03	Transaction code error	Transaction code (01, 11) required



04	Provider software ID error	Dispensary's Provider Software ID required
05	Provider software version error	Dispensary's Provider Software Version required
21	Pharmacy ID code error	Dispensary's Pharmacy ID Code required
22	Provider transaction date error	Date (YYMMDD) of service required
23	Trace number error	A numeric value greater than 0
	Client ID # error	Client ID error may occur due to any one of following:
32		Client ID number missingInvalid health card number for Ontario
		Invalid format for other provinces
34	Patient date of birth error	Birth date of patient must be entered. Must be valid date value and must be in format of YYYYMMDD and not future dated
35	Cardholder Identity error	Cardholder identity must be one of following values: • Province of health coverage: ON, AB, BC, MB, NB, NL, NS, NU, NT, PE, QC, SK, YT • Canadian Forces: CF • Royal Canadian Mounted Police: RCMP



		 First Nations, Inuit, and Aboriginal Health: FNIAH Out-of-Country resident: ONG Other acceptable ID: ONO No identification: ONX Office Use: ONOU
37	Patient first name error	Patient first name is mandatory
38	Patient last name error	Patient last name is mandatory
40	Patient gender error	Patient gender must be one of following values: "M", "F", or "U" if unknown
55	Current Rx # error	Must be numeric value greater than 0
56	DIN/GP#/PIN error	Must be a valid DIN/PIN as of Date of Service. Must be found in Monitored Drugs list as of Date of Service
57	SSC error	Must be "6"
58	Quantity error	Quantity of medication dispensed must be entered on transaction as numeric value. Cannot be value of zero
59	Days supply error	Days supply must be entered on transaction as numeric value. Cannot be value of zero
60	Prescriber licensing authority code error	The Prescriber ID Reference field must be "01", "02", "03", "05", "08", "44"

This field cannot be blank and a valid prescriber registration number is required. For transactions in which the Prescriber ID relates to a prescriber who has not been registered on the HNS, no Message Line is returned and only response code 61 will appear. MH" = override -prescriber ID The use of the MH Intervention Code is based on the professional judgement of the pharmacist. Proper documentation to support the use of the MH Intervention Code must be maintained (e.g., documentation explaining why the prescription is still valid and being dispensed), and is 61 Prescriber ID error subject to inspection and postsubmission verification. Resources are available on the OCP website here. For prescribers (other than physicians licensed with the College of Physicians and Surgeons of Ontario [CPSO]) who are not registered on the HNS, no Message Line is returned. The claim can be resubmitted with an "MH" intervention code and the proper Prescriber ID and Prescriber ID Reference. For physicians licensed with the College of Physicians and Surgeons of Ontario (CPSO) who are not registered on the HNS, no intervention code can be used. Please contact the ODB Pharmacy Help Desk at 1-800-



		668-6641, and the physician will be added to the HNS, as soon as possible.
65	Intervention code error	Must be a valid intervention code. Intervention code "DU" is accepted for NMS inquiry transactions. Intervention code "MH" is accepted for overriding prescriber ID error
76	Pharmacist ID code error/missing	This field cannot be blank. A valid Pharmacist ID is required for all ODB and NMS submissions. Response Code 76 will also be received for transactions that include a Pharmacist ID of a pharmacist, whose licence is suspended.
90	Adjudication date error	Must be a numeric value (YYMMDD format). This field must be completed for reversal submissions
A1	Claim too old	Transaction date must be less than 365 days from current date
A2	Claim is post-dated	Date must not greater than the current date
A8	Original transaction missing or not found	No transaction on file that matches reversal transaction information submitted
A9	Reversal processed previously	Transaction previously reversed
B1	Pharmacy not authorized to submit claims	Pharmacy ID is required. Dispensary must be registered with MOHLTC for NMS transaction submission on date of service



	Duplicate prescription number error	Prior transaction exists for:
		-same dispensary
)(-		-same date of service
		-same prescription number.
		Prescription number must be unique for each dispense transaction
E1	Host processing error	System error. Contact the ODB business helpdesk

Warning Response Codes and Messages:

Response Code	Message Description	Field Requirement or Explanation of Condition Generating Response Code
34	Patient date of birth error	Birth date of patient must match date on file
37	Patient first name error	Must match the first initial of the patient on file
38	Patient last name error	Must match the last name of the patient on file
40	Patient gender error	Patient gender must match gender value on file
A3	Identical claim processed	 Prior dispense transaction exists for: same patient same DIN/PIN or interchangeable product same date of service



		same dispensary
DF	Insufficient space for all warnings	There is insufficient space for all response codes. Additional response codes are available by calling the ODB business helpdesk.
FX	Possible Forgery-Check authenticity	Indicates that the ODB program has been made aware of alleged forgeries for specific drugs (mostly monitored drugs) and/or stolen prescription pads Refer to Section 13 for information on Prescription Forgery reporting process.

Note: For patient identification warning response code, pharmacists must submit a reversal transaction, correct the data error, and resubmit the NMS dispense transaction. If patient identification information has been confirmed and a warning response is received, please contact the ODB business helpdesk at 1-800-668-6641.

15.8 Drug Utilization Review (DUR) Warning Response Codes

When a pharmacist receives a DUR warning message, the message may indicate a potential overuse/misuse situation. The DUR message is based on a review of the current dispense or inquiry transaction and previously submitted dispense transactions that are recorded in the NMS database. Pharmacists must evaluate the response codes received and, in conjunction with other appropriate resources including the prescriber and the patient, determine the appropriate course of action.

The following DUR response codes may be received from the NMS:

- MH May be Double Doctoring
- MI Poly Pharmacy Use Indicated
- DE Refill Too Late
- D7 Refill Too Soon



• MY - Duplicate Drug Other Pharmacy

DUR Response Codes and Messages

Response Code	Message Description	Field Requirement or Explanation of Condition Generating Response Code
D7	Refill too soon	Based on days supply of previous dispense transaction, indicates that a refill should not be required at this time . The pharmacist may want to ensure that the medication is taken appropriately and verify if there have been any changes to the therapy (e.g., changed dose or directions).
DE	Fill/refill too late	Based on days supply of previous dispense transaction, indicates that a refill is overdue at this time. The pharmacist may want to ensure that the recipient is compliant and taking adequate doses.
МН	May be double doctoring	Indicates that, including the current submission, the recipient has obtained monitored drugs prescribed by 3 or more different prescribers in the previous 28 days.
MI	Poly-pharmacy use indicated	Indicates that, including the current submission, the recipient has obtained monitored drugs from 3 or more different dispensaries in the previous 28 days.



		Prior dispense transaction exists for:
		same patient
MY	Duplicate drug other pharmacy	same DIN/PIN or interchangeable product
		same date of service
		different dispensary

Note: The Ministry does not warrant the reliability of information supplied by third parties including, but not limited to, prospective DUR information and prescriber data. Such information is advisory only and is not intended to replace sound clinical judgment in the delivery of health care services. Pharmacists are required to use their discretion and professional judgment when determining what appropriate action is required when warning response codes are received from the NMS.

- For Drug Utilization Review (DUR) warning responses, pharmacists may
 decide to not dispense the monitored drug. If an inquiry transaction has been
 submitted, no further action is required. If a dispense transaction has been
 submitted, a reversal transaction is required
- For DUR warning responses, pharmacists may decide to proceed with dispensing. If an inquiry transaction has been submitted, a dispense transaction is required. If a dispense transaction has been submitted, no further action is required
- Reversal transactions are not required for any NMS inquiry transactions

DUR Message Line

When the NMS returns any of the above DUR response codes, the System Response will also include a message line. Each System Response may include up to three DUR response codes and message lines.

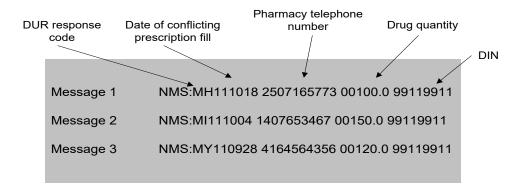
The DUR message line will include the following information:

- The transaction date of the conflicting transaction
- The pharmacy phone number that filled the conflicting transaction



- The quantity dispensed for the conflicting transaction
- The drug identification number (DIN) of the conflicting transaction

The following is an example of a DUR message line:



Please note that messaging may appear differently based on pharmacy software.

Note: In some instances, the pharmacy telephone number may not be available, and will appear as blanks. If this occurs, please contact the ODB business helpdesk at 1-800-668-6641 to obtain information about the previous dispensing pharmacy.

If you have questions regarding NMS transactions, NMS response messages or the Monitored Drugs List, please contact the ODB business helpdesk at 1-800-668-6641.



Section 16: 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 <u>Section 16.1</u>)
- The two types of issues/inquiries with which the ODB Help Desk is prepared to provide assistance (see <u>Section 16.2</u>)
- How the phone call will be handled by the ODB Help Desk (see <u>Section 16.3</u>)

16.1 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)
Cannot Complete Call or Time out Messages or	Consult your Pharmacy Software Vendor's manual; then
Network Error or	Contact your Pharmacy Software Vendor and/or your Corporate Internal Helpdesk
System Not Available or Process Error/	Then, if the issue cannot be resolved, contact your Acquirer Host.
Host Processing Error	

16.2 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.



16.3 How Your Call is Handled

Be prepared to provide your <u>Pharmacy ID Code</u> (see <u>Section 2.1</u>) 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 <u>Acquisition Cost Calculations in Section</u> 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 <u>O. Reg 201/96</u> 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
СТО	Cost to Operator
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 Policy which permits dispensing of prescripe not yet registered as eligible on the HNS	otions for recipients
EO Executive Officer Establish Policy which permits dispensing of prescripe eligibility not yet registered as eligible on the HNS	otions for recipients
Establish Policy which permits dispensing of prescrip eligibility not yet registered as eligible on the HNS	otions for recipients
eligibility not yet registered as eligible on the HNS	otions for recipients
Exception Code Code used with online transactions to ident	tify special
situations (same meaning as Intervention Co	ode)
FAQ Frequently Asked Question	
FIPPA Freedom of Information and Protection of F	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	
HSP Health service provider, which includes Loc	cal Health
Integration Networks (may also be known a	
and Community Care Support Services orga	anizations)
ID Identification	
Intervention Code used with online transactions to over	ride specific
Code situations (same meaning as Exception Cod	de)
IV Intravenous	
LHIN Local Health Integration Network	
LTC Long-Term Care	



	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
МОН	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 <u>Section 5.1</u>
ОСР	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
OHT	Ontario Health Team
OLTP	On-Line Transaction Processing
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
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
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
Retention Period	A period of at least 10 years from the last recorded pharmacy service provided to the ODB recipient, or 10 years after the day on which the ODB recipient reached or would have reached the age of 18 years, whichever is longer.
Reversal	Transaction that reverses a previous claim submission



DELL	Deacon for Lice
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	Seniors 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
Methadone preparation (using methadone powder).	N/A	09857499
Exceptional Access Program approval is required for methadone compounding from powder.		
2. Preparation is for oral consumption and	3 or 5	N/A
contains a solid oral dosage form of a listed drug product compounded into a liquid or capsule and no other medicinally active substance.	Note: Enter the DIN/PIN of the listed drug product with the highest cost in all cases	
3. Preparation is for administration via infusion 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.	6 (when using the DIN/PIN of a listed drug product)	09850627
Claim each prepared unit (i.e., bag) as a quantity		
of 1. For example:		
claimed quantity for three 50mL bags is 3 claimed quantity for one 250mL bag is 1		



Note: Use of this PIN is limited to infusions and should be used for the preparation of ALL IV bags for infusion		
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.	O, 1 or 2 Note: Enter the DIN/PIN of the listed drug product with the highest cost in all cases	N/A
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.	N/A	09850694
Claim each prepared unit as a quantity of 1.		
11. IV Cassette preparation 100mL size.	N/A	09850708
Claim each prepared unit as a quantity of 1.		
12. Other IV Infusion Device* up to 100mL.	N/A	09857134
Claim each prepared unit as a quantity of 1.		
13. Other IV Infusion Device* 101mL to 250mL.	N/A	09857135
Claim each prepared unit as a quantity of 1.		
14. Other IV Infusion Device* greater than 250mL.	N/A	09857136
Claim each prepared unit as a quantity of 1.		

*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

²Compounding 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 <u>Section 6.1</u>). 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 PINs

The LTC home pharmacy service providers (PSPs) may submit claims with the following PINs.

PIN	Product
9857143	Acetaminophen 325mg Tab
9857144	Acetaminophen 500mg 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
9850783	Chlorpheniramine Maleate 4mg Tab
9857151	Cyanocobalamin 1mg/mL Inj Sol
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
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
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
9850996 Dimethylpolysiloxane 20% Cr 9850791 Diphenhydramine 25mg Tab or Caplet 9850805 Diphenhydramine 50mg Tab or Caplet 9857153 Docusate Sodium 100mg Cap
9850791 Diphenhydramine 25mg Tab or Caplet 9850805 Diphenhydramine 50mg Tab or Caplet 9857153 Docusate Sodium 100mg Cap
9850805 Diphenhydramine 50mg Tab or Caplet 9857153 Docusate Sodium 100mg Cap
9857153 Docusate Sodium 100mg Cap
J 1
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



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 C: Allergen Products

DIN/PIN	Product
09850724	Allergen Extracts
00509558	Epipen 1/1000
00578657	Epipen Jr. 0.5mg/mL
00464988	Pollinex R
02382059	Allerject 0.15mg/0.15mL
02382067	Allerject 0.3mg/0.3mL
02458446	Emerade™ 0.3 mg/0.3 mL
02458454	Emerade™ 0.5 mg/0.5 mL



Appendix D: Attestation / Notice of Change in LTC Home Primary Pharmacy Service Provider Form

Ministry of Health	Ministère de la Santé	Ontario 👸
Health Programs and Delivery Division	Division des programmes de santé et de la prestation des services	
Office of the Executive Officer and Assistant Deputy Minister	Bureau de l'administratrice en chef et sous-ministre adjointe	
438 University Avenue, 10th floor	438 avenue University, 10e étage	

Attestation Notice of Change in LTC Home Primary Pharmacy Service Provider Form

This form is to be completed and sent to the Health Programs and Delivery Division if there are any changes to your Attestation to Receive Capitation Payments as a Primary Pharmacy Service Provider Form at any time during the calendar year ("Attestation") OR if you are a new primary pharmacy service provider for a long-term care (LTC) home and previously did not receive an Attestation.

For example, you must complete this form if:

- Your pharmacy is entering or has entered into a new contract with a longterm care (LTC) home that was *not* originally identified in the Attestation ("New LTC Home Client(s)"); or
- Your pharmacy is ending, or has ended, its contract with a LTC home that was originally identified in the Attestation ("Former LTC Home Client(s)").

This form must be submitted to the ministry by the 15th of the previous month before the effective date of the change, in accordance with the Ministry's Policy and



your Health Network System Subscription Agreement. Failure to notify the ministry may result in a delay of payment and/or an incorrect payment.

Without completing this form, capitation payments for providing professional and dispensing pharmacy services under the capitation model may be delayed.

Primary Pharmacy Service Provider Information:

Pharmacy ID #	
Pharmacy Name	
Pharmacy Address	
Pharmacy Fax	
Pharmacy 0365 email	
-	
Address	
To Add New LTC Home Client(s)):
Long-Term Care Home	
Agency ID#	
L L	
Long-Term Care Home Name	
Long-Term Care Home	
Address	
Address	
Effective Start Date of the	
Contract	
Contract	
To Remove Former LTC Home C	lient(s):
Long-Term Care Home	
Agency ID#	
, (go.10) 1011	
Long-Term Care Home Name	
5	



Long-Term Care Home Address		
Effective End Date of the Contract		
To attest that the information abo pharmacy manager, must comple	•	•
Pharmacy Designated Manager	or Owner (please print)
Signature		Date

Please send completed forms (all pages) to the Health Programs and Delivery Division by email at ODBLTCcap@ontario.ca.

Note: knowingly furnishing false or incomplete information to the Ministry in connection with the administration of the Ontario Drug Benefit Program is an offence under the *Ontario Drug Benefit Act*.



Appendix E: Templates for the Pharmacy Smoking Cessation Program

Readiness Assessment

Nam	e:							Da	ite:	
	e answer the question	ns belo	DW:							
	1. Are you a smoker who is interested in quitting in the next month?									
					Yes	or No)			
	2. Are you willing to set a QUIT date?									
ASK					Yes	or No)			
	3. If you answered YES to these questions would you like to enrol in the Ontario Government's FREE Quit Smoking Program?									
					Yes	or No)			
	Quitting smoking is the most important thing									
	you can do to protect your health now and in the future.									
Ä	Evidence suggests smoking cessation programs can reduce the risk of chronic disease,									
ADVISE	other health complications, and subsequent use of the health care system. If you are									
AD	willing to quit in the next 30 days your community pharmacist can help to establish the									
	best option for you including pharmacological therapy and other support mechanisms.									
	If you are interested in learning more about the FREE Quit Smoking Program, please ask									
	your pharmacist.			Цол	, Dooe	۸۷۸	Vau	<u> </u>		
	How Ready Are You? How important is it for you to QUIT SMOKING for good?									
	1 (not at all)	2	3	4	5	6	7	8	9	10 (completely)
SS	How practical is it fo	or you	to quit	NOW	?					μ
ASSESS	1 (not at all)	2	3	4	5	6	7	8	9	10 (completely)
•	How confident are	you to	do wh	at it ta	kes to	quit sr	noking	FOR (GOOD?	
	1 (not at all)	2	3	4	5	6	7	8	9	10 (completely)
	You may be ready to enrol!									

To be filed for documentation and auditing purposes

If the patient has decided to enrol and is willing to set a quit date, the pharmacist
may proceed with the consultation and agreement / consent forms

After reviewing this form, please return it to your pharmacist.

Date:

Pharmacist:



Pharmacy Smoking Cessation Program Patient Agreement to Enrol & Patient Consent Form

Patient Name:	
Address:	
Phone:	
Email:	
Patient's Signature:	

Patient Enrolment

By signing the enrolment form, the patient agrees to work together with the pharmacist to stop smoking on the date indicated.

Pharmacist's Name:	
Pharmacist's Signature:	
Date of Enrolment:	
Expected QUIT Date:	

Patient Consent

It may be necessary for the pharmacist to discuss and share your health information with other health care professionals (e.g., physicians, nurses, etc.) in the process of assisting you with this quit smoking program.

By signing below, you authorize the pharmacist to disclose and collect your personal health information to and from other health care professionals who are or have provided medical services to you for the purpose of assisting you during this quit smoking program.

Please sign below to indicate your consent to this exchange of information.

r touse sign beteff to maisu	to your consent to time exertaings of information.
Patient's Signature:	
Date:	
Comments (if any):	

To be completed prior to the first consultation meeting

Please note: It is important to set a QUIT date for program enrolment
To be filed for documentation and auditing purposes
Please provide a copy to the patient



FIRST QUIT CONSULTATION MEETING

Nam	ne: Date:						
Арр	Appointment location:						
Where possible, the First Quit Consultation should be an in person meeting at the pharmacy. If in-person meeting is not possible, please indicate method of appointment							
□ln	person Telephone Video-conferencing Email Other						
	Tobacco Use History: □ Daily smoker □ Occasional smoker						
	Current use: Number of cigarettes per day for years						
	# of Pack-years: Years smoked x Packs per day: = Pack-years						
	How soon after waking is first cigarette? minutes						
	Where do you smoke most often?						
	What time of day is smoking predominantly done?						
	Days of week predominantly smoking:						
	With whom do you smoke (alone or socially)?						
	Number of other household smokers: Workplace smoking: (Yes/No)						
ST	Are you a source of 2nd hand smoke for family & friends? (Yes/No)						
ASSIST	Number of previous attempts to quit (24 hrs or more of intentional stop):						
,	Duration of Past Quit Attempts:						
	Previous methods used and reason for relapse, if applicable:						
	a. Patch:						
	b. Gum:						
	c. Losenge:						
	d. Inhaler:						
	e. Medication:						
	f. "Cold Turkey":						
	g. Hypnosis:						
	h. Other:						



	From the methods indicated above, which was associated with the best results to date (fron								
	your perspective, e.g. not based on what you've heard)?								
	What led you to relapse?								
	Withdrawal symptoms: (Yes/No) Negative mood: (Yes/No)								
	Habit: (Yes/No) Being with other smokers: (Yes/No) Stress: (Yes/No)								
	Other:								
	Do you drink (alcohol) when you smoke? (Yes/No) Number of drinks per day:								
	Do you drink coffee when you smoke? (Yes/No) Number of cups per day:								
	Are you under the care of your primary care provider for smoking cessation? (Yes/No)								
	Modication Polated History May attach print out or ModsChook if available								
	Medication Related History: May attach print out or MedsCheck if available								
	Allergies/Intolerance to medications:								
	Concurrent medications: Benzodiazepines: (Yes/No) Antipsychotic: (Yes/No)								
	Antidepressants: (Yes/No) Other:								
	Chronic conditions and consequences of smoking:								
	Cardiac History: High Blood Pressure (Yes/No) Blood Pressure:								
	Arrhythmia: (Yes/No) Heart Rate: Heart Failure: (Yes/No)								
	Hypercholesterolemia: (Yes/No) Other heart related:								
F	Diabetes: (Yes/No) Type 1 Type 2								
ASSIST	Respiratory History: Asthma (Yes/No) COPD: (Yes/No)								
A	Lung related problems: (Yes/No)								
	Past Seizure history: (Yes/No)								
	Cancer: (Yes/No)								
	Hormone Replacement Therapy: (Yes/No) Oral contraceptives: (Yes/No)								
	Alcohol Use:								
	Depression: (Yes/No) Anxiety: (Yes/No) Eating disorder: (Yes/No)								
	Bipolar disease: (Yes/No) Schizophrenia: (Yes/No)								
	Smoking-related health symptoms:								
	□ Cough □ Wheeze □ Shortness of breath □ Distorted Smell/Taste □ Other								



Triggers:	Strategies to consider:		
1.	☐ Set a quit date		
	☐ Start an exercise program		
2.	☐ Change diet/start healthy snacking		
3.	☐ Take up a new hobby/activity		
-	☐ Get plenty of rest;		
4.	□ Learn to relax/meditate		
_	☐ Join a smoking cessation group forum		
5.	☐ Use quit smoking help-lines		
	☐ Get counselling		
	☐ Seek help/support from family/friend		
	$\hfill\Box$ Spend more time with non-smokers		
	$\hfill\Box$ Drink lots of water/cut down on alcoh		
	☐ Other (specify)		
QUIT DATE:			
CONSIDERING PHARMACOTHERAPY?			
□ Nicotine Patch □ Nicotine Gum □ Nicotir	ne Lozenge 🗆 Nicotine Inhaler		
☐ Bupropion ☐ Varenicline ☐ None ☐	Other		
Start date: Dose:			
Advice regarding drug therapy for this patient:			
If experiencing adverse events, patient to contact			
ii experiencing adverse events, patient to contact			
OTHER NOTES:			

Refer to <u>Section 7.3</u> for claims submissions (limit to one claim per year)

To be filed for documentation and auditing purposes
A copy may be provided to the patient



My Quit Plan

Plan for Preparation to Quit Smoking						
Name		Phone Number			Email	
Quit Date:						
Medication: (check all the	nat apply	/)				
□ Nicotine Patch	□Nicot	ine Gum	□ Nicotine Inhaler	•	□ Nicotine Lozenge	
Start Date:	Start D	ate:	Start Date:		Start Date:	
□ Bupropion	□Vare	nicline	□Other		□ No medication	
Start Date:	Start D	ate:	Start Date:			
Preparing environment	:					
Remove tobacco and sr	noking fr	om:				
□ Home	□Work	area	□ Automobile		□ Other	
Possible challenges to	anticipa	te:				
□Stress		☐ Other smokers		□ Drinking alcohol		
□ Nicotine urges		☐ Smoking cues		☐ Availability of cigarettes		
□ Weight gain		□ Other		□ Other		
Strategies to overcome	these c	hallenges:				
□ Delay tactic		□ Distraction strategies (e.g., walking)				
□ Places to avoid		□ Places to go (where smoking prohibited)				
☐ Use quit smoking help-lines		☐ Join a smoking cessation group forum				
□ Exercise program		☐ Change diet/start healthy snacking				
☐ Take up a new hobby/activity ☐ ☐		□ Other				
Next appointment date:						
Pharmacist's Name: Pharmacist's contact information:						

Pharmacists to provide a copy for patient use; and a copy to attach to the patient's pharmacy file.



Primary Follow-up Counselling Sessions #1-3

Nam	e: Date:						
Appointment location:							
Method of appointment: ☐ In person ☐ Telephone ☐ Email ☐ Video-conferencing ☐ Other							
1400	ica of appointment. Emperson E retopnione E Emait E video conferencing E other						
	Primary Follow-up Counselling Sessions 1 - 3:						
	Primary Follow-up counselling sessions 1-3 that are billable occur within the first 21 days of						
	the program. Circle which appointment you are billing for. You may bill for 3 visits only. Recommended meeting time-lines from date of first meeting:						
	#1: Day 3 – 5 (approximately 10 minutes)						
	#2: Day 7 – 10 (approximately 10 minutes)						
	#3: Day 14 – 21 (approximately 10 minutes)						
	Quit Status:						
	 Have you had any cigarettes since your quit date? (Yes/No) 						
	 If No, congratulate the patient 						
	 If Yes, encourage the patient to keep trying 						
	Medication status (if applicable):						
	Are you finding that the medication () you are taking is helping? You (No.) You (No.)						
GE	Yes/NoAny side effects that are bothersome?						
AN	Triggers:						
ARRANGE	Have you been able to overcome your triggers? (Yes/No)						
•	What has worked?						
	What has <u>not</u> worked?						
	 Are you having problems dealing with cravings or withdrawal symptoms? 						
	(Yes/No)						
	What helps? What doesn't help?						
	Program Withdrawal : At any time after the first consultation, a patient may decide to						
	withdraw from the program whether successful or not. The pharmacist may inform patients						
	who withdraw and are not successful in quitting of their eligibility to re-enrol at a later date						
	(one year from the date of the first consultation).						
	Should this occur, pharmacists are asked to evaluate the patient's quit status. Refer to						
	Program Evaluation form.						
	Additional Information:						
	Name of Dharmanists						
Nam	e of Pharmacist:						

Refer to <u>Section 7.3</u> for claims submissions (limit to 3 claims per year)

If patient withdraws from the program please refer to Program Evaluation Form

To be filed for documentation and auditing purposes; A copy may be provided to the patient



Secondary Follow-up Counselling Sessions #4-7

Nam	e:	Date:				
Appointment location:						
	Method of appointment: □ In person □ Telephone □ Email □ Video-conferencing □ Other					
ARRANGE	Secondary Follow-up Counselling Sessions 4 - 7: The four Secondary Follow-up sessions occur after day 30 as descria appointment you are billing for. You may bill for 4 visits only. #4: Day 30 - 60 (approximately 3 - 5 minutes) #5: Day 90 - 120 (approximately 3 - 5 minutes) #6: Day 180 - 210 (approximately 3 - 5 minutes) #7: Day 240 - 365 (approximately 3 - 5 minutes) Ouit Status: • Have you had any cigarettes since your quit date? (Yes/Nontermole) o If No. congratulate the patient o If Yes, encourage the patient to keep trying Medication status (if applicable): • Are you finding that the medication (ibed. Circle which o) you are taking is tient may decide to nacist may inform patients to re-enrol at a later date				
INGIII	c of Final macist.					

If continuing with the program and on completion of documentation, Refer to <u>Section 7.3</u> for claims submissions (limit to 4 claims per year)

If patient withdraws from the program, please refer to Program Evaluation Form To be filed for documentation and auditing purposes; A copy may be provided to the patient



Program Evaluation

Name:	Date:

This form is used for the purpose of program evaluation of the patients quit smoking status.

Successful Quit: PIN 93899944

• The successful quit PIN is claimed when a patient indicates at any time during the program that he or she has successfully quit smoking. Once the PIN is claimed, no further meetings are scheduled or billable.

Unsuccessful Quit: PIN 93899945

- The unsuccessful quit PIN is claimed when a patient indicates at any time during the program that he or she has not succeeded in quitting smoking. Once the PIN is claimed, no further meetings are scheduled.
- The pharmacist should inform patients who withdraw from the program of their eligibility to re-enroll at a later date (one year from the date of their first consultation with the pharmacist).

Unknown Status / Program Withdrawal: PIN 93899946

 The unknown status PIN is claimed when a patient cannot be reached to continue with his/her program or when a patient withdraws from the program without indicating their success in quitting smoking.

Additional Information:

Name of Pharmacist:

EVALUATION

On completion of documentation, Refer to <u>Section 7.3</u> for claims submissions

> successful quit un-successful quit unknown quit status

(limit to ONE of the above claims per year as applicable to quit smoking status)

To be filed for documentation and evaluation purposes

A copy may be provided to the patient