

Executive Officer Notice: Prescribing & Dispensing Publicly Funded PaxlovidTM in Ontario Pharmacies

Effective December 12, 2022

Part A pharmacists are authorized to prescribe the oral antiviral treatment for COVID-19, Paxlovid™ (nirmatrelvir/ritonavir) in accordance with Ontario Regulation 107/96 under the Regulated Health Professions Act, 1991 (RHPA). Part A pharmacists who prescribe Paxlovid™ must follow the Initiating, Adapting and Renewing Prescriptions guidelines issued by the Ontario College of Pharmacists (OCP) and possess the required clinical knowledge, skills, competency, and understanding of legislative requirements and practice standards. No other member of the OCP (i.e., Part B pharmacist, registered pharmacy student, intern, pharmacy technician, pharmacist (emergency assignment), and pharmacy technician (emergency assignment)) is authorized to prescribe Paxlovid™.

All pharmacies with a Health Network System (HNS) account and valid HNS Subscription Agreement with the ministry (hereinafter referred to as "pharmacy" or "pharmacies") are eligible to submit claims for payment (claims) for providing prescribing and dispensing services related to publicly funded Paxlovid™ for eligible individuals.

This Executive Officer (EO) Notice and the accompanying Frequently Asked Questions (FAQs) document set out the terms and conditions for a pharmacy's submission of claims for prescribing and dispensing services related to publicly funded Paxlovid™ for eligible individuals. Each document is a Ministry Policy that pharmacy operators must comply with under section 3.2 of the HNS Subscription Agreement for Pharmacy Operators. Participating pharmacies must comply with all of the terms and conditions set out in the EO Notice and FAQs.

This EO Notice (Prescribing and Dispensing Publicly Funded Paxlovid™ in Ontario Pharmacies) replaces the Executive Officer Notice: Supplying of Publicly Funded Oral Antiviral COVID-19 Treatment in Ontario Pharmacies that was effective July 26th, 2022.





Individual Eligibility – Prescribing Services

A pharmacy may submit a claim for providing prescribing services related to publicly funded Paxlovid™ in accordance with this Notice for an individual who meets the following criteria ("eligible individual"):

- The individual lives, works, or studies in Ontario or is visiting Ontario from another province/territory or country; AND
- The individual has received a positive COVID-19 test result; AND
- The individual will be starting Paxlovid™ treatment within five days of symptom onset (symptom onset day is considered day zero); AND
- The individual is not on supplemental oxygen and is,
 - 60 years of age and older,
 - o 18 years of age or older but less than 60 years of age, and is:
 - immunocompromised¹;
 - at high risk of severe COVID-19 because the individual has one or more comorbidities²; or
 - at high risk of severe COVID-19 because they have inadequate immunity due to being unvaccinated, having an incomplete series of primary COVID-19 vaccination or not having had a COVID-19 vaccine dose or COVID-19 infection within the past six months.

Individual Eligibility – Dispensing

A pharmacy may submit a claim for dispensing publicly funded Paxlovid™ in accordance with this Notice for an individual who meets the following criteria ("eligible individual"):

- The individual lives, works, or studies in Ontario or is visiting Ontario from another province/territory or country; AND
- The individual has received a positive COVID-19 test result; AND
- The individual will be starting Paxlovid[™] treatment within five days of symptom onset (symptom onset day is considered day zero); AND
- The individual has a valid prescription for Paxlovid™.

¹ Please refer to O. Reg. 107/96 under the RHPA for examples of individuals who are immunocompromised.

² Please refer to O. Reg. 107/96 under the RHPA for a definition of "comorbidities".



General Billing Information

Note that an eligible individual may not have a valid Ontario health number and may not be an Ontario Drug Benefit Program recipient (e.g., if they are visiting Ontario from another province/territory or country). If a pharmacist provides prescribing or dispensing services related to publicly funded Paxlovid[™] for an eligible individual who does not have a valid Ontario health number, then the pharmacy must submit the claim using the Proxy ID (see billing procedures section below).

General Billing Information – Prescribing Services

- Table 1 lists the Product Identification Numbers (PINs) that may be claimed for different Prescribing Services related to Paxlovid™.
- There is no cost to eligible individuals who receive Prescribing Services related to publicly funded Paxlovid™ from an eligible pharmacy.
- For each valid claim submitted for prescribing services using one of the PINs in Table 1, a pharmacy will receive \$19 as payment for providing the following prescribing services ("Prescribing Services") to eligible individuals, regardless of whether a prescription is given.
 - Obtain informed consent from the individual or the individual's substitute decision maker to provide Prescribing Services (may be given verbally or in writing);
 - Collect and review all relevant information about the individual to determine whether or not to issue a prescription for publicly funded PaxlovidTM, considering the individual's medical history and current medications, and to manage any potential drug interactions. This may include access to medication history and lab results. Pharmacists can use systems such as ConnectingOntario Clinical Viewer or ClinicalConnect.
 - Determine through a shared decision-making process with the individual the appropriate care plan (e.g., referral, monitor, prescribe Paxlovid™ with or without modifications to other prescribed drug therapies, recommend over-the counter and/or non-pharmacological therapy);
 - Implement the care plan, which may involve issuing a prescription or referring the individual to a physician/nurse practitioner/clinical assessment centre, providing the individual with related education, and maintaining a record as noted in the Pharmacy Documentation Requirements section below;
 - Notify the individual's primary care provider if Paxlovid™ is prescribed;



- o Follow-up with the individual to establish monitoring parameters, evaluate safety and efficacy of the care plan and additional next steps as required;
- o Ensure care is provided within the treatment window (i.e., individual is able start Paxlovid[™] treatment within five days since the start of symptoms).
- A claim may be submitted for providing the Prescribing Services using the applicable PIN listed in Table 1 below. Each PIN is specific to a scenario that depends on whether the Prescribing Services were provided in-person or virtually/by telephone and whether a prescription was issued for Paxlovid™.
- A PIN listed in Table 1 may only be claimed after the Prescribing Services have been completed.
 - A PIN cannot be claimed if an individual is not eligible for PaxlovidTM (see Individual Eligibility – Prescribing Services above).
 - Pharmacies must use the correct PIN corresponding to the specific circumstances.
- The eligible individual must be informed that they are permitted to take the Paxlovid™ prescription to any pharmacy of their choice for dispensing. Where the eligible individual decides to have their prescription filled at another pharmacy, the pharmacy/pharmacist that provided the Prescribing Services must follow-up with the individual to ensure that treatment is initiated within the treatment window of five days post-symptom onset.
- A pharmacy cannot claim a Pharmaceutical Opinion Program (POP) fee when
 providing the Prescribing Services, or when dispensing Paxlovid[™] pursuant
 to a prescription issued by a pharmacist at the same pharmacy.

Table 1: PINs for Payment of Prescribing Services related to Publicly Funded Paxlovid™ (nirmatrelvir/ritonavir) in Ontario Pharmacies

Refer to the points above for additional billing information related to Table 1.

Only one PIN may be claimed per eligible service.

PIN	Description
09858233	Paxlovid™ Prescription Issued by the pharmacist (in-person care)
	For Prescribing Services that are provided to an eligible individual who visits the pharmacy location and result in the eligible individual receiving a Paxlovid TM prescription.
	A maximum of one \$19 fee may be claimed per eligible individual per day, and for the duration of a COVID-19 infection.



PIN	Description
09858234	Paxlovid™ Prescription Not Issued by the pharmacist (in-person care)
	For Prescribing Services that are provided to an eligible individual who visits the pharmacy location and result in the eligible individual not receiving a Paxlovid [™] prescription and/or referral to a physician or nurse practitioner or clinical assessment center (e.g., due to a contraindication, drug interaction that cannot be managed by the pharmacist).
	The PIN cannot be claimed if an individual is not eligible for Paxlovid™ (see Individual Eligibility – Prescribing Services above).
	A maximum of one \$19 fee may be claimed per eligible individual per day, and for the duration of a COVID-19 infection.
09858235	Paxlovid™ Prescription Issued by the pharmacist (virtual care/telephone*)
	For Prescribing Services that are provided to an eligible individual who remotely contacts the pharmacy location, follows the OCP <u>Virtual Care Policy</u> and result in the eligible individual receiving a Paxlovid [™] prescription.
	A maximum of one \$19 fee may be claimed per eligible individual per day, and for the duration of a COVID-19 infection.
09858236	Paxlovid™ Prescription Not Issued by the pharmacist (virtual care/telephone*)
	For Prescribing Services that are provided to an eligible individual who remotely contacts the pharmacy location, follow the OCP <u>Virtual Care Policy</u> and result in the eligible individual not receiving a Paxlovid TM prescription and/or referral to a physician or nurse practitioner or clinical assessment center (e.g., due to a contraindication, drug interaction that cannot be managed by the pharmacist).
	The PIN cannot be claimed if an individual is not eligible for Paxlovid™ (see Individual Eligibility – Prescribing Services above).
	A maximum of one \$19 fee may be claimed per eligible individual per day, and for the duration of a COVID-19 infection.

^{*} Services provided by virtual care / telephone must take place from the location of the pharmacy.





General Billing Information – Dispensing

- No drug cost will be paid to pharmacies as pharmacies will receive Paxlovid[™] freeof-charge through participating pharmaceutical distributors.
- Pharmacies will not incur any costs to order Paxlovid™. Pharmacies are encouraged to maintain a supply of Paxlovid™ on-hand (on-shelf) to minimize delays in treatment.
- There is **no cost** to eligible individuals who receive publicly funded Paxlovid[™] at a pharmacy.
- Table 2 lists the publicly funded oral antiviral treatment currently available to pharmacies³. Please use the correct PIN corresponding to the dose pack of Paxlovid™ dispensed.

Table 2: PINs for Payment of Dispensing Publicly Funded Paxlovid™ (nirmatrelvir/ritonavir) in Ontario Pharmacies

PIN	Description	Total Amount Paid
09858154	Paxlovid™ Dispensing Fee	\$13.25
	For packages containing 300 mg nirmatrelvir and 100 mg ritonavir per dose	
09858162	Paxlovid™ Renal Dosage Dispensing Fee	\$13.25
	For packages containing 150 mg nirmatrelvir and 100 mg ritonavir per dose for use in moderate renal impairment only	

Paxlovid[™] Dispensing and the Pharmaceutical Opinion Program (POP)

A professional intervention fee for a POP service may be claimed for individuals eligible to receive publicly funded Paxlovid™ (including for non-ODB recipients) if the pharmacist identifies a potential drug therapy problem during the course of dispensing Paxlovid™ pursuant to a prescription issued by a prescriber outside of the pharmacy.

³ Inclusion of a product in the list of publicly funded oral antivirals available for pharmacies does not guarantee supply of the product through the participating pharmaceutical distributors.



A POP fee cannot be claimed when:

- A pharmacist recommends to another prescriber that an eligible individual be
 prescribed Paxlovid[™] or that their drug therapy be adapted / adjusted, if the
 pharmacist takes on the authority to prescribe for Paxlovid[™] and, if applicable,
 adapts/ adjusts other prescription drug therapy as identified by the pharmacist.
- When a pharmacist has submitted a claim for a PaxlovidTM Prescription **Not** Issued fee (see Table 1 above, PIN 09858234 or PIN 09858236).

Table 3 below lists the PINs and descriptions for use. Pharmacies must use the correct PIN corresponding to the specific circumstances.

To be eligible for a POP fee in relation to **dispensing** Paxlovid[™], the pharmacist must document and make a recommendation to the prescriber regarding Paxlovid[™] and one of the following individual health outcomes must occur.

- 1. **Paxlovid™ prescription 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.
- 2. **No change in prescription therapy.** Recommendations by the pharmacist were discussed with the prescriber and no change was made to prescription therapy.
- 3. **Change in prescription therapy.** Recommendations by the pharmacist were discussed with the prescriber and led to significant changes in other drug therapy. Note:
 - a. Adaptation of prescriptions are within the scope of practice of pharmacists and do not qualify for a POP fee.

Please refer to the <u>Professional Pharmacy Services Guidebook</u> "Guidebook" located on the ministry's <u>website</u> and <u>Section 7.2 (Pharmaceutical Opinion Program) of the Ontario Drug Programs (ODP) Reference Manual</u> for detailed information regarding the POP, including the claim submission process** and documentation guidelines. Despite the Guidebook and Manual, a professional intervention fee for a POP service may be claimed in respect of an eligible individual in the circumstances described above regardless of whether they are an ODB program recipient or not.

Note that a POP claim may only be submitted after the prescription intervention has occurred, the eligible individual has been informed, the prescriber has been contacted, and documentation is completed and signed by the pharmacist.

**Claims submission process for non-ODB eligible recipients and those without an Ontario health number is described in the Billing Procedures – Detailed section below.





Table 3: PINs for Payment of the POP Service for Publicly Funded Paxlovid™

Note that these PINs must be used to support payment of a professional intervention fee for a POP service related to **dispensing** Paxlovid™ pursuant to a prescription from a prescriber outside of the pharmacy. **Do not use the existing POP PINs noted in the Guidebook or ODP Reference Manual.**

Paxlovid™ POP PINs are not to be used where the pharmacist is the one providing the Paxlovid™ Prescribing Services for a particular eligible individual.

PIN	Description
93899994	Prescription for Paxlovid™ not filled
93899995	Change in prescription therapy
93899996	No change in prescription therapy

Billing Procedures – Summary

- Claims for prescribing or dispensing publicly funded Paxlovid[™] 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.
- Each claim must include one of the PINs noted in Table 1 or Table 2 above (do not use the DIN of the product).
- The person submitting the claim must ensure that the eligible individual's date of birth, Ontario health number (if available) and name (as it appears on the health card, if available) 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 individuals.
 - For eligible individuals without an Ontario health number, pharmacies must use the proxy patient ID: 79999 999 93 (see below for further details).



Pharmacy Documentation Requirements

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

For purposes of post-payment verification, pharmacy records related to claims for prescribing and/or dispensing services for publicly funded Paxlovid™ 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 eligible individual, or until 10 years after the day on which the eligible individual reached or would have reached the age of 18 years, whichever is longer.

Pharmacies must keep a record of every course of publicly funded COVID-19 oral antiviral treatment (Paxlovid™) supplied to an eligible individual. Standard documentation requirements for prescriptions apply.

Overpayments due to inappropriate claim submissions are subject to recovery.

Documentation for Prescribing Services: The following pharmacy documentation must be maintained in a readily retrievable format for the purposes of post-payment verification when providing Prescribing Services for publicly funded Paxlovid™:

- Documentation of all relevant information that was reviewed to determine whether or not to issue a prescription for publicly funded Paxlovid™;
- A written record by the prescribing pharmacist that follows relevant OCP guidelines⁴ and includes, but is not limited to, the following:
 - eligible individual's name, address, date of birth, Ontario heath number or alternate identification;
 - how the informed consent of the eligible individual or their substitute decisionmaker was received for Prescribing Services (e.g., verbal consent from the eligible individual or the eligible individual's substitute decision maker);
 - how the eligible individual meets the eligibility criteria for receiving publicly funded Prescription Services;
 - the date and result of the eligible individual's COVID-19 test (e.g., verbal confirmation from individual, test result obtained from the Ontario Laboratories Information System (OLIS), test conducted in the pharmacy);
 - the date of onset for the eligible individual's COVID-19 symptoms;

⁴ OCP guidelines may include Initiating, Adapting and Renewing Prescriptions and the OCP Virtual Care Policy



- a care plan for the eligible individual based on a review of the eligible individual's medical history, lab results, and current medications and how any potential drug interactions will be managed, follow-up/monitoring, and notification to the primary care provider, if applicable.
- A copy of the prescription that was issued, if applicable, to the eligible individual for publicly funded Paxlovid[™] and a record of information as per the OCP guidelines for <u>Initiating</u>, <u>Adapting and Renewing Prescriptions</u>, such as:
 - Date prescribed
 - o Eligible individual's name, address and date of birth
 - Drug name, directions for use, quantity prescribed
 - o Pharmacist's signature / authorization

Documentation for Dispensing: The following pharmacy documentation must be maintained in a readily retrievable format for the purposes of post-payment verification when dispensing publicly funded Paxlovid[™] for an eligible individual:

- A copy of the prescription for Paxlovid™;
- Documentation of the COVID-19 test result and date (e.g., verbal confirmation from eligible individual, test result obtained from the Ontario Laboratories Information System (OLIS), etc.);
- Details of the services related to a POP fee, if applicable;
- A written record made by the dispenser that they:
 - confirmed the eligible individual would be starting treatment within 5 days of COVID-19 symptom onset;
 - confirmed the eligible individual does not have any contraindications to Paxlovid[™] drug therapy and reviewed any potential interactions with other drugs and medical conditions; and
 - provided the eligible individual with proper instructions for use and information regarding side effects of Paxlovid™.

Other Exclusions and Restrictions

 Publicly funded Paxlovid[™] cannot be prescribed by a Part A pharmacist for off-label use (e.g., travel) or for individuals who do not meet the eligibility criteria. Fees paid for such invalid claims will be subject to recovery.



- A maximum of one \$19 fee for **Prescribing** Services may be claimed per eligible individual per day. A maximum of one \$19 fee for Prescribing Services may be claimed for the duration of a COVID-19 infection.
- A fee for a MedsCheck Follow-Up cannot be claimed in combination with Prescribing Services related to publicly funded Paxlovid™
- A POP fee may be claimed in conjunction with a dispensing fee for Paxlovid[™], but only where the dispensing was pursuant to a prescription issued by a prescriber outside of the pharmacy. Paxlovid[™] POP fees cannot be claimed where the pharmacist is the prescriber and has claimed a fee for Prescribing Services.
 - Note: Adapting a prescription is within the pharmacist's scope of practice and is not billable as a POP.
- Professional services, including prescribing and/or dispensing services and POP fee related to publicly funded Paxlovid[™] are considered under the LTC capitation funding model and must be provided by the LTC home's contracted primary pharmacy service provider. Pharmacies must submit claims for prescribing or dispensing services related to publicly funded Paxlovid[™] with a zero-dollar fee. In emergency situations, secondary pharmacy service providers (i.e., those that do not have a contract with a LTC home) may be reimbursed an applicable fee for prescribing and/or dispensing services related to publicly funded Paxlovid[™] to LTC home residents, in accordance with this Notice.

Billing Procedures – Detailed

Claims submission requirements are as follows:

For ODB-eligible recipients

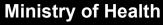
The claim submission follows the usual process (See <u>Section 5</u> of the Ontario Drug Programs Reference Manual ("Manual")) for submitting claims on the HNS with the following additional information:

- Intervention code 'PS': (Professional Care Services)
- PIN: see Table 1 or Table 2 or Table 3 above for list of PINs
- Valid Pharmacist ID

For Non-ODB recipients

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

- Patient Gender: 'F' = female; 'M' = male
- Patient Date of Birth: Valid YYYYMMDD





- Patient's Ontario Health number*
- Intervention codes:
 - PS: Professional Care Services
 - ML: Established eligibility coverage (i.e., 1 day of the Plan 'S' coverage)
- Carrier ID: 'S'
- PIN: see Table 1 or Table 2 or Table 3 above for list of PINs
- Valid Pharmacist ID

*For patients without an Ontario health number

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

- First Name: Patient's first name
- Last Name: Patient's last name
- Patient Gender: 'F' = female; 'M' = male
- Patient Date of Birth: Valid YYYYMMDD
- Proxy patient ID: 79999 999 93
- Intervention codes:
 - PS: Professional Care Services
 - PB: Name entered is consistent with ID provided
- Valid Pharmacist ID

Additional Information:

For pharmacy billing: Please call ODB Pharmacy Help Desk at: 1-800-668-6641

For COVID-19 related issues in pharmacy: Please email the ministry at: OPDPInfoBox@ontario.ca

For COVID-19 antiviral treatment information: Please access this website

For Ministry COVID-19 Information and Planning Resources

- For vaccines, please access this <u>website</u>
- For guidance, please access this website

For all other Health Care Providers and the Public: Please call ServiceOntario, Infoline at 1-866-532-3161 TTY 1-800-387-5559. In Toronto, TTY 416-327-4282.