Executive Officer Notice: Prescribing Oral Antiviral Treatments for Respiratory Viruses in Ontario Pharmacies

Effective January 17, 2025

This EO Notice updates and replaces the EO Notice: Prescribing Oral Antiviral Treatments for Respiratory Viruses in Ontario Pharmacies dated May 17, 2024. Updates include:

- Clarification that pharmacists who are prescribing oral antiviral treatments for ODB-eligible individuals can provide the reason for use code on the prescription (based on Limited Use criteria)
- An updated reference to the regulation under the *Pharmacy Act, 1991* that sets out the authority of Part A pharmacists (including pharmacists (emergency assignment)) to prescribe oral antiviral treatments
- Removal of references to the provincial supply of Paxlovid® that expired in May 2024.

Pharmacies are eligible to submit claims for payment (claims) for providing a therapeutic assessment of eligible individuals resulting or not resulting in a prescription for oseltamivir and/or Paxlovid® - nirmatrelvir/ritonavir ("Paxlovid®"). These publicly funded services are free for eligible individuals with a valid Ontario health number.[1]

Several oseltamivir and Paxlovid® products are listed on the Ontario Drug Benefit (ODB) Formulary as Limited Use (LU) benefits. These medications are funded under the ODB program for eligible ODB program recipients, in accordance with ODB program rules.

For non-ODB program recipients (e.g., individuals with private insurance or who pay out of pocket), usual and customary dispensing fees and costs for oseltamivir and Paxlovid® apply. Pharmacies are encouraged to maintain a supply of oseltamivir and Paxlovid® to minimize delays in treatment.

With respect to therapeutic assessments for prescribing Paxlovid®, high-risk individuals who are symptomatic and positive for COVID-19 but who are unable to take Paxlovid®

[1] 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.

(e.g., due to a contraindication, drug interaction that cannot be managed by the pharmacist, or >5 days since symptom onset) should be referred to a physician or nurse practitioner or Health811 for clinical assessments for alternate treatment options (e.g., intravenous remdesivir via Home and Community Care Support Services).

Disclaimer: This EO Notice and the accompanying Qs & As are intended to provide pharmacy operators with information about the requirements for the publicly funded program for providing therapeutic assessments for the purpose of considering the prescribing of oseltamivir and/or Paxlovid® for respiratory viruses. The EO Notice and the accompanying Qs & As do not provide any medical diagnosis, symptom assessment, health counselling or medical opinion for patients and do not constitute medical advice or legal advice for pharmacy operators or pharmacists. Pharmacy operators and pharmacists are responsible for complying with any obligations they may have in connection with providing therapeutic assessments and prescribing oseltamivir and/or Paxlovid® under applicable laws and policies, including under the *Pharmacy Act, 1991*, the *Drug and Pharmacies Regulation Act*, *Regulated Health Professions Act, 1991*, the *Health Care Consent Act, 1996*, the *Personal Health Information Protection Act, 2004*, the *Ontario Drug Benefit Act*, and any instructions or guidelines provided by the Ontario College of Pharmacists or the ministry.

Overview

Part A pharmacists (including pharmacists (emergency assignment))[2] are authorized to prescribe the oral antiviral treatments oseltamivir, solely for the treatment of influenza, and Paxlovid®, solely for the treatment of COVID-19, in accordance with Ontario Regulation 256/24 under the *Pharmacy Act, 1991*. Part A pharmacists who prescribe oseltamivir or 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, intern, pharmacy technician, intern technician, and pharmacy technician (emergency assignment)) is authorized to prescribe oseltamivir or Paxlovid.

All pharmacies with a Health Network System (HNS) account and valid HNS Subscription Agreement with the Ministry of Health (hereinafter referred to as "pharmacy" or "pharmacies") are eligible to submit claims for a Part A pharmacist's therapeutic assessment for the prescribing or non-prescribing of oseltamivir and/or Paxlovid.

[2] References in this document to Part A pharmacists include pharmacists (emergency assignment).

The Part A pharmacist must make a determination as to the patient's risk for any drug interactions[3] that cannot be properly managed or that prevent antiviral treatment(s) from being prescribed and shall not prescribe the drug if such an interaction exists. Additionally, the Part A pharmacist shall notify the patient's primary care provider, if any, within a reasonable time that the pharmacist prescribed antiviral treatment(s) to the patient and provide details respecting the prescription.

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 providing a therapeutic assessment resulting or not resulting in a prescription for oseltamivir and/or Paxlovid. The terms and conditions for *dispensing* these medications as LU benefits under the ODB program are described in the Ontario Drug Programs Reference Manual. 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 the terms and conditions set out in the EO Notice and FAQs.

This EO Notice replaces the EO Notice (Prescribing and Dispensing Oral Antiviral Treatments for Respiratory Viruses in Ontario Pharmacies) dated May 17, 2024.

Individual Eligibility – Therapeutic Assessment for Oral Antiviral Prescribing

A claim may be submitted for completing a therapeutic assessment of a patient resulting or not resulting in a prescription for oseltamivir and/or Paxlovid® in accordance with this Notice for an individual with a valid Ontario health number[4], as applicable:

Influenza (Oseltamivir)

- The individual has documented instructions to obtain oseltamivir for influenza prophylaxis as directed by the local Public Health Unit or institutional Infection Prevention and Control (IPAC) in response to an outbreak; OR,
- The individual:

[3] For Paxlovid, refer to Paxlovid - What Pharmacists and Prescribers Need to Know (with Appendix) (hivclinic.ca)

[4] "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.

- has a laboratory-confirmed influenza A or influenza B infection OR has suspicion of an influenza A or influenza B infection based on clinical judgment[5], which includes a negative COVID-19 test result; AND,
- will be starting oseltamivir within two days of symptom onset (symptom onset day is considered day zero); OR

- The individual:
  - is a direct contact of someone who has a PCR-confirmed influenza infection (the "index case"); AND,
  - will be starting oseltamivir within two days of exposure to the index case (day of exposure is considered day zero).

COVID-19 (Paxlovid®)

- The individual:
  - Has received a positive COVID-19 test result AND;
  - Will be starting Paxlovid® treatment within five days of symptom onset (symptom onset day is considered day zero); AND,
  - Has one or more risk factors associated with more severe COVID-19 outcomes where antiviral therapy may be recommended or considered as set out in Ontario Health Recommendations for Antiviral Therapy for Adults with Mild to Moderate COVID-19.[6]

Dispensing Oral Antiviral Treatments

Oseltamivir and Paxlovid® are listed on the ODB Formulary as Limited Use (LU) benefits. These medications are funded under the ODB program for eligible ODB recipients who meet the applicable LU criteria, in accordance with ODB program rules.

As per the ODP Reference Manual, LU products will be funded 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. Claims for dispensing oseltamivir and Paxlovid® for ODB program recipients must follow ODB program requirements (see Ontario Drug Programs Reference Manual).

For non-ODB program recipients (e.g., individuals with private insurance or who pay out of pocket), usual and customary dispensing fees and costs will apply.

[5] This may include a combination of: symptoms of influenza-like illness and a negative COVID-19 test result; and/or, influenza confirmed to be circulating in the Public Health Unit [see Public Health Ontario Respiratory Virus Tool]. See accompanying FAQs for information.
[6] See Appendix A (page 11) for guidance.

General Billing Information – Therapeutic Assessment for a Prescription

- There is no cost to eligible individuals who receive a therapeutic assessment related to prescribing or not prescribing oseltamivir or Paxlovid® from a pharmacy.
- Table 1 lists the Product Identification Numbers (PINs) that may be claimed for a therapeutic assessment related to prescribing or not prescribing oseltamivir and Paxlovid.
- For each valid claim submitted for a therapeutic assessment using one of the PINs in Table 1, a pharmacy will receive $19 as payment for providing the following 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 the 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 oseltamivir and/or Paxlovid, 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 with the individual the appropriate care plan, including referral (to physician or nurse practitioner or Health 811), monitoring, prescribing oseltamivir and/or Paxlovid® with or without modifications to other prescribed drug therapies, and recommending over-the counter and/or non-pharmacological therapy;
    - Implementing the care plan, including issuing a prescription or referring the individual to a physician, nurse practitioner, or Health 811; providing the individual with related education; and maintaining a record as noted in the Pharmacy Documentation Requirements section below;
    - Notifying the individual's primary care provider, if any, if oseltamivir and/or Paxlovid® is prescribed;
    - Following-up with the individual to establish monitoring parameters and, evaluating the safety and efficacy of the care plan;
    - Ensuring care is provided within the treatment window. An individual must be able to start treatment with oseltamivir within two days of symptom onset or Paxlovid® within five days of symptom onset.

- A claim may be submitted for providing the therapeutic assessment services using the applicable PIN listed in Table 1 below. A claim based on a PIN listed in Table 1 **may only be claimed after** the therapeutic assessment services have been completed.
    - A PIN cannot be claimed if an individual is not eligible for the therapeutic service relating to oseltamivir and/or Paxlovid® (see Individual Eligibility – Therapeutic Assessment for Oral Antiviral Prescribing above).
    - Pharmacies must use the correct PIN corresponding to the specific circumstances.
    - **Only one PIN in Table 1 can be claimed per day per eligible individual.** Pharmacies are encouraged to check the provincial Clinical Viewers for professional service fee claims.

- The eligible individual must be informed that they are permitted to take the 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 therapeutic assessment services must follow-up with the individual to ensure that treatment is initiated within the treatment window.

- A pharmacy cannot claim a Pharmaceutical Opinion Program (POP) fee when providing the therapeutic assessment services, or when dispensing oseltamivir and/or Paxlovid® pursuant to a prescription issued by a pharmacist at the same pharmacy**.**

Table 1: PINs for Payment of Therapeutic Assessment for Prescription related to Oseltamivir and/or 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 (in-person) 09858235 (virtual)	**Paxlovid® Prescription Issued** by the Part A Pharmacist (in-person or virtual care) Therapeutics assessment for eligible individual resulting in 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 and cannot be used in combination with any other PIN from Table 1.

PIN	Description
09858321 (in-person) 09858322 (virtual)	**Oseltamivir Prescription Issued** by the Part A Pharmacist (in-person or virtual care) Therapeutics assessment for eligible individual resulting in an oseltamivir prescription. A maximum of one $19 fee may be claimed per eligible individual per day, and for the duration of an influenza infection and cannot be used in combination with any other PIN from Table 1.
09858323 (in-person) 09858324 (virtual)	**Oseltamivir and Paxlovid® Prescriptions Issued** by the Part A Pharmacist (in-person or virtual care) Therapeutic assessment for eligible individual resulting in a Paxlovid® and an oseltamivir prescription. A maximum of one $19 fee may be claimed per eligible individual per day, and for the duration of the COVID-19 and influenza infection and cannot be used in combination with any other PIN from Table 1.
09858325 (in-person) 09858326 (virtual)	Prescription **Not Issued** by the Part A Pharmacist (in-person or virtual care) A therapeutic assessment for an eligible individual is completed but does not result in a prescription for Paxlovid® or oseltamivir (e.g., decision is made to monitor, patient receives a referral to a physician or nurse practitioner or Health 811 due to a contraindication or drug interaction that cannot be managed by the pharmacist). The PIN cannot be claimed if an individual is not eligible to be assessed for Paxlovid® or oseltamivir (see Individual Eligibility – Prescribing Services above). A maximum of one $19 fee may be claimed per day and cannot be used in combination with any other PIN from Table 1.

*** Services provided by virtual care / telephone must take place from the location of the pharmacy and be documented.**

Pharmaceutical Opinion Program (POP)

POP fees cannot be claimed where the Part A pharmacist is the prescriber and has claimed a fee for therapeutic assessment services for prescription.

Please refer to the Professional Pharmacy Services Guidebook ("Guidebook") located on the Ministry of Health's ("ministry") website and Section 7.2 (Pharmaceutical Opinion Program) of the Ontario Drug Programs (ODP) Reference Manual for detailed information regarding the POP, including the claim submission process and documentation guidelines.

Billing Procedures – Summary

- Claims for providing therapeutic assessment services related to the prescribing or non-prescribing of Paxlovid® and/or oseltamivir 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.
- Claims for therapeutic assessment for prescribing an oral antiviral must include one of the PINs noted in Table 1 above, the Eligible Individual's date of birth, Ontario health number and name (as it appears on the health card). Failure to do so – especially for non-ODB program recipients – may impact the ability to submit future claims for these individuals.
- If a person is considered eligible for a therapeutic assessment and **is not** an ODB program recipient, they must either have private insurance or pay out of pocket for any oral antivirals that may be dispensed pursuant to prescriptions issued during the therapeutic assessment.

Pharmacy Documentation Requirements

Pharmacies and Part A 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 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.

Overpayments due to inappropriate claim submissions are subject to recovery.

Documentation for Therapeutic Assessment for Prescription: The following pharmacy documentation must be maintained in a readily retrievable format for the purposes of post-payment verification when providing therapeutic assessment services related to the prescribing or non-prescribing of Paxlovid® and/or oseltamivir:

- All relevant information that was reviewed to determine if to issue a prescription for oseltamivir and/or Paxlovid®

- A written record by the Part A pharmacist providing the services that follows relevant OCP guidelines[7] and includes, but is not limited to, the following:
    - eligible individual's name, address, date of birth, and Ontario heath number;
    - how the informed consent of the eligible individual or their substitute decision-maker was received for the 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 the services;
    - the date and result of the eligible individual's COVID-19 test as applicable (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 and/or influenza symptoms;
    - 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 oseltamivir or Paxlovid® and a record of information as per the OCP guidelines for Initiating, Adapting and Renewing Prescriptions, such as:
    - Date prescribed
    - Eligible individual's name, address and date of birth
    - Drug name, directions for use, quantity prescribed
    - Pharmacist's signature / authorization

Other Exclusions and Restrictions

- Therapeutic assessments cannot be billed for prescriptions issued by a Part A pharmacist to use Paxlovid® for an off-label indication (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 therapeutic assessment for prescription services may be claimed per eligible individual per day for either COVID-19 or influenza (or both). A maximum of one $19 fee for therapeutic assessment for prescription services may be claimed for the duration of the infection related to the

[7] OCP guidelines may include Initiating, Adapting and Renewing Prescriptions and the OCP Virtual Care Policy

assessment. Pharmacies are encouraged to check the provincial Clinical Viewers for professional service fee claims.

- A fee for a MedsCheck Follow-Up **cannot** be claimed in combination with therapeutic assessment for prescription services related to oseltamivir or Paxlovid.

- Professional services, including therapeutic assessment for prescription and/or POPs 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 therapeutic assessment for prescription 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 therapeutic assessment for prescription to LTC home residents, in accordance with this Notice.

Billing Procedures – Detailed

Claims submission requirements are as follows:

For ODB program recipients
The claim submission follows the usual process (See Section 5 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 above for list of PINs
- Valid Pharmacist ID

For Non-ODB program recipients
When submitting a claim for a Therapeutic Assessment for an eligible individual who is not an ODB program recipient, Part A 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 above for list of PINs

- Valid Pharmacist ID

Additional Information:
For pharmacy billing: Please call ODB Pharmacy Help Desk at: 1-800-668-6641
For COVID-19 related issues or questions 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 and 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.

Appendix A: Recommendations for Antiviral Therapy for Adults with Mild to Moderate COVID-19 (adapted from Ontario Health Guidance on Antiviral Treatment)

Defining a high-risk population is challenged by the evolving nature of the SARS-CoV-2 virus. Evidence continues to emerge to inform risk assessments.

Risk factors where antiviral therapy is RECOMMENDED

1. **Adults ≥ 65 years of age, regardless of vaccination status, with no other risk factors**
2. **Adults who are immunocompromised (age 18 and older, regardless of vaccination status or prior COVID-19 infections). Examples include:**
    - Advanced untreated human immunodeficiency virus (HIV) or treated HIV with a CD4 count equal or less than 200/mm3 or CD4 fraction equal or less than 15%
    - Bone marrow transplant or stem cell transplant
    - Solid organ transplant
    - Have active, or recently received treatment, for hematological malignancy
        - E.g., have received treatment with any anti-CD20 agents or B-cell depleting agents in the last 2 years
    - Chimeric antigen receptor (CAR) T-cell therapy in the last 6 months
    - Treatment for cancer (including solid tumors), limited to: systemic therapy in the last 6 months (e.g., chemotherapy, molecular therapy, immunotherapy, targeted therapies, monoclonal antibodies, excluding those receiving adjunctive hormonal therapy only) or radiation therapy in the last 3 months
    - Prednisone use equal to or greater than 20 mg/day (or corticosteroid equivalent) for 14 days or more, or other moderately or severely immunosuppressive therapies (e.g., alkylating agents)
    - Primary immunodeficiencies

Risk factors where antiviral therapy MAY BE CONSIDERED

Risk for More Severe COVID-19 Outcomes	Number of Risk Factors**
Higher	3 or more
Moderate	2
Lower	0-1

1. **Vaccination status, i.e.,**
    - Have never received a COVID-19 vaccine

2. **Medical conditions**:

- Active tuberculosis (treated or untreated)
- Cerebrovascular disease
- Chronic kidney disease, especially CKD stage 4 or 5 and dialysis
- Chronic lung diseases, limited to: asthma, bronchiectasis, chronic obstructive pulmonary disease, interstitial lung disease, pulmonary embolism, pulmonary hypertension
- Chronic liver diseases, limited to: cirrhosis, non-alcoholic fatty liver disease, alcoholic liver disease, autoimmune hepatitis
- Cystic fibrosis
- Diabetes mellitus, type 1 or type 2
- Disabilities and developmental delay, including Down syndrome
- Heart conditions (e.g., heart failure, coronary artery disease, cardiomyopathies)
- Mental health conditions, limited to: mood disorders (including depression), schizophrenia spectrum disorders
- Neurologic conditions that cause an inability to control respiratory secretions or communicate disease progression (e.g., cognitive disorders such as Alzheimer-type dementia)
- Obesity (body mass index above 30 kg/m2)
- Pregnancy or recent pregnancy (42 days post-partum/end of pregnancy)

Certain medical or social vulnerabilities may confer an increased risk of disease progression because affected individuals may experience challenges in recognizing, communicating or acting on progressive COVID-19 symptoms. People who are at a high risk of poor outcomes from COVID-19 based on social determinants of health should be considered priority populations for access to antivirals. Individuals at high risk include Indigenous people, Black people, other members of racialized communities; people experiencing intellectual, developmental, or cognitive disabilities; people who use substances regularly (e.g., alcohol); people who live with mental health conditions; and people who are underhoused.