Ontario

Ontario Drug Benefit Formulary/Comparative Drug Index

Edition 43

Summary of Changes – May 17, 2024

Drug Programs Policy and Strategy Branch
Health Programs and Delivery Division
Ministry of Health

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Ontario

New Single Source Products

Generic Name: NIRMATRELVIR & RITONAVIR

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02524031	Paxlovid	150mg & 100mg	Tab-30 Pk	PFI	1288.8800/Pk
02527804	Paxlovid	150mg & 100mg	Tab-20 Pk	PFI	1288.8800/Pk

Reason For Use Code and Clinical Criteria

Code 673

For the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in patients **65 years of age or older** with:

- a positive result from direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing (either using rapid antigen test or PCR), and
- symptoms present for 5 days or fewer.

Paxlovid (DIN: 02527804) is intended for patients with renal impairment or on dialysis. If Paxlovid (DIN: 02524031) is being dispensed for such patients, it requires dose adjustment.

Treatment decisions should be individualized based on the prescriber's assessment of patient risk because not all medical or social vulnerabilities carry the same risk. Prescribers should consult Ontario Health Recommendations for Antiviral Therapy for Adults with Mild to Moderate COVID-19 (April 2024).

Pharmacists and prescribers should be informed of and stay current with a drug product's official indications in accordance with Health Canada's approved product monograph. Some aspects of the above criteria may differ from the official indications as described in the product monograph for Paxlovid. The Executive Officer's funding of drug products is informed by advice from expert committees that consider evidence regarding the safety, clinical efficacy, and cost-effectiveness of drug products.

Note: The funded treatment is one dose pack* for a treatment duration of 5 days.

*Dose pack for DIN: 02524031 is package of 30 tablets divided in 5 daily-dose blister cards containing 4 nirmatrelvir tablets (150mg each) and 2 ritonavir tablets (100mg each).

*Dose pack for DIN: 02527804 is a package of 20 tablets divided in 5 daily-dose blister cards containing 2 nirmatrelvir tablets (150mg each) and 2 ritonavir tablets (100mg each).

LU Authorization Period: 5 days to align with funded treatment duration.

New Single Source Products (Continued)

Code 674

For the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in **immunocompromised* patients 18 years of age or older regardless of vaccine status or prior COVID-19 infections** with:

- a positive result from direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing (either using rapid antigen test or PCR), and
- symptoms present for 5 days or fewer.

* Prescribers should consult Ontario Health Recommendations for Antiviral Therapy for Adults with Mild to Moderate COVID-19 (April 2024).

Examples of immunocompromised include:

- Advanced untreated human immunodeficiency virus (HIV) or treated HIV with a CD4 count equal or less than 200 per mm3 or CD4 fraction equal or less than 15%
- Bone marrow or stem cell transplant
- Solid organ transplant
- Have active hematological malignancy 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 20mg/day (or corticosteroid equivalent) for 14 days or more, or other moderately or severely immunosuppressive therapies (e.g., alkylating agents)
- Primary immunodeficiencies. For example:
    - Hypogammaglobulinemia
    - Combined immune deficiencies affecting T-cells - Immune dysregulation (e.g., familial hemophagocytic lymphohistiocytosis)
    - Type 1 interferon defects caused by a genetic primary immunodeficiency disorder or secondary to anti-interferon autoantibodies
    - Diagnosed by an immunologist and requires ongoing immunoglobulin replacement therapy (IVIg or SCIg)
    - Primary immunodeficiency with a confirmed genetic cause (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)

New Single Source Products (Continued)

Paxlovid (DIN: 02527804) is intended for patients with renal impairment or on dialysis. If Paxlovid (DIN: 02524031) is being dispensed for such patients, it requires dose adjustment.

Treatment decisions should be individualized based on the prescriber's assessment of patient risk because not all medical or social vulnerabilities carry the same risk.

Pharmacists and prescribers should be informed of and stay current with a drug product's official indications in accordance with Health Canada's approved product monograph. Some aspects of the above criteria may differ from the official indications as described in the product monograph for Paxlovid. The Executive Officer's funding of drug products is informed by advice from expert committees that consider evidence regarding the safety, clinical efficacy, and cost-effectiveness of drug products.

Note: The funded treatment is one dose pack** for a treatment duration of 5 days. In exceptional circumstances, the funded treatment is two dose packs** for a treatment duration of 10 days based on prescriber clinical judgement in consultation with an infectious disease specialist. Pharmacy operators must obtain and retain appropriate documentation to support claims for such extended therapy. For guidance, prescribers may consult Ontario Health – Frequently Asked Questions on Antiviral Therapy for Adults with Mild to Moderate COVID-19 (April 2024).

**Dose pack for DIN: 02524031 is package of 30 tablets divided in 5 daily-dose blister cards containing 4 nirmatrelvir tablets (150mg each) and 2 ritonavir tablets (100mg each).

**Dose pack for DIN: 02527804 is a package of 20 tablets divided in 5 daily-dose blister cards containing 2 nirmatrelvir tablets (150mg each) and 2 ritonavir tablets (100mg each).

LU Authorization Period: 5 days or 10 days to align with funded treatment duration.

New Single Source Products (Continued)

Code 675

For the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in patients **18 to 64 years of age with at least 1 risk factor* associated with more severe COVID-19 outcomes** with:

- a positive result from direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing (either using rapid antigen test or PCR), and
- symptoms present for 5 days or fewer.

The risk of progression to severe COVID-19 depends on the quantity of underlying medical conditions and how controlled the medical conditions are.

*When assessing risk factors, prescribers may want to consult Ontario Health Recommendations for Antiviral Therapy for Adults with Mild to Moderate COVID-19 (April 2024). Examples of risk factors include:

Vaccination Status:

- Have never received a COVID-19 vaccine

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 30kg per m2)
- Pregnancy or recent pregnancy (42 days post-partum/end of pregnancy)

New Single Source Products (Continued)

Note for consideration: 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.

Paxlovid (DIN: 02527804) is intended for patients with renal impairment or on dialysis. If Paxlovid (DIN: 02524031) is being dispensed for such patients, it requires dose adjustment.

Treatment decisions should be individualized based on the prescriber's assessment of patient risk because not all medical or social vulnerabilities carry the same risk.

Pharmacists and prescribers should be informed of and stay current with a drug product's official indications in accordance with Health Canada's approved product monograph. Some aspects of the above criteria may differ from the official indications as described in the product monograph for Paxlovid. The Executive Officer's funding of drug products is informed by advice from expert committees that consider evidence regarding the safety, clinical efficacy, and cost-effectiveness of drug products.

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LU Authorization Period: 5 days to align with funded treatment duration.