SECTION **High Cost / Special Authorization**	PAGE Page 1 of **3**
SUBJECT/TITLE **Nirmatrelvir/Ritonavir (Paxlovid®)**	ORIGINAL DATE **May 30, 2024**

Background

The federal supply of Paxlovid® has ended and as such, a funding framework for the commercially available supply for use in Type A Continuing Care Homes covered under the Calgary Zone Long Term Care Formulary has been developed. Coverage criteria is in alignment with Alberta Drug Benefit List (ADBL), AHS Provincial criteria and CADTH reimbursement recommendations for Paxlovid®.

Considerations Before Prescribing

- Refer to COVID-19 Outpatient Treatment | Alberta Health Services
- The product monograph for Paxlovid® is posted on the Health Canada website at Drug Details (canada.ca)
- Paxlovid® has many drug interactions and medical contraindications that clinical teams must be aware of.

The resident / alternate decision maker, the most responsible health care practitioner and the health care team shall discuss the risks versus benefits of therapy so that a shared decision can be made to initiate, continue, or stop therapy.

Criteria for Drug Funding Coverage

Paxlovid® coverage may be approved for mild-to-moderate coronavirus disease 2019 (COVID-19) in adults with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. Treatment with nirmatrelvir-ritonavir should be initiated as soon as possible after a diagnosis of COVID-19 has been made, and within 5 days of symptoms onset in adult patients who have either the following:

Coverage may be approved for up to 300mg nirmatrelvir (two 150mg tablets) with 100mg ritonavir (one 100mg tablet) twice daily for a **5-day course.**

S**evere immunosuppression** such as:

- Solid organ transplant recipients*
- Treatment for malignant hematologic condition
- Bone marrow, stem cell transplant or transplant-related immunosuppressant use
- Receipt of anti-CD20 agents or B-cell depleting agents (such as rituximab) in the previous 2 years
- Severe primary immunodeficiencies including combined immunodeficiencies affecting T-cells, immune dysregulation (particularly familial hemophagocytic lymph histiocytosis or those with type 1 interferon defects caused by a genetic primary immunodeficiency disorder or secondary to anti-interferon autoantibodies.

**Transplant patients have a significant risk of life-threatening drug interactions between nirmatrelvir-ritonavir and transplant-related immunosuppressants. Treatment of transplant patients should be discussed with their*

transplant specialist/team.

Moderate immunosuppression such as:

- Treatment for cancer including solid tumors
- Significantly immunosuppressing drugs (e.g., biologic in the last three months, oral immune suppressing medication in the las t months, oral steroid [20 mg/day of prednisone equivalent taken on an ongoing basis] in the last month, or immune-suppressing infusion or injection in the last three months)
- Advanced HIV infection
- Moderate primary immunodeficiencies. a primary immunodeficiency with a genetic cause at any time; or a primary immunodeficiency and immunoglobulin replacement therapy in the last year
- Renal conditions (i.e., hemodialysis, peritoneal dialysis, glomerulonephritis and dispensing of a steroid, eGFR < 15 mL/min)

Submission Process

- Requests for coverage will be submitted using the Special Authorization Form SA-31 (see Appendix A below). Clinical teams do not have to wait for a response. **Funding may be declined or terminated by Calgary Zone LTC Drug Management when criteria are not met. If there is an incomplete form, the requestor will be contacted by email or phone.**
- **By submitting this application, the care team, attending physician and pharmacist have considered the decision to treat, consent and risks/benefits**

References

1. Alberta Drug Benefit List (ADBL) status. Available at: **Alberta Health - Drug Benefit List (bluecross.ca)** (Accessed May 27, 2024)
2. CADTH Common Drug Review: CADTH Canadian Drug Expert Committee Reimbursement Recommendations: Nirmatrelvir-Ritonavir (Paxlovid). April 2024. Available online at: **nirmatrelvir/ritonavir | CDA-AMC (cadth.ca).**

Appendix A

Nirmatrelvir-Ritonavir (Paxlovid®) SA-32

Form submission is required with initial drug provision.

Processing Instructions: Please complete the form in its entirety.
Requester emails to ISFL Long Term Care Pharmacist at:
cc.drugmanagement@albertahealthservices.ca **OR** fax to **403-943-0232**

Resident Code[1]	Date of Birth (*yyyy-Mon-dd)*	Type A Continuing Care Home
Prescriber		Provision Date(*yyyy-Mon-dd)*

Coverage Criteria

Coverage will be approved for mild-to-moderate coronavirus disease 2019 (COVID-19) in adults with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. Treatment with nirmatrelvir-ritonavir should be initiated as soon as possible after a diagnosis of COVID-19 has been made, and within 5 days of symptom onset in adult patients who have either the following:

Severe immunosuppression such as:

- Solid organ transplant recipients*
- Treatment for malignant hematologic condition
- Bone marrow stem cell transplant or transplant-related immunosuppressant use
- Receipt of anti-CD20 agents or B-cell depleting agents (such as rituximab) in the previous 2 years
- Severe primary immunodeficiencies including combined immunodeficiencies affecting T-cells, immune dysregulation (particularly familial hemophagocytic lymph histiocytosis or those with type 1 interferon defects caused by a genetic primary immunodeficiency disorder or secondary to anti-interferon autoantibodies.

**Transplant patients have a significant risk of life-threatening drug interactions between nirmatrelvir-ritonavir and transplant-related immunosuppressants. Treatment of transplant residents should be discussed with their transplant specialist/team.*

Moderate immunosuppression such as:

- Treatment for cancer including solid tumors
- Significantly immunosuppressing drugs (e.g., biologic in the last three months, oral immune suppressing medication in the last months, oral steroid [20 mg/day of prednisone equivalent taken on an ongoing basis] in the last month, or immune-suppressing infusion or injection in the last three months)
- Advanced HIV infection
- Moderate primary immunodeficiencies, a primary immunodeficiency with a genetic cause at any time; or a primary immunodeficiency and immunoglobulin replacement therapy in the last year
- Renal conditions (i.e. hemodialysis, peritoneal dialysis, glomerulonephritis and dispensing of a steroid, eGFR < 15 mL/min)

[1] First four letters of surname followed by first two letters of given name

Funding may be declined or terminated by Calgary Zone LTC Drug Management when criteria are not met. If there is an incomplete form, the submitter will be contacted by email or phone. By submitting this application, the care team, attending physician and pharmacist have considered the decision to treat, consent and risks/benefits

Coverage is limited to a **5-day course**. Paxlovid® will not be funded for prophylaxis therapy.	**All Criteria must be met**
1) Resident has mild-to-moderate COVID-19 with a positive SARS-CoV-2 viral test, and is at high risk for progression to severe COVID-19, including hospitalization or death	☐
AND	
2) Resident has moderate to severe immunosuppression	☐
AND	
3) Symptom onset is 5 days or less	☐

Pharmacist or Physician's Name

Submission Date (*yyyy-mon-dd)*

THIS SECTION IS FOR ALBERTA HEALTH SERVICES USE ONLY

Reviewed for completeness by:
Date (*yyyy-mon-dd)*:
Comments or Follow-up: