



COVID-19 Care in the Community - Case Management in Pharmacy Operational Guide September 2023

Paxlovid[™] Supply

Eligibility Criteria:

A COVID-19 antiviral eligibility review may be claimed for:

A trained Pharmacist undertaking a clinical review and consultation with the patient for the supply of a COVID-19 antiviral where an antiviral is <u>not</u> supplied, because <u>the patient does not meet the PHARMAC criteria.</u>

or

A Medication Management Consult may be claimed for:

A trained Pharmacist undertaking a clinical review and consultation with the patient for the supply of PaxlovidTM via a Prescription or as a Pharmacist Only Medicine, via phone or virtual consultation, as set out in this operational guide and/or PSNZ requirements, where the patient does meet the PHARMAC criteria.

The pharmacy may also claim for (if utilised):

- Medication delivery.
- Compliance packaging for COVID-19 specific medicines.

Background

Nirmatrelvir/ritonavir (PaxlovidTM) is the first oral antiviral treatment available in New Zealand for COVID-19. It is indicated as the first line treatment of acute symptomatic COVID-19 in adults 18 years of age and older, who do not require initiation of supplemental oxygen due to COVID-19. It reduces the risk of hospitalisation for those who have a higher risk of hospitalisation or becoming seriously unwell. Treatment should be initiated as early as possible and within five days of symptom onset.

Nirmatrelvir is a protease inhibitor, which blocks virus replication. Ritonavir which boosts the levels of nirmatrelvir. The mechanism of action of ritonavir is boosting the levels of nirmatrelvir is by inhibiting CYP3A4. Ritonavir is also an inhibitor of CYP2D6 and P-glycoprotein transporters. Therefore PaxlovidTM unfortunately comes with a large array of drug interactions. It is imperative that all patients are assessed for drug interactions prior to initiating treatment. Renal dose adjustment is required for the nirmatrelvir component of PaxlovidTM.

In late July 2022 oral antivirals were re-classified as Pharmacist Only (Restricted) Medicines. The process for supplying PaxlovidTM on a prescription or as a pharmacist-only medicine are essentially the same:

- Assess eligibility and symptoms.
- Clinically review.
- Communicate with prescriber or primary care/ document.
- Counsel the patient.
- Communicate with usual pharmacy.





Rebound infection

COVID-19 rebound infection has been associated with the use of antiviral treatments, including Paxlovid®. However, it's important to note that a rebound of symptoms can occur in patients with or without antiviral treatment.

Current recommendations are that if patients' symptoms return within 28 days from their previous infection, they are not required to repeat a Rapid Antigen Test (RAT) and should stay at home until 24 hours after symptoms resolve. Typically, this rebound infection resolves within 3 to 5 days without any specific treatment.

If the patient has already been treated with antivirals such as Paxlovid®, **further antiviral treatment should not be provided**. There is no evidence to suggest that repeat treatment provides any additional benefit, as rebound symptoms are usually mild and require only supportive treatments.

What are the tools and training required to dispense oral antivirals?

To supply Paxlovid[™] as a Pharmacist Only or Prescription medicine you will need:

	Pharmacist Only (restricted) Medicine	Prescription Medicine
Training	Complete PSNZ COVID-19 Antiviral Medicines	No specific training required.
	Clinical Training Programme and follow this	Follow this operational guide.
	operational guide.	
Clinical tools	Clinical Portal and Primary Care Portal within	Clinical Portal and Primary
available	Clinical Portal	Care Portal within clinical
	ReCare	portal
	CCCM	ReCare
Communication	AHANZ telehealth practice in New Zealand (see pg. 3 and 4)	
tools and skills	<u>Telehealth Online learning modules</u> from Collaborative Aotearoa	

What is the process for suppling Paxlovid™?

Assess eligibility criteria and symptoms

Confirm the person has ONLY mild to moderate symptoms of COVID-19 and is well enough to be managed in the community (see the PSNZ Clinical Decision Pathway for more information). Pharmac has specific eligibility for patients to access PaxlovidTM. For more information on eligibility criteria see tools below.

If the person does not meet the Pharmac criteria:

If after reviewing the patient for eligibility you discover that they do not meet the access criteria, you cannot supply PaxlovidTM. You may claim a **COVID-19 antiviral eligibility review. Multiple slots cannot be claimed.**

Clinically review

Check for contraindications

Oral antivirals are not recommended in pregnancy or breastfeeding.

Refer to the PaxlovidTM Medsafe data sheet for a full description of contraindications.

Check the patient's renal function

The dosing of nirmatrelvir is dictated by renal function, therefore you must have a current (preferably within the last 6 months but not older than 12 months) renal function measurement. It is recommended that you use a calculated creatinine clearance if BMI $<20 \text{kg/m}^2$ or $>40 \text{kg/m}^2$ or in age over 75 year.





Ways to obtain a renal function result for a patient are:

- Prescribers are asked to include an eGFR (if available) on the prescription.
- Clinical Portal or ReCare.
- Contact the General Practice.
- Contact the Practice's Clinical Pharmacist Facilitator.

Dosing

- eGFR above 60mL/min/1.73m²: **Two** 150mg tablets of nirmatrelvir and one 100mg tablet of ritonavir are to be taken together twice a day for five days.
- eGFR 30 60mL/min/1.73m²: One 150mg tablets of nirmatrelvir and one 100mg tablet of
 ritonavir are to be taken together twice a day for five days. Pharmacists adjusting the dose
 for this purpose may refer to information provided by the supplier, or the tablets may be
 repackaged in a compliance pack.
- eGFR below 30mL/min/1.73m²: Paxlovid[™] is not currently recommended.

Assess patient's liver function

There is no dose adjustment necessary in mild to moderate impairment, avoid Paxlovid[™] in severe impairment (Child-Pugh score of C). Almost all patients with severe liver disease will be known to healthcare services. Unless you have a good reason to suspect that the patient may have severe liver disease, supply can still proceed.

Review patient medication history and identify potential drug interactions

The pharmacist will need to review for potential for drug interactions. To do this you will need to ascertain a full list of medications that the patient is taking. Sources may include:

- The patient and/or their whānau.
- General practice.
- The patient's usual pharmacy.
- Clinical Portal. Details on how to access clinical information from Clinical Portal can be
 accessed here. If you do not have access to Clinical Portal please contact the HBDHB System
 Lead for Medicine.
- The Practice's Clinical Pharmacist Facilitator.
- CCCM
- ReCare. Details on how to access clinical information from ReCare can be accessed here.

To assess the risk of interactions:

- Use the <u>University of Liverpool's COVID-19 interaction checker</u>.
- Consult the Ontario Science Brief for specific advice on management of interactions.
- New Zealand Formulary is also a reliable resource but may not be updated as quickly and frequently as the Liverpool and Ontario websites.

Managing identified drug interactions

If an interaction between PaxlovidTM and the patient's other medicines are identified, the pharmacist needs to have a conversation with the prescriber around managing these interactions options for managing interactions in general can be summarised as:

Whatu Ora 1 New Zealand	HEA	
Avoid	Prescribe an alternative, non-interacting medication or stop the target interacting medication temporarily.	
Adjust	Change the dosage or timing of one (or both) of the interacting medications.	
Monitor	Monitor clinically (e.g for dizziness or muscle aches) or with investigations (e.g INR, LFTs, BP) and give guidance about possible adverse effects with advice on management.	
No action	Where there is no corrective action or monitoring required for the management of the interaction.	

Communicate with prescriber/ document

Pharmacists will need to contact the prescriber, or the patient's usual GP to resolve issues collaboratively if:

- a prescription is not endorsed,
- a prescribed dose is not the recommended dose for the patient's renal function,
- any interacting medications are identified,
- or any other clinical issues are identified.

Prescribers are asked to provide their contact phone number on the prescription. If you cannot contact the prescriber then you will need to contact the practice. It is recommended that communication follows the ISBAR framework.

Any a discussion with the prescriber and the patient should be documented and any consultation for an antiviral as a Pharmacist-only medicine needs to be recorded in CCCM irrespective of whether the patient receives the antiviral or not.

Counselling the patient

Adverse effects

Common side effects are generally mild and include impaired sense of taste, diarrhoea, vomiting and headache. Less commonly high blood pressure and muscle aches are reported.

Advise patient to contact the prescriber or pharmacy if they experience adverse events or worsening of condition. Pharmacists and prescribers are asked to report any adverse events to the Centre for Adverse Reactions Monitoring (CARM).

Contraception advice

Women should use contraception during and for 7 days after the final dose. The use of ritonavir may reduce the efficacy of combined hormonal contraceptives containing ethinylestradiol - additional contraceptive precautions are advised.

How to take Paxlovid[™]

Treatment must be started within 5 days of first symptoms.

The 5 day course of two medicines contains:

- Nirmatrelvir: 2 (or 1 in renal impairment) pink tablets twice daily. The pharmacist will need to physically adjust the whole-pack for renal impairment for the patient and ensure the instruction label states a renal dose.
- Ritonavir: 1 white tablet twice daily.

Communicate with usual pharmacy

Advise the patient's usual pharmacy that PaxlovidTM has been dispensed.





Claiming

Paxlovid[™] is listed as XPharm on the Pharmaceutical Schedule.

• Dispense as an NSS prescription and the ensure the cost is calculated as \$0. There is no charge to the patient.

The following can be claimed for via the Halcyon claiming form if eligible and utilised:

- A Medication Management Consult per 15 minutes of consultation (maximum of 3 slots may be claimed).
- Medication Delivery.
- Compliance packaging for COVID-19 specific medicines.

Medication Delivery

Patients are encouraged to ask non-isolating support people to visit the pharmacy and pick up their medications. Where this is not possible the pharmacy can use their usual delivery service (or a contracted alternative funded by the pharmacy) and claim a Medication Delivery fee at one claim per day per person.

Compliance packaging

The pharmacy may claim a compliance packaging fee at one claim per person if a pharmacist or clinician deems it appropriate for an oral antiviral to be repackaged into compliance packaging provided that:

- The reason for compliance packaging is stated within the patient's record.
- The patient/carer is provided training on compliance packaging via phone or virtually.
 Compliance packaging for this patient is **not** funded via any other sources or agreement.

Obtaining Stock

Stock of Paxlovid[™] is available to be ordered from approved wholesalers (currently <u>ProPharma</u>) using standard processes.

Tools available:

- PSNZ Covid-19 Antiviral Clinical Training Programme
- He ako hiringa Treating COVID-19 with Paxlovid in primary care
- <u>Christchurch medicines information service: Drug interactions with nirmatrelvir with</u> ritonavir
- Pharmac access criteria for oral COVID-19 treatments
- Pharmac COVID-19 antiviral access criteria flow chart
- COVID-19: Advice for all health professionals
- PaxlovidTM data sheet
- NZF Paxlovid PIL
- Health Navigator Paxlovid™ information sheet in several languages
- Useful pages on the <u>Liverpool website</u> include a flow chart "Assessing a patient for treatment with Paxlovid" and drug interaction tables "Interactions with selected WHO essential medicines and Paxlovid".
- ISBAR communication framework between health care workers
- Patient fact sheet: COVID-19 Seeking medical help when and how
- AHANZ telehealth practice in New Zealand (see pg. 3 and 4)
- Positions to make breathing easier





- CCCM support: 0800 223 987 or citc@contacttracing.health.nz
- <u>COVID-19</u>: Advice for all health professionals | Ministry of Health NZ (includes advice around advanced prescriptions)

References:

- Pharmac. Updated access criteria for antiviral COVID-19 treatments. <u>Updated Access Criteria for antiviral COVID-19 treatments Pharmac | New Zealand Government</u>. Accessed March 2023.
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- New Zealand Ministry of Health. Information and guidance for the health sector: Paxlovid[™] oral therapeutic for COVID-19 community treatment. March 2022
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