Information and guidance for the health sector: Paxlovid™ oral therapeutic for COVID-19 community treatment

March 2022

Paxlovid™ has arrived and will be available to prescribe and dispense from Tuesday 5 April. Pharmac has secured access to 60,000 courses of Paxlovid™ for use in NZ throughout 2022.

Contents:

1.Introduction

Indication

Paxlovid™ (nirmatrelvir with ritonavir) is an oral antiviral used to treat COVID-19 positive patients. Preliminary evidence suggests Paxlovid™ is effective against Omicron. It reduces the risk of hospitalisation for those who have a higher risk of hospitalisation or becoming seriously unwell. These patients are going to be a subset of the patients who are receiving active management for their COVID-19 illness. It should be noted that the COVID vaccination booster dose is also very effective against reducing the rate of hospitalisation and should be prioritised for all people with higher risk conditions.

Special considerations

It is a 5 day course of two medicines:

- a protease inhibitor **nirmatrelvir** (2 pink tablets twice daily) that blocks virus replication
- **ritonavir** (1 white tablet twice daily) which slows the breakdown of nirmatrelvir.

Treatment is recommended to be started within 5 days of first symptoms.

Dose adjustment of the nirmatrelvir component is necessary where there is renal impairment.

Ritonavir is a potent CYP3A4 inhibitor and has multiple drug interactions which may require dose adjustment of either the ritonavir component of Paxlovid™ or the some of the usual medications.

A face-to-face consultation is not needed unless the clinician feels it is indicated.

There is currently no private supply. Prescriptions for off-label use or patients who do not meet eligibility criteria, will not be able to be dispensed.

2. Key Resources

- Pharmac Access Criteria
- Clinical guidance will be published on Health Pathways on Monday 4 April.
- The New Zealand Formulary (NZF) drug monograph for Paxlovid™
- He Ako Hiringa have a resource to guide review of drug interactions with Paxlovid™
- Paxlovid™ datasheet

Paxlovid™ is new to the market, and information about its prescribing and dispensing safety is important to consider. The use of Paxlovid™ is further complicated by the large number of clinically important drug-drug interactions. For these reasons, pharmacists and prescribers are strongly encouraged to keep up to date with training opportunities, and drug information.

A Webinar, with a focus on COVID-19 therapeutics (HealthPathways, Ministry of Health, RNZCGP, Pharmac) is planned for 13 April.

3. Responsibilities

Distribution:

- Paxlovid™ is being distributed by the wholesaler to participating pharmacies that have been selected on the basis of their capacity to service high needs populations.
- Participating pharmacies have been determined at a local level. Details will be available on HealthPathways on Monday 4th April.

Prescribing:

- Eligible patients will be identified and confirmed as meeting access criteria on the initial clinical assessment of the COVID-19 positive case.
- The prescriber has the responsibility for ensuring the dose is appropriate for the renal function, that potential drug interactions are being managed appropriately, and that there are no other contraindications. The prescription will be sent to the local participating pharmacy.

Dispensing:

- The participating pharmacy will ensure the patient is aware of the drug interactions, and how to adjust their medications if necessary. This may entail contacting the patient's usual pharmacy if the participating pharmacy is not the patient's usual pharmacy. The pharmacy will dispense the medicine, provide advice to the patient, and organise delivery.

Monitoring:

- The Ministry of Health and Pharmac will be regularly reviewing supply and COVID-19 case data to inform stock management, and quality control processes.
- Paxlovid™ is new to the market, and information about its safety and effectiveness is limited. It is therefore important for pharmacists and prescribers to report any side effects to CARM.

4. Process details

Prescriber

How will the COVID-19 positive cases who are at higher risk of hospitalisation be identified?

- A desktop risk assessment for COVID-19 cases will identify the COVID-19 positive individuals who need an initial clinical assessment.
- The eligibility for treatment will be determined using clinical judgement and access criteria. This assessment and the prescribing process are undertaken on the initial COVID-19 Care in Community initial clinical assessment consultation.
- Many practices will already be aware of several of their patients who are most vulnerable (for example, the severely immunosuppressed include those that were eligible for third primary dose of COVID-19 vaccination).
- Cases that aren't enrolled with local GP will be prioritised at Care Coordination Hub level for an initial clinical assessment based on age, ethnicity and vaccination status. Information provided on the NCTS self-assessment form will assist with prioritisation and allocation to clinical provider.
- Prescriptions for Paxlovid™ must be endorsed by the prescriber confirming that the patient meets the Pharmac Access Criteria (note this is not a Special Authority process).

Checks and considerations when prescribing Paxlovid™

- Check whether the patient meets the Pharmac access criteria.
- Review suitability of the therapeutic, specifically any contraindications and whether the patient wishes for active intervention.
- Review renal function.
- Check for potential drug interactions.

- Manage any necessary dose adjustments of medications, communicate this clearly to the patient and document details in notes. The dispensing pharmacist will also be undertaking a medication review and will need to be able to contact you with any concerns.
- Document key information on prescription, including endorsing that the person meets the access criteria, Day Zero, latest eGFR (if available), prescribers contact phone number.
- The contact number provided to the pharmacist needs to support easy access or urgent queries regarding medication management. Due to the tight timelines involved, prescribers and practices are asked to prioritise calls from the pharmacists.
- Issue the prescription and send electronically to the local participating pharmacy.

What needs to happen next?

- Active case management will include regular review and management of clinical progress.
- Check for adverse effects and send report of these to CARM.
- Audit of prescriptions, including eligibility criteria and outcomes is encouraged.

Pharmacists

Who is the wholesaler?

Pharmac have contracted ProPharma as the wholesaler for Paxlovid™.

What are participating pharmacies?

Due to limited stock, and to help ensure equitable access to Paxlovid™, a number of participating pharmacies have been identified to deliver this service. These pharmacies have been identified locally and can be updated over time.

Only participating pharmacies are able to order and supply Paxlovid™.

How do I order stock of Paxlovid™?

Stock of Paxlovid™ can be ordered from ProPharma using standard processes. Initially, there will be allocations of stock to each DHB. Further guidance will be provided to pharmacies around how this works in practice.

What do I need to do when reviewing a script for Paxlovid™?

Every prescription must be reviewed for completeness and appropriateness, including:

- Reviewing the potential for drug interactions and their appropriate management. The participating pharmacy may need to access a shared patient information database (e.g. Testsafe), or contact the general practice, patient, or patient's usual pharmacy if an up-to-date list of medicines is not readily available.
- Checking the therapy is appropriate where renal impairment is present. The prescriber should record the patient's most recent renal function (if available) on the prescription.

- Check that any other contraindications have been identified and appropriately managed.
- Ensure that Paxlovid™ can be initiated within five days of symptom onset. The prescriber should annotate what Day Zero is on the prescription.
- Ensure the prescription is endorsed that the patient meets Pharmac's access criteria.

Pharmacists will need to contact the prescriber if there are any clinical issues with the prescription and resolve these collaboratively. 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 or care coordination hub.

How do I dispense Paxlovid™?

The dispensing process for Paxlovid™ is largely the same as any medicine. The pharmacist will physically need to adjust the whole-pack for renal impairment for the patient and ensure the instruction label states a renal dose.

How is Paxlovid™ delivered to patients?

Pharmacies can use existing local courier networks to deliver Paxlovid™ to patients. Pharmacies are encouraged to collaborated with local care coordination hubs if delivering Paxlovid™ to hard-to-reach areas is an issue.

When counselling a patient:

- Provide them with a copy of the Health Navigator Paxlovid™ information sheet.
- Advise them to contact the prescriber or pharmacy if they experience adverse events or worsening of condition.

How am I funded for supplying Paxlovid™?

Paxlovid™ (and the delivery) is **free of charge** to eligible patients.

Paxlovid™ is listed as XPharm on the Pharmaceutical Schedule, meaning pharmacies are not able to claim subsidy through normal claiming systems as alternative funding arrangements have been established.

COVID-19 Care in the Community funding will cover the costs of pharmacists' medicines management activities, and delivery of the medicine to the patient. There is no co-payment associated with this medicine.

DHBs are responsible for ensuring that systems are in place to enable claiming of this funding.

The Patient Journey

How will I know if I'm eligible?

- There is advice for people with COVID 19 who are at higher risk on the Ministry of Health website.

- Your GP team will be aware of your underlying conditions and will be in touch with you to assess your condition, and whether the treatment is suitable for you, once they know you are COVID-19 positive.
- If you are receiving COVID-19 care from a different healthcare provider, the healthcare provider will be alerted to your underlying conditions by the information you have provided on the self-assessment form.
- If you are not in the same locality as your enrolled GP, or have no enrolled GP, and have not completed the online self-assessment form, the Care Coordination Hub will call you to assess your needs.
- You can call Healthline or GP practice if you are concerned about being severely unwell with COVID 19.

How will I get the medication in time?

- Get tested as soon as symptoms develop. If you test positive for COVID-19, your Day Zero is the day you first experienced symptoms.
- Once you have received a text confirming your COVID-19 infection, if you are at risk of severe illness, you should receive an initial clinical assessment within 24 hours.
- If you are at risk of severe illness, the decision and planning for your COVID 19 care will be on the initial clinical assessment.
- The prescription will be sent directly to the participating pharmacy, who will arrange delivery of the medication in time to start before the end of your Day 5.

Will it cost me anything?

- No, the testing, clinical assessment, prescription, advice and delivery are all covered by the COVID-19 Care in Community funding and free to eligible patients.