

Advance Prescriptions for Oral COVID-19 Antiviral Medicines

Guidance for relevant appropriately qualified prescribers and pharmacists

On 14 July 2022, the Minister for COVID-19 Response Hon Dr Ayesha Verrall announced that eligible patients could receive an advance ("back pocket") prescription for the following oral COVID-19 antiviral medicines - Nirmatrelvir with ritonavir (Paxlovid) and Molnupiravir (Lagevrio).

The purpose of this guidance document is to:

- 1. Clarify when and why this may be appropriate; and
- 2. Provide additional guidance and support for prescribers and pharmacists.

Background

This was one of several initiatives designed to improve timeliness of access to COVID-19 antivirals for those who need them. Other changes that were implemented, include the reclassification of these medicines from "prescription-only" to "restricted" or "pharmacist-only" medicines, enabling pharmacists to supply the medicines to eligible patients without a prescription from an prescriber.

Advance prescriptions can provide assurance to someone at high risk of poor COVID-19 related health outcomes that they will be able to access these COVID-19 antiviral medicines when needed, acknowledging the window of effectiveness is very tight between symptom onset and time needed to initiate treatment.

Situations where issuing of advance prescriptions may be particularly useful are:

- for patients who are at very high risk of becoming infected with COVID-19 in the near future
 e.g. patients who meet eligibility criteria, and who are household contacts but not yet
 symptomatic or COVID-19 positive, but may become a case in the near future.
- Patients who are travelling to other regions within New Zealand and may struggle to contact their usual health provider at that time.
- Patients who live in remote and rural areas and limited availability of primary care or pharmacies that can provide anti-viral medication without a prescription.

Primary care teams will be able to identify those people who would gain most benefit from an advanced prescription. It is anticipated that there is likely to be a short intervening period between the issuing of the advance prescription and when it is likely to be dispensed. It is not expected that advance prescriptions will be issued for all those eligible for COVID-19 anti-viral medication, it is aimed to be targeted for those deemed most clinically appropriate, at the discretion of the prescriber.

Consultation in advance provides an opportunity for an in-person or virtual conversation about oral therapeutics and education on the oral anti-viral therapies and potential side effects. The funding for an advance prescription is to be used when this is the sole focus of the consult. It also provides an opportunity to undertake any tests that would support the safe use of oral COVID-19 antiviral medicines, such as renal function when clinically indicated. Once a person is COVID-19 positive, inperson encounters are kept to a minimum.

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Eligibility

Pharmac has confirmed its position on advance prescriptions: as long as a person meets the eligibility criteria at the time of supply of the medication, then there is no impediment to issuing or dispensing an advance prescription.

This means that whilst the *prescription* can be provided in advance to people that meet the <u>Pharmac eligibility criteria</u> (other than the requirements relating to being a current COVID-19 <u>confirmed or probable case</u>), the medicine *cannot be dispensed* by a pharmacist until all the eligibility criteria are met, including the requirements relating to being a current COVID-19 <u>confirmed or probable case</u>.

To be eligible for an advance prescription for oral COVID-19 therapeutic agents, the patient must meet <u>Pharmac eligibility criteria</u> (other than the requirements relating to being a current COVID-19 <u>confirmed or probable case</u>).

For an advance prescription to be dispensed, the patient must meet ALL of the Pharmac eligibility criteria (including the requirements relating to being a current COVID-19 confirmed or probable case).

Advance prescriptions remain valid for 90 days, in line with existing Pharmac guidelines for the prescription of funded medicines.

Clinical assessment

As is current practice, at each stage in the process, the responsible clinician will undertake a review to ensure it safe for the patient to take this medicine.

Note that the medicine will not be dispensed until the person has been determined to be a <u>confirmed or probable case</u>, therefore advance prescriptions are not appropriate for people who are seeking COVID-19 therapeutics to take with them on overseas travel.

Prescribing and endorsements

Advance prescriptions for oral COVID-19 antiviral medicines will not be clinically appropriate for some patients that otherwise meet the eligibility criteria. There is no obligation for a clinician to issue an advance prescription.

Prescribers must exercise their clinical judgement to consider whether it is appropriate to issue an advance prescription in relation to the patient's clinical needs. Considerations may include:

- Note that the medicine will not be dispensed until the person becomes a COVID-19 case
- What is the chance of a significant change in either renal function or other medicines in the next 90 days?
- Does the patient and/or whānau have a good understanding of use of the advance prescription?

It is critical that prescribers clearly indicate endorsements on the advance prescription. This will ensure important information is communicated to pharmacists and streamlines processes if/when a patient tests positive for COVID-19 and requires the prescription to be filled.

The endorsements MUST include:

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- 1. 'Advance Prescription. Meets Pharmac eligibility criteria (other than the requirements relating to having a current COVID-19 infection)'
- 2. 'Not to be dispensed until diagnosed with COVID-19'
- 3. Renal function information
- 4. Prescriber's contact details (including out of hours which could be the local COVID-19 hub if appropriate)
- 5. 'Non-funded' if privately funded molnupiravir

Electronic prescriptions are preferred over paper prescriptions. Before issuing an advance prescription, prescribers should consider which pharmacy is most appropriate. Considerations should include patient/whānau preference, any planned domestic travel, extended opening hours, and current pharmacy suppliers of these medicines. Healthpoint holds details of <u>supplying pharmacies</u>. To search: By Service, select 'Pharmacy'; Service Area, select 'COVID-19 antiviral medicines (if you have a prescription from your doctor or nurse)'.

Expiration of advance prescription

An advance prescription done for COVID-19 antiviral medication will expire 90 days after the prescription is issued (as per standard prescriptions). It is therefore important to ensure patients are aware of this.

Dispensing

When a patient develops COVID-19 and proceeds to fill the prescription, the pharmacist undertakes a clinical, laboratory test (if necessary), and medicines review, following existing processes. Considerations may include:

- Current clinical assessment is the patient currently very unwell? Could there be an alternative diagnosis?
- Is renal function or other medicines likely to have changed since the prescription was issued?
- Are there any new medicines that interact with the COVID-19 antiviral?
- Does the patient and/or whānau understand how to use the medicine, its side effects, when to seek medical advice, and substances to avoid while taking it?
- Referral back to the prescriber may be necessary if the clinical situation has changed since the prescription was issued.

COVID-19 is self-reported under current high trust settings. If a patient has self-reported a positive RAT through My COVID Record, it can be seen in the COVID Care in the Community Module (CCCM) electronic system. If the patient has not yet self-reported their positive test, the pharmacist should encourage or assist them to do so, to ensure appropriate follow-up and monitoring can occur. If the patient is unable, or refuses, to log their positive RAT result in My COVID Record, the pharmacist must create a case in CCCM. Refer to the CCCM training material on how to achieve this.

Once dispensed, the COVID-19 antiviral medicine should be delivered to the patient's home (or place of self-isolation) if required (i.e. if they do not have whānau or friends who can collect on their behalf).

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Information for consumers

It is important for the prescriber and pharmacist to discuss with the patient correct use of the medicine, its side effects, when to seek medical advice, and medicines to avoid while taking it.

Interpreter services should be utilised where required. Whānau and others should be part of consultation as appropriate.

The importance of not sharing these medicines with family and friends should be emphasised.

Explaining to the patient that the advance prescription expires 90 days after it has been issued.

Many people experience an unpleasant taste in the mouth while taking Paxlovid. The importance of completing the full course despite this should be emphasised.



Process Map – Advance prescriptions for Oral COVID-19 antiviral medicines

| | Prescription in advance is sought | Clinical consultation | Medicine is prescribed | Medicine is dispensed |
|------------|---|---|--|--|
| Who | Patient | | Prescriber ¹ | Pharmacist |
| Activities | prescriber OR prescriber contacts patient • Contact may be using telehealth (video/phone) OR in-person as clinically | Conduct clinical review and medicine counselling² Use telehealth OR inperson as clinically appropriate Explain the purpose and correct use of advance prescription (set expectations) If clinically appropriate, the clinician requests a renal function test | Add endorsements to prescription: 'Advance Prescription. Meets Pharmac criteria (other than the requirements relating to having a current COVID-19 infection)' 'Not to be dispensed until diagnosed with COVID-19' Renal function information Prescriber's contact details (including after-hours, which could be the local COVID-19 hub if appropriate) 'Non-funded' if privately funded molnupiravir (Lagevrio) Select which pharmacy based on patient/whānau preference, domestic travel plans, extended opening hours, and current pharmacies offering dispensing of COVID antiviral medicines³ Issue prescription⁴ | Review the patient's eligibility criteria (including being COVID-19 case), clinical status and other medicines⁵ CCCM holds details of self-reported cases⁶ Discuss use of the medicine, side effects, when to seek medical advice, substances to avoid Referral back to prescriber may be necessary if clinical situation has changed since prescription was issued⁷ Dispense the medicine Telehealth consultations only |
| Equity | Consultation in-person in advance of becoming a COVID-19 case provides an opportunity to discuss these medicines for those less able to do so using telehealth Utilise interpreter services where required. Include whānau and others as appropriate Reinforce the importance of not sharing these medicines with family and friends as it may be harmful to them | | | |
| Funding | • An extension of existing funding rates which were previously agreed for general practice and pharmacy encounters relating to COVID-19 ⁸ | | | |

Notes

- ¹ Any authorised prescriber within their area of practice i.e. pharmacist prescriber, nurse practitioner, medical doctor, or designated (registered) nurse prescriber
- ² All Pharmac eligibility criteria must be met EXCEPT for the requirement relating to having a current COVID-19 infection (must be determined to be COVID-19 <u>case</u> for prescription to be dispensed). There is no requirement to prescribe COVID-19 antivirals in advance if this is not clinically appropriate
- ³ (See list in <u>Healthpoint</u>. To search: By Service, select 'Pharmacy'; Service Area, select 'COVID-19 antiviral medicines (if you have a prescription from your doctor or nurse)'
- ⁴ Electronic prescriptions preferred. Advance prescription remains valid for 90 days
- ⁵ Ensure all eligibility criteria are met before dispensing, **including being a** <u>COVID-19 case</u>
- ⁶ If the patient has not yet self-reported a positive test result on My Covid Record, encourage or assist them to do so. If the patient is unable, or refuses, to log their positive RAT result in My COVID Record, the pharmacist must create a case in CCCM. Refer to the CCCM training material for instructions
- ⁷ Contact local COVID Hub for support if prescriber unavailable
- $^{\rm 8}$ Funding applies regardless of the mode of consultation or the type of prescriber

FAQ: Advance Prescriptions for Oral COVID-19 Antiviral Medicines

1. How is a 'probable' COVID-19 case defined?

The COVID-19 case definitions below can also be found on the Ministry of Health website.

2. How does the pharmacist confirm COVID status?

CCCM holds details of self-reported cases. If the patient has not yet self-reported a positive result, encourage or assist them to do so. If the patient is unable, or refuses, to log their positive RAT result in My COVID Record the pharmacist must create a case in CCCM. Refer to the CCCM training material on how to achieve this (see Tell

3. Is there a list of pharmacies supplying these medicines?

<u>Healthpoint</u> has a list of <u>supplying pharmacies</u>. (To search use: By Service, select 'Pharmacy'; Service Area, select 'COVID-19 antiviral medicines (if you have a prescription from your doctor or nurse)'

4. What should the pharmacist do if they can't get hold of the prescriber?

Referral back to prescriber may be necessary if clinical situation has changed since the advance prescription was issued.

If the prescriber is not available, the pharmacist can contact the local COVID Hub or the Whakarongarau Clinical support line.

5. What if the person is out of town when they get COVID-19?

The prescriber should include any domestic travel plans when considering which pharmacy to issue the prescription to.

If the prescription has been put 'on hold' by a pharmacy in the New Zealand electronic Prescription Service (NZePS), only that pharmacy can dispense it. It the same challenge if the 'on hold' pharmacy is closed after-hours and/or weekends etc. when the person becomes COVID-19 positive.

On 27 July 2022, the oral COVID-19 antiviral medicines were reclassified as 'restricted ('pharmacy only') medicines. This means an alternative is to obtain a pharmacist-initiated supply from a participating pharmacy (i.e., there is no need for an advance prescription).

Healthpoint has a <u>list of pharmacies</u> that are supplying COVID-19 antiviral medicines without need for a prescription from an authorised prescriber. To search use: By Service, select 'Pharmacy'; Service Area, select 'COVID-19 antiviral medicines (if you have a prescription from your doctor or nurse)'

6. How will the pharmacist check possible medicine interactions for a patient that does not usually have their medicines dispensed from that pharmacy?

This is the case with any prescribing or supply from a practitioner who is not the patient's usual GP, or even the usual GP. It is incumbent on the dispensing pharmacist to assure themselves that there is not a possibility of a significant medicine interaction. Pharmacists should use usual processes to confirm current medications. A patient's medicines list is typically available through the COVID Care in the Community Module (CCCM) and/or the regional clinical information sharing services (eg, TestSafe, HealthOne, reCare).

7. Medicines may have been prescribed by secondary care practitioners without the GP knowing. How can the GP check for interactions?

This is a potential problem with all prescribing. Secondary care clinicians should inform the patient's GP that an advance prescription has been issued, and prescribers and dispensers should routinely ask about new medications.

If the hospital-generated prescription was dispensed by a community pharmacy the medicine(s) are also captured in the New Zealand electronic Prescription Service (NZePS) and will usually be available through the COVID Care in the Community Module (CCCM) and/or the regional clinical information sharing services (eg, TestSafe, HealthOne, reCare).

8. How should the pharmacist check for interactions for new medicines prescribed between prescription and dispensing?

The pharmacist who is dispensing an advance prescription should repeat a clinical, laboratory test (where required), and medicine review prior to dispensing the medicine. Guidance on the management of interactions between Paxlovid and other medicines is available on the <u>University of Liverpool's COVID-19 interaction checker</u>, and then the <u>Ontario Science Brief</u> should be consulted for specific advice on management of interactions.

9. Can patients request an advance prescription to carry with them while they travel overseas?

No. Advance prescriptions are not appropriate for people who wish to access COVID-19 antiviral medicines to take with them on overseas travel. The oral COVID-19 antiviral medicines can only be dispensed if the person has been diagnosed as a confirmed or probable COVID-19 case.

10.Are pharmacists expected to check liver dysfunction for a restricted medicine supply of Paxlovid?

A pharmacist will need to have access to current laboratory results in order assess liver function before dispensing Paxlovid. Further guidance is provided in the <u>Te Whatu Ora /Pharmaceutical Society of New Zealand pharmacist training material</u>. If the pharmacist has any concern about liver function they should discuss this with the prescriber. See question 4 for advice if the prescriber is not available.

11. Who can issue an advanced prescription?

Any authorised prescriber within their area of practice, including pharmacist prescriber, nurse practitioner, medical doctor, or designated (registered) nurse prescriber, may prescribe the oral COVID-19 antiviral medicines Paxlovid and molnupiravir.

12.Is a general practice expected to identify all their potentially eligible patients?

There is no expectation that practices must proactively offer advance prescriptions to their patients who are most at risk. Practitioners are not obligated to offer an advance prescription unless they have determined that it is clinically appropriate to do so. As with any prescription, the practitioner is still required to conduct a clinical, laboratory test (as required), and medicines review prior to prescribing or dispensing oral COVID-19 antiviral medicines.

13. What if a patient is seeking molnupiravir privately?

If a patient is seeking privately funded molnupiravir, the prescription must be endorsed 'Nonfunded'. The patient will have to pay the full cost of the medicine supply.

Note: No privately funded Paxlovid is available in New Zealand. All the Paxlovid in New Zealand is publicly funded, and people must meet the Pharmac eligibility criteria to receive Paxlovid.