NEWS

GPs will soon be able to prescribe two new COVID treatments

Anastasia Tsirtsakis

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The TGA's provisional approval of the first oral treatments for COVID-19 in Australia has been welcomed as a 'new hope'.

Clinical trial data on both antivirals has shown the treatments to be very effective in reducing death. (Image: Supplied/Pfizer)

GPs will soon have two new treatments in their arsenal to help prevent severe disease in high-risk patients, including the elderly and immunocompromised, who test positive to COVID-19.

The Therapeutic Goods Administration (TGA) released a statement on Thursday confirming the regulator has provisionally approved two oral antivirals, molnupiravir (sold as Lagevrio) and nirmatrelvir in combination with ritonavir (sold as Paxlovid).

Speaking at a press conference following the announcement, Federal Health Minister Greg Hunt said the medicines will be available 'subject to prescription by a general practice or in the hospital environment' at no cost to the patient.

'If it's your GP that's prescribing it, it will be available from a pharmacist,' Minister Hunt said.

'So simple and easy, subject to the gateway of a GP focusing on both the need, the efficacy and the safety elements.

'This is about new hope and new protection.'

Both antivirals have been approved for use in patients aged 18 and over who develop mild-to-moderate COVID-19 and do not require initiation of oxygen but are deemed to be at increased risk of progression to hospitalisation or death.

To be effective, either treatment must be administered within five days of the onset of symptoms.

The Australian Government has secured access to 500,000 treatment courses of nirmatrelvir and ritonavir, and 300,000 courses of molnupiravir, with the first deliveries anticipated in the coming weeks.

Dr Anita Muñoz, who is Chair of the RACGP's Victorian Faculty and a member of the college's COVID-19 Working Group, told *newsGP* the provisional approval of the treatments is a 'welcome development' given the pressures on Australia's health system.

'Anything that's going to help us reduce the severity of the disease and keep people out of hospital and out of ICU is very positive,' she said.

'We definitely hope that there will be good supply channel out into our most vulnerable communities, particularly regional and rural and certainly out into Aboriginal and Torres Strait Islander communities to make sure that every Australian who's eligible for the drug has equal access to it.'

However, Dr Muñoz notes that it will be important to establish precise prescribing guidelines so that GPs can better understand the context within which the treatments can be used.

'Once that detail is made available, we'll be more or less a step away from the use of the drugs becoming a reality,' she said.

'And of course then we will need some solid information about the drugs themselves so that we can prescribe it safely and no doubt there will be, and we will call for, some succinct information and education for prescribers.'

Meanwhile, given both treatments are required to be administered as soon as possible, within five days of symptoms presenting, Dr Muñoz said that if access is dependent on a positive PCR or rapid antigen test (RAT) that success would be dependent on testing availability.

'And again, I circle back to my comments about vulnerable and remote communities. We need to absolutely make sure that they're not left behind,' she said.

In the meantime, TGA National Manager Professor John Skerritt said clinical guidance on priority groups is being worked out in

conjunction with the National COVID-19 Clinical Evidence Taskforce together with the various sectors, which is expected to be finalised in the coming days.

When asked whether one treatment is superior to another, Professor Skerritt said there is evidence both medicines are 'very effective in reducing death'.

'It's common and an ideal situation in medicine, whether for cancer or a virus or common things like diabetes, to have a selection of medicines because there will be times when one is indicated for certain groups of patients and one for another group of patients,' he said.

While acknowledging the important role of antiviral treatments in the fight against COVID, Professor Skerritt stressed that neither medicine is intended to be used as a substitute for vaccination.

'We do not want people to feel that if they can pop a pill they do not need to be vaccinated because for all infectious diseases, for decades, prevention has been better than cure,' he said.

'However, we realise that some individuals, maybe because of their weaker immune response or age or whatever, may still become ill with COVID if they're vaccinated, the same way with some other diseases.

'So in this case having a treatment is also beneficial, even if you are vaccinated.'

How do the treatments work?

Nirmatrelvir and ritonavir
Paxlovid is sold as separate tablets, with a dose of 300 mg of nirmatrelvir (two 150 mg tablets) and 100 mg of ritonavir recommended to be taken twice a day (every 12 hours) for five days.

Nirmatrelvir works by blocking the activity of a protease enzyme

required by SARS-CoV-2 in order to replicate. Meanwhile, a low dose of ritonavir helps to slow the metabolism of nirmatrelvir so that the drug can remain active in the body for longer periods of time and at higher concentrations.

Clinical trial data has so far been promising, with a final analysis of the phase 2/3 Evaluation of Protease Inhibition for COVID-19 in High-Risk Patients (EPIC-HR) demonstrating an 89% reduction in hospitalisation or death in patients treated within three days of symptom onset, compared to those who received a placebo, and an 88% reduction in those treated within five days.

In patients aged 65 and older, relative risk reduction was 94%, with just one out of 94 patients who received nirmatrelvir and ritonavir hospitalised and zero deaths recorded through day 28, compared to 16 hospitalisations and six deaths in the placebo group.

Earlier this week, Pfizer also released details of a study that suggest the treatment maintains its efficacy against COVID-19 infection caused by the Omicron variant.

While detailed clinical guidance has yet to be released, the antiviral is not recommended in patients who:

- are pregnant
- are breastfeeding
- have severely reduced kidney function
- have severely reduced liver function.

It is also advised that women of childbearing potential who are sexually active use contraception for the duration of the treatment.

Meanwhile, nirmatrelvir in combination with ritonavir is also contraindicated for patients who take a number of other commonly used medicines.

Product information on nirmatrelvir and ritonavir is available through the TGA website.

Molnupiravir
Molnupiravir will be available as 200 mg capsules, with the recommended 800 mg dose to be taken every 12 hours for five days.

The antiviral, which was originally developed to treat influenza, is absorbed by virus-infected cells, which then convert the molecules to inhibit replication of the SARS-CoV-2 virus. As molnupiravir is designed to target the RNA that makes up the virus' building blocks, it is anticipated that the drug could be effective against all variants, including Omicron.

Data from the MOVe-OUT trial found people who were treated with molnupiravir had a 7.3% risk of hospitalisation or death through to day 29, compared to 14.1% for the placebo group. During this period, only one death was reported in the molnupiravir group compared to nine in the placebo group.

As with nirmatrelvir, the antiviral is not recommended for use in women who are pregnant or breastfeeding, and it is advised that women of childbearing potential who are sexually active use contraception. Similarly, men prescribed the treatment are also advised to use contraception both during the treatment course and for three months after its completion.

Given that nirmatrelvir in combination with ritonavir does interact with a number of other drugs, Professor Skerritt said doctors may consider alternatives, if deemed clinically appropriate, such as molnupiravir.

'As it is the case for all prescribing of new medicines, it will be important for the doctor to look at what the individual is on ... and that will also influence the decision about whether or not they're an appropriate candidate for which one of these particular drugs,' he said.

Product information on molnupiravir is available through the TGA website.

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