Advertising

NEWS

COVID-19 antiviral pills to be reserved primarily for the unvaccinated

Jolyon Attwooll

3/02/2022 3:23:11 PM







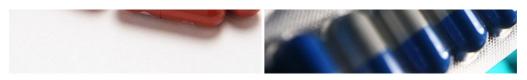




Despite TGA approval last month, the two new COVID-19 treatments developed by Pfizer and Merck will not be widely available for prescription in the short-term.







The efficacy of both molnupiravir and nirmatrelvir plus ritonavir is unclear in both vaccinated and partially vaccinated patients. (Images: AAP)

Unvaccinated COVID-19 patients will be the main focus of two new oral antiviral treatments recently approved for use in Australia, new clinical guidelines suggest.

Guidance for oral antiviral treatments molnupiravir (sold as Lagevrio) and nirmatrelvir plus ritonavir (Paxlovid) specify they should be considered for use at an early stage of the virus in unvaccinated adults at risk at disease progression.

The guidelines, which were released this week, highlight that trials did not include people who had received two vaccine doses, and that their efficacy is unclear in both vaccinated and partially vaccinated patients.

However, the guidance indicates the treatments can also be used by patients who are 'immunosuppressed or not immunocompetent' or at 'high risk of severe disease on the basis of age and multiple risk factors', regardless of vaccination status.

Both treatments were provisionally approved for use in COVID-19 patients aged 18 and over by the Therapeutic Goods Administration (TGA) last month.

The Federal Government has ordered 500,000 treatment courses of the Pfizer-developed nirmatrelvir plus ritonavir, while an order of 300,000 treatment courses of molnupiravir, developed by Merck, was confirmed in October.

But even though the new COVID-19 treatments are on their way to Australia, most GPs will need to exercise patience before they can prescribe them to patients.

On Monday this week, Federal Health Minister Greg Hunt said the first treatments 'will be made available to the states to assist with vulnerable groups during the course of this week'.

However, more precise details have been hard to establish.

The Department of Health (DoH) has described the arrival time as 'in the coming weeks' and 'imminent' but has not provided any further detail on timelines or available quantities when asked, citing 'commercial in confidence' arrangements with the drug developers.

A spokesperson for MSD (Merck Sharp & Dohme) said the company is 'working closely with Government to expedite delivery of Lagevrio to the National Medical Stockpile in accordance with the terms between MSD and the Australian Government'.

Meanwhile, a Pfizer spokesperson said they are working to have treatment courses delivered to Australia from the first quarter of this year.

Global supply shortages have impacted the number of treatment courses available in other countries where the drugs have been approved, and both companies noted the distribution of the treatments is the responsibility of the Australian Government.

As a result, supplies of both antiviral treatments will be restricted in the short-term for general practice, and limited to GP-led Respiratory Clinics in the early phases.

'The initial deliveries of oral treatments will be made available to states and territories, Aboriginal community controlled health services, GP Respiratory Clinics and residential aged care facilities through the National Medical Stockpile, who will ensure the most vulnerable Australians can access the oral treatments as soon as possible,' the DoH said in a statement provided to *newsGP*.

The department also said the Government is working with the companies on a Pharmaceutical Benefits Scheme (PBS) listing, which would allow widespread prescribing through general practice.

'By law medicines can only be listed on the PBS following a positive recommendation from the Pharmaceutical Benefits Advisory Committee [PBAC],' a spokesperson said.

Chief Medical Officer Professor Paul Kelly said this week that the country's most vulnerable communities will be the first recipients.

'Once the treatments do start to come into the country, the Australian Government will be working closely with the state and territory governments to ensure these treatments get distributed to those people who are most at risk,' he told reporters on Monday.

'This, in the first instance, is likely to include people infected in outbreaks in remote Aboriginal and Torres Strait Islander communities, and those infected in outbreaks in residential aged care and disability care settings.

'Then, over coming months, as supply increases, we may see more wide distribution available across the population.'

Dr Michael Bonning, a GP and the medical director at Inner West Respiratory Clinic in Sydney, welcomed the prospect of having access to the treatment.

'It is a really positive step to have oral treatments available soon through GP Respiratory Clinics as we often see people at high risk of deterioration of their COVID illness,' he told *newsGP*.

Dr Bonning said sotrovimab has worked well but is hard to access from outside the hospital system or major urban centres.

'Oral treatments will give greater equity to patients across the country,' he said.

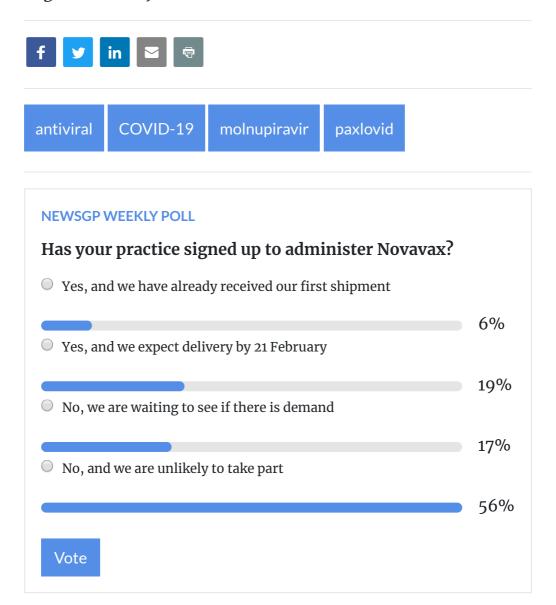
'GP Respiratory Clinics have a key role in providing comprehensive care in the community for COVID and these oral treatments will give options for management and prevent unnecessary hospitalisations.'

Dr Bonning also said the prescribing guidelines will need to be very clear so that GPs can be confident they are using the medications for the relevant patients.

'Just as there continues to be training for other elements of COVID prevention and care there should be prescribing education and tools made available so the right people get the right treatment at the right time,' he said.

The updated clinical guidelines published by the National COVID-19 Clinical Evidence Taskforce state the treatments should be administered within five days of symptom onset.

Log in below to join the conversation.



Login to comment

Dr Ian 4/02/2022 8:12:05 AM

There is another medication Remdesivir which has been used widely in Hospital for Covid 19 but was found to be effective if used early in the first few days of the infection in a trial by Gottleib R et Al written up in the NEJM Jan27 2022.

It now has authorisation by the National Institute of Health USA and reduced progression to severe disease in patients with Covid 19 with one risk factor by 87%.

General Practitioners ought be aware of this although it does require Intravenous administration but it ought be available.

This was also for unvaccinated patients who had not been hospitalised for Covid 19.

Whether it is to be expanded to high risk patients who have two vaccines but have not been boosted has not been declared.

Dr Edgard Arslan 4/02/2022 8:17:51 AM

This is good news, we have more weapon to overcome this devastating pandemic, specially for elderly nursing home resident (my main practice

).and immunosuppressed patients, i'm not sure about the unvaccinated, i think the same rules should be applied, If they are at risk and elderly we should provided to them, other wise young and healthy people their chance of having mild disease is very high nearly >99%. we are waiting for further clear guidelines from the TGA. i'm optimistic that we are heading toward treating this pandemic like the seasonal flu in the coming few months.

Dr Muhammad Igram Pervez 4/02/2022 9:34:31 AM

We may be nicely encouraging people to not to get vaccinated, wording could be changed for guideline!!

Dr Elizabeth Mary Miller 4/02/2022 1:10:15 PM

"Consider using molnupiravir within 5 days of symptom onset in unvaccinated* adults with COVID-19 who do not require oxygen and who have one or more risk factors for disease progression"

Why not add "unvaccinated" to the list of risk factors rather than highlighted as the primary group for therapy.

It sends an unintended message to unvaxed people reinforcing their decision & complicates the guidelines risking a dr in a stressed system deciding not to treat because a patient has been vaccinated. Sadly, some fully vaxed patients still end up in ICU.

Every dose should be used until this pandemic is done. Remember wasted stockpiles of Tamiflu during H1N1 2012.

Would RACGP consider a more succinct flow chart for early use & advocate for general access to therapy in primary care, while we applaud the initial availability to vulnerable groups including Aboriginal community health services and RACFs.

Access to medication should be about relative risk, not vaccination status.

Drs Beth&Mark

Oral treatment should have been number one than well experienced vaccines.



Terms and conditions | Privacy statement | RACGP | recruit GP | AJGP

© 2018 The Royal Australian College of General Practitioners (RACGP) ABN 34 000 223 807