Ministers
Department of Health and Aged Care

This content relates to a former minister

TGA approves new COVID-19 treatment for use in Australia

Australians with COVID-19 who are at risk of hospitalisation will now have access to an additional antibody treatment, as the Therapeutic Goods Administration (TGA) announced today it has granted provisional approval for sotrovimab to be used in Australia.

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Australians with COVID-19 who are at risk of hospitalisation will now have access to an additional antibody treatment, as the Therapeutic Goods Administration (TGA) announced today it has granted provisional approval for sotrovimab to be used in Australia.

Earlier this month, the Australian Government secured an initial allocation of over 7,700 doses of the novel monoclonal antibody treatment sotrovimab and a first shipment is already in the country and ready to be deployed through the National Medical Stockpile from next week.

The sotrovimab treatment requires a single dose to be administered through an intravenous (IV) infusion in a health care facility and has been shown to reduce hospitalisation or death by 79 per cent in adults with mild to moderate COVID-19, who are at risk of developing severe COVID-19.

Minister for Health and Aged Care, Greg Hunt, said sotrovimab will provide an important new way to treat the disease and reduce hospitalisations for people who are most at risk from COVID-19.

“Vaccination remains the most important and safest way for Australians to protect themselves and their loved ones from COVID-19 – and I continue to thank Australians for their take up of the COVID-19 vaccine,” Minister Hunt said.

“This treatment will provide another tool in the ongoing challenge against COVID-19, in addition to the COVID-19 vaccines, which are being rolled out in record numbers across the country.”

Sotrovimab will provide further options to protect vulnerable Australians at risk of developing severe COVID-19, however, not all Australians with COVID-19 will need to access the treatment.

It is expected that sotrovimab will be targeted for the treatment of Australians over 55 years old who have COVID-19 and also have one or more of the following risk factors for disease progression – diabetes, obesity, chronic kidney disease, heart failure, lung disease and moderate to severe asthma.

The National COVID-19 Clinical Evidence Taskforce is finalising its recommendation for use. People who are asymptomatic or who are not at risk of developing severe COVID-19 will not require access to sotrovimab.

Medical experts estimate that eight to 15 per cent of adults with COVID-19 will be recommended for treatment with sotrovimab and this treatment must be given within five days of symptoms onset.

Where a doctor prescribes this treatment for their patients with mild to moderate COVID-19, who are at risk of developing severe COVID-19, it will be made available free of charge through the public health system.

The TGA has given approval to GlaxoSmithKline (GSK) Australia Pty Ltd to make sotrovimab available for use in Australia. It is the second COVID-19 treatment to receive regulatory approval in Australia, following the TGA's approval of Remdesivir.

Sotrovimab is approved for emergency use in the US, Singapore and Canada, however Australia is the first OECD country to issue a formal regulatory approval for sotrovimab.

As with all products procured for the Stockpile, this treatment will be provided to states and territories as needed.

Australia's purchase of sotrovimab has been supported by the Science and Industry Technical Advisory Group (SITAG), which is the Australian Government's expert group advising on COVID-19 vaccine and treatment purchases.

Tags:

Communicable diseases | Immunisation

Former ministers:
The Hon Greg Hunt MP