Sotrovimab Guidance for GPs

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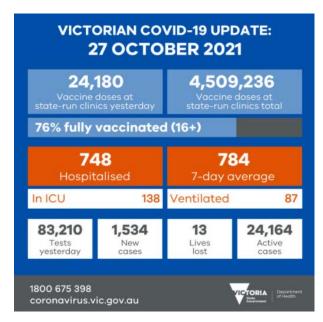
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Wednesday 27 October 2021



Victoria's sixth lockdown ended - Thursday 21 October 2021, at 11:59pm

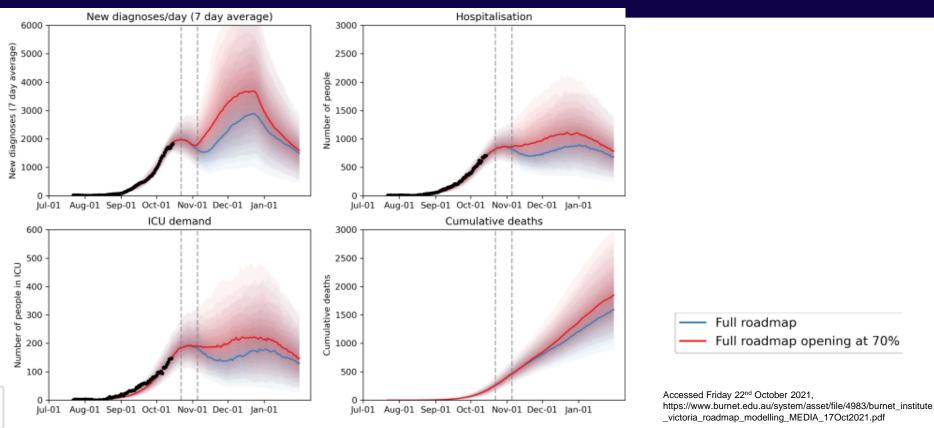


			each point in the roadmap, easing restrictions will depend on public health adv as to the surrent epidemiology		
DELIVERING THE NATIONAL PLAN		National Plan: Phase B	Check the full How We Live and How	on including full industry settings pileo We Work roadmaps National Piers Phase D	
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Accessed Wednesday 27 October 2021; https://twitter.com/VicGovDH/status/1453119779036794882/photo/1 Accessed Wednesday 27 October 2021, file:///C:/Users/dwhi0303/Downloads/Victorias-roadmap-summary-25Octv2web.pdf

Victoria's next few months Burnet Institute's roadmap scenario: opening at 70%



Dashed vertical lines represent estimated dates of reaching 70% and 80% two-dose coverage among people 16+

- In August 2021, the Therapeutic Goods Administration provisionally approved the use of Sotrovimab for the treatment of COVID-19 in adults
- The National COVID-19 Clinical Evidence Taskforce recommends the use of Sotrovimab to reduce the risk of hospitalisation <u>https://covid19evidence.net.au/#living-guidelines</u>
- This treatment is for mild COVID-19 in patients who are at increased risk of progression to hospitalisation or death
- Provisional approval is based on the COMET-ICE trial which demonstrated a 79% reduction in hospitalisations >24 hours
- Novel monoclonal antibody

Governance of Sotrovimab

- Federally approved and managed through the National Medical Stockpile the state supply chain held through Alfred Health
- Initial limited supply to Australia, this has now been increased to an additional 15,000 doses
- Over the last week on average approximately 25 doses have been administered in Victoria on a daily basis. Overall, Vic and NSW have administered similar numbers, with NSW slightly more.
- As more health services begin to administer, use is expected to rise

Criteria for use:

- Confirmed SARS-CoV2
- < 5 days from onset of symptoms
- No oxygen requirement
- Either unvaccinated or partially vaccinated with risk factors

or

Immunosuppressed (irrespective of vaccination status)

It is recommended pregnant women in the second or third trimester who meet the inclusion criteria above be administered Sotrovimab. Can be used in adolescents (12 years and older and >40kg)

Either unvaccinated or partially vaccinated with risk factors (at least one)

- Diabetes (requiring medication)
- Obesity (BMI > 30 kg/m2)
- Chronic kidney disease (i.e. eGFR < 60 by MDRD)
- Congestive heart failure (NYHA class II or greater)
- Moderate-to-severe asthma (requiring an inhaled steroid to control symptoms or prescribed a course of oral steroids in the previous 12 months)
- Age \geq 55 years
- Chronic obstructive pulmonary disease (history of chronic bronchitis, chronic obstructive lung disease, or emphysema with dyspnoea on physical exertion)

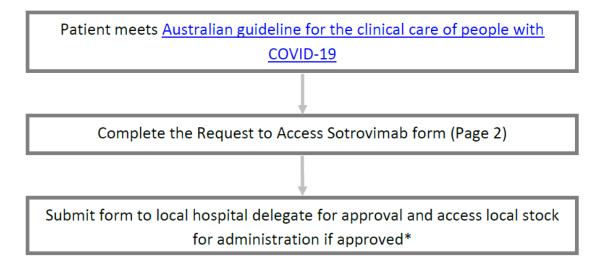
Immunosuppressed criteria:

- Primary or acquired immunodeficiency
- Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes
- Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months)
- Other significantly immunocompromising conditions.
- Immunosuppressive therapy (current or recent) examples include:
 - o Chemotherapy or radiotherapy
 - High-dose corticosteroids (\geq 20 mg of prednisone per day, or equivalent) for \geq 14 days
 - All biologics and most disease-modifying anti-rheumatic drugs (DMARDs)
 OFFICIAL

Medication administration

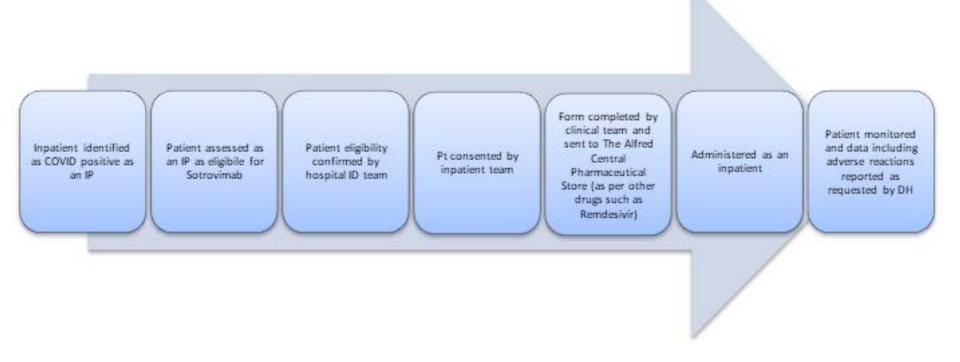
- Sotrovimab is administered as an IV infusion over 30 minutes
- Single dose only
- Requires post administration observation for 60 minutes
- No adverse events have been recorded in Australia to date

Access and administration approval process



*NOTE: Stock will be supplied by Alfred Pharmacy and organised by the local hospital pharmacy department for approved patients

Inpatient model: identified as COVID positive and eligible



Outpatient models

ED presentation – Sotrovimab may be administered if appropriate physical environment and suitably trained staff are present.

Outpatient clinic – physical separation from other patient areas, dedicated separate patient access, clinical oversight, ventilation requirements and transport needs discussed.



Who to contact if you have a patient you believe is eligible for Sotrovimab

Intake and assessment lead services

North East Metro Health Service Partnership Lead health service: Austin Health Intake number: 03 9496 6606 Email: <u>COVIDcarepathways@austin.org.au</u> Days/hours of operation: Mon-Fri 8am-8pm; Sat-Sun 8am-12pm

South East Metro Health Service Partnership Lead health service: Monash Health Intake lead: Central Bayside Community Heath Service Intake number: 03 8587 0359 Email:<u>intake1@cbchs.org.au</u> flag 'COVID pathway' Days/hours of operation: 9am - 5pm; 7 days per week

West Metro Health Service Partnership Lead health service: Melbourne Health Intake lead: Werribee Mercy Hospital Intake number: 03 8754 3000 Email: <u>covidnotifications@mercy.com.au</u> Days/hours of operation: 9am - 5pm; 7 days per week

Barwon Health Intake number: 1300 942 241 Email: <u>phu@barwonhealth.org.au</u> Days/hours of operation: 8am - 8 pm; 7 days per week Intake and assessment lead services

Latrobe Regional Hospital Intake number: (03) 5173 5451 Email: <u>phu@lrh.com.au</u> Days/hours of operation: 8am - 5pm; 7 days per week

Ballarat Health Services Intake number: 0428 493 084 Email:<u>phu@bhs.org.au</u> Days/hours of operation: 24 hours a day; 7 days per week

Goulburn Valley Health Intake number: 1800 313 070 Email: <u>phu@gvhealth.org.au</u> Days/hours of operation: Normal hours: Monday to Friday 8:30am to 5:00pm Outbreak hours: 7 days per week 8:00am to 8:00pm

Albury Wodonga Health Intake number: 0400 645 476 Email: <u>phu@awh@org.au</u> Days/hours of operation: 8:00am to 5:00pm; 7 days per week

Bendigo Health Intake number: 1800 959 400 and 03 5454 9139 Email: <u>phu@bendigohealth.org.au</u> Days/hours of operation: 8:30am to 8:30pm; 7 days per week

Considerations for the Sotrovimab model of care

- Resource requirements and efficiencies
- Requires at least one nurse and one doctor and up to 2 hours per patient
- Risk associated with ventilation and physical space and exposure to multiple COVID+ve patients in an unknown environment

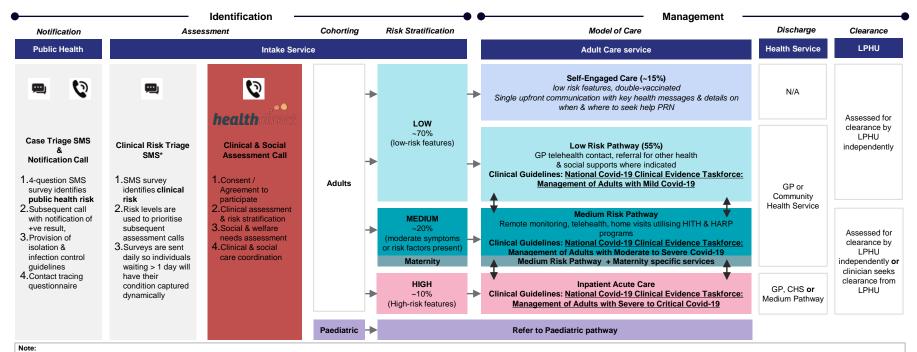
Due to these resources and requirements, although considered, primary care settings including the HITH model were deemed not appropriate.

Other current challenges

- Sotrovimab eligibility requirements:
 - Approx 8-15% of COVID positive patients will be eligible
 - < 5 day symptom onset, a challenge to get eligible patients in time
 - As vaccination status in the country increases, eligibility will decrease
 - Access for Aboriginal people
 - Reviewing criteria for age and culturally safe access for communities in consultation with Aboriginal Community Controlled Organisations

Covid Positive Care Pathways: Adults

Summary of all care pathways



* The Clinical Risk Triage SMS is only operational in catchments utilising Covid Monitor

- All COVID+ patients are assessed for clearance from the Program by the LPHU. For patients under Inpatient Acute Care, this may also be done by the treating delegated clinician.

- After 14 days, if clinically appropriate, the health service will discharge the patient and seek clearance from the LPHU.

Covid-19 Positive Pathways

October 2021

Self-Engaged Pathway Criteria defining the self-engaged care cohort

Criteria	Proposed parameter	Details			
Conditions		All must apply			
Age	<65	-			
Vaccination Status	Fully vaccinated	Individual has received two doses of a Covid-19 vaccine			
Pregnancy	Not pregnant				
Social	No barrier to home isolation	Individual does not need any support to isolate at home (e.g. food or medicine delivery)			
Symptoms	Nil or Mild	See Appendix 1 for CLEG-endorsed symptom classification (2020)			
Comorbidities	None or Low-risk comorbidities	See Appendix 2 for CLEG-endorsed comorbidity classification (2020)			

Low Care Pathway

Overview of Adult Clinical Risk Stratification

COVID-19 Positive Patients		Risk Category						
		Self-Engaged Care	Low	Medium - Clinically Well	Medium - Unwell	High		
Conditions		Requires vaccination status, symptoms, comorbidities & Social all to be met	Requires Age, Symptoms & Social all to be met	Only one of Age, Comorbidity or 'Unwell' Symptoms need be met. Differentiated by Symptoms		Requires Symptoms & / or Social only		
Determinants	Age	<65	<55 not fully vaccinated	>75 regardless of vaccination status 55-74 not fully vaccinated		Any		
	Vaccination Status	Fully vaccinated	55-74 fully vaccinated			Any		
	Pregnancy Status	Not pregnant	Not Pregnant	Any		Any		
	Symptoms*	Nil or Mild	Nil or Mild	Nil or Mild	Moderate	Severe		
	Comorbidities*	None or Low-risk comorbidities	Low-risk comorbidities	High-risk comorbidities		Any		
	Social	No barrier to home isolation	No barrier to home isolation	No barrier to home isolation		Barrier to home isolation		
Plan		Self-engaged Care	Low Risk Pathway	Medium Risk Pathway - Well	Medium Risk Pathway - Unwell	Inpatient Care		

*See Appendix for details of Symptoms and Comorbidities

October 2021

Covid-19 Positive Pathways

As GPs what can we do?

- Proactively engage patients in care
- Encourage support staff to understand about COVID telehealth from day five
- Engage whole households in your care
- Refer to services for social supports
- Speak with your patients about COVID specific therapy
- Arrange follow up for post acute/long COVID

GP's role in identify patients to eligible for Sotrovimab

- Cohort of COVID+ people that choose to have their care delivered by their GP
- GPs are well placed to identify at-risk patients early in the course of their illness
- Discussion of eligibility and advocacy for early engagement to care crucial to the success of the intervention
- Engagement with hospital-based services or commitment to increased surveillance in period after infusion

Sotrovimab links and resources

- The National COVID-19 Clinical Evidence Taskforce Clinical care guidelines for Sotrovimab
 <u>https://covid19evidence.net.au/#living-guidelines</u>
- Link for clinicians on the DH website <u>https://www.dhhs.vic.gov.au/vaccines-and-medications-patients-coronavirus-covid-19</u>
- Sotrovimab fact sheet for clinicians
 PDF published with this webinar or follow the link for clinicians on the DH website above
- Sotrovimab patient information sheet (PDF published with this webinar)
- TGA Sotrovimab Product Information
 <u>https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2021-PI-01995-</u>
 <u>1&d=20211018172310101</u>
- Clinical notes have also been added in healthpathways for Sotrovimab

changes to guidance will appear on this weblink

Post acute/long COVID links and resources

- Clinical guidance and resources manage patients with ongoing symptoms after acute COVID-19 infection https://www.dhhs.vic.gov.au/clinical-guidance-and-resources-covid-19
- Further guidance for GPs on long-COVID care is available from:
 - the RACGP <u>https://www.racgp.org.au/FSDEDEV/media/documents/RACGP/Coronavirus/Post-</u> <u>COVID-19-conditions.pdf</u> and;
 - through Primary Health Networks HealthPathways <u>https://vtphna.org.au/care-pathways-and-referral/</u>
- Information for people with long-COVID symptoms or their carers
 <u>https://www.coronavirus.vic.gov.au/information-people-long-covid-19-symptoms</u>

Thank you for participating tonight

Department of Health and RACGP's next webinar Wednesday 24th November 2021, 6pm-7pm

Topic: COVID vaccination and allergies

For the latest information <u>www.dhhs.vic.gov.au/coronavirus</u> Information is available in 50+ community languages at www.dhhs.vic.gov.au/translations