Sotrovimab Guidance for GPs

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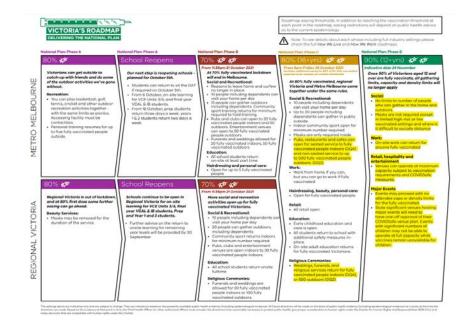
Director, Ambulance and Governance, Department of Health

Wednesday 27 October 2021



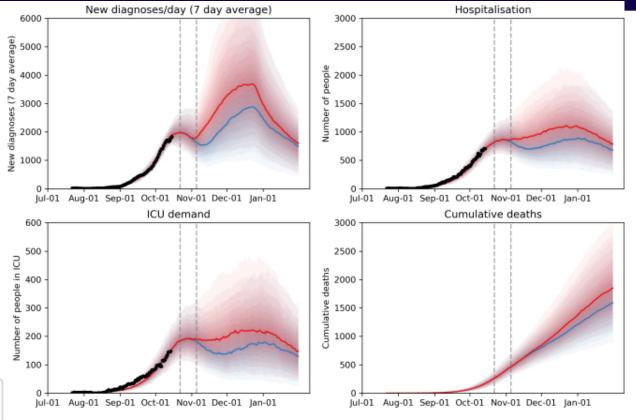
Victoria's sixth lockdown ended - Thursday 21 October 2021, at 11:59pm





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%



Full roadmapFull roadmap opening at 70%

Accessed Friday 22nd October 2021, https://www.burnet.edu.au/system/asset/file/4983/burnet_institute _victoria_roadmap_modelling_MEDIA_17Oct2021.pdf

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 https://covid19evidence.net.au/#living-guidelines
- 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 ≥ 55 years
- Chronic obstructive pulmonary disease (history of chronic bronchitis, chronic obstructive lung disease, or emphysema with dyspnoea on physical exertion)

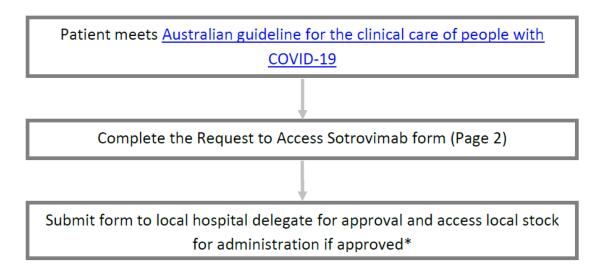
Immunosuppressed criteria:

- 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:
 - Chemotherapy or radiotherapy
 - High-dose corticosteroids (≥20 mg of prednisone per day, or equivalent) for ≥14 days
 - All biologics and most disease-modifying anti-rheumatic drugs (DMARDs)

Medication administration

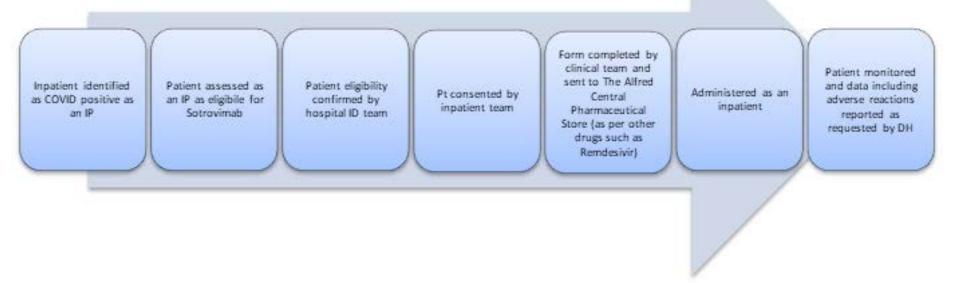
- Sotrovimab is administered as an IV infusion over 30 minutes
- Single dose only
- Requires post administration observation for 60 minutes
- No adverse events have been recorded in Australia to date

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.

Patients use own Pt entred onto Patient At time of entry Form completed transport or Pt consented by COID +ve Patient booked monitored and to COVID +ve by clinical team transportation oversight team into stand alone pathway with data including Pt identified as pathway patient and sent to The (via AEOC) facility which and provided COVID positive initial TREVI flag adverse assessed for Alfred Central booked and through PH (within 3 days of details for meets model reactions eligibility for Pharmaceutical patient symptoms and booking criteria reported as Sotrovimab transported to Store over 54yrs) requested by DH designated site

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

OFFICIAL

Intake and assessment lead services

North East Metro Health Service Partnership

Lead health service: Austin Health Intake number: 03 9496 6606

Email: COVIDcarepathways@austin.org.au

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: intake1@cbchs.org.au 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: covidnotifications@mercy.com.au

Days/hours of operation: 9am - 5pm; 7 days per week

Barwon Health

Intake number: 1300 942 241

Email: phu@barwonhealth.org.au

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: phu@lrh.com.au Days/hours of operation: 8am - 5pm; 7 days per week

Ballarat Health Services Intake number: 0428 493 084 Email:phu@bhs.org.au

Days/hours of operation: 24 hours a day; 7 days per week **Goulburn Valley Health**

Intake number: 1800 313 070 Email: phu@gvhealth.org.au

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**

Email: phu@awh@org.au Days/hours of operation: 8:00am to 5:00pm; 7 days per week

Intake number: 0400 645 476

Bendigo Health

Intake number: 1800 959 400 and 03 5454 9139

Email: phu@bendigohealth.org.au

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

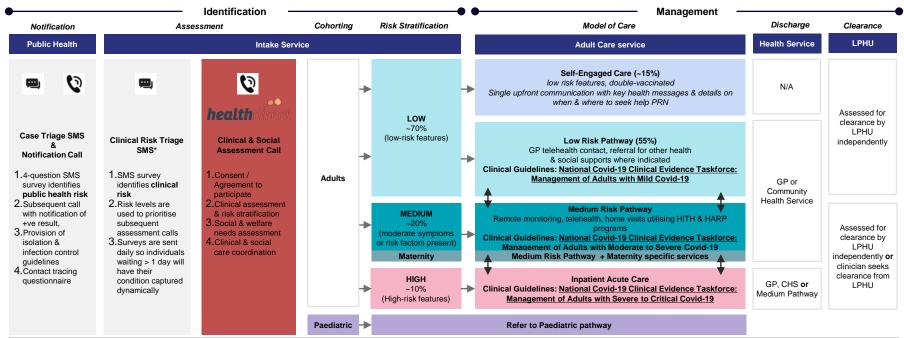
Due to these resources and requirements, although considered, primary care settings including the HITH model were deemed not appropriate.

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
 </p>
 - 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



Note:

- * 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

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)			

Covid-19 Positive Pathways

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 55-74 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

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 https://covid19evidence.net.au/#living-guidelines
- Link for clinicians on the DH website
 https://www.dhhs.vic.gov.au/vaccines-and-medications-patients-coronavirus-covid-19
- 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
 https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2021-PI-01995-1&d=20211018172310101
- 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 https://www.racgp.org.au/FSDEDEV/media/documents/RACGP/Coronavirus/Post-COVID-19-conditions.pdf and;
 - through Primary Health Networks HealthPathways https://vtphna.org.au/care-pathways-and-referral/
- Information for people with long-COVID symptoms or their carers
 https://www.coronavirus.vic.gov.au/information-people-long-covid-19-symptoms

Thank you for participating tonight

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

Topic: COVID vaccination and allergies

