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Model of care for the use of sotrovimab in adults in NSW

In August 2021, the Therapeutic Goods Administration (TGA) provisionally approved the use of sotrovimab for the treatment of COVID-19 in adults. This medication will become available in limited supply for use in Australia in late August 2021.

This drug is for the treatment of mild COVID-19 that is likely to progress to severe disease.

The purpose of this guidance is to outline the model by which sotrovimab will be used in NSW. This model will be updated as required and based on:

- changes in the evidence
- increased access to supply
- the context of outbreaks in NSW.

Local access to sotrovimab will be through usual Drug and Therapeutic Committee processes.

Methodology

The model is based on recommendations from the National Clinical Evidence Taskforce guidelines[2] and evidence from the COMET-ICE study[3].

This evidence was considered by an expert group of NSW clinicians to inform the development of this model. This included infectious diseases, hospital in the home, aged care, respiratory, medication safety, drug and therapeutics and oncology.

Additional advice regarding administration settings was subsequently developed by the same clinical working group and included representatives from metropolitan and rural local health districts.

The model was reviewed by the Expert Advisory Group of the NSW COVID-19 Clinical Council.

Who can be treated with sotrovimab?

Clinical criteria

As per the National Taskforce Guidelines, sotrovimab is appropriate for use in non-pregnant adults and pregnant women in their second or third timester:

- within five (5) days of symptom onset (symptoms may be very mild); AND
- who do not require oxygen for COVID-19; AND
- who have not been fully vaccinated (note: fully vaccinated means 2nd dose > 2 weeks ago); AND
- who have **one or more** of the following risk factors for disease progression;
  - 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)
  - chronic obstructive pulmonary disease (history of chronic bronchitis, chronic obstructive lung disease, or emphysema with dyspnoea on physical exertion)
  - 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.

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The following additional risk factors should also be considered:

- patients who are immunosuppressed, even if they are partially or fully vaccinated
- Aboriginal and/or Torres Strait Islander patients > 35 years old.

Clinical judgement should be used when assessing the severity of specific risk factors. This may include other significant chronic health conditions including but not limited to cardiac failure, chronic lung disease, immunosuppression and active malignancy.

Prioritised cohorts in NSW

Access for patients should be considered in the context of the outbreak in NSW. As such, it is the recommendation of the clinical working group that the following cohorts are prioritised. Patients identified as part of the following groups also need to meet the clinical criteria above.

- Aboriginal and/or Torres Strait Islander communities.
- Rural, regional and remote communities:
  a. Where there is a significant outbreak impacting the community.
  b. For patients who have been brought to a regional centre (from a remote location) for monitoring due to their risk of acquiring severe disease.
  c. For patients who are located in a remote location and prefer to remain in their community and/or on country.
- To support the public health response in metropolitan areas with large outbreaks.
- Nosocomial patients – those who have acquired a COVID-19 infection in hospital or healthcare setting.
- Patients who have acquired COVID-19 infection in high risk settings such as disability group homes and residential aged care facilities.

It may be prudent to plan access for patients in the above groups who have been exposed but have not yet developed symptoms.

Principles for settings for administration

1. Sotrovimab infusion may be delivered in a range of settings, depending on local requirements. Choice of setting should consider storage and transport of the drug in respect of the cold chain, preparation of the infusion and administration and disposal.
2. As much as possible, it should avoid putting additional pressure on acute care services such as emergency departments.
3. It should be done where the safety of patients and providers can be maintained. This includes the requirements to observe the patient receiving sotrovimab infusion for 90 minutes (30 minutes during administration and 60 minutes post-infusion) and managing any adverse events safely.
4. Local resourcing should be taken into account when deciding on when and how to administer.
5. Irrespective of the setting, use of sotrovimab should be under the governance of the local Drug and Therapeutic Committee and approved protocols.

Administration

Specifications for administration of sotrovimab are outlined in the NSW Therapeutic Advisory Group (TAG) Drug Guideline for sotrovimab.[4]

Specific notes for the community and rural setting:

Many patients with COVID-19 are receiving care in the community as outlined in the guidance Caring for adults with COVID-19 in the community.

Adverse events

- Patients should be monitored for adverse events during and post infusion. More information is outlined in the NSW TAG guidance.
- Following the observation period, patients should be provided with advice post infusion requirements, including adverse effects and who to contact for more information.
- All adverse events should be reported via:
  - IMS+; AND
  - The TGA at https://www.tga.gov.au/reporting-problems.

Patient consent

- Informed consent should be obtained from the patient (or responsible person) prior to initiating treatment with sotrovimab. An Information Leaflet for Patients, Family and Carers and a Written Consent Form for sotrovimab is available from the NSW TAG.
- The prescriber should conduct a detailed discussion about the benefits and potential harms associated with use of the medicine with the patient or responsible person prior to them signing the form.

Documentation

- Prescribers should complete a Prescribing Declaration/Individual Patient Usage Form available from NSW TAG, for each patient they intend to treat with sotrovimab and submit this to their local Drug and Therapeutics Committee for approval. Contact the local pharmacy department for more information, if required.
- The Individual Patient Use form should clearly indicate their patient's eligibility criteria. The completed form will need to be submitted to HealthShare NSW with orders for sotrovimab prior to release of stock.

Monitoring of outcomes

- The use of sotrovimab requires reporting and monitoring of outcomes.
- For more information, contact NSW TAG or see the NSW TAG.
- To assist in monitoring outcomes of treatment, it is suggested that the following information is also collected:
  - Collect one Serum Separator Tube (SST) and request anti-SARS-CoV-2 spike antibody testing. This should be documented in the clinical notes as 'COVID-19, baseline prior to sotrovimab treatment'.
  - Collect combined nasopharyngeal and throat swabs and request SARS-COV-2 PCR, culture and whole genome sequencing – refer to ICPMR, Westmead. This should be documented in the clinical notes as 'COVID-19, baseline prior to sotrovimab treatment'.
- For recipients who are subsequently hospitalised (or who progress to require oxygen, for those who were inpatients at the time of sotrovimab administration, or otherwise have repeat swabs collected for any reason after sotrovimab treatment) also:
  - Collect combined nasopharyngeal and throat swabs and request SARS-COV-2 PCR, culture and whole genome sequencing – refer to ICPMR, Westmead. This should be documented in the clinical notes as 'COVID-19, given sotrovimab on ##/##/####. ?resistance mutations'.

Access and supply

The access and supply of sotrovimab is managed by HealthShare and is aligned to the processes for other COVID-19 medications.

Flowchart for administration of sotrovimab in adult with mild and moderate COVID-19

Patient meets clinical criteria

CLINICAL CRITERIA

- Non-pregnant adults and pregnant women in their second or third trimester
- Within five (5) days of symptom onset (symptoms may be very mild); AND
- Who do not require oxygen; AND
- Who are not fully vaccinated
  (note: fully vaccinated means 2nd dose > 2 weeks ago); AND
- Who have one or more of the following risk factors;
  - diabetes requiring medication
  - obesity (BMI > 30kg/m2)
  - chronic kidney disease (eGFR < 60 by MDRD)
  - congestive heart failure (NYHA class II or greater)
  - chronic obstructive pulmonary disease (history of chronic bronchitis, chronic obstructive lung disease, or emphysema with dyspnoea on physical exertion)
  - moderate to severe asthma (requiring an inhaled steroid to control symptoms or have been prescribed a course of oral steroids in previous 12 months)
  - age >/= 55 years
  - patients who are immunosuppressed, even if they are partially or fully vaccinated
  - Aboriginal and/or Torres Strait Islander patients > 35 years old

Prioritised cohorts in NSW

PRIORITISED COHORTS IN NSW

- Aboriginal or Torres Strait Islander communities
- Rural/regional/remote communities
- To support the public health response in metropolitan areas with large outbreaks
- Nosocomial infection
- Acquired in high risk setting such disability homes and RACFs

Identify administration setting

- Choice of setting should consider storage and transport of the drug in respect of the cold chain, preparation of the infusion and administration and disposal.
- Avoid putting additional pressure on acute care services such as emergency departments.
- It should be done where the safety of patients and providers can be maintained.
- Local resourcing should be taken into account when deciding on when and how to administer.
- Should be under the governance of the LHD and DTC.

Follow NSW TAG guidance for storage and administration

Single use vial of 500mg in 8mL (62.5mg/mL) concentrated injection for infusion.
Store refrigerated at 2-8oC in original package.

Ensure patient is monitored throughout infusion

Document baseline observations.
If patient has deteriorated since initial assessment for sotrovimab,
DO NOT proceed and escalate care.
Administer sotrovimab 500mg intravenously over 30 minutes.

Monitor for 60 minutes post infusion

Document post infusion observations.
All adverse events should be reported via:

- IMS+
  AND
- TGA at https://www.tga.gov.au/reporting-problems

Undertake outcomes reporting.

Transfer of care must include plan for escalation if patient deteriorates

Caring for adults with COVID 19 in the community

Prescription, governance and settings for administration

Operationalisation of models of care for use of medications for treatment of COVID-19 should be determined in consultation with local clinicians and the local Drug and Therapeutics Committee.

Use in community setting and hospital in the home (HITH)

The clinical working group has recommended that sotrovimab is not delivered in hospital in the home or community care settings. This aligns to advice released by the Society of Hospital Pharmacists of Australia on administration of the medicine[5, 4] and reflects the approach of other Australian jurisdictions.

This is in recognition that sotrovimab is a new treatment requiring monitoring during and after infusion. It is also informed by the rate and severity of the infusion reactions during the trial.[3,4]

It is acknowledged that some local health districts may adopt a HITH approach for the administration of sotrovimab locally where they can address the considerations below and feel it meets the needs of their local community.

As staff need to be on site for at least two hours, local health districts will need to manage processes for extended COVID-19 exposure.

Staff need to have competency in monitoring for infusion reactions, managing adverse events and resuscitation skills in the event of anaphylaxis.

Principles

1. The indication is for administration within five days of symptom onset. Treatment can be planned and will rarely need to occur after hours.
2. Administration of sotrovimab should occur in a health care facility, which may be in an inpatient or outpatient setting. The setting within the facility must meet patient flow, infection prevention and control and adverse event management requirements.
3. Local health districts (LHDs) and specialty health networks (SHNs) should establish local processes to:
    a. Proactively identify eligible patients based on the clinical criteria and priority populations outlined in the model of care.
    b. Define governance arrangements for authorised prescribers. In addition to infectious disease and respiratory physicians, these arrangements should outline any oversight, approval and stewardship requirements for other medical staff caring for COVID-19 positive patients who are seeking to prescribe this treatment.
    c. Establish a communication process with the pharmacy department to confirm supply of stock before booking patients.
    d. Ensure access to the medication through outreach settings is done under usual LHD and Drug and Therapeutics Committee (DTC) arrangements for prescribers in these settings.
    e. Coordinate the service model including the outpatient location, staffing and infection control procedures.
4. A prescribing declaration/individual patient use (IPU) application should be completed prior to prescription of sotrovimab and approved by the local DTC to ensure appropriate and safe administration of sotrovimab. The local DTC should confirm local governance arrangements.
5. LHDs and SHNs should establish a booking process for patient treatment including:
    a. Provide information on the treatment via phone and email with the patient or carer and then obtain consent via phone prior to attendance at the facility for infusion. Depending on the local staffing and coordination model, booking and consent may be undertaken via a multi-step process and involve multiple communications with the patient or carer. (See NSW TAG sotrovimab patient information leaflet and verbal and written consent forms for sotrovimab).
    b. Whether informed consent is verbally obtained by the prescriber or is provided using written consent form, it should be documented in the medical record prior to administration. (See NSW TAG sotrovimab patient information leaflet and verbal and written consent forms for sotrovimab).

c. Ensure patients are provided with information on:
   i. PPE requirements for attending their infusion
   ii. how to find the infusion area to expedite access and minimise access to other parts of the facility and exposure to other patients and staff
   iii. confirmation of the appointment to support patients leaving isolation to attend the health care facility
   iv. transport arrangements (where required).

d. Confirm follow up arrangements post treatment, including who to contact for more information and advice around timelines for vaccination. See information on the TAG website.

e. Provision of printed information should be available for patients including information about the treatment and post treatment care. See NSW TAG patient information leaflet. It is preferable to provide this information at the time of booking at the infusion clinic. Consider access to interpreter services as required.

6. Ensure staff, such as emergency department, site managers, screening station and security staff, are aware of the location and arrangements for the infusion treatment to assist patients to find their way. Where practical, temporary signage should be posted to assist patients and staff.
7. Ensure reporting requirements are communicated, documented and submitted, including adverse events. This needs to be done via via the NSW TAG outcomes form, IMS+ and the TGA.
8. Ensure appropriate equipment and medicines to deal with an adverse event including anaphylaxis are readily available.
9. Arrangements for patient follow up should be defined and may be supported by the infusion service or community care, virtual care or HITH services, depending on local resources and need.

Administration in the inpatient setting

- Patients who fulfil the priority eligibility criteria who are already admitted to a healthcare facility may be given the infusion in a ward setting provided the monitoring requirements can be met. This may be appropriate for patients already admitted to a COVID-19 ward, or who have nosocomial infection.
- This will prevent patient transfer to the nominated outpatient area, minimising movement for the patient and potential exposure to other areas of the hospital.

Administration in the outpatient setting

- Given limited supply of sotrovimab, a hub and spoke model may be appropriate where one site within the LHD is identified for the administration of sotrovimab.
- There needs to be a dedicated and physically appropriate location at the health facility for the infusion, that:
  - offers pathways to access this location, as patients must not pass through other patient areas
  - ensures infection prevention and control requirements for administration, ventilation and cleaning.
  - enables line of sight to support clinicians monitoring patients during the observation period.
- If different to usual local clinical emergency response system protocols, agree, document and communicate arrangements for escalation in the event of clinical deterioration. This should also include access to a resuscitation trolley.
- Confirm transport options to enable patient access as part of the booking process. LHDs and SHNs should implement a patient self-transport approach wherever possible.
  - Identify an accessible car park for patient use as close to the infusion location as possible.
  - Provide instructions for patients on locating the car park and directions on how to access the infusion area via a ‘hot entrance’.
  - Provide information to patients regarding their appointment if they are stopped by authorities for leaving isolation.
  - Consider informing local authorities regarding the provision of this service and that patients will need to self-transport for treatment.

  - Where patients are not able to self-transport, arrangements should be made with HealthShare for access via the Patient Transport Service (PTS). Given the current demand on these services, requests should be planned and notified to PTS with as much notice and flexibility around appointment times as possible.
- Ensure the appropriate level of nursing coverage and competency is available including:
  - infusion preparation, cannulation and administration of intravenous medication
  - monitoring for adverse events including initial management of anaphylaxis.
- Access to medical advice and review should be readily available for adverse events.

Administration in the outreach setting

- Access to sotrovimab via outreach should be established by LHDs and SHNs based on a local assessment of need.
- Identification of eligible patients should occur as early as possible to enable planning for the outreach service including travel requirements and time.
- As with outpatient settings, the outreach service should be provided in an appropriate health care setting which meets patient flow, infection prevention and control and resuscitation equipment requirements, for example, a multipurpose service or a general practice.
- Depending on local resources and requirements, it may be appropriate to provide access outside of health care facility utilising specialist medical and nursing workforce. For example, these could be the Rural Flying Doctor Service and Justice Health or correctional services. This should be locally determined based on patient needs and resources and must be comply with usual LHD, DTC prescriber arrangements.
- Medical and nursing workforce with the appropriate skills and competency will need to be mobilised, including staff with skills such as these:
  - infusion preparation cannulation and administration of intravenous medication
  - monitoring for adverse events including management of anaphylaxis.
- Workforce planning should also consider appropriate rostering to support travel requirements over long distances.
- Establish equipment and medication requirements for the outreach team, including arrangements for access and re-supply of the medication and resuscitation equipment.
- Consider escalation processes for ambulance and retrieval services in the event of adverse events requiring ongoing management or admission to hospital.
- Consider storage and transport requirements for sotrovimab in respect of maintenance of cold chain.

References

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