Model of Care for the use of sotrovimab in Western Australia

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V 3.3
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Introduction

In August 2021, the Therapeutic Goods Administration (TGA) provisionally approved the use of sotrovimab for the treatment of COVID-19 in adults.

This medication became available in limited supply for use in Australia from August 2021.

Sotrovimab is approved for the treatment of mild COVID-19 that is likely to progress to severe disease to reduce the risk of hospitalisation.

This medication is regulated by the Commonwealth National Medical Stockpile. Access to stock requires completion of the WA Emergency COVID-19 Treatment Approval form (via REDCap) form and confirmation by the prescriber that the patient fulfils required criteria. Supply of COVID-19 therapeutics via the National Medical Stockpile (NMS) is uncertain and availability is expected to fluctuate with demand and constraints in the supply chain.

The purpose of this guidance is to outline the community/outpatient model by which sotrovimab will be used in Western Australia.

This model will be updated as required and based on:

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

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

COVID-19 (2019-nCoV) is a notifiable infectious disease in Western Australia. Cases must be reported to the Public Health Unit.

PART 1 Who is eligible for treatment with sotrovimab?

Clinical criteria

As per the National Taskforce Guidelines, adult patients (including pregnant women in the second and third trimester) and adolescents (aged 12 years and over and weighing at least 40 kg) are eligible for sotrovimab:

- within five (5) days of symptom onset (symptoms may be very mild); **AND**
- who do not require oxygen; **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;

Adults:

  - diabetes (requiring medication)
  - obesity (BMI > 30 kg/m^2)
  - chronic kidney disease (*eGFR < 60 mL/minute)
  - 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.

Adolescents:

For consideration of use in adolescents aged 12 years and over and weighing at least 40 kg, recommend discussion with paediatric infectious diseases specialist at Perth Children's Hospital to determine appropriateness of adolescent risk factors (including neurodisability, obesity (>95th centile for age and gender based on CDC growth charts), severe asthma, immune deficiency) and need for sotrovimab.

Clinical judgement should be used when assessing the severity of specific risk factors.

To ensure equity of access and conserve sotrovimab therapy for those patients at the highest risk of COVID-19 disease progression, a tiered access criterion is in place (Appendix 1) to allocate stock based upon current supply. Even within the most restricted tiers, access may be limited and available only on a first-come-first-served basis.

The following are considered high risk groups in the Access Criteria for Sotrovimab (Appendix 1) when prioritising patients for sotrovimab:

- Patients who are unvaccinated or partially vaccinated
- Immunocompromised patients
- Aboriginal and/or Torres Strait Islander patients > 35 years old.
- Patients who are pregnant (second or third trimester)

PART 2 Where and how should sotrovimab be administered?

2.1 Principles for settings for administration

1. It is recommended that sotrovimab is not delivered outside a qualified health care facility. This aligns to advice released by the Society of Hospital Pharmacists of Australia on administration of the medicine[4,5] and reflects the approach of other Australian jurisdictions.
2. 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]
3. Choice of setting should consider availability of clinical staff with appropriate skills to:
    a. prepare the infusion for administration,
    b. ability to cannulate patient
    c. administer and monitor a patient for infusion reactions,
    d. manage adverse events (with resuscitation skills in the event of anaphylaxis),and
    e. safely dispose the medicine and administration equipment.

    The staff and setting must also meet safe and appropriate and storage and transport requirements of the medicine with respect to the cold chain management. Clinical staff must be onsite with a patient for at least two hours to cover preparation of infusion, the 30-minute infusion time and the one-hour post-infusion monitoring period. This raises considerations around staff safety due to extended exposure to COVID-19 and efficiency of the service.
4. Choice of setting should also consider the need for a dedicated and physically appropriate location for the infusion, that:
    a. offers pathways to access this location, as patients must not pass through other patient areas
    b. ensures infection prevention and control requirements for administration, ventilation and cleaning.

c. enables line of sight to support clinicians monitoring patients during the observation period.

5. As much as possible, it should avoid putting additional pressure on acute care services such as emergency departments.
6. Local resourcing should be taken into account when deciding on when and how to administer sotrovimab.
7. Irrespective of the setting, use of sotrovimab must be approved for use by the Chief Health Officer (or delegate) and prescribed and administered within the health professional's scope of practice and in adherence with approved protocols.

2.2 Administration

Specifications for preparation and administration of sotrovimab are outlined in the **WA Guidelines for Use of SOTROVIMAB for COVID-19 in Adults.**

For use in paediatric patients (18 years of age and under) please follow paediatric monograph as per link provided – ChAMP Guidelines for Use of Sotrovimab for COVID-19 Paediatric Patients.

2.3 Adverse events

- It is important that sotrovimab be administered in an environment where adverse events can be managed.

- Though very rare, anaphylaxis can occur following administration of sotrovimab and must be managed quickly and appropriately. An anaphylaxis response kit (Appendix 2) must always be readily available and easily accessible by health professional administering sotrovimab. Protocols must be in place for maintenance of kits including verifying that all the supplies are still present and none of the medications have expired.

- Patients should be monitored for adverse events during and post infusion. Observe the patient during the infusion and for 60 minutes after infusion cessation in case of hypersensitivity reactions or anaphylaxis.
  Infusion reactions include fever, chills, dizziness, dyspnoea, pruritis and rash.
  - For mild to moderate infusion reactions, slow or stop the infusion and treat accordingly[5], noting that in the COMET-ICE trial, mild hypersensitivity reactions did not require pausing or discontinuation of the infusion.[7]

- Anaphylactic reactions are rare but are a medical emergency. Stop the infusion and commence treatment immediately.

- Following the observation period, patients should be provided with post infusion advice, including adverse effects and who to contact for more information/advice.

- It may be difficult to distinguish between adverse effects of sotrovimab and signs and symptoms of COVID-19. As the proposed use is for a provisionally approved medicine which has no relevant post-marketing data, it is important to document and report all (from possible to confirmed) adverse effects experienced by the patient during treatment to inform its safety profile and future use. Refer to product information for complete list of possible adverse effects.
    - Common (>1%):
      Diarrhoea (1%), hypersensitivity reactions (includes rash (2%), infusion-related reaction, bronchospasm).
    - Rare: Anaphylaxis.
- All adverse events should be reported via the TGA at https://www.tga.gov.au/reporting-problems .
- Clinical incidents must be entered into the Clinical Incident Monitoring System (e.g.Datix CIMS for WA Health)

2.4 Patient consent

- The consumer (or carer) should receive appropriate medicine information from a health professional prior to any consent process.
    - Sotrovimab (Xevudy®) consumer information from TGA website
    - Use of Sotrovimab (Xevudy®) in Adults with COVID-19 from NSW TAG website

- Informed consent should be obtained by the prescriber from the patient (or responsible person) and be documented in the patient's medical record prior to initiating treatment with sotrovimab.

- **An Information Leaflet for Patients, Family and Carers for sotrovimab** must be provided before administration.

- A **Patient Consent Form** (for documenting written or verbal consent) for sotrovimab must be completed by the patient and prescriber before commencing treatment.

- 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 consent form.

2.5 Documentation

- Prescribers should complete and submit a **WA Emergency COVID-19 Treatment Approval for Sotrovimab Form** (available from LINK), for approval for each patient they intend to treat with sotrovimab.

- The **WA Emergency COVID-19 Treatment Approval for Sotrovimab Form** must clearly state that the patient meets the eligibility criteria. The completed form will need to be submitted to the Chief Health Officer for approval prior to release of stock.

2.6 Monitoring of outcomes

The use of sotrovimab requires reporting and monitoring of outcomes including:

- If the patient had full recovery
- If the patient required admission to a hospital
- If a patient required escalated care admission to an intensive care unit
- If the patient requires ventilation.
- If the patient died of COVID-19 related causes.

It is the responsibility of the administering Health Service Provider (HSP) to provide patient follow-up at 14 days post therapy to determine patient outcomes as listed above for Commonwealth reporting. The prescriber requesting therapy will also be sent an email to assist with capturing this information.

2.7 Access and supply

- Sotrovimab stock is made available through the National Medical Stockpile and requires review and approval from an Infectious Disease Physician before it can be released.
- The **WA Emergency COVID-19 Treatment Approval Form for Sotrovimab** must be completed by the requesting prescriber (general practitioner or treating hospital doctor). Once completed the form will automatically be onforwarded for approval.

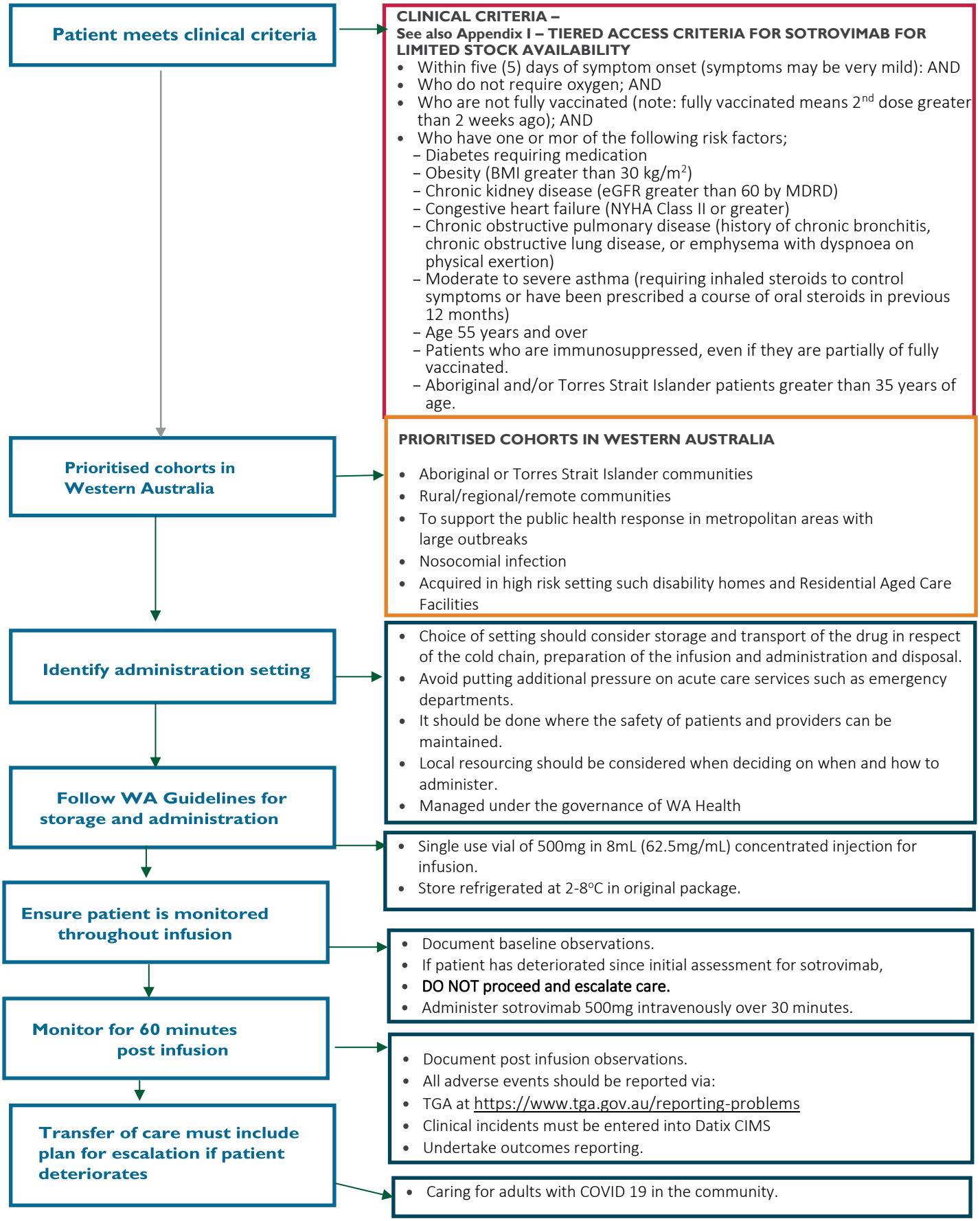
- To ensure the form is received and attended to in a timely manner, it is the responsibility of the prescriber requesting sotrovimab to contact the on-call Infectious Disease Physician when submitting the request. For patients under the COVID CARE at HOME monitoring program, the on-call Infectious Disease Physician will be contacted to follow-up to determine patient suitability for sotrovimab treatment.
- An on call Infectious Disease Physician will review all requests. If the patient meets eligibility criteria and tiered access to supply requirements, the patient will be referred to the nearest Health Service Provider (HSP) to arrange administration of sotrovimab. If the patient does not meet the eligibility criteria, then an email will be sent to the referring prescriber to inform them of this decision.

Commonwealth Reporting requirements

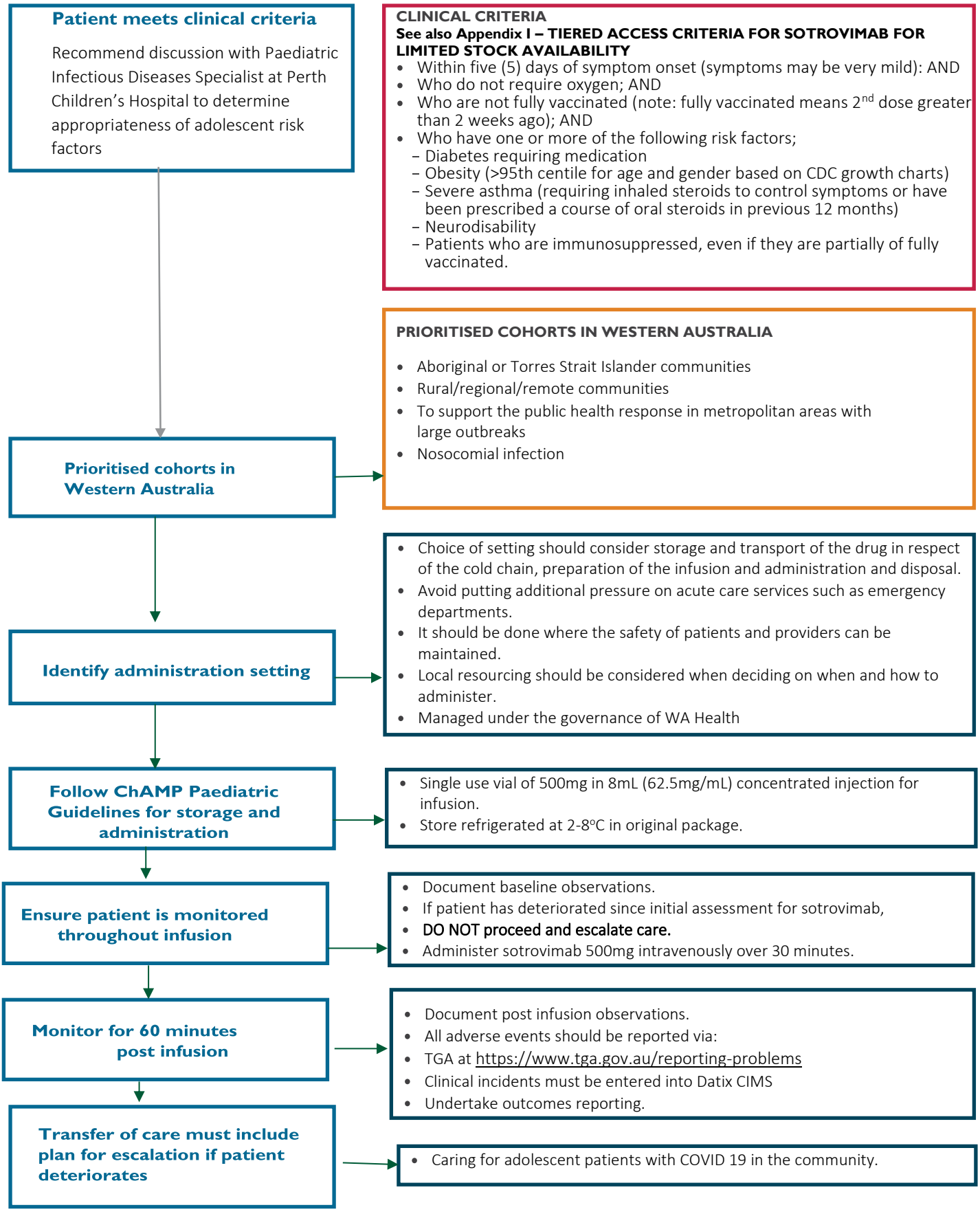
Each National Medical Stockpile medicine requires information to be collected and forwarded to the Commonwealth Department of Health. For sotrovimab the following information must be collected and forwarded to the Commonwealth on a fortnightly basis.

- **Age**
- **Sex** - male, female, non-binary, not disclosed
- **Vaccinated** – Unvaccinated, Partially vaccinated, fully vaccinated
- **Indication** – Mild illness, Moderate illness, Fever, Dry cough, sore throat, tiredness, aches and pains, headache, rash, chest pressure or pains, diarrhoea, mild or moderate illness not requiring oxygen, Other (please specify).
- **Comorbidities** – Diabetes (requiring medication), Obesity (BMI > 30 kg/m^2, Chronic Kidney Disease, Congestive Heart Failure (NYHA class II or greater), Chronic Obstructive Pulmonary Disease, Moderate to Severe Asthma, Age >55 years of age
- **Quantity Used**
- **Clinical Outcomes** – Recovery, Hospitalised, ICU, Ventilated, Death

2.8 Summary chart for management of sotrovimab in adult patients with mild and moderate COVID-19 symptoms



2.9 Summary chart for management of sotrovimab in adolescent patients (aged 12 years and over and weighing at least 40 kg) with mild and moderate COVID-19 symptoms



1. 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 the Chief Health Officer.

3.1 Principles

1. The indication is for administration **within five days of symptom onset** (day of symptom onset is Day 0). Treatment can be planned to occur during day service provision.

2. For patients already admitted to hospital, Health Service Providers 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 to review patient and submit ***WA Emergency COVID-19 Treatment Approval for Sotrovimab*** form. 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. This should also include informing the Pharmacy Department of supply requirement.
    c. Coordinate the service model including the location, staffing and infection control procedures.

3. A ***WA Emergency COVID-19 Treatment Approval for Sotrovimab*** application should be completed prior to prescription of sotrovimab and approved by an Infectious Disease Physician.

4. Health Service Providers **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 WA Health sotrovimab **patient information leaflet** and **verbal and written consent forms** for sotrovimab).

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 WA Health sotrovimab patient information leaflet and verbal and written consent forms for sotrovimab).

b. **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).
c. Confirm patient is able to facilitate own transport to the site for administration or organise transportation on behalf of the patient.
d. **Confirm follow up arrangements post treatment**, including who to contact for more information and advice around timelines for vaccination. See information on the WA HEALTH website.
e. **Provision of printed information** should be available for patients including information about the treatment and post treatment care. See WA Health patient information leaflet. It is preferable to provide this information at the time of booking at the infusion clinic. Interpreter services should be used as required.

5. 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.

6. Ensure **reporting requirements are communicated, documented and submitted, including adverse events**.
    a. Side effects to sotrovimab should be reported to the Therapeutics Goods Administration
    b. Clinical incidents involved in prescribing, supply, dispensing or administration of sotrovimab must be reported via the Datix CIMS if provided within a Health Service Provider.

7. Ensure **appropriate equipment and medicines to deal with an adverse event** including anaphylaxis are readily available.
8. **Arrangements for patient follow up** must include a summary of care provided to the community monitoring service and the patient's General Practitioner (GP) at the time of discharge.

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.

3.2 Administration in the outreach setting

- Access to sotrovimab via an outreach service should be established by WA Health 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.
- An outreach service must be provided in an appropriate health care setting which meets patient flow, infection prevention and control and resuscitation equipment requirements. There needs to be a dedicated and physically appropriate location 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.
- 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 Royal Flying Doctor Service and correctional services. This should be locally determined based on patient needs and resources and must comply with usual National Medical Stockpile access requirements.
- 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.

APPENDIX 1: ACCESS CRITERIA FOR MEDICINES TO TREAT COVID-19 THAT ARE PART OF THE NATIONAL MEDICAL STOCKPILE

Access to stock requires completion of a WA Emergency COVID-19 Treatment Approval form (via an electronic REDCap form linked to Formulary One) and confirmation by the prescriber that the patient fulfils required criteria. Supply of COVID-19 therapeutics via the National Medical Stockpile (NMS) is uncertain and availability is expected to fluctuate with demand and constraints in the supply chain. To ensure equity of access and conserve therapy for those patients at the highest risk of progression, a tiered access criterion is in place to allocate stock based upon current supply. Even within the most restricted tiers, access may be limited and available only on a first-come-first-served basis.

- Tier 1 - Limited supply, access restricted to Tier 1 category
- Tier 2 - Ready supply, access restricted to Tier 1 and 2 indications
- Tier 3 - Unlimited supply, all tiers of access open

Vaccination status

As per Australian Technical Advisory Group on Immunisation (ATAGI) advice on vaccination status.

Up to date status is defined as follows:

Individuals aged 16 years and over - after completing an appropriate primary course of a Therapeutic Goods Administration (TGA) approved or recognised vaccine.
To optimise protection from the Omicron SARS-CoV-2 variant, individuals should receive a booster dose 3 months after completion of their primary schedule.
A person will be considered **'overdue'** if a booster has not been received within 6 months of completing their primary schedule.

Children and adolescents aged 5-15 years - after completion of a primary course of vaccination.
A booster dose is not currently recommended for this age group.

Severely immunocompromised individuals aged 5 years and over after completion of a 3rd primary dose of a COVID-19 vaccine from 2 months (and no later than 6 months) after dose 2 to remain up-to-date.
Those who are aged 16 years and over are recommended a booster (4th) dose, 3 months after dose 3 of their primary vaccination course. However, for the purpose of being up-to-date in the Australian Immunisation Register [AIR] (which does not contain any information on medical conditions) only a total of 3 doses will be counted as being up-to-date in this subgroup.

Individuals who have had prior COVID-19, including asymptomatic SARS-CoV-2 infection, still require completion of the above vaccination schedule, but can defer receipt of the next dose for up to 4 months following their infection.
This recommendation has changed from the previous 6-month interval. Some people may choose to be vaccinated prior to 4 months. Refer to ATAGI clinical guidance on people with a past SARS-CoV-2 infection.

Partially vaccinated – person has received part of the recommended course of a TGA approved, or recognised vaccine as recommended above.

Unvaccinated – person has not received a Therapeutic Goods Administration (TGA) approved or recognised vaccine.

Note: Patients are deemed to have developed protective antibody levels 14 days after a COVID-19 vaccination dose. Doses given within this 14-day period should be classified as not having received a vaccination for the purposes of treatment eligibility in this guideline.

TIER	Criteria	Eligibility
TIER 1	**ADAPTED FROM COMET-ICE CRITERIA FOR UNVACCINATED ADULTS AND ADULTS AT HIGH RISK OF SEVERE DISEASE** TIER system based on National Institutes of Health Statement on Patient Prioritisation for Outpatient Therapies	**Unvaccinated** and age equal or greater than 75 years OR **Unvaccinated** and age equal or greater than 65 years of age (or Aboriginal and Torres Straight Islanders [ASTI]) patients equal or greater than 35 year of age) with additional risk factors as below: - • Diabetes (including gestational diabetes) requiring medication • Obesity (BMI > 30 kg/m^2) • Chronic kidney disease (i.e. eGFR < 60 mL/minute) • Congestive heart failure (New York Heart Association [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) • Chronic obstructive pulmonary disease (history of chronic bronchitis, chronic obstructive lung disease, or emphysema with dyspnoea on physical exertion) • Down syndrome There is a cumulative increase in risk of progression to severe disease with each additional risk factor, which may further impact eligibility at times of extreme product shortage.
	PREGNANT WOMEN IN SECOND OR THIRD TRIMESTER	**Unvaccinated or partially vaccinated (not up to date)** OR **Full vaccination and severe immunocompromised**

	SEVERE IMMUNO-COMPROMISED
	
	Subset of immunocompromised persons as per ATAGI Recommendations on the use of a 3rd primary dose of COVID-19 vaccine in individuals who are severely immunocompromised
		Severe immunocompromised regardless of vaccination status:
		• Patients who are within 1 year of receiving B-cell depleting therapies (e.g., rituximab, ocrelizumab, ofatumumab, alemtuzumab)
		• Patients receiving Bruton tyrosine kinase inhibitors
		• Chimeric antigen receptor T cell recipients
		• Post-hematopoietic stem cell transplant recipients who have chronic graft versus host disease or who are taking immunosuppressive medications for another indication
		• Patients with hematologic malignancies who are on active therapy
		• Lung transplant recipients
		• Patients who are within 1 year of receiving a solid-organ transplant (other than lung transplant) or haematopoietic stem cell transplant
		• Solid-organ transplant recipients with recent treatment for acute rejection with T or B cell depleting agents
		• Patients with certain primary immunodeficiencies
		  ○ Primary Immunodeficiencies (PID) affecting cellular and humoral immunity (severe and other combined immunodeficiencies (https://doi.org/10.1007/s10875-019-00737-x)
		  ○ PIDs with profoundly decreased or absent B cell number or function
		  ○ PIDs with impaired interferon responses
		• Patients with untreated HIV who have a CD4 T lymphocyte cell count <50 cells/mm^3

		• Patients on any of the following agents not already listed ○ Anti-CD20 antibodies rituximab, obinutuzumab, ocrelizumab, ofatumumab ○ Bruton's tyrosine kinase (BTK) inhibitors ibrutinib, acalabrutinib, zanubrutinib ○ Sphingosine 1- phosphate receptor modulators fingolimod, siponimod ○ Anti-CD52 antibodies alemtuzumab ○ Anti-complement antibodies eculizumab ○ Anti-thymocyte globulin
	PAEDIATRIC	Paediatric Infectious Diseases Specialist review required (Perth Children's Hospital (PCH) to determine appropriateness of adolescent risk factors. Within 2 years of Hematopoietic stem-cell transplantation (HSCT) or Solid Organ Transplant regardless of vaccination status will be prioritised.
TIER 2	**FOR UNVACCINATED AND PARTIALLY VACCINATED ADULTS AT HIGH RISK OF SEVERE DISEASE**	**Unvaccinated** and age equal or greater than 55 years (or ATSI patients equal or greater than 35 year of age) OR **Partially vaccinated (not up to date)** and age equal or greater than 55 years (or ATSI patients equal or greater than 35 year of age) with one additional risk factor as outlined above in Tier 1 OR **Unvaccinated or partially vaccinated (not up to date) AND moderate immunocompromised**, as per the following criteria, regardless of age or clinical risk factors. Moderate immunocompromised: ○ Primary immunodeficiency including combined immunodeficiency and syndromes, major antibody deficiency (e.g. common variable immune deficiency (CVID) or agammaglobulinemia), defects of innate immunity (including phagocytic cells), defects of immune regulation, complement deficiencies and phenocopies of primary immunodeficiencies ○ Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes ○ Greater than 12 months post-transplant: haematopoietic stem cell transplant. ○ Advanced or untreated HIV with CD4 counts <200/microL, or those with a higher CD4 count unable to be established on effective anti-retroviral therapy, recent (within 12 months) AIDS-defining condition, or persistent/recurrent viraemia OR not on antiretroviral therapy (excluding elite controllers). ○ Haemodialysis or peritoneal dialysis ○ Immunosuppressive therapy (current or recent) examples include: ○ Chemotherapy or radiotherapy ○ Janus kinase (JAK) inhibitors - tofacitinib, baricitinib, ruxolitinib ○ High-dose corticosteroids (≥20 mg of prednisone per day, or equivalent) for ≥14 days in a month, or pulse corticosteroid therapy. ○ Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDS) including mycophenolate, methotrexate (>0.4 mg/kg/week), leflunomide, azathioprine (≥ 3mg/kg day), 6-mercaptopurine (≥ 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus).

		NOTE – The following agents are not considered to impart risk - Anti-integrins natalizumab, vedolizumab - Anti-TNF-α antibodies infliximab, adalimumab, etanercept, golimumab, certolizumab - Anti-IL1 antibodies anakinra - Anti-IL6 antibodies tocilizumab - Anti-IL17 antibodies secukinumab, ixekizumab - Anti-IL4 antibodies dupilumab Anti-IL23 antibodies ustekinumab - Immune checkpoint inhibitors nivolumab, pembrolizumab, ipilimumab, atezolizumab * OR **Solid organ transplant recipient regardless of vaccination status.**
	PREGNANCY	**Unvaccinated** who do not meet Tier 1 criteria (strong recommendation for discussion with ID physician and/or Womens and Newborns Health Service obstetrician before consideration) OR **Partially vaccinated (not up to date)** and at least one of the following risk factors who do not meet Tier 1 criteria: ○ Gestational diabetes requiring medication ○ Obesity (BMI > 30 kg/m^2 or for paediatric patients BMI >95th centile for age and gender based on Clinical Growth Chart [CDC] chart) ○ Chronic kidney disease (i.e. eGFR < 60 mL/minute) ○ 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) ○ Chronic obstructive pulmonary disease (history of chronic bronchitis, chronic obstructive lung disease, or emphysema with dyspnoea on physical exertion)
	PAEDIATRIC	Paediatric Infectious Diseases Specialist (PCH) review required and referral of unvaccinated or partially vaccinated adolescents with risk factors including: • paediatric chronic complex condition, • obesity (>95th centile for age and gender based on CDC growth charts), • severe asthma, • chronic obstructive lung disease, • diabetes (on insulin), • severe cardiac disease, • end stage renal disease, • sickle cell disease, • immune deficiency
TIER 3	**MODERATE RISK OF SEVERE DISEASE**	**All other patients who do not meet Tier 1 and Tier 2 criteria but do meet recommendations for use as per the National COVID-19 Clinical Evidence Taskforce.** • **Unvaccinated or partially vaccinated patients** less 55 years of age with additional risk factors OR • **Immunocompromised** that do not meet criteria for Tier 1 and Tier 2 OR

		• **Partially vaccinated** and age equal or greater than 55 years of age (or ATSI patients equal or greater than 35 year of age) without risk factor. Note: Patients that do not meet recommendations for use as per the National COVID-19 Clinical Evidence Taskforce are not included in any tier as they will not be considered to be eligible for treatment.

NOTE: Molnupiravir is PBS listed for treatment of symptomatic COVID infection in certain at-risk groups.

Please refer to current PBS guidelines for detailed prescribing information in the following groups:

a) patients over 65 years of age,

b) moderately to severely immunocompromised patients and

c) Aboriginal or Torres Strait Islander patients over 50 years of age

APPENDIX 2: Anaphylaxis Kits

An anaphylaxis response kit must always be readily available and easily accessible by health professional administering sotrovimab.

The recommended contents of these pre-prepared kits are based on the Australian Immunisation Handbook and the WA COVID-19 Vaccination Clinical Reference Group.

Item	**Quantity per kit**
Needle 23 Gauge x 25mm	10 per kit
1mL 'single use only' syringes (not insulin syringes)	10 per kit
Cotton wool swab	10 per kit
Manual resuscitator set Adult: Mask; Flow Diverter;4.2m Oxygen tubing; single patient use.	1 per kit
Manual resuscitator set Paediatric: Mask; Flow Diverter;4.2m Oxygen tubing; single patient use.	1 per kit
Adrenaline 1:1000	10 ampoules per kit
Guedel Airway - Adult	1 per kit
Guedel Airway - Paediatric	1 per kit
Mask – non-rebreather – Adult	1 per kit
Mask – non-rebreather - Paediatric	1 per kit
Laminated copy of 'Recognition and Treatment of Anaphylaxis' Australian Immunisation Handbook Table. Recognition and treatment of anaphylaxis | The Australian Immunisation Handbook (health.gov.au)	1 per kit
Laminated copy of 'Doses of intramuscular 1:1000 adrenaline for anaphylaxis' – Australian Immunisation Handbook Doses of intramuscular 1:1000 adrenaline for anaphylaxis | The Australian Immunisation Handbook (health.gov.au)	1 per kit
Documentation to record treatment of anaphylaxis	1 per kit
Address of venue	1 per kit
Digital Clock/Timer (for timing of adrenaline)	1 per kit
Pens	2 per kit
A4 notebook	1 per kit
Anaphylaxis Response Kit Storage (e.g. backpack)	1 per kit
Razor	1 per kit

APPENDIX 3: Guidelines for Safe Handling and Administration of Monoclonal Antibodies

(Adapted from WACHS Safe Handling and Administration of Monoclonal Antibodies)

1. Guiding Principles

Monoclonal antibodies (MABs) are large protein drugs that have an affinity for a specific antigen. They are used in the management of cancer and non-cancer diseases. Administration is by injection or infusion and the route is usually subcutaneous or intravenous.[8]

The action of MABs is different from traditional cytotoxic therapies and most are not inherently cytotoxic and do not need to be handled with cytotoxic precautions.[8,9,10,11,12,13]

With the continuing development of new MABs, the advent of fixed dosing and expansion of indications for existing MABS, a universal approach is required when assessing the risk to healthcare workers as well as the management of these medications.

2. Guideline

This guideline has been developed to advise healthcare staff of the minimum level of personal protection required when preparing, handling, administering and disposing of MABs. This guideline will also provide guidance and direction on the preparation of low risk MABs on site.

2.1 Risk Assessment of MABs

All MABs need to be risk assessed. The occupational health and safety risk of handling MABs is dependent on the risk of internal exposure as well as the toxicity and immunogenicity of the MAB. Although each MAB is unique, the safe handling requirements of these agents can be considered as a class.[8,9,10]

Cytotoxic MABs are not included in the scope of this document.

- Any MAB conjugated to a cytotoxic molecule must be handled with cytotoxic precautions and should only be prepared in a manufacturing unit.[8,10,11,13]
- Current cytotoxic MABs available:
  - Brentuximab vedotin (Adcetris®)
  - Trastuzumab emtansine (Kadcyla®)

If unsure about specific handling for a MAB product please contact your pharmacist.

Where the products for administration is supplied via a community pharmacy by a patient, confirmation of suitability to prepare and administer locally is required from the regional pharmacist.

2.1.1 Occupational exposure

Concerns over the handling of MABs arose due to the uncertainty over the effects of potential occupational exposure to this diverse group of drugs. Factors associated with the risk of occupational exposure include the actions of the drug, the methods used to prepare and administer the drug, staff experience, potential route of exposure and likely level of exposure.[8,11,12]

Potential Routes of Exposure	Summary of literature
Inhaled	• Animal models have shown that there can be systemic absorption of MABs through inhalation • The generation of aerosolised particles are greatest during preparation or when dis/connecting lines, although the likelihood of producing a liquid aerosol in the clinical setting is low
Mucosal	• Animal models have shown that there is the potential for local and systemic absorption from mucosal uptake (nasal and ocular) • The generation of aerosolised particles are greatest during preparation or when dis/connecting lines, although the likelihood of producing a liquid aerosol in the clinical setting is low
Dermal	• Due to the molecular size of most MABs dermal absorption is considered unlikely • Healthcare workers with exposed damaged skin may be at an increased risk
Oral	• Animal and human models have shown the oral route is a potential route of absorption • Hand to mouth contamination is the most likely cause • The level of occupational exposure is unlikely to cause toxicity

Table 1: Potential routes of occupational exposure of MABs [8,10,11,13]

2.2 Minimum personal protective equipment requirements during handling

Non-cytotoxic MABs do not need be handled with cytotoxic precautions; however, they do require greater handling precautions than other non-hazardous injectable medications. Table 2 has the recommended safeguards to minimise the risk to healthcare workers when MABs are handled outside of an aseptic manufacturing unit.[8,9,10,11,13]

Personal Protective Equipment	Recommendations
Gloves and effective hand hygiene	• Use to minimise the risk of contamination and infection as part of good aseptic technique
Gowns	• Not warranted for preparation or administration
Mask (N95)	• Worn during dose preparation. • Not mandated during administration but may be considered when dis/connecting administration lines during intravenous administration due to potential aerolisation risk
Protective Eyewear	• Worn during dose preparation • Not mandated during administration but may be considered when dis/connecting administration lines during intravenous administration due to potential aerolisation risk

Table 2: Minimum Personal Protective Equipment [8,9,10,11,13]

2.3 Preparation of low risk MABs

There may be occasions in regional areas that MABs are required to be prepared on site. Preparation is the process of preparing or being prepared for use and is different to the process of administration. Examples of these include subcutaneous MABs or if a prepared infusion has a short expiry. These should be prepared just before administration when the patient is ready to receive treatment. They should not be prepared in advance and stored in a refrigerator.

When determining the appropriate site of preparation of a MAB please refer to the occupational health and safety risk assessment in the Australian consensus guidelines for the safe handling of monoclonal antibodies for cancer treatment by healthcare professionals or regionally endorsed assessment form for non-cancer MABs. The risk assessment must be conducted with input from medical teams, nursing and regional pharmacist.[8]

Nursing staff preparing and administering MABs should be competent in aseptic technique. Preparation should be undertaken in a dedicated area away from patients and carers. Pregnant or currently immunocompromised staff are not to be involved in the preparation of MABs for administration.[8,9,10]

For directions on preparation and administration of sotrovimab, please refer to the **WA Guidelines for User of Sotrovimab for COVID-19 Treatment.**

2.4 Disposal of waste, patient waste and spills

MABs should be disposed of in the same manner as other non-hazardous injectable medications.[1,3,4]

Exposure to waste products including waste and /or bodily fluids of patients should not present an additional occupational health and safety risk to healthcare workers. They should be disposed of in accordance with the disposal of clinical waste. Patients do not require additional contact precautions when receiving treatment with a MAB.[8,10,11]

If a spill occurs during preparation, administration or disposal of a MAB, it is recommended that the spill clean-up procedure is managed in the same manner as other non-hazardous injectable medications.[8,10,11]

2. References

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Version Control

Version	Date	Comments
1.0	10/01/2022	
2.0	02/02/2022	EAG APPROVED PSCQ ED APPROVED
3.0	28/02/2022	Updated Access Criteria EAG APPROVED PSCQ ED APPROVED
3.1	02/03/2022	Update to Appendix 1: Access criteria for medicines to treat COVID-19 that are part of the National Medical Stockpile
3.2	11/3/2022	Update to Appendix 1: Access criteria for medicines to treat COVID-19 that are part of the National Medical Stockpile to include molnupiravir PBS listing information
3.3	17/03/2022	EAG APPROVED removing molnupiravir from Tier 3 and creating a note at end of table.

This guidance is correct at the time of publishing. However, as it is subject to updates, please use the hyperlinks to confirm the information is accurate.

WA guidance may be amended as additional federal guidance is finalised and/or further information becomes available.

The latest version of this guidance will be made available on the COVID-19 information for health professional webpage.

This document can be made available in alternative formats on request for a person with disability.