Sotrovimab prescribing guideline

Department of Health

December 2021
Sotrovimab prescribing guideline
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1. Purpose
This guideline has been developed by the Queensland Health COVID-19 Therapeutics Working Group to provide clinicians with information and guidance around the appropriate prescribing and safe administration of sotrovimab (Xevudy®) in patients diagnosed with COVID-19, and to ensure equity of access to new COVID-19 therapeutics. This guideline requires endorsement by local Drugs and Therapeutics Committees or equivalent prior to implementation.

2. Background
This guideline and procedure are based on the findings of the COMET-ICE trial, the recommendations of the National COVID-19 Clinical Evidence Taskforce (NCCET) and the NSW Therapeutic Advisory Group guideline document. These guidelines will be updated frequently as new evidence is made available.

2.1 Regulatory status
Sotrovimab has been granted provisional approval by the Therapeutic Goods Administration (TGA) for the treatment COVID-19 in adults and adolescents (age ≥12 years and weighing at least 40 kg); who do not require initiation of oxygen and who are at increased risk of progression to hospitalisation or death.

Approval has been made based on short-term efficacy and safety data. Continued approval depends on evidence from ongoing clinical trials and post-market assessment. The product is subject to additional monitoring in Australia.

2.2 Mechanism of action
Sotrovimab is a recombinant human immunoglobulin monoclonal antibody targeting the spike protein receptor binding domain of SARS-CoV-2, which is understood to prevent membrane fusion after the virus binds to the human ACE-2 receptor, thus neutralising the virus.

2.3 Efficacy
The data supporting sotrovimab primarily comes from the COMET-ICE trial which established efficacy and safety data amongst 291 patients in the sotrovimab treatment arm. A single 500mg infusion of sotrovimab was found to decrease the risk of hospitalisation if given within 5 days of symptom onset in non-hospitalised, partially or unvaccinated patients with confirmed COVID-19 who did not require oxygen and were at high risk of medical complications. The number needed to treat with sotrovimab to prevent one hospitalisation event is approximately 16.
3. Prescription and governance

Sotrovimab has a restricted listing on the Queensland Health Medicines Formulary (List of Approved Medicines): on the advice of an Infectious Diseases physician for the treatment of COVID-19 in accordance with recommendations in the Statewide COVID-19 Treatment Guidelines and Sotrovimab Prescribing Guidelines.

Individual governance of sotrovimab prescribing should be managed by a lead clinician in each Hospital and Health Service.

3.1 Authorised prescribers

Prescribers are to complete a Request to Access Form (adult or paediatrics) for each patient, confirming patient suitability and consent to treatment.

For adult patients, patients should be assessed by their treating clinician, with suitable patients then discussed with the on-call adult Infectious Diseases physician or approved delegate for your service.

For paediatric patients, high risk children should be assessed initially by their treating paediatrician, with patient suitability confirmed on discussion with on-call paediatric Infectious Diseases for your service or at Children’s Health Queensland (CHQ).

3.2 Patient consent

There are no additional requirements for consent to administer sotrovimab than is usual practice for any other TGA registered pharmaceutical. Clinicians should discuss the risks and benefits of treatment with the patient and/or their carer and document that this has been done in the patient record. A sotrovimab Patient Information leaflet has been developed to assist with this and should be provided to the patient. Some clinicians may wish to obtain formal written consent and a consent form has been developed for this purpose. Consent forms and Patient Information are available online.

4. Access and supply

Access to sotrovimab is regulated by the National Medical Stockpile and managed centrally in Queensland by Central Pharmacy. Supply of COVID-19 therapeutics via the National Medical Stockpile (NMS) is uncertain and availability may fluctuate due to demand such as in the context of an outbreak.

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As such it is the recommendation of the COVID-19 Therapeutics Working Group that certain high risk cohorts are prioritised. Refer to Appendix 1. These patients must also meet the eligibility criteria outlined above.

A small amount of stock will be made available to healthcare facilities that have the capacity to appropriately store and monitor sotrovimab. Access will be closely monitored, and prescribers will be required to complete a Request to Access Sotrovimab form for each patient. Paediatric and Adult request forms are online.

5. Model of care

5.1 Overarching elements

1. Sotrovimab should be commenced as soon as possible after the patient has a positive result and within 5 days of symptom onset.

2. Hospital and Health Services should develop local processes to ensure identified eligible patients are supported to access sotrovimab as early as possible.

3. Sotrovimab infusion may be delivered in a range of appropriate healthcare 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 disposal.

4. It should be administered where the safety of patients, carers and providers can be maintained. This includes the requirements to observe the patient receiving sotrovimab infusion for a minimum of 90 minutes and having access to personnel and equipment to manage anaphylaxis or other adverse drug reactions.

5. As much as possible, it should avoid putting additional pressure on acute care services such as emergency departments.

Settings successful in other Australian jurisdictions include:

- Dedicated outpatient infusion areas/infusion lounges separated from acute care areas where ideally patients can be isolated in single rooms or appropriately cohorned.
- Designated bed/s in COVID ward allocated as a day procedure bed
- Marquee, tent or mobile truck set up on hospital grounds
5.2 Hospital in the home (HITH)

It is recommended that sotrovimab is not delivered in hospital in the home. This is in recognition that sotrovimab is a new treatment requiring monitoring during and after infusion with readily available resuscitation facilities, aligns with the advice of the Society of Hospital Pharmacists of Australia and reflects the approach of other Australian jurisdictions.

5.3 Hospitalised patients

COVID-19 positive inpatients who meet the clinical criteria for treatment and are not admitted for primary management of COVID-19 symptoms should be considered for sotrovimab infusion in the inpatient setting.

6. Clinical criteria for treatment

6.1 Indications

1. Non-pregnant adults, and pregnant women in their second or third trimester*, who are:
   - COVID-19 positive and within 5 days of symptom onset; **AND**
   - Do not require oxygen for COVID-19; **AND**
   - Not fully vaccinated, refer to table 1 **OR**
   - Are immunosuppressed# (regardless of their vaccination status) – these patients do not need an additional risk factor below.

**AND** (with the exception of immunosuppressed patients regardless of vaccination status) who have at least one of the following risk factors for severe disease:

- Diabetes (requiring medication)
- Obesity (BMI > 30 kg/m²)
- Chronic kidney disease (i.e. eGFR <60 mL/min/1.73m²)
- 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 or age >35 years if Aboriginal or Torres Strait Islander

* Pregnant women were not included in the COMET-ICE trial and there are currently no data on the effects of sotrovimab on a pregnant woman or her baby. Sotrovimab is a human immunoglobulin G (IgG) and may cross the placenta, the potential impact of this is not known. However, it is known that pregnant women with COVID-19 are at increased risk of developing severe disease, which can have serious health implications for the woman and her baby

# Immunosuppressed patients are those that

a) have a primary or acquired immunodeficiency such as haematological neoplasms, are post-transplant [solid organ (on immunosuppressive therapy) or haematopoietic stem cell transplant within 24 months], or have HIV/AIDS or other significant immunocompromising condition or

b) are on/have been on recent immunosuppressive therapy such as chemotherapy or, high dose corticosteroids (equivalent to 20 mg or more of prednisone)

Table 1: Definition of fully vaccinated: must be ≥ 14 days following receipt of the final dose of a TGA approved COVID-19 vaccine,

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Patient age ≥ 70</td>
<td>2 dose primary course and 3rd dose booster (&gt; 3 months post primary course)</td>
</tr>
<tr>
<td>• Patient age ≥ 55 (or ≥35 for Aboriginal and Torres Strait Islander patients) with multiple comorbidities</td>
<td>2 dose primary course</td>
</tr>
<tr>
<td>• Patient age &lt; 55</td>
<td>2 dose primary course</td>
</tr>
<tr>
<td>• Patient age ≥ 55 and &lt; 70 (or ≥35 for Aboriginal and Torres Strait Islander patients) without multiple comorbidities</td>
<td>3 dose primary course</td>
</tr>
</tbody>
</table>

2. Adolescents aged ≥12 years and weighing at least 40kg*, who are:

• COVID-19 positive and within 5 days of symptom onset; **AND**

• Do not require oxygen for COVID-19; **AND**
• Have not been fully vaccinated (fully vaccinated patients are those who have received a second dose >2 weeks previously); OR
• Are immunosuppressed\(^\ddagger\) (regardless of their vaccination status) – these patients are at highest risk if an additional risk factor also present as below but may also be eligible without an additional risk factor.

**AND who are at high risk of deterioration**

• Complex life limiting neurodisability with respiratory involvement
• Heart failure
• respiratory conditions, e.g.: chronic lung disease requiring oxygen, severe cystic fibrosis, severe asthma)
• obesity (BMI ≥95th [CDC] / ≥97th [WHO] centile for age)
• or
• two or more complex chronic conditions or comorbidities

\(^\ddagger\) Guidance and detailed risk stratification available in the [CHQ Paediatric Guideline](#).

Monoclonal antibody therapy is a limited resource and is currently reserved for those at the very highest risk of disease progression. Although established adult COVID-19 risks do extend into younger age groups (i.e. age, obesity, comorbidity) even these children remain at lower risk of severe disease than adults.

Fulfilling eligibility criteria does not automatically result in its prescription in children. Use in mild disease should be based on the patient’s individual risk of severe disease, including age, multiple risk factors, and COVID-19 vaccination status.

Approval to use sotrovimab will be considered on a case-by-case basis after discussion with Paediatric Infectious Diseases.

### 6.2 Contraindications

• Patients under 40kg and less than 12 years of age
• Known hypersensitivity to sotrovimab, or any of the excipients (histidine, histidine hydrochloride monohydrate, sucrose, methionine, polysorbate 80) in the product, Chinese Hamster Ovary cell products or other recombinant human or humanised antibodies.
6.3 Precautions

- There is no evidence on the use of sotrovimab after receipt of a previous COVID-19 monoclonal antibody such as casirivimab and imdevimab. Caution should be taken with prescribing sotrovimab within 4 weeks.

- History of anaphylaxis to other medications.

- Renal impairment is not a precaution for sotrovimab: sotrovimab is not renally excreted. Population pharmacokinetic studies show no difference in sotrovimab pharmacokinetics in patients with mild, moderate or severe renal impairment. (eGFR <30mL/min/1.73m²)

- Hepatic impairment is not a precaution for sotrovimab: sotrovimab is degraded by widely distributed proteolytic enzymes, not restricted to hepatic tissue, therefore changes in hepatic function are unlikely to affect elimination. Population pharmacokinetics analyses show no difference in sotrovimab pharmacokinetics in patients with mild and moderate hepatic impairment. There is limited data in patients with severe hepatic impairment.

- Pregnancy: Sotrovimab is pregnancy category B2. There is potential for placental transfer of sotrovimab from the mother to the developing foetus and the potential impact of this is not known. Sotrovimab is not recommended in the first trimester of pregnancy. It may be administered to pregnant women in the second and third trimester of pregnancy, but a risk/benefit discussion should be engaged between clinician and patient.

- Breastfeeding: There are no available data on the excretion of sotrovimab in human milk and the potential risks and benefits to a breastfed baby are unknown. The amount present in breastmilk is likely to be very low as sotrovimab is a large protein molecule. The median elimination half-life of sotrovimab is 49 days. A decision whether to discontinue breastfeeding or abstain from sotrovimab therapy should consider the benefit of breastfeeding in the baby and the benefit of therapy for the woman.

6.4 Drug interactions

No formal interaction studies have been conducted with sotrovimab. Sotrovimab is not renally excreted or metabolised by the CYP450 enzymes. Sotrovimab is degraded by proteolytic enzymes widely distributed in the body and not restricted to hepatic tissue.
7. Prescribing and administration

7.1 Clinical setting

Sotrovimab should be administered in an appropriate site by staff with experience in monitoring infusion reactions and managing adverse events (including anaphylaxis).

In determining choice of setting, consider:

- Personnel and equipment to manage anaphylaxis must be present during the minimum 30-minute infusion and for at least 60 minutes of post-infusion observation.

- Availability of an adequate dedicated area for the reconstitution and preparation of the infusion. Ideally sotrovimab is given immediately after preparation. However, if this is not possible, the diluted solution may be prepared in an appropriate place elsewhere and stored in a refrigerator for up to 24 hours (include infusion time).

7.2 Baseline tests

Immediately prior to commencing the infusion, where feasible it is recommended that patients have blood taken for COVID serology (request COVGQ). Sotrovimab infusion should not be delayed for serology results.

7.3 Dose

Sotrovimab is given as a single dose of 500mg by intravenous infusion over 30 minutes

- There is no adjustment required for age, weight, renal or hepatic impairment.

- Co-prescribe adrenaline IM as a single dose as per local guidelines for the emergency management of anaphylaxis.

**ieMR ordering:** to prescribe sotrovimab select “Add order” and search for drug name “sotrovimab”.

- **For adults:** Choose order set “Sotrovimab 500 mg in sodium chloride 0.9% 100mL (single bag) adult” and complete prescription

- **For children > 12 years and >40 kg:** Choose order set “Sotrovimab 500 mg in sodium chloride 0.9% 100mL (single bag) paediatric >/= 12 yrs and >/= 40 kg” and complete prescription

(See Appendix 2 for ieMR prescribing examples)
Non ieMR ordering: sotrovimab should be prescribed as a STAT order on the front of the National Inpatient Medication Chart: “sotrovimab 500 mg in 100 mL sodium chloride 0.9% infused over 30 minutes”

7.4 Presentation

Available as a single use glass vial containing 500 mg/8 mL (62.5 mg/mL) concentrated injection solution for infusion for dilution prior to administration. The vial has an overfill of 0.6mL to allow a deliverable volume of 8mL.

The solution in the vial should be clear and colourless to yellow or brown.

7.5 Storage and stability

Undiluted vials: Refrigerate at 2-8°C in original package. Do not freeze. Protect from light.

Infusion solution: The diluted solution of sotrovimab is intended for immediate use. If immediate administration is not possible, the diluted solution may be stored at room temperature (up to 25°C for up to 6 hours or refrigerated (2-8°C) for up to 24 hours from the time of dilution until the end of administration.

7.6 Preparation and administration

CAUTION: The occupational hazard of intermittent low dose exposure to sotrovimab is not known. Therefore, additional precautions are advised when preparing and administering sotrovimab:

- Wear a P2/N95 mask, disposable gloves, protective eyewear, and a disposable apron.
- The infusion bag must be prepared using standard aseptic technique
- Reconstitution or preparation of sotrovimab should occur in a dedicated preparation area away from patients and carers
- Do not shake vials when reconstituting as this can damage the protein and form a froth

ALERT: Emergency resuscitation personnel, equipment and medications must be available for immediate use in the event of a hypersensitivity or anaphylactic reaction to sotrovimab. Refer to local HHS policies for the management of anaphylaxis
## Preparation Steps

1. Remove vial from refrigerator and allow to come to ambient room temperature, protected from light, for approximately 15 minutes.

2. Visually inspect the vial to ensure it is free from particulate matter and that there is no damage to the vial. If the vial is identified to be unusable, contact Pharmacy. Do not discard the vial – quarantine in a separate clearly marked section of the refrigerator.

3. Gently swirl the vial several times before use, without creating air bubbles. DO NOT SHAKE or vigorously agitate the vial, as this can damage the protein and cause a froth.

4. Withdraw 8 mL (= 500 mg) solution from the sotrovimab vial

5. Inject 8 mL (= 500 mg) sotrovimab solution into a 100mL sodium chloride 0.9% infusion bag

6. Prior to infusion, to mix, gently rock the infusion bag back and forth 3 to 5 times. DO NOT invert the bag. Avoid forming air bubbles.

7. Discard the vial including any unused solution

## Administration Steps

1. Do not use the same IV line to administer other medications at the same time.

2. Attach an infusion set to the infusion bag using standard bore tubing. Use of a 0.2 micron in-line filter is recommended, but not required by the manufacturer. Do not delay infusion if an in-line filter is not available.

3. Prime the infusion set with the sotrovimab infusion and then infuse intravenously over 30 minutes (until the bag is finished) via a central or peripheral line.

4. After the sotrovimab infusion is completed, flush the giving set with at least 20 mL of sodium chloride 0.9% (at the same rate as the sotrovimab infusion)

5. **Observe the patient during the infusion and for 60 minutes after infusion cessation** in case of hypersensitivity reactions or anaphylaxis.
7.7 Observation and monitoring

Patients must be observed during and for at least 60 minutes after the end of the infusion.

- Infusion reactions include fever, chills, dizziness, dyspnoea, pruritis and rash.
- For mild-moderate infusion reactions, slow or stop the infusion and treat accordingly.
- If signs and symptoms of a significant hypersensitivity/anaphylaxis occur – STOP the infusion immediately and commence supportive care.

7.8 Adverse effects and reporting

Adverse events reported in the COMET-ICE trial included nausea, diarrhoea, and headaches at similar rates to placebo.

- Common (≥1%): hypersensitivity reactions (includes rash (2%), infusion-related reaction, bronchospasm)
- Rare (≥0.01%): anaphylaxis

It may be difficult to distinguish between adverse effects of sotrovimab and signs and symptoms of COVID-19. However, because sotrovimab is a provisionally approved product with no post-marketing data, all possible and confirmed adverse events must be reported. These should be notified to the TGA Reporting adverse events | Therapeutic Goods Administration (TGA) and reported via Riskman.

7.9 Monitoring of treatment outcomes

The use of sotrovimab requires reporting of clinical outcomes to the National Medical Stockpile Taskforce. Prescribers agree to these terms when completing a Sotrovimab Notification Form. Data required includes eligibility, confirmation of full dose delivery and outcome: recovery, progression to hospitalisation, oxygen requirement, ICU or death.

8. Vaccination post sotrovimab infusion

The US Centers for Disease Control and Prevention have updated their advice concerning COVID-19 vaccination after the administration of monoclonal antibodies. The current recommendation is that there is no need to defer vaccination following treatment.
Patients can be provided with a letter documenting the date and location of their infusion. A template is available here.

9. Compliance and evaluation

Regular prescribing reports will be provided through interrogation of iPharmacy, ieMR and CHARM programs. Reports will be made available to Medication and Pharmacy Planning Response Group (MPPRG).
# Appendix 1 – Priority groups for treatment

<table>
<thead>
<tr>
<th>ELIGIBLE PATIENTS</th>
<th>PRIORITY GROUPS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pregnant women</strong></td>
<td>Consider in second and third trimester</td>
</tr>
<tr>
<td>not fully vaccinated and with <strong>moderate</strong> risk factor as below OR fully vaccinated and are immunosuppressed*</td>
<td></td>
</tr>
<tr>
<td>*pregnancy itself is not considered an immunosuppressive condition – must have an additional immunosuppressive syndrome or be on immunosuppressive therapy as listed below.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patients who are Unvaccinated or partially vaccinated</th>
<th>With a moderate risk factor*:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Age ≥ 55 (or &gt; 35 if Aboriginal and Torres Strait Islander)</td>
<td></td>
</tr>
<tr>
<td>• Obesity (BMI ≥ 30 kg/m²)</td>
<td></td>
</tr>
<tr>
<td>• Chronic kidney disease (eGFR &lt; 60 mL/min/1.73m²²)</td>
<td></td>
</tr>
<tr>
<td>• Serious cardiac condition (such as heart failure, coronary artery disease or cardiomyopathy)</td>
<td></td>
</tr>
<tr>
<td>• Chronic obstructive pulmonary disease disease (history of chronic bronchitis, chronic obstructive lung disease, or emphysema with dyspnoea on physical exertion)</td>
<td></td>
</tr>
<tr>
<td>• Moderate-to-severe asthma (requiring inhaled steroid as a preventor) or prescribed a course of oral steroids in the previous 12 months</td>
<td></td>
</tr>
<tr>
<td>• Diabetes mellitus (type 1 or 2 requiring medication)</td>
<td></td>
</tr>
<tr>
<td>• Medical related technologic dependence (CPAP, other ventilation not related to COVID-19)</td>
<td></td>
</tr>
<tr>
<td>• Neurodevelopment disorders (including cerebral palsy, Down’s syndrome etc)</td>
<td></td>
</tr>
<tr>
<td>• Sickle cell disease</td>
<td></td>
</tr>
<tr>
<td>• Patients with neuromuscular disease with respiratory muscle involvement (spinal cord injury, post-polio syndrome, spinal muscular atrophy, motor neurone disease, Duchenne or other muscular dystrophy, myotonic dystrophy, myasthenia gravis)</td>
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<table>
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<tr>
<th>High risk patients:</th>
</tr>
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<tbody>
<tr>
<td>• Age ≥ 70 years</td>
</tr>
<tr>
<td>• &gt;55 years with an additional COVID risk factor (obesity, diabetes (non-diet controlled), CKD with GFR &lt; 60 mL/min/1.73m²², heart failure) OR significant underlying bronchiectasis</td>
</tr>
<tr>
<td>• &gt;35 years and Aboriginal and Torres Strait Islander with an additional COVID risk factor (obesity, diabetes (non-diet controlled), CKD with eGFR &lt; 60 mL/min/1.73m²², heart failure) OR significant underlying bronchiectasis</td>
</tr>
</tbody>
</table>
**ELIGIBLE PATIENTS**

*NB: sotrovimab is likely to be of little additional benefit in patients who have received a booster dose.*

### REGARDLESS OF VACCINATION STATUS

<table>
<thead>
<tr>
<th>Patients with chronic kidney disease (irrespective of vaccination status)</th>
<th><strong>PRIORITY GROUPS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Dialysis dependent with any moderate or high COVID-19 risk factors in addition to CKD (as listed above)</td>
<td>• Rituximab / obintuzumab / BITE antibodies within 12 months</td>
</tr>
<tr>
<td>• Rituximab / obintuzumab / BITE antibodies within 12 months</td>
<td></td>
</tr>
<tr>
<td>• CAR-T within 24 months</td>
<td></td>
</tr>
<tr>
<td>• Alemtuzumab within 6 months</td>
<td></td>
</tr>
<tr>
<td>• Ibrutinib, acalabrutinib, venetoclax within 6 months</td>
<td></td>
</tr>
<tr>
<td>• Daratumumab within 6 months</td>
<td></td>
</tr>
<tr>
<td>• Lenalidomide / pomalidomide</td>
<td></td>
</tr>
<tr>
<td>• Bortezomib / carfilzomib</td>
<td></td>
</tr>
<tr>
<td>• TKIs and other targeted therapies (dasatinib, nilotinib, imatinib, osimertinib, erlotinib, crizotinib, alectinib, loralatinib, etc)</td>
<td></td>
</tr>
<tr>
<td>• Complement inhibitors (eculizumab)</td>
<td></td>
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<tr>
<td>• S1PR modulators (lingolimod, siponimod)</td>
<td></td>
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<tr>
<td>• Belimumab</td>
<td></td>
</tr>
<tr>
<td>• Prednisone ≥ 20mg day (or equivalent) for &gt; 4 weeks</td>
<td></td>
</tr>
<tr>
<td>• Combination therapy with corticosteroids and x 2 DMARDs</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patients on immunosuppressive therapy: Biologic agents / TKIs / cellular therapies (irrespective of vaccination status)</th>
<th><strong>PRIORITY GROUPS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Rituximab / obintuzumab / BITE antibodies within 12 months</td>
<td></td>
</tr>
<tr>
<td>• CAR-T within 24 months</td>
<td></td>
</tr>
<tr>
<td>• Alemtuzumab within 6 months</td>
<td></td>
</tr>
<tr>
<td>• Ibrutinib, acalabrutinib, venetoclax within 6 months</td>
<td></td>
</tr>
<tr>
<td>• Daratumumab within 6 months</td>
<td></td>
</tr>
<tr>
<td>• Lenalidomide / pomalidomide</td>
<td></td>
</tr>
<tr>
<td>• Bortezomib / carfilzomib</td>
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<td>• Combination therapy with corticosteroids and x 2 DMARDs</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Other immunosuppressive therapy: Corticosteroids / DMARDs</th>
<th><strong>PRIORITY GROUPS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Prednisone ≥ 20mg /day (or equivalent) for ≥ two weeks</td>
<td></td>
</tr>
<tr>
<td>• Abatacept</td>
<td></td>
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<tbody>
<tr>
<td>(irrespective of vaccination status)</td>
<td></td>
</tr>
<tr>
<td>• Dapsone</td>
<td>• Autologous stem cell transplantation within 6 months</td>
</tr>
<tr>
<td>• Hydroxychloroquine</td>
<td>• Solid organ transplantation on immunosuppression</td>
</tr>
<tr>
<td>• Calcineurin inhibitors (cyclosporin, tacrolimus)</td>
<td>• Allogeneic stem cell transplant within 2 years or on immunosuppression / chronic GVHD</td>
</tr>
<tr>
<td>• mTOR inhibitors (sirolimus, everolimus)</td>
<td></td>
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<tr>
<td>Transplantation (irrespective of vaccination status)</td>
<td>• Autologous stem cell transplantation within 12mths</td>
</tr>
<tr>
<td>• Solid organ transplantation on immunosuppression</td>
<td>• Lung cancer on active chemotherapy +/- immunotherapy within 6 months</td>
</tr>
<tr>
<td>• Allogeneic stem cell transplantation within 2 years or on immunosuppression / chronic GVHD</td>
<td>• Other malignancies (both haematological and solid cancer): moderate intensity chemotherapy within 2 weeks</td>
</tr>
<tr>
<td>• Recent whole body radiotherapy or total lymphoid irradiation</td>
<td>• Major antibody deficiency (i.e CVID or XLA)</td>
</tr>
<tr>
<td>Chemotherapy / malignancy (irrespective of vaccination status)</td>
<td>• Combined immunodeficiency syndromes including transplanted SCID where immunoglobulin replacement is required.</td>
</tr>
<tr>
<td>• Acute myeloid leukaemia induction / consolidation within 6 months</td>
<td>• HIV infection with CD4 &lt; 250</td>
</tr>
<tr>
<td>• Acute lymphoblastic leukaemia induction / consolidation / maintenance within 12 months</td>
<td>• Aplastic anaemia on active therapy</td>
</tr>
<tr>
<td>• Lung cancer on active chemotherapy +/- immunotherapy within 6 months</td>
<td>• Primary immunodeficiency syndromes where immunoglobulin replacement is required (excluding specific antibody deficiency)</td>
</tr>
<tr>
<td>• Other malignancies (both haematological and solid cancer): moderate intensity chemotherapy within 2 weeks</td>
<td>• Secondary hypogammaglobulinemia requiring immunoglobulin replacement – risk related to underlying therapy / disease resulting in 2nd hypogammaglobulinaemia</td>
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<tr>
<td>Immunodeficiency disorders (irrespective of vaccination status)</td>
<td>• Major antibody deficiency (i.e CVID or XLA) with an additional COVID risk factor (age &gt;55, obesity, diabetes (non-diet controlled), CKD, heart failure) OR significant underlying bronchiectasis OR on immunosuppressive therapy.</td>
</tr>
<tr>
<td>• Combined immunodeficiency syndromes including transplanted SCID where immunoglobulin replacement is required.</td>
<td>• HIV with CD4 &lt;250</td>
</tr>
<tr>
<td>• Aplastic anaemia on active therapy</td>
<td>• Aplastic anaemia on active therapy</td>
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<tr>
<td>Class</td>
<td>Examples</td>
</tr>
<tr>
<td>------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Anti-integrins</td>
<td>natalizumab, vedolizumab</td>
</tr>
<tr>
<td>Anti-TNF-α antibodies</td>
<td>infliximab, adalimumab, etanercept, golimumab, certolizumab</td>
</tr>
<tr>
<td>Anti-IL1 antibodies</td>
<td>anakinra</td>
</tr>
<tr>
<td>Anti-IL6 antibodies</td>
<td>Tocilizumab</td>
</tr>
<tr>
<td>Anti-IL17 antibodies</td>
<td>secukinumab, ixekizumab</td>
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<tr>
<td>Anti-IL4 antibodies</td>
<td>dupilumab</td>
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<td>Anti-IL23 antibodies</td>
<td>ustekinumab</td>
</tr>
<tr>
<td>Immune checkpoint inhibitors</td>
<td>nivolumab, pembrolizumab, ipilimumab, atezolizumab</td>
</tr>
</tbody>
</table>
Appendix 2 – ieMR screenshots

Orders for Signature

Details for sotrovimab additive 500 mg + Sodium Chloride 0.9% intravenous infusion 100 mL

- Route of administration: IV continuous infusion
- Requested start date/time: 02 Dec 2021 1204 AEST
- Stop date/time: 02 Dec 2021 1423 AEST
- Duration: 1
- Duration unit: bag(s)
- Indication: COVID-19

Orders for Signature

Details for sotrovimab additive 500 mg + Sodium Chloride 0.9% intravenous infusion 100 mL

- Indication: COVID-19
- Special instructions: For use only in age >= 12 years AND weight >= 40 kg
- Priority: NOW
- Bolus dose: None
- Bolus discard: Routine

Details for sotrovimab additive 500 mg + Sodium Chloride 0.9% intravenous infusion 100 mL

- Base Solution
  - Sodium Chloride 0.9% intravenous infusion 100 mL
- Additive
  - sotrovimab additive
- Additive Dose
  - 500 mg
- Normalized Rate
  - 100 mL/hr
- Delivers
  - 1 hour(s)
- Occurrence
  - E8
- Total Bag Volume
  - 100 mL
- Weight
  - kg
- RSA
## 10. Version control

<table>
<thead>
<tr>
<th>Version</th>
<th>Amendments</th>
<th>Author/s</th>
<th>Approved</th>
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<tr>
<td>v 1-0</td>
<td>New document</td>
<td>Tina Patterson, Andrew Henderson</td>
<td>2/12/2021</td>
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<tr>
<td>v 1-2</td>
<td>Review and feedback incorporated</td>
<td>COVID-19 Therapeutics Working Group (CTWG)</td>
<td>14/12/2021</td>
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<td>Medications and Pharmacy Planning and Response Group (MPPRG)</td>
<td>17/12/2021</td>
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<tr>
<td>v 1-3</td>
<td>Endorsed</td>
<td>COVID-19 System Response Group</td>
<td>4/01/2022</td>
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| v 1-4   | s3.0 Prescription & Governance – insertion of statement that governance of sotrovimab prescribing to be managed by a lead clinician in each HHS  
s3.1 Authorised prescribers – clarification that patients assessed as eligible should also be discussed with the ID on-call physician or approved delegate  
s6.1 Indications - ^Footnote added to definition of fully vaccinated to clarify definition for dialysis dependent patients as being a 3-dose course and additional statement that dialysis dependent patients not considered immunosuppressed unless they are concomitant immunosuppression or have another immunosuppressive syndrome. | Andrew Henderson  
Endorsed: Keith McNeil  
A/Deputy Director-General, CMO and CCIO Prevention Division | 13/01/2022 |
| v 1-5   | s4.0 Access & Supply – insertion of advice regarding tiered levels of access to respond to fluctuations in the supply chain.  
s6.0 Clinical criteria for treatment – addition of a statement that criteria may be restricted depending on current stock levels.  
p9 – statement regarding variable response to COVID-19 vaccination added at footnote #Immunosuppressed patients  
Addition of Appendix 1 – Tiered access criteria table | Endorsed: Keith McNeil  
A/Deputy Director-General, CMO and CCIO Prevention Division | 25/01/2022 |
<table>
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<tr>
<td>V 1-6</td>
<td>s4.0 Access &amp; Supply – removal of advice regarding tiered levels of access. Replaced with priority groups.</td>
<td>Endorsed: Keith McNeil A/Deputy Director-General, CMO and CCIO Prevention Division</td>
<td></td>
</tr>
<tr>
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<td>s6.0 Clinical criteria for treatment – removal of statement that criteria may be restricted depending on current stock levels.</td>
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</tr>
<tr>
<td></td>
<td>s6.1 Clinical criteria for treatment – insertion of table 1: definition of fully vaccinated patients</td>
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</tr>
<tr>
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<td>p9 – removal of statement regarding variable response to COVID-19 vaccination added at footnote #Immunosuppressed patients</td>
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<td>s8.0 Vaccination post sotrovimab infusion – updated advice that a deferral period is no longer recommended</td>
<td></td>
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<td>Appendix 1 – Tiered access criteria table removed and replaced with Priority Groups for Treatment</td>
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