There are a range of anti-SARS-CoV-2 monoclonal antibodies (MAB) and antiviral medications that have been provisionally approved by the Therapeutic Goods Administration. These medications are for the treatment of patients in the early phase of infection with COVID-19 who are at risk of progression to severe disease.

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

- changes in the evidence, including impacts of new variants on the efficacy of these medications
- availability of new medications in Australia
- access to supply
- the context of COVID-19 outbreaks in NSW.

This document should be read in conjunction with the drug guidance developed for NSW use by the Clinical Excellence Commission (CEC) and the NSW Therapeutic Advisory Group (NSW TAG).

**Methodology**

The National Clinical Evidence Taskforce Guidelines specify recommendations for the use of anti-SARS-CoV-2 monoclonal antibodies and antivirals in adults and adolescents in Australia based on available evidence.\(^3\) This model of care is based on these recommendations and the evidence checks undertaken by the NSW Critical Intelligence Unit (CIU).\(^1,2\)

Due to the limited supply of these medicines and high case numbers of COVID-19 (Omicron variant) in NSW, there is a need to identify the people who are at most risk and therefore potentially likely to benefit from the administration of these medicines. Key risk factors (based on the National Clinical Evidence Taskforce recommendations and outlined in Table 1 and Table 2) will be targeted to identify people in these high-risk cohorts within NSW.\(^3\)

The available evidence was considered by an expert group of NSW clinicians to inform the development of this model and identification of NSW specific key risk factors. Emerging medications are also being monitored by the CIU and will be included in this document, as required.

**Updates**

The following updates are included in this version:

- Re-inclusion of casirivimab and imdevimab into Table 1.
- Inclusion of tixagevimab and cilgavimab, Table 3.
- Inclusion of a new table, Table 4, outlining specific considerations for medications.
- Minor updates to the figures.
Who can be treated?

Clinical criteria and risk factors

The medications covered in this model of care currently include:

- sotrovimab (see Table 1 and Table 2)
- casirivimab and imdevimab (see Table 1)
- molnupiravir (see Table 1)
- nirmatrelvir plus ritonavir (see Table 1)
- tixagevimab and cilgavimab (see Table 3)

Generally, these drugs are for use early in the course of the disease before significant symptoms or severe disease have developed, and within a window of 5 days from the onset of infection (or as early as possible). These agents prevent the replication and spread of the virus and are likely to work best soon after infection has occurred. This limits the spread of the virus beyond the respiratory tract and before a severe systemic immune response has been initiated.

Note: Tixagevimab and cilgavimab can be used for pre-exposure prophylaxis and casirivimab and imdevimab for post-exposure prophylaxis.

Antiviral medications are not approved for use in children or adolescents under 18 years. Some monoclonal treatments are approved for adolescents aged 12 to 17 years and weighing > 40kg.

Not everyone with COVID-19 will benefit, nor be eligible for these medicines. They are not an alternative to vaccination for COVID-19.

Vaccination remains the best way to protect vulnerable populations from the adverse outcomes of COVID-19 infection.

Although the indications for these medications are similar, they are not identical. As such, medication-specific risk factors, criteria and individual drug guidance should be reviewed. Of note, the CEC published medication guidance and NSW-specific key risk factors differ slightly due to the aforementioned need to identify and target those most likely to benefit from these medications within the NSW context.

Criteria and medication-specific risk factors for sotrovimab, casirivimab and imdevimab, molnupiravir, and nirmatrelvir plus ritonavir are outlined in Table 1 for adults or Table 2 for adolescents. As the medicine-specific risk factors are different to other medications outlined in this document, the use of tixagevimab and cilgavimab is specified in Table 3.

Considerations for all these medications, such as efficacy against sub variants and for patient populations, are outlined in Table 4.

Prioritised cohorts in NSW

Access for patients should be considered in the context of NSW outbreaks. 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 criteria specified in the drug guidance.

- Patients who have acquired COVID-19 infection in high-risk settings, such as disability group homes and residential aged care facilities.
- Aboriginal and/or Torres Strait Islander communities.
- Rural, regional and remote communities.
- Patients in areas with large outbreaks.
- Patients with nosocomial infection (i.e. those who have acquired a COVID-19 infection in hospital or healthcare setting).

Data collected and monitored in NSW has indicated that there may be a higher risk of severe disease and mortality for people from Pasifika populations. It may be prudent to plan access for patients in the above groups who have been exposed, but have not yet developed symptoms.

Medication guidance

Specifications for administration are available on the CEC medication safety pages:

- sotrovimab
- casirivimab and imdevimab
- molnupiravir
- nirmatrelvir plus ritonavir
- tixagevimab and cilgavimab
The NSW Safety Notice 024/21 outlines risks associated with the use of casirivimab plus imdevimab, with the aim of ensuring its safe and appropriate use.

Clinicians should consider the SARS-CoV-2 variant being targeted and the possibility of reduced sensitivity. Early evidence shows casirivimab plus imdevimab is not as effective against Omicron as other variants. As such, sotrovimab is the preferred monoclonal antibody for treatment of the Omicron variant of concern. It is further recommended that casirivimab plus imdevimab is NOT used for post-exposure prophylaxis where the source exposure is Omicron.

There is no data currently on the clinical effectiveness of the oral antivirals against Omicron. This guidance is intended to support their use.

Table 1. NSW-specific risk factors for high priority cohorts for use of sotrovimab, casirivimab and imdevimab, molnupiravir and nirmatrelvir plus ritonavir

<table>
<thead>
<tr>
<th>Risk factors that must be met for prescription of any of the four medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Commence within 5 days of symptom onset (or 7 days for casirivimab plus imdevimab) <strong>AND</strong></td>
</tr>
<tr>
<td>• No oxygen requirement due to COVID-19 <strong>AND</strong></td>
</tr>
<tr>
<td>• Reduced immunity to COVID-19 by being:</td>
</tr>
<tr>
<td>− unvaccinated (i.e. received no doses of a COVID-19 vaccination) <strong>OR</strong></td>
</tr>
<tr>
<td>− vaccination not up-to-date (as per ATAGI guidance)** OR**</td>
</tr>
<tr>
<td>− immunocompromised (as per ATAGI guidance)** AND**</td>
</tr>
<tr>
<td>• Have at least TWO medication-specific risk factors as outlined below.</td>
</tr>
</tbody>
</table>

* patients that are immunocompromised do NOT need to meet the medication-specific risk factor criteria. They are eligible to receive an anti-SARS-CoV-2 monoclonal antibody or oral antiviral medicine on the basis of immunosuppression alone.

Medication-specific risk factors

Sotrovimab

• Pregnant women in their second or third trimester
• Non-pregnant adults who are aged ≥60 years or aged ≥35 years if Aboriginal and/or Torres Strait Islander
• Obesity (BMI ≥30kg/m²)
• Serious cardiovascular disease such as heart failure, coronary artery disease, cardiomyopathies
• Chronic lung disease, including COPD, severe asthma (requiring a course of oral steroids in the previous 12 months), interstitial lung disease and bronchiectasis
• Type 1 or 2 diabetes mellitus requiring medication
• Severe chronic kidney disease
• Severe chronic liver disease
• Active cancer, especially haematological malignancy
• Other specific conditions outlined in the National Clinical Evidence Taskforce guidance but not in the above list
## Medication-specific risk factors

### Casirivimab plus imdevimab
- Pregnant women
- Non-pregnant adults who are aged ≥60 years or aged ≥35 years if Aboriginal and/or Torres Strait Islander
- Obesity (BMI ≥30kg/m²)
- Serious cardiovascular disease such as heart failure, coronary artery disease, cardiomyopathies
- Chronic lung disease, including COPD, severe asthma (requiring a course of oral steroids in the previous 12 months), interstitial lung disease and bronchiectasis
- Type 1 or 2 diabetes mellitus requiring medication
- Severe chronic kidney disease
- Severe chronic liver disease
- Active cancer, especially haematological malignancy
- Other specific conditions outlined in the [National Clinical Evidence Taskforce guidance](https://www.aci.health.nsw.gov.au) but not in the above list

### Molnupiravir
- Non-pregnant adults who are aged ≥60 years or aged ≥35 years if Aboriginal and/or Torres Strait Islander.
- Obesity (BMI ≥30kg/m²)
- Serious cardiovascular disease such as heart failure, coronary artery disease, cardiomyopathies.
- Chronic lung disease, including COPD, severe asthma (requiring a course of oral steroids in the previous 12 months), interstitial lung disease and bronchiectasis
- Type 1 or 2 diabetes mellitus requiring medication
- Severe chronic kidney disease
- Severe chronic liver disease
- Active cancer, especially haematological malignancy
- Other specific conditions outlined in the [National Clinical Evidence Taskforce guidance](https://www.aci.health.nsw.gov.au) but not in the above list

### Nirmatrelvir plus ritonavir
- Non-pregnant adults who are aged ≥60 years or ≥35 years if Aboriginal and/or Torres Strait Islander
- Obesity (BMI ≥30kg/m²)
- Serious cardiovascular disease such as heart failure, coronary artery disease, cardiomyopathies.
- Chronic lung disease, including COPD, severe asthma (requiring a course of oral steroids in the previous 12 months), interstitial lung disease and bronchiectasis
- Type 1 or 2 diabetes mellitus requiring medication
- Chronic kidney disease with eGFR 30-60mL/min (contraindicated with eGFR <30mL/min) – note dose reduction required
- Chronic liver disease Child-Pugh Class A or B
- Active cancer, especially haematological malignancy
- Other specific conditions outlined in the [National Clinical Evidence Taskforce guidance](https://www.aci.health.nsw.gov.au) but not in the above list
As per the ATAGI guidance, immunocompromised means having a weakened immune system due to a medical condition or treatment. Consider this irrespective of age. Many conditions can cause immunocompromise, including:

- cancer, especially blood cancer (leukaemia or lymphoma) that is not in remission
- treatments for cancer (e.g. chemotherapy, targeted therapies, radiotherapy and CAR-T cell therapy) that weaken the immune system
- having a bone marrow, stem cell or solid organ transplant
- immune deficiencies
- HIV infection (particularly if the CD4 count is low)
- taking medications that weaken your immune system (called immunosuppressants or immunomodulators).

### Table 2. NSW-specific risk factors for use of sotrovimab

<table>
<thead>
<tr>
<th>Risk factors that must be met for prescription in adolescents</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Aged 12 to 17 years <strong>AND</strong></td>
</tr>
<tr>
<td>• Weighing at least 40kg <strong>AND</strong></td>
</tr>
<tr>
<td>• Within 5 days of symptom onset <strong>AND</strong></td>
</tr>
<tr>
<td>• No oxygen requirement due to COVID-19 <strong>AND</strong></td>
</tr>
<tr>
<td>• Reduced immunity to COVID-19 by:</td>
</tr>
<tr>
<td>− unvaccinated (i.e. received no doses of a COVID-19 vaccination) <strong>OR</strong></td>
</tr>
<tr>
<td>− vaccination not up-to-date (as per ATAGI guidance) <strong>OR</strong></td>
</tr>
<tr>
<td>− immunocompromised* (as per ATAGI guidance), irrespective of vaccine status <strong>AND</strong></td>
</tr>
<tr>
<td>• Medication-specific age and risk factors outlined below</td>
</tr>
</tbody>
</table>

**Medication-specific risk factors**

**Sotrovimab**

**AND at least two of the following risk factors:**

- Paediatric complex chronic condition (PCCC): congenital and genetic, cardiovascular, gastrointestinal, malignancies, metabolic and neuromuscular
- Diabetes (requiring medication)
- Obesity (BMI ≥95th centile for age)
- Chronic kidney disease (GFR <15mL/min/1.73m²)
- Heart failure, or congenital heart disease with persisting cyanosis or pulmonary hypertenstion
- Chronic obstructive lung disease (e.g. chronic lung disease requiring oxygen, cystic fibrosis with reduced lung function)
- Severe asthma (in the past 12 months: ≥1 exacerbation requiring ICU admission OR IV treatment OR ≥2 hospital admissions for asthma)

_in other exceptional circumstances, please discuss eligibility with a paediatric infectious diseases specialist._

*As per the ATAGI guidance, immunocompromised means having a weakened immune system due to a medical condition or treatment. Consider this irrespective of age. Many conditions can cause immunocompromise, including:*

- having a bone marrow, stem cell or solid organ transplant
- immune deficiencies
- HIV infection (particularly if the CD4 count is low)
- taking medications that weaken your immune system (called immunosuppressants or immunomodulators).

### Table 3. NSW risk factors that must be met for prescription of tixagevimab and cilgavimab

Reduced immunity to COVID-19 by being:

- unvaccinated due to contraindication **OR**
- are expected to have an inadequate response to vaccination **AND**

Severely immunocompromised due to:

- post bone marrow transplantation and/or CAR T-cell therapy in the first 3 months **OR**
- solid organ transplant
### Table 4. Overview of medications

<table>
<thead>
<tr>
<th>Medication</th>
<th>Route of administration</th>
<th>Usage</th>
<th>Variant considerations</th>
<th>Patient populations</th>
<th>Clinical conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sotrovimab</td>
<td>Intravenous infusion</td>
<td>Treatment</td>
<td>Reduced effectiveness against Omicron BA.2</td>
<td>Adults</td>
<td>Pregnant women in their 2nd or 3rd trimester</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Adolescents (12 years or older and weighing at least 40 kg)</td>
<td></td>
</tr>
<tr>
<td>Casirivimab plus imdevimab</td>
<td>Intravenous infusion or subcutaneous injection</td>
<td>Treatment Post-exposure prophylaxis</td>
<td>Reduced effectiveness against Omicron BA.1</td>
<td>Adults</td>
<td>Pregnant women</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Adolescents (12 years or older and weighing at least 40 kg)</td>
<td></td>
</tr>
<tr>
<td>Molnupiravir</td>
<td>Oral</td>
<td>Treatment</td>
<td></td>
<td>Adults</td>
<td>Note advice about breastfeeding and use of contraception for those of childbearing potential.</td>
</tr>
<tr>
<td>Nirmatrelvir plus ritonavir</td>
<td>Oral</td>
<td>Treatment</td>
<td></td>
<td>Adults</td>
<td>Not to be used in those with severe liver disease (Child-Pugh C)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>In those with severe renal disease:</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Not to be used in those with eGFR &lt;30mL/min</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Dose reduction required in those with eGFR 30 – 60 mL/min</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Note advice about breastfeeding and use of contraception for those of childbearing potential.</td>
</tr>
<tr>
<td>Tixagevimab and cilgavimab</td>
<td>Intramuscular injection</td>
<td>Pre-exposure prophylaxis</td>
<td></td>
<td>Adults</td>
<td>Caution in those with pre-existing cardiovascular disease or those with clinically significant bleeding disorders.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Pregnant people</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Adolescents</td>
<td></td>
</tr>
</tbody>
</table>

The National COVID-19 Clinical Evidence Taskforce has also developed a risk classification tool for adults with mild COVID-19 which assists clinicians to select the medication likely to be the most effective.10
Rapid antigen testing

A positive rapid antigen test (RAT) is sufficient to establish indication for the use of these medications in the appropriate population. RATs must be reported to Service NSW, so that patients are triaged via the NSW Health digital screening pathway into the Patient Flow Portal (PFP).

Ideally, the positive RAT should be confirmed via PCR/rapid PCR prior to treatment. However, treatment should not be withheld if there is a delay in receiving the PCR result.

Vaccination

Routine use of these medications is not encouraged in patients who are fully vaccinated, unless the patient may have a suboptimal response to a primary course of COVID-19 vaccination (e.g. severe immunosuppression from a medical condition or medication).3

People who are adequately vaccinated should not require a monoclonal antibody or antiviral as they will be significantly protected against severe disease.

The Australian Technical Advisory Group on Immunisation (ATAGI) specifies the interval for vaccination. Vaccination can take up to 14 days to be effective.6

Due to the impact of these drugs on the SARS-CoV-2 spike protein, it may be possible that monoclonal antibodies could interfere with the development of effective immune responses to COVID-19 vaccines. As such, it is recommended that COVID-19 vaccines should not be given for at least 90 days after administration.

For oral antivirals, patients should delay vaccination until they have recovered from their acute illness (approximately 4 to 6 weeks).

Adverse events

- For infusions, patients should be monitored for adverse events during and post infusion throughout the observation period. Patients should then be provided with advice regarding post infusion requirements, including adverse effects and who to contact for more information.

- For the oral agents, patients should be provided with education and information on side effects and drug interactions, as well what to do if an adverse event occurs.

- Molnupiravir is contraindicated in pregnancy and breastfeeding. It is recommended that those of childbearing potential or those sexually active with a partner of childbearing potential use contraception for three months afterwards.4

- The use of nirmatrelvir plus ritonavir is also not recommended in pregnancy or breastfeeding, or for patient’s of childbearing potential. It is recommended that those of childbearing potential or those sexually active with a partner of childbearing potential use contraception.3

- All adverse events should be reported to the Therapeutic Goods Administration (TGA) at www.tga.gov.au/reporting-problems. NSW Health staff must also report adverse events via the local incident management system.

Patient consent

- Informed consent should be obtained from the patient (or responsible person) prior to initiating treatment. Information leaflets (for patients, family and carers) and patient consent forms are available on the CEC website.

- 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

- Where required, prescribers should complete a Prescribing Declaration/Individual Patient Usage Application Form for each patient they intend to treat. The forms are available at https://www.cec.health.nsw.gov.au/keep-patients-safe/medication-safety/medicine-updates

- The Individual Patient Use Application Form should clearly indicate the patient’s eligibility criteria. Where required for specific medications, the completed forms will need to be submitted to HealthShare NSW with medication orders prior to the release of stock.
Monitoring of outcomes

- For recipients who are subsequently hospitalised (or who progress to require oxygen); for those who were inpatients at the time of administration, or otherwise have repeat swabs collected for any reason after treatment, the following is recommended:
  - 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 [medication] oral antiviral/monoclonal antibody on [dd/mm/yyyy], query resistance mutations’.
Figure 1. Decision pathway: outpatient suitability for sotrovimab, casirivimab and imdevimab, molnupiravir and nirmatrelvir plus ritonavir

Patient meets eligibility criteria, as per predefined screening as outlined in Tables 1 and 2.

Is the patient an adolescent or pregnant in their second or third trimester?
- **YES**: Consider monoclonal antibody administration
- **NO**: Is the patient of childbearing potential or sexually active with a partner of childbearing potential and unable to effectively use suitable contraception?
  - **YES**: Consider monoclonal antibody administration
    - Neither oral agent is recommended in pregnancy and molnupiravir has potential teratogenic effects
    - Oral antivirals must only be used in patients of childbearing potential or sexually active with a partner of childbearing potential in conjunction with suitable contraception
  - **NO**: Does the patient have pre-existing severe liver disease?
    - **YES**: Consider monoclonal antibody administration
    - Nirmatrelvir plus ritonavir causes hepatotoxicity and should not be administered to patients with these pre-existing conditions
  - **NO**: Does the patient have pre-existing renal disease?
    - **YES**: eGFR <30mL/min
      - Consider monoclonal antibody administration
      - OR molnupiravir only
    - eGFR 30 – 60mL/min
      - Consider monoclonal antibody administration
      - OR molnupiravir
      - OR a dose reduction of nirmatrelvir plus ritonavir
    - **NO**: Will the patient have difficulty accessing an infusion clinic?
      - For example, due to poor mobility and/or frailty, geographical location or residential aged care facility (RACF) residents
      - **YES**: Consider oral antiviral agents due to ease of administration
      - **NO**: Patient is suitable for either monoclonal antibody infusion or oral antiviral agents
        Supply considerations and prescribing arrangement may inform decision
Figure 2. Flowchart for administration of sotrovimab and casirivimab and imdevimab in adults and adolescents with mild and moderate COVID-19

**PRIORITISED COHORTS IN NSW**
- Acquired in high-risk setting such as disability homes and RACFs
- Aboriginal and Torres Strait Islander communities
- Rural, regional and remote communities
- Patients from metropolitan areas with large outbreaks
- Nosocomial infection

- Post-exposure prophylaxis**
  Progress with casirivimab plus imdevimab, as per the drug guidance for initial and repeat dosing

- Pre-exposure prophylaxis
  Progress with tixagevimab and cilgavimab administration, as per drug guidance

- Treatment: is intravenous infusion appropriate for the patient?
  - YES
    - Within 5 days of symptom onset, administer sotrovimab intravenously, as per drug guidance
    - Day 6 and 7 following symptom onset, administer casirivimab plus imdevimab**
  - NO
    - Within 7 days, administer casirivimab plus imdevimab subcutaneously, as per drug guidance**

- 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 considered when deciding on when and how to administer.
  - Treatment should be under the governance of the LHD and Drug and Therapeutics Committee.
  - Follow guidance for storage and preparation of the medication.

- Ensure patient is monitored throughout
  - Document baseline observations.
  - If patient has deteriorated since initial assessment for treatment or prophylaxis, **DO NOT proceed and escalate care.**
  - Administer treatment, as per drug guidance.

- Monitor post-treatment
  - Document post-infusion or injection observations for a period of 60 minutes.
  - All adverse events should be reported via the TGA at: [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).
  - NSW Health staff must also report adverse events via the local incident management system.
  - Undertake outcomes reporting.

- Transfer of care must include plan for escalation if patient deteriorates
  - Unless in hospital, patients should be transferred back to their care arrangements in the community. See Caring for adults and children in the community with COVID-19.
  - Post-treatment information should be provided to the patient. For prophylaxis, arrangements for follow-up appointments should be pre-booked, where possible.

* Clinicians should consider the SARS-CoV-2 variant being targeted and the possibility of reduced sensitivity. Early evidence shows casirivimab plus imdevimab is not as effective against Omicron BA.1 and sotrovimab is not as effective against Omicron BA.2.

** It is recommended casirivimab plus imdevimab is NOT used for post-exposure prophylaxis where the source exposure is Omicron BA.1.

Note: these medications should not be used in patients who are asymptomatic.
Figure 3: Flowchart for administration of oral antivirals in adults with mild and moderate COVID-19

Patient meets eligibility criteria (including symptom onset within the timeframe) without any contraindications specified in the relevant drug guideline

Prioritised cohorts in NSW
- Acquired in high-risk settings, such as disability homes and RACFs
- Aboriginal and Torres Strait Islander communities
- Rural, regional and remote communities
- Patients from metropolitan areas with large outbreaks
- Nosocomial infection

Medication prescribed

Medication collected by patient/carer or distributed from allocated NSW Health hospital pharmacy or via community pharmacy for molnupiravir only

Monitored throughout treatment course

Monitored post-treatment course

Via:
- GP network
- Through RACF pathways
- Specialist physician

- Patient education and information must be provided at dispensing

As triaged, following the NSW health digital screening pathway:
- GP
- Care in the community service
- Self-managed

- Patients must be provided with information on what to do if they experience an adverse event or clinical deterioration
- All adverse events must be reported via the TGA at: www.tga.gov.au/reporting-problems
- NSW Health staff must also report adverse events via the local incident management system

Note: these medications should not be used in patients who are asymptomatic.
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 (DTC).

Principles

- Patients at high risk and potentially eligible for these treatments are identified via the NSW Health digital screening pathway following report of a positive PCR or RAT. These patients are then identified in the PFP and where appropriate, notification will be sent to the registered GP.
- Depending on the medication, the indication for administration is within five to seven days of symptom onset. Treatment can be planned and will rarely need to occur after hours.
- Administration of monoclonal antibody treatment should occur in a healthcare facility, which may be in an inpatient, outpatient or outreach setting.
- Confirm communication processes with primary care and ‘care in the community’ pathways.
- LHDs and SHNs should establish local processes for the following:
  - Proactively screen patients in the PFP which have been identified via the NSW Health digital screening pathway to confirm eligibility.
  - Define governance arrangements for authorised prescribers, including registered GPs, in line with statewide distribution models. 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 in the priority cohorts who are seeking to prescribe this treatment (for example, geriatricians).
  - Establish a communication process with the pharmacy department to confirm supply of stock before booking patients and/or prescribing treatment.
  - Ensure access to the medication through outreach settings is done under usual LHD and DTC arrangements for prescribers in these settings.
- Coordinate the service model, including the outpatient location, staffing and infection control procedures.
- Pathways for the dispensing of oral antivirals from the hospital pharmacy.
- Where required, a prescribing declaration/individual patient use (IPU) application should be completed. The local DTC should confirm local governance arrangements.
- For infusions, LHDs and SHNs should establish a booking process for patient treatment including the following:
  - 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 information leaflets and consent forms available on the CEC website.
  - 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.
  - Ensure patients are provided with information on:
    i. personal protective equipment requirements for attending their monoclonal antibody infusion or for collection of oral antivirals
    ii. how to find the treatment or collection 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 or collection requirements to support patients leaving isolation to attend the healthcare facility
    iv. transport arrangements (where required).
  - Confirm follow-up arrangements, including who to contact for more information and advice around timelines for vaccination. Refer to information on the CEC website.
• Hub and spoke models may be appropriate where one or two sites within the LHD are identified for dispensing of oral antivirals.

• Pathways for the dispensing of oral antivirals from the hospital pharmacy, or via community pharmacy for molnupiravir only, should be clearly defined and documented. The LHD and pharmacy department should establish a system where medications will be supplied to remote locations, RACF and individuals who are unable to arrange the safe collection of oral agent courses.

• There needs to be clear instructions provided for dispensing that:
  − defines who may collect the medication from the hospital pharmacy
  − outlines instructions on locating the car park and directions on how to access the dispensing location
  − defines infection prevention and control requirements.

**Administration of monoclonal antibodies and oral antivirals in the inpatient setting**

• Patients who fulfil the priority eligibility criteria who are already admitted to a healthcare facility may be given monoclonal antibody or oral antiviral treatment.

• The administration of monoclonal antibodies can occur 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.

**Dispensing of oral antivirals in the outpatient setting**

• Oral treatments can be self-managed at home or at the usual place of residence following dispensing and education on their use.
- Identify an accessible car park for patient use as close to the treatment location as possible.
- Provide instructions for patients on locating the car park and directions on how to access the treatment 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 demand on these services, requests should be planned and notified to PTS with as much notice and flexibility around appointment times as possible.
- Medical and nursing workforce with the appropriate skills and competency will need to be mobilised, including staff with skills such as:
  - infusion preparation, cannulation and administration of intravenous medication
  - preparation and administration of subcutaneous 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 monoclonal antibodies in respect of maintenance of cold chain.

**Administration of monoclonal antibodies in the outreach setting**

- Access 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 infusion service should be provided in an appropriate healthcare 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 the healthcare 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:
  - infusion preparation, cannulation and administration of intravenous medication
  - preparation and administration of subcutaneous 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 monoclonal antibodies in respect of maintenance of cold chain.

**Use of monoclonal antibodies in community setting and hospital in the home**

The clinical working group has recommended that monoclonal antibodies requiring an infusion are not delivered in HITH or community care settings.

It is acknowledged that some LHDs may adopt a HITH approach for the administration of anti-SARS-CoV-2 monoclonal antibodies 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 a period of up to two hours, LHDs 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.
References


## Document information

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<tr>
<td><strong>Version number</strong></td>
<td>10</td>
</tr>
<tr>
<td><strong>Original publication date</strong></td>
<td>31 August 2021</td>
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<tr>
<td><strong>Consultation</strong></td>
<td>• Ministry of Health</td>
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<td>• Clinical Excellence Commission</td>
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<td>This document has been informed by the National Clinical Evidence Taskforce guidance.</td>
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<tr>
<td><strong>Endorsed by</strong></td>
<td>Nigel Lyons</td>
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<tr>
<td><strong>Review date</strong></td>
<td>22 March 2022</td>
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<tr>
<td><strong>Reviewed by</strong></td>
<td>Clinical working group (as above) and Expert Advisory Group of Clinical Council</td>
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<td><strong>For use by</strong></td>
<td>Health services and clinicians assessing patients suitable for sotrovimab infusion and its administration:</td>
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