

Model of care for the use of anti-SARS-CoV-2 monoclonal antibodies and antivirals

for people with mild and moderate COVID-19

FEBRUARY 2022

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.

Local access to these medications will be through the usual Drug and Therapeutic Committee processes at the local health district (LHD) and specialty health network (SHN) level. 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 model is based on recommendations from the National Clinical Evidence Taskforce guidelines and the evidence checks undertaken by the [NSW Agency for Clinical Innovation's Critical Intelligence Unit](#) (CIU).^{1,2}

The evidence was considered by an expert group of NSW clinicians to inform the development of this model.

Emerging medications are also being monitored by the CIU and will be included in this document, as required.

Who can be treated?

Clinical criteria and risk factors

The National Clinical Evidence Taskforce Guidelines outline the clinical criteria for the use of these medications in adults and adolescents.³ These are further specified in NSW guidance developed by the NSW TAG and CEC.

The medications covered in this model of care currently include:

- [sotrovimab](#)⁴
- [casirivimab and imdevimab](#)^{5,6}
- [molnupiravir](#)⁵
- [nirmatrelvir plus ritonavir](#)⁵

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.

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, also outlined in [Table 1](#) and [Table 2](#), will be targeted to identify people in these high-risk cohorts within NSW.

Although the indications for these medications are similar, they are not identical. As such, individual risk factors, criteria and drug guidance should be reviewed.

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.

The following key criteria must be met for prescription of these medications:

- Commencement within 5 days of symptom onset (or 7 days for casirivimab plus imdevimab) **AND**
- No oxygen requirement due to COVID-19 **AND**
- Reduced immunity to COVID-19 by being:
 - not fully/unvaccinated **OR**
 - overdue for booster (as per [Australian Technical Advisory Group on Immunisation \(ATAGI\) guidance](#)) **OR**
 - immunocompromised, as per [ATAGI guidance](#) (irrespective of vaccine status and age) **AND**
- Medication-specific risk factors outlined in [Table 1](#) for adults or [Table 2](#) for adolescents (unless the patient is immunocompromised, whereby no additional medication-specific or age risk factor is required).

The required criteria and indications for these medications are further specified in NSW guidance developed by the NSW TAG and CEC. These must be confirmed as part of the prescription process.

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](#)⁴
- [casirivimab and imdevimab](#)^{5,6}
- [molnupiravir](#)⁵
- [nirmatrelvir plus ritonavir](#)⁵

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.² 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 in adults

Risk factors that must be met for prescription of any of the four medications
<ul style="list-style-type: none"> • Within 5 days of symptom onset AND • No oxygen requirement due to COVID-19 AND • Reduced immunity to COVID-19 by being: <ul style="list-style-type: none"> – unvaccinated (i.e. received no doses of a COVID-19 vaccination) OR – not fully vaccinated (i.e. has not completed their primary course of COVID-19 vaccination) OR – overdue for booster (as per ATAGI guidance) OR – immunocompromised* (irrespective of vaccine status or age) AND • Medication-specific age and risk factors outlined below
Medication-specific risk factor/s
<p>Sotrovimab</p> <p>1a. Pregnant women in their second or third trimester OR</p> <p>1b. Non-pregnant adults who are aged ≥ 65 years or ≥ 35 years if Aboriginal and/or Torres Strait Islander</p> <p>AND one of the following risk factors:</p> <ul style="list-style-type: none"> • Obesity (BMI ≥ 30 kg/m²) • Severe cardiovascular disease (including hypertension) • Severe chronic lung disease; including severe asthma (requiring a course of oral steroids in the previous 12 months), COPD and interstitial lung disease • Type 1 or 2 diabetes mellitus • Severe chronic kidney disease, including those that are on dialysis • Severe chronic liver disease <p>OR</p> <p>2. Aged ≥ 18 years if immunocompromised*</p>
<p>Casirivimab plus imdevimab</p> <p>1a. Pregnant women OR</p> <p>1b. Non-pregnant adults who are aged ≥ 65 years or ≥ 35 years if Aboriginal and/or Torres Strait Islander</p> <p>AND one of the following risk factors:</p> <ul style="list-style-type: none"> • Obesity (BMI ≥ 30 kg/m²) • Severe cardiovascular disease (including hypertension) • Severe chronic lung disease; including severe asthma (requiring a course of oral steroids in the previous 12 months), COPD and interstitial lung disease • Type 1 or 2 diabetes mellitus • Severe chronic kidney disease, including those that are on dialysis • Severe chronic liver disease <p>OR</p> <p>2. Aged ≥ 18 years if immunocompromised*</p>

Table 1. NSW-specific risk factors for high priority cohorts in adults (continued)

Medication-specific risk factor/s
<p>Molnupiravir</p> <p>1. Non-pregnant adults who are aged ≥ 65 years or ≥ 35 years if Aboriginal and/or Torres Strait Islander</p> <p>AND one of the following risk factors:</p> <ul style="list-style-type: none"> • Obesity (BMI ≥ 30 kg/m²) • Severe cardiovascular disease (including hypertension) • Severe chronic lung disease; including severe asthma (requiring a course of oral steroids in the previous 12 months), COPD and interstitial lung disease • Type 1 or 2 diabetes mellitus • Severe chronic kidney disease, including those who are on dialysis and unable to receive monoclonal antibody treatment • Severe chronic liver disease <p>OR</p> <p>2. Aged ≥ 18 years if immunocompromised*</p>
<p>Nirmatrelvir plus ritonavir</p> <p>1. Non-pregnant adults who are aged ≥ 65 years or ≥ 35 years if Aboriginal and/or Torres Strait Islander</p> <p>AND one of the following risk factors:</p> <ul style="list-style-type: none"> • Obesity (BMI ≥ 30 kg/m²) • Severe cardiovascular disease (including hypertension) • Severe chronic lung disease; including severe asthma (requiring a course of oral steroids in the previous 12 months), COPD and interstitial lung disease • Type 1 or 2 diabetes mellitus <p>OR</p> <p>2. Aged ≥ 18 years if immunocompromised*</p>

* 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 adolescents

Risk factors that must be met for prescription in adolescents
<ul style="list-style-type: none"> • Aged 12 to 17 years AND • Weighing at least 40kg AND • Within 5 days of symptom onset AND • No oxygen requirement due to COVID-19 AND • Reduced immunity to COVID-19 by: <ul style="list-style-type: none"> – unvaccinated (i.e. received no doses of a COVID-19 vaccination) OR – partially vaccinated (i.e. only 1 dose of COVID-19 vaccine) OR – immunocompromised* (as per ATAGI guidance), irrespective of vaccine status AND • Medication-specific age and risk factors outlined below
Medication-specific risk factors
<p>Sotrovimab</p> <p>AND at least two of the following risk factors: :</p> <ul style="list-style-type: none"> • Paediatric complex chronic condition (PCCC): congenital and genetic, cardiovascular, gastrointestinal, malignancies, metabolic and neuromuscular • Diabetes (requiring medication) and pre-gestational diabetes (requiring medication) in pregnant women • Obesity (BMI \geq 95th centile for age) • Chronic kidney disease (GFR $<$15 mL/min/1.73m²) • Heart failure, or Congenital Heart Disease with persisting cyanosis or pulmonary hypertension • Chronic obstructive lung disease (e.g. chronic lung disease requiring oxygen, cystic fibrosis with reduced lung function) • Severe asthma (in the past 12 months: \geq1 exacerbation requiring ICU admission OR IV treatment OR \geq2 hospital admissions for asthma) <p><i>In other exceptional circumstances, please discuss eligibility with a paediatric infectious diseases specialist.</i></p>

* 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).

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 booster doses.⁷

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 sexually active women of childbearing potential use contraception and men also use contraception treatment and for three months afterwards.³
- The use of nirmatrelvir plus ritonavir is also not recommended in pregnancy or breastfeeding, and in women of childbearing potential. It is recommended that sexually active women 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. 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 monoclonal antibodies or oral antivirals

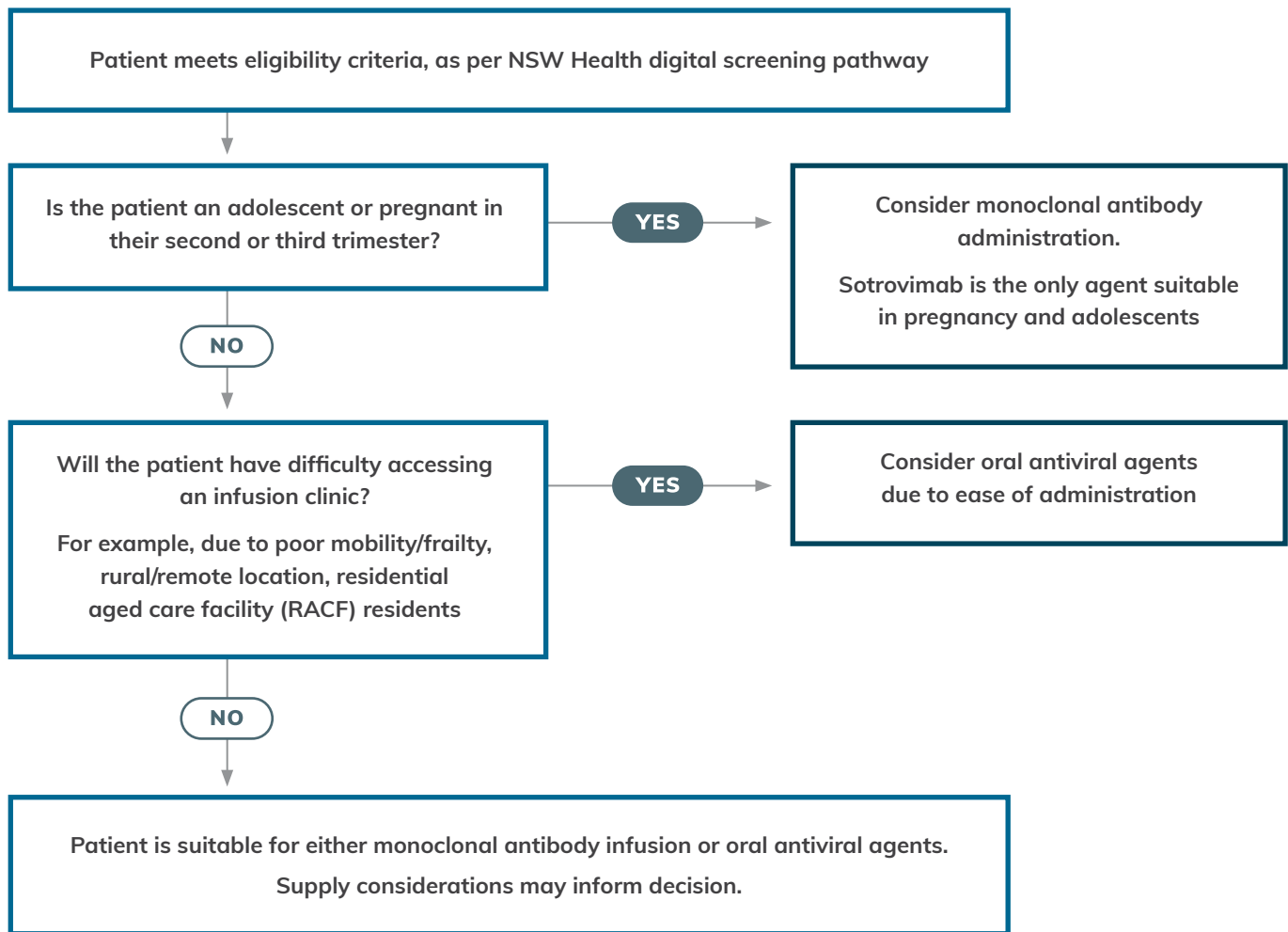
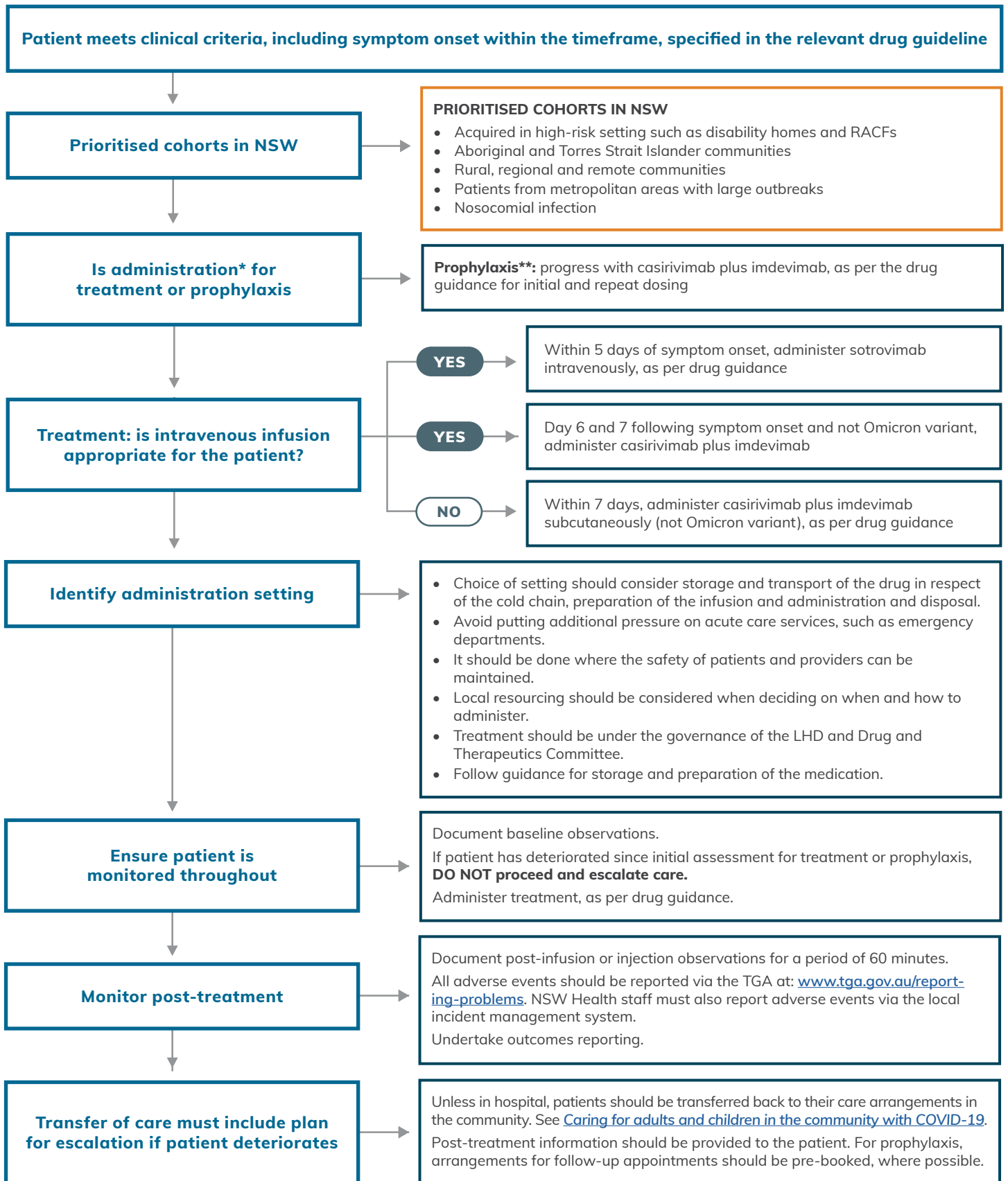


Figure 2. Flowchart for administration of monoclonal antibodies in adults and adolescents with mild and moderate COVID-19

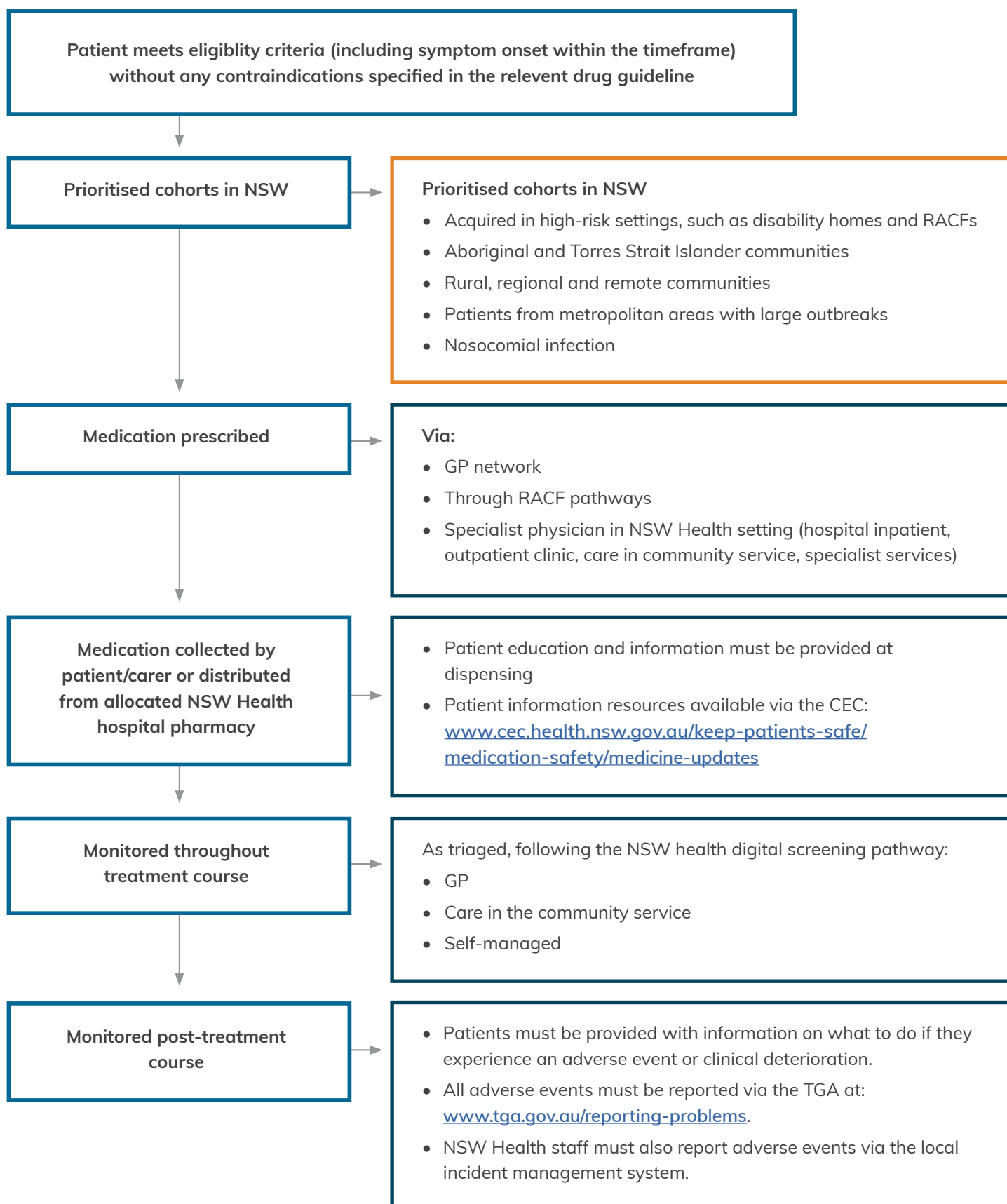


* Clinicians should consider the SARS-CoV-2 variant being targeted and the possibility of reduced sensitivity. Early evidence shows casirivimab plus imdevimab is not as effective against Omicron as other variants. As such, sotrovimab is the preferred medication for treatment of Omicron.

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

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



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](#).

- Provision of printed information should be available for patients, including information about the treatment and post-treatment care. See information on [CEC website](#). For monoclonal antibodies, it is preferable to provide this information at the time of booking at the infusion clinic. For oral antivirals, this information should be provided at the point of dispensing. Consider access to interpreter services as required.
- Ensure staff, such as emergency department, site managers, screening station and security staff, are aware of the location and arrangements for accessing these treatments to assist patients to find their way. Where practical, temporary signage should be posted to assist patients and staff.
- Ensure reporting requirements are communicated, documented and submitted, including adverse events. This needs to be done via the [local incident management system](#) and the [TGA](#).
- Arrangements for patient follow-up should be defined and may be supported by the treatment service or primary care, community care, virtual care or Hospital in The Home (HITH) services, depending on local resources and need.

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.

- 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 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 in the outpatient setting

- Hub and spoke models may be appropriate where one or two sites within the LHD are identified for the administration of monoclonal antibodies.
- For the infusions, there needs to be a dedicated and physically appropriate location at the health facility for the treatment, 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
 - has a defined and documented clinical emergency response system protocol in the event of clinical deterioration, if different to usual protocols (this should also include access to a resuscitation trolley).
- Confirm transport options to enable patient access as part of the booking process. LHDs and SHNs should implement a patient self-transport approach wherever possible, including the following:

- 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.
 - Ensure the appropriate level of nursing coverage and competency is available, including:
 - infusion preparation, cannulation and administration of intravenous medication
 - preparation and administration of subcutaneous medication
 - monitoring for adverse events, including initial management of anaphylaxis.
 - Access to medical advice and review should be readily available for adverse events.
- 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.

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

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.

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Document information	
Version number	8
Original publication date	31 August 2021
Developed by	Working Group comprising representatives of the Infectious Diseases CoP, Aged Care CoP, Cancer Care CoP, Respiratory CoP, Care in the Community CoP, Drug and Therapeutics CoP, Emergency Department CoP, General Practice, Intensive Care CoP, Agency for Clinical Innovation, Clinical Excellence Commission, Ministry of Health.
Consultation	<ul style="list-style-type: none"> • Ministry of Health • Clinical Excellence Commission This document has been informed by the National Clinical Evidence Taskforce guidance.
Endorsed by	Nigel Lyons
Review date	9 February 2022
Reviewed by	Clinical working group (as above) and Expert Advisory Group of Clinical Council
For use by	Health services and clinicians assessing patients suitable for sotrovimab infusion and its administration: <ul style="list-style-type: none"> • COVID-19 Response teams • Community services and Hospital in the Home • Respiratory, Infectious Diseases, Immunology • Drug and Therapeutics Committees



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SHPN 211149 | ISBN 978-1-76023-049-4 | TRIM: ACI/D21/2110 | ACI-5062 [2/22]