

# Clinical Practice Guideline COVID-19 Treatment in Pregnancy

## Peninsula Care Goal Safe

### Target Audience

Medical staff, midwives, nurses and allied health staff caring for pregnant and postnatal women with **confirmed COVID-19 infection**.

### Purpose

This guideline provides recommendations for COVID-19 related treatment in pregnant and postpartum women.

Please refer to the following documents for guidance on clinical management in other aspects of pregnancy-related care during an admission. This document does not include non-COVID related treatment or management in pregnancy or postpartum period.

### Key Aligned Documents

- [COVID-19 Adult and Adolescent \(≥16 years\) Clinical Guideline](#)
- [COVID-19 Care in Maternity](#)

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## 1. Background

Due to the physiological changes in the immune and cardiopulmonary systems, pregnant women are more likely to develop severe illness after infection with respiratory viruses. COVID-19 infection during pregnancy is associated with adverse pregnancy and neonatal outcomes.

## 2. Classification of disease severity

<b>Mild</b>	<ul style="list-style-type: none"> <li>• no symptoms or mild upper respiratory tract symptoms</li> <li>• no new shortness of breath or reduction in oxygen saturations</li> <li>• stable clinical picture</li> </ul>
<b>Moderate</b>	<p>Stable patient presenting with respiratory and/or systemic symptoms or signs. <b>Able to maintain oxygen saturation &gt; 94% for obstetric patients</b> (up to 4L/min oxygen via nasal prongs with a respiratory rate of &lt;30 breaths/minute)</p> <p>Characteristics:</p> <ul style="list-style-type: none"> <li>• prostration, severe asthenia, fever &gt; 38°C or persistent cough</li> <li>• clinical or radiological signs of lung involvement</li> <li>• no clinical or laboratory indicators of clinical severity or respiratory impairment</li> </ul>
<b>Severe</b>	<p>Patients meeting any of the following criteria:</p> <ul style="list-style-type: none"> <li>• respiratory rate <math>\geq</math> 30 breaths/min</li> <li>• <b>oxygen saturation <math>\leq</math> 94% at rest with 4L/min O<sub>2</sub> via NP</b></li> <li>• arterial partial pressure of oxygen (PaO<sub>2</sub>)/ inspired oxygen fraction (FiO<sub>2</sub>) <math>\leq</math> 300</li> </ul>

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<b>Critical</b>	<p>Patient meeting any of the following criteria:</p> <p>Severe respiratory failure</p> <p>PaO<sub>2</sub>/FiO<sub>2</sub> ratio &lt; 200), respiratory distress or acute respiratory distress syndrome (ARDS). This includes patients deteriorating despite advanced forms of respiratory support (NIV, HFNO) OR patients requiring mechanical ventilation</p> <p><b>OR</b> other signs of significant deterioration</p> <ul style="list-style-type: none"> <li>• Hypotension or shock</li> <li>• Impairment of consciousness</li> <li>• Other organ failure</li> </ul>
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**Table 1: Classification of COVID-19 Disease Severity**

### 3. Management of patients in the community

All pregnant women with confirmed COVID-19 infection will be managed under the care of the Community Care Covid Positive Pathway and notified to the Complex Pregnancy Clinic (CPC). The CPC team will assist in the outpatient care in collaboration with Community Health, the Infectious Diseases (ID) unit and the Maternal Fetal Medicine Unit at Monash Medical Centre.

Guidelines for referrals and safe processes for admission (if required) are summarised in the [COVID-19 Care in Maternity](#) Clinical Practice Guideline.

The CPC team will identify whether any additional fetal surveillance is required in the community (usually only for additional obstetric or fetal indications).

### 4. Management of patients in the hospital

Inpatient care will be coordinated by CPC, ID, ICU, IPACU, anaesthetics, theatres, paediatrics and the obstetric team on duty.

#### Baseline investigations on admission

- FBE, U+E, CRP, LFTS, CMP, PT, APTT, INR, fibrinogen, D-Dimer, CRP, LDH, VBG for venous lactate, CK, troponin, ferritin, glucose, procalcitonin, ECG (check QT interval, check for ischaemia). **See COVID-19 proven ward baseline tests (under COVID Powerplans)**
- Blood cultures (if fever >38°C or immunocompromised)
- Portable CXR

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Several markers used to assess COVID-19 related hyper-inflammatory response can be elevated in women who are pregnant without COVID. The interpretation of these results need to be made on a case by case basis with a multi-disciplinary team (MDT) including Maternity, Infectious Diseases, Haematology & Respiratory Units as required.

### 5. Fetal surveillance

A plan for fetal surveillance during admission will depend on the maternal circumstances, such as the degree of respiratory compromise, gestation, and any additional risk factors. CTG and / or ultrasound surveillance is to be planned by the obstetric team and reviewed daily.

Maternal stabilisation and wellbeing will take priority over monitoring of fetal wellbeing.

Delivery for fetal reasons should not take priority over maternal stabilisation, even in the event of fetal compromise.

Delivery for maternal reasons, such as deteriorating respiratory function, may be required and should be a collaborative decision made between the multidisciplinary team (MDT) listed above.

### 6. Criteria for escalation of care

Clinicians MUST be aware that young, fit women can compensate for deterioration in respiratory function and are able to maintain normal oxygen saturations until sudden decompensation.

**In hypoxic patients, deliver oxygen via nasal prongs (1- 4L/min) to achieve target saturations of 94-98%.**

A woman's care should be escalated urgently to the MDT including if any of the following signs of decompensation develop:

- increasing oxygen requirements to maintain O<sub>2</sub> saturation >94%
- increasing respiratory rate (RR>24) or increased work of breathing
- reduction in urine output when this is being monitored
- acute kidney injury
- drowsiness, even if the oxygen saturations are normal.

The possibility of myocardial injury should be considered, as the symptoms are similar to those of respiratory complications of COVID-19.

The appropriateness and frequency of fetal heart rate monitoring should be considered on an individual basis, accounting for the gestational age and the maternal condition.

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Notify ICU immediately if

- requiring oxygen 4L/min OR
- haemodynamically unstable OR
- clinical concern

Triggers for ICU with pregnant women < 20 weeks are as for non-pregnant COVID patients.

COVID-19 can be a hypercoagulable, pro-inflammatory state and careful consideration of differential diagnoses in pregnant women who have persistent, unexplained or progressive symptoms/ signs suggestive of complications including pulmonary embolism/ acute coronary syndromes/ myocarditis need to be considered with a multi-disciplinary team where appropriate.

## 7. Relevant Medications in Pregnancy

### 7.1 Venous thromboembolism (VTE) prophylaxis

All pregnant women admitted with confirmed or suspected COVID-19 should be offered prophylactic low molecular weight heparin, unless birth is expected within 12 hours or there is significant risk of haemorrhage (coagulopathy or platelet <30).

Low dose aspirin should be ceased in any woman using this for obstetric reasons (e.g. high-risk pre-eclampsia).

Indication	Recommendation
Self-isolating at home with mild COVID-19 and who have no additional risk factors for VTE	Routine pharmacological prophylaxis is not recommended
Self-isolating at home with mild COVID-19 and who have additional risk factors for VTE	<p><b>Enoxaparin 40mg daily</b></p> <p>Additional risk factors:</p> <ul style="list-style-type: none"> <li>• BMI &gt; 35, or weight &gt; 100kg</li> <li>• Personal history of VTE (provoked or unprovoked)</li> <li>• Gross varicose veins</li> <li>• Sickle cell disease</li> <li>• ANY thrombophilia e.g. protein C/S deficiency, heterozygous Factor V Leiden</li> </ul> <p><i>Continue for at least 14 days or until COVID-19 related morbidity has resolved (including immobility, shortness of breath or dehydration)</i></p>

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Admitted to hospital (for any indication) and who have COVID-19	<b>Enoxaparin 40 mg daily</b>  <i>Continue for at least <b>14 days</b> after discharge or until COVID-19-related morbidity has resolved.</i>
Pregnant women with <b>Severe or Critical COVID-19</b> , or where there are additional risk factors for VTE	<b>Enoxaparin 40 mg bd</b>  <i>Continue for at least <b>4 weeks</b> after discharge or until COVID-19-related morbidity has resolved.</i>

If maternal weight is greater than >120 kg: **Enoxaparin 60mg**

**Table 2: Venous thromboembolism (VTE) prophylaxis**

### 7.2. Antenatal Corticosteroids

There are clear benefits to using antenatal corticosteroids for women at risk of preterm birth at less than 34 weeks gestation for fetal lung maturity. There is currently no evidence to suggest that antenatal corticosteroids cause additional maternal or fetal harm in the setting of COVID-19 when used for this indication. They should therefore be given where indicated. Corticosteroids are indicated for women with Covid-19 requiring oxygen as a disease modifying agent. See [Section 8.1](#) for further discussion regarding the use of Dexamethasone for this indication.

### 7.3 Magnesium sulfate

The use of magnesium sulfate in pregnancy for fetal neuroprotection and management of pre-eclampsia or eclampsia is supported as part of standard care, independent of the presence of COVID-19. There is currently no evidence to suggest that magnesium sulfate can cause additional maternal or fetal harm (such as pulmonary oedema) in the setting of COVID-19 when used for this indication. Magnesium sulfate should therefore be given where indicated.

In pregnant women with COVID-19 who are receiving magnesium sulfate, renal function and fluid balance should be monitored.

An altered magnesium sulfate procedure for fetal neuroprotection is recommended for women infected with COVID -19 less than 30 weeks' gestation given the risk of further exacerbating respiratory function with magnesium sulfate and where there may be renal dysfunction.

Administer a loading dose of Magnesium Sulfate 4 gram IV over 60 minutes. No ongoing maintenance infusion is required.

For women with increasing oxygen requirements, consider the risk-to-benefit ratio before using magnesium for fetal neuroprotection

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#### 7.4 Antibiotics

Antibiotics are not required for the treatment of mild-moderate COVID-19. Even in severe diseases, concurrent bacterial infection is infrequent. Severe bacterial infection is unlikely if procalcitonin is normal.

### 8. Disease-Modifying Treatments for COVID-19

**Evidence for COVID-19 therapies is rapidly evolving. Please refer to [The National COVID-19 Clinical Evidence Taskforce](#) living guidelines for the latest evidence based recommendations.**

Most trials evaluating the efficacy and safety of disease-modifying treatments did not include pregnant women. The following recommendations are conditional based on available data and current recommendations outlined in the National Taskforce Living Guidelines. Treatment decisions are to be made in close consultation with COVID ID Consultant and the Maternity team (including MFM support where available).

#### 8.1 Dexamethasone

Corticosteroids should be given to all patients requiring oxygen therapy. The recommended regimen is Dexamethasone 6mg daily intravenously or orally for up to 10 days.

If corticosteroids are not indicated for fetal lung maturity, consider switching to hydrocortisone (IV) 50mg 6-hourly or Prednisolone (oral) 50mg daily after 48 hours of Dexamethasone to reduce fetal exposure as these do not cross the placenta. Patients who have received Dexamethasone within 7 days will not require additional corticosteroids for lung maturation if preterm delivery is indicated.

If steroids are indicated for fetal lung maturity in women at risk of preterm birth, a standard antenatal corticosteroid regimen should be used (e.g. Dexamethasone 6 mg every 12 hours for four doses), followed by 6 mg Dexamethasone daily until 10 days has been reached (see 7.2- Antenatal Corticosteroids).

#### 8.2 Remdesivir

Remdesivir is an antiviral and may be considered for pregnant or breastfeeding women with **mild disease at high risk of progression** or hospitalised with moderate to severe COVID-19 who do not require ventilation. Remdesivir may reduce time to recovery. It is unlikely to be of significant benefit if given late in the illness.

Pregnant women were excluded from all clinical trials of Remdesivir in COVID-19. However, animal studies do not suggest reproductive toxicity, and small case series of use in COVID-19 in pregnant or breastfeeding women overseas have not demonstrated safety concerns.

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### 8.3 Tocilizumab

Tocilizumab is a humanised anti-IL-6 receptor monoclonal antibody which antagonises IL-6 binding and thus inhibiting its pro-inflammatory effects, reducing inflammation. It may reduce mortality in patients with severe COVID who have evidence of severe inflammation.

Safety information is largely derived from pregnant women with non-COVID indications such as rheumatoid arthritis. There is no embryopathy at doses used to treat COVID-19. There is insufficient data to estimate other effects on the pregnancy, but they are likely to be less significant than the effect of COVID.

For the babies of women who received Tocilizumab during pregnancy (after 20 weeks of gestation), live vaccines (rotavirus and BCG) should be avoided in the first six months of life. All non-live vaccinations are safe and should be undertaken.

Only small amounts of Tocilizimab are detected in breastmilk. In women who receive Tocilizumab while breastfeeding only, live vaccines (rotavirus and BCG) can be given to the baby.

### 8.4 Baricitinib

Baricitinib is a Janus kinase inhibitor-1 and -2. It inhibits cytokine signaling, thus reducing inflammation. It may reduce mortality in patients with severe COVID who have evidence of severe inflammation.

It is not recommended in pregnancy outside of clinical trials. It may however be considered in post-partum women who are not breastfeeding as an alternative to Tocilizumab.

### 8.5 Budesonide

Inhaled Budesonide may be considered for the treatment of symptomatic COVID-19 in adults who do not require oxygen and who have one or more risk factors for disease progression.

Results are primarily based on the PRINCIPLE trial in which adults were treated with inhaled budesonide (by breath actuated inhaler) 800 µg twice daily for up to 14 days. However, this trial was only conducted in patients above 50 years old.

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### Summary of Treatment Recommendations

#### Mild Disease (O<sub>2</sub> saturation of > 94% RA)

Consider **Remdesivir** (200mg loading then 100mg daily iv) for 3 days if

- Symptom onset within 7 days
- >13 weeks pregnant
- Unvaccinated/partially vaccinated (<3 doses)

Consider inhaled **Budesonide** (800 microgram BD) if

- Symptom onset within 14 days **AND** at increased risk of progression

#### Moderate to Severe Disease (O<sub>2</sub> saturation of ≤ 94%)

Give **Dexamethasone** (6mg daily IV/oral) for up to 10 days

Consider **Remdesivir** (200mg loading then 100mg daily iv) for 5 days if

- Symptoms onset within 7 days (unless immunocompromised) **AND**
- On supplemental oxygen **AND not on** non-invasive/mechanical ventilation

Consider **Tocilizumab**\* If

- requiring > 4L O<sub>2</sub> **or** extensive pulmonary infiltrates **or** rapid deterioration **AND**
- ≥ 1 sign of severe inflammation (CRP >75, Ferritin >500)

**Baricitinib**\* may be considered as an alternative to Tocilizumab in postpartum women who are NOT breastfeeding.

#### \*ID approval required

# Disease-modifying agents for moderate to severe disease can be ceased when patient no longer require oxygen supplementation or treatment course completed (whichever is earlier)

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See [Table 3](#) & [Appendix](#) for detailed contraindications, precautions and dosing of each agent.

	Eligibility criteria	Contraindications / Precautions	Dose	Approvals required prior to prescription
<b>Remdesivir</b>	$\leq$ 7d symptoms 2 <sup>nd</sup> or 3 <sup>rd</sup> trimester Immunosuppressed OR unvaccinated, partially vaccinated high risk patients meeting <a href="#">National Stockpile Criteria</a>	Weight < 40kg ALT > 5x ULN or ALT > 3x ULN & Bili>2x ULN eGFR< 30/ RRT Multi-organ failure Significant cardiomyopathy Coagulopathy	<b>200mg IV</b> loading dose, then <b>100mg daily</b> for up to another 2 days	<b>Approved prescribers: COVID treating team consultant, ID consultant</b>  Complete " <a href="#">Request to Access Medication for Mild COVID-19 (Remdesivir, Sotrovimab, Nirmatrelvir, Ritonavir, Molnupiravir)</a> "
<b>Budesonide</b>	$\leq$ 14d symptoms Risk of progression		<b>800mcg inhaled twice daily</b>	No approval required.
<b>Dexamethasone</b>	Sats $\leq$ 94% RA		<b>6mg IV/PO daily</b> Up to 10 days	No approval required.
<b>Remdesivir</b>	$\leq$ 7d symptoms Sats $\leq$ 94% RA Supplemental O <sub>2</sub> <b>not on</b> NIV/mechanical ventilation	Weight < 40kg ALT > 5x ULN or ALT > 3x ULN & Bili>2x ULN eGFR< 30/ RRT Multi-organ failure Significant cardiomyopathy Coagulopathy	<b>200mg IV</b> loading dose, then <b>100mg daily</b> for up to another 4 days	<b>Approved prescribers: COVID treating team consultant, ID consultant</b>  Complete "Request to access remdesivir declaration" when charting order
<b>Tocilizumab</b>	Severe hypoxia <b>AND</b> signs of systemic inflammation (where baricitinib cannot be used)	Other active severe infection ALT/AST > 5x ULN Platelet < 50, Neut < 0.5	>90kg = 800mg 65-90kg = 600mg 40-65kg = 400mg <40kg= 8mg/kg Single dose	<b>ID approval</b>

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<b>Baricitinib</b>	Severe hypoxia <b>AND</b> signs of systemic inflammation  (CRP > 75, Ferritin > 500)	<b>eGFR&lt;15 Pregnancy/Breastfeeding</b>  Other active severe infection  Lymph < 0.2, Neut < 1, Hb < 80	eGFR > 60 <b>4mg daily</b>  eGFR 30-59 <b>2mg daily</b>  eGFR 15-29 <b>2mg every second day</b>  Up to 14 days	<b>ID approval</b>
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**Table 3: Summary of Disease-Modifying COVID-19 therapies**

## 9. Follow-up post discharge

Patients should be referred to the Peninsula Health COVID-19 Community Care pathway on discharge (or Maternity Services if cleared of COVID-19 at time of discharge) for ongoing follow-up.

VTE prophylaxis should continue if appropriate.

## 10. References


1. National COVID-19 Clinical Evidence Taskforce Living Guidelines. Available from <https://covid19evidence.net.au>
2. Royal College of Obstetrician and Gynaecologist Coronavirus (COVID-19) Infection in Pregnancy. Information for Healthcare Professional Version 14.2: Published 06/12/21. Available from <https://www.rcog.org.uk/coronavirus-pregnancy>
3. Monash Health COVID-19 Infection in Pregnancy and Postnatal (Coronavirus ) Guidelines
4. Monash Health Coronavirus (COVID-19) Treatment in Pregnancy Guidelines

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## Appendix: COVID-19 Therapeutics Drug Information

<b>DEXAMETHASONE</b>	
<b>Mechanism of Action</b>	Immunosuppressant and anti-inflammatory, including suppression of cytokine release.
<b>Dose</b>	6mg IV or oral daily (if no IV access or patient improving), for up to 10 days
<b>Administration</b> 	<u>IV infusion</u> Use volumetric pump. Dexamethasone is listed in Drug Library. Dilute with 50-100 mL of sodium chloride 0.9% or glucose 5% and infuse over 15 minutes.  <u>IV injection</u> Inject slowly over 3 to 5 minutes. May be diluted with 10 mL of sodium chloride 0.9% to facilitate slow injection.
<b>Indication</b>	Supplemental oxygen or oxygen saturations $\leq$ 94% on room air, receiving NIV or mechanical ventilation – including pregnant women
<b>Contraindications</b>	Known hypersensitivity to dexamethasone Alternative corticosteroids : Hydrocortisone (IV) 50mg 6-hourly or Prednisolone (oral) 50mg daily)
<b>Adverse effects</b>	Varied, including infection, oedema, hypertension, hyperglycaemia, dyspepsia/peptic ulceration, mood and sleep disturbance
<b>Monitoring</b>	Blood glucose monitoring, daily electrolyte measurement and monitoring for behavioural side effects (especially in elderly patients) is required.
<b>Drug interactions</b>	Check with pharmacist or <a href="https://www.covid19-druginteractions.org/">https://www.covid19-druginteractions.org/</a>
<b>Access</b>	Use ward imprest stock.

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<b>REMEDESIVIR</b>	
<b>Mechanism of Action</b>	Antiviral; Inhibits RNA-dependent RNA polymerase
<b>Dose</b>	<p><b>Mild COVID-19:</b> 200 mg IV on day one, then 100 mg daily for up to another 2 days (Total 3 days)</p> <p><b>Moderate-Severe COVID-19:</b> 200 mg IV on day one, then 100 mg daily for up to another 4 days (Total 5 days)</p>
<b>Administration</b>	<a href="#">Refer to drug administration protocol</a>
<b>Indication</b>	<p><b>Mild COVID-19:</b></p> <ul style="list-style-type: none"> <li>• Within 7 days of symptom onset</li> <li>• No oxygen or ventilation required due to COVID-19</li> <li>• Meets eligibility criteria according to <a href="#">"Request to access medications for mild COVID-19" form</a></li> </ul> <p><b>Moderate-Severe COVID-19:</b> On supplemental oxygen but patient not on NIV or intubated at commencement</p>
<b>Contraindications</b>	<p>Known hypersensitivity to remdesivir, the metabolites, or formulation excipient.</p> <p>Weight &lt; 40kg.</p> <p>ALT &gt; 5x ULN and/or ALT &gt; 3x ULN and Bili &gt; 2x ULN</p> <p>Evidence of multiorgan failure including coagulopathy (significant thrombocytopenia), hepatic failure elevated bilirubin) or renal failure (low urine output or eGFR &lt; 30 ml/min or dialysis or CVVH) or significant cardiomyopathy (low cardiac output)</p>
<b>Adverse effects</b>	<p>Common: Increased transaminases, gastrointestinal intolerance, rash, hyperglycaemia, decreased eGFR</p> <p>Rare: Hypersensitivity, infusion-related and anaphylactic reactions</p>
<b>Monitoring</b>	<p>Baseline ECG</p> <p>Monitor FBE/UEC/LFT daily</p>
<b>Drug interactions</b>	<p>Check with pharmacist or <a href="https://www.covid19-druginteractions.org/">https://www.covid19-druginteractions.org/</a>.</p> <p><b>Avoid concomitant use with hydroxychloroquine.</b></p>

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<b>Access</b>	<p>Access to remdesivir is provided by the National Medicines Stockpile. Patient <b>MUST</b> meet eligibility criteria before supply and administration.</p> <p>Use <b>MUST</b> be <b>approved by COVID treating team or ID consultant</b>. Obtain verbal consent from patient/family. Complete “request to access remdesivir declaration” when charting the order on cerner.</p> <p>Stock is available in imprest in COVID designated wards, stored in S11 cupboard. Usage to be recorded on S11 medication registers or HS8 program.</p>
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BARICITINIB														
Mechanism of Action	Baricitinib is a Janus kinase inhibitor-1 and -2. It inhibits cytokine signalling, thus reducing inflammation and possibly inhibits SARS-CoV-2 endocytosis.													
Dose	For up to 14 days eGFR≥60mL/min: 4mg daily eGFR=30-59 ml/min: 2mg daily eGFR=15-29mL/min: 2mg every SECOND day													
Administration	<p>Do no crush or break baricitinib tablets.</p> <p>Tablets can be dispersed for patients who cannot swallow tablets OR enteral tube administration. Staff who are actively trying to conceive or who are pregnant or breast-feeding should not prepare or handle a dispersed dose.</p> <p>Place baricitinib tablet in an enteral syringe with room temperature water (see Table 1) and disperse with gentle swirling. Administer dispersed volume immediately. The container should be rinsed with additional room temperature water (see Table 1) and these contents also administered.</p> <p><b>Table 1: Dispersion instructions for 2 mg and 4 mg baricitinib tablet(s)</b></p> <table><tr><th>Administration via</th><th>Dispersion Volume</th><th>Container rinse volume</th></tr><tr><td>Oral dispersion</td><td>10 mL</td><td>10 mL</td></tr><tr><td>Gastrostomy tube</td><td>15 mL</td><td>15 mL</td></tr><tr><td>Nasogastric tube~</td><td>30 mL</td><td>15 mL</td></tr></table> <p>~ To avoid clogging of small diameter tubes (smaller than 12 Fr), the syringe can be held horizontally and shaken during administration.</p>		Administration via	Dispersion Volume	Container rinse volume	Oral dispersion	10 mL	10 mL	Gastrostomy tube	15 mL	15 mL	Nasogastric tube~	30 mL	15 mL
Administration via	Dispersion Volume	Container rinse volume												
Oral dispersion	10 mL	10 mL												
Gastrostomy tube	15 mL	15 mL												
Nasogastric tube~	30 mL	15 mL												
Indication	Hypoxia AND at least one sign of severe inflammation													
Contraindications/Precautions	<p>Known hypersensitivity to baricitinib</p> <p>Severe renal impairment (eGFR&lt;15mL/min)</p> <p>Pregnancy/breastfeeding</p> <p>Use with caution in patients with</p> <ul style="list-style-type: none"><li>• risk factors for thrombosis (other than covid-19)</li><li>• at risk of GI perforations (eg diverticulitis)</li><li>• Active bacterial/fungal infection</li><li>• Active TB</li><li>• Current Cytopenia (Lymphocytes &lt;0.2, Neutrophils &lt;1, Hb &lt;80)</li></ul>													
Adverse effects	<p>Common: Infection (29%, serious infection &lt;1%), nausea, liver enzyme abnormalities. Rare: thrombosis, bone marrow suppression, acne, allergy.</p>													

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<b>Monitoring</b>	<p>Before commencing treatment measure FBE and LFTs.</p> <p>Monitor inflammatory markers 12 Hours after dose. Monitor FBE/UEC/LFT daily.</p>
<b>Drug interactions</b>	<p>Precaution if patient on other immunosuppressive or immunomodulatory drugs.</p> <p>Probenecid increases concentration of baricitinib.</p>
<b>Access</b>	<p>Use MUST be approved by Infectious Diseases Consultant. Obtain verbal consent from patient/family.</p> <p>Stock is available in imprest, stored in S11 cupboard. Usage to be recorded on S11 medication registers or HS8 program.</p>



## Clinical Practice Guideline COVID-19 Treatment in Pregnancy

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TOCILIZUMAB	
<b>Mechanism of Action</b>	Recombinant humanised anti-IL-6 receptor monoclonal antibody that inhibits the binding of IL-6 to both membrane and soluble IL-6 receptors, blocking IL-6 signalling and reducing inflammation
<b>Dose</b>	<p>Single intravenous infusion, with the potential for a second dose to be administered either 12 or 24 hours later if the patient's condition has not improved.</p> <p>The suggested dose is dependent on body weight:</p> <ul style="list-style-type: none"> <li>• Patients &gt; 90 kg: 800 mg tocilizumab</li> <li>• Patients &gt; 65 and ≤ 90 kg: 600 mg tocilizumab</li> <li>• Patients &gt; 40 and ≤ 65 kg: 400 mg tocilizumab</li> <li>• Patients ≤ 40 kg: 8 mg/kg tocilizumab</li> </ul>
<b>Administration</b> 	Use volumetric pump. Tocilizumab is listed in Drug Library. Dilute the dose to 100 mL of sodium chloride 0.9%, invert gently to avoid foaming. <b>Do not shake</b> . Infuse over 60 minutes.
<b>Indication</b>	Hypoxia PLUS with at least one sign of severe inflammation and unable to receive baricitinib
<b>Contraindications /Precautions</b>	<p>Known hypersensitivity to tocilizumab</p> <p>ALT/AST &gt; 5x ULN</p> <p>Platelets &lt;50, Neutrophils &lt;0.5</p> <p>Use with caution if</p> <ul style="list-style-type: none"> <li>• patient already on other immunosuppressant or immunomodulatory drugs,</li> <li>• active bacterial, fungal infection or tuberculosis</li> <li>• Risk of GI perforations (eg diverticulitis)</li> </ul>
<b>Adverse effects</b>	<p>Common: Infections, neutropenia, increased liver enzymes, gastritis, mouth ulcers, hypertension, allergic reactions.</p> <p>Infrequent: gastrointestinal perforation, thrombocytopenia.</p> <p>Rare: hepatotoxicity.</p>
<b>Monitoring</b>	<p>Observe for hypersensitivity reactions for 30 minutes post infusion. Recheck inflammatory markers 12 hours after first dose. Monitor FBE/UEC/LFT daily.</p> <p>Tocilizumab inhibits CRP, so a reduction in CRP should not be used as a marker of clinical improvement.</p>
<b>Drug interactions</b>	Precaution if patient on other immunosuppressive or immunomodulatory drugs.

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<b>Access</b>	<p>Patient <b>MUST</b> meet eligibility criteria before supply and administration.</p> <p>Use <b>MUST</b> be <b>approved by an Infectious Diseases Consultant</b>.</p> <p>Obtain verbal consent from patient/family.</p> <p>Contact pharmacy for supply:  08:30-17:00 Mon-Fri - ID Pharmacist (03) 9784 8209  09.00-13:00 Sat-Sun – Dispensary (03) 9784 7602  After hours - on-call pharmacist via switchboard.</p>
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# Clinical Practice Guideline COVID-19 Treatment in Pregnancy

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### BUDESONIDE

<b>Mechanism of Action</b>	Immunosuppressant and anti-inflammatory in the airways, including suppression of cytokine release.								
<b>Dose</b>	<p>Inhaled budesonide (by 'Turbuhaler', breath actuated inhaler) 800 micrograms twice daily for up to 14 days. If patient is already on inhaled corticosteroid, consider adjustment to equivalent dose of 800micrograms budesonide – a change of inhaler is not required.</p> <table border="1"> <caption>Table of equivalent dosing of inhaled corticosteroids to budesonide 800mcg</caption> <tr> <td>Beclomethasone</td><td>400micrograms</td></tr> <tr> <td>Ciclesonide</td><td>320micrograms</td></tr> <tr> <td>Fluticasone furoate</td><td>100micrograms</td></tr> <tr> <td>Fluticasone propionate</td><td>500micrograms</td></tr> </table>	Beclomethasone	400micrograms	Ciclesonide	320micrograms	Fluticasone furoate	100micrograms	Fluticasone propionate	500micrograms
Beclomethasone	400micrograms								
Ciclesonide	320micrograms								
Fluticasone furoate	100micrograms								
Fluticasone propionate	500micrograms								
<b>Administration</b>	<p>Self-administration by patient.</p> <p>Refer to fact sheet and inhaler device video on <a href="https://lungfoundation.com.au/resources/turbuhaler-inhaler-device-technique-fact-sheet/">https://lungfoundation.com.au/resources/turbuhaler-inhaler-device-technique-fact-sheet/</a></p>								
<b>Indication</b>	<p>Consider using inhaled budesonide for the treatment of symptomatic COVID-19 in adults who do not require oxygen and who have one or more risk factors for disease progression.</p> <p>In patients with confirmed COVID-19 who do not require oxygen but who are subsequently hospitalised due to disease progression, budesonide probably decreases the requirement of supplemental oxygen if taken within 14 days of onset of symptoms.</p> <p>Results are primarily based on the PRINCIPLE trial, in which adults were treated with inhaled budesonide (by breath actuated inhaler) 800 micrograms twice daily for up to 14 days. Based on the inclusion criteria for this trial, risk factors for disease progression include age <math>\geq</math> 65 years or <math>\geq</math> 50 years with one or more of the following comorbidities:</p> <ul style="list-style-type: none"> <li>• Diabetes (not treated with insulin)</li> <li>• Heart disease and/or hypertension</li> <li>• Asthma or lung disease</li> <li>• Weakened immune system due to a serious illness or medication (e.g. chemotherapy)</li> <li>• Mild hepatic impairment</li> </ul>								


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	<ul style="list-style-type: none"> <li>Stroke or other neurological problems</li> </ul>
<b>Contraindications</b>	Known hypersensitivity to budesonide
<b>Adverse effects</b>	Common: dysphonia, oral thrush, bruising. Rare: allergic reactions
<b>Monitoring</b>	Ensure patient is aware to rinse mouth after inhalation to minimize risk of oral thrush.
<b>Drug interactions</b>	Nil significant for inhaled formulation.
<b>Access</b>	<p>For inpatients: on COVID designated ward imprest.</p> <p>For patients in community: contact community care team on 9788 1700</p>

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## Peninsula Care Goal Safe

<b>SOTROVIMAB</b>	
<b>Mechanism of Action</b>	Engineered human IgG1 monoclonal antibody that neutralizes SARS-CoV-2 and SARS-CoV.
<b>Dose</b>	Single dose 500mg IV infusion. No dose adjustment is required for patients with renal or hepatic impairment.
<b>Administration</b> 	<p>Prepare infusion using closed system transfer device. Refer to <a href="#">Learning Hub demonstration video</a> or the <a href="#">Preparation and management of monoclonal antibodies CPG</a> for further information.</p> <p>Allow 15 minutes for the vial (leave in the box) to reach room temperature. Gently swirl the vial several times. <b>Do not shake.</b></p> <p>Remove 8mL from a bag of 100mL sodium chloride 0.9% or glucose 5%. Add 8 mL of sotrovimab to the bag, gently rock the bag 3 to 5 times. Do not invert or shake the bag. Do not allow air bubbles to form.</p> <p>Infuse over 30 minutes. Use 0.2 micrometre inline filter. Use volumetric pump. Sotrovimab is listed in Drug Library.</p>
<b>Indication</b>	<ul style="list-style-type: none"> <li>• Within 5 days of symptom onset</li> <li>• No oxygen or ventilation required due to COVID-19</li> <li>• Meets eligibility criteria according to "<a href="#">Request to access medications for mild COVID-19</a>" form</li> </ul>
<b>Contraindications</b>	<p>Hypersensitivity to sotrovimab or any of the excipients.</p> <p>Age &lt;12 years</p> <p>Age 12-18 years and weight &lt; 40kg.</p> <p>Patients on supplemental oxygen. There is no data available for patients on home oxygen with COPD.</p>
<b>Adverse effects</b>	<p>Common: gastrointestinal disorders, pneumonia, headache, rash, infusion-related reactions and bronchospasm</p> <p>Infrequent: anaphylaxis</p>
<b>Monitoring</b>	<p>Baseline COVID blood panel pre-administration.</p> <p>Observe for hypersensitivity reactions for 1 hour post infusion.</p>
<b>Drug interactions</b>	None reported yet
<b>Access</b>	<p>Access to sotrovimab is provided by the National Medicines Stockpile. Patient MUST meet eligibility criteria before supply and administration.</p> <p><b>ID consultant approval required before prescribing.</b> Obtain verbal consent from patient/family. Complete <a href="#">Request to Access Medications for Mild COVID-19 form</a> electronically and emailed to <a href="mailto:PharmacyID@phcn.vic.gov.au">PharmacyID@phcn.vic.gov.au</a>.</p> <p>Contact pharmacy for supply <b>after e-form is submitted</b>:  08:30-17:00 Mon-Fri - ID Pharmacist (03) 9784 8209  09.00-13:00 Sat-Sun – Dispensary (03) 9784 7602</p>

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	After hours – schedule infusion for 9am the following day. If urgent (eg. Day 5 of symptom onset) contact PSM via switchboard.
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