

DRUG TREATMENTS FOR PREGNANT OR BREASTFEEDING WOMEN WITH COVID-19



	Not requiring oxygen WITHOUT lower respiratory tract disease	Not requiring oxygen WITH lower respiratory tract disease	Requiring oxygen WITHOUT mechanical ventilation	Requiring invasive mechanical ventilation
DEFINITION OF DISEASE SEVERITY	<p>Mild</p> <p>An individual with no clinical features suggestive of moderate or more severe disease:</p> <ul style="list-style-type: none"> no OR mild symptoms and signs (fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhoea, loss of taste and smell) no new shortness of breath or difficulty breathing on exertion no evidence of lower respiratory tract disease during clinical assessment or on imaging (if performed) 	<p>Moderate</p> <p>A stable patient with evidence of lower respiratory tract disease:</p> <ul style="list-style-type: none"> during clinical assessment, such as <ul style="list-style-type: none"> oxygen saturation 92-94% on room air at rest desaturation or breathlessness with mild exertion or on imaging 	<p>Severe</p> <p>A patient with signs of moderate disease who is deteriorating OR</p> <p>A patient meeting any of the following criteria:</p> <ul style="list-style-type: none"> respiratory rate ≥ 30 breaths/min oxygen saturation $< 92\%$ on room air at rest or requiring oxygen lung infiltrates $> 50\%$ 	<p>Critical</p> <p>A patient meeting any of the following criteria:</p> <ul style="list-style-type: none"> respiratory failure (defined as any of) <ul style="list-style-type: none"> severe respiratory failure ($\text{PaO}_2/\text{FiO}_2 < 200$) respiratory distress or acute respiratory distress syndrome (ARDS) deteriorating despite non-invasive forms of respiratory support (i.e. non-invasive ventilation (NIV), or high-flow nasal oxygen (HFNO)) requiring mechanical ventilation hypotension or shock impairment of consciousness other organ failure
RECOMMENDED			<p>Use dexamethasone intravenously or orally for up to 10 days in pregnant or breastfeeding women with COVID-19 who require oxygen (including mechanically ventilated patients).</p> <p>If steroids are indicated for fetal lung maturity in women at risk of preterm birth, a standard antenatal corticosteroid regimen should be used.</p> <p>If steroids are not indicated for fetal lung maturity, use dexamethasone daily intravenously or orally for up to 10 days.</p>	
CONDITIONAL RECOMMENDATION FOR	<p>Consider using remdesivir <i>within 7 days of symptom onset</i> in pregnant women with COVID-19 who do not require oxygen and who have one or more additional risk factors[^] for disease progression.*</p>		<p>Consider using remdesivir in pregnant or breastfeeding women with COVID-19 who require oxygen but do not require non-invasive or invasive ventilation.</p>	
	<p>Consider using inhaled corticosteroids (budesonide or ciclesonide) <i>within 14 days of symptom onset</i> in adults with COVID-19 who do not require oxygen and have one or more risk factors[^] for disease progression.</p>		<p>Consider using tocilizumab for the treatment of COVID-19 in pregnant or breastfeeding women who require supplemental oxygen, particularly where there is evidence of systemic inflammation.</p>	
	<p>Consider using one of the following:</p> <p>Consider using sotrovimab <i>within 5 days of symptom onset</i> in pregnant women with COVID-19 in the second or third trimester who do not require oxygen and who have one or more additional risk factors[^] for disease progression.</p> <p>Where infection with Omicron BA.2 is confirmed or considered likely, use of sotrovimab should only be considered where other treatments are not suitable or available.^{##}</p> <p>Consider using casirivimab plus imdevimab (Ronapreve) <i>within 7 days of symptom onset</i> in pregnant or breastfeeding women with COVID-19 who do not require oxygen and have one or more risk factors[^] for disease progression.^{#,Δ}</p>			
CONSENSUS RECOMMENDATION FOR	<p>Consider using casirivimab plus imdevimab (Ronapreve) in seronegative pregnant or breastfeeding women hospitalised with moderate to critical COVID-19.^{##*}</p>			
	<p>Within the population of pregnant women for whom sotrovimab is conditionally recommended for use (as listed above), decisions about the appropriateness of treatment with sotrovimab should be based on the patient's individual risk of severe disease, on the basis of multiple risk factors[^], and COVID-19 vaccination status.</p> <p>Where infection with Omicron BA.2 is confirmed or considered likely, use of sotrovimab should only be considered where other treatments are not suitable or available.^{##}</p> <p>Consider using sotrovimab in patients who are not up-to-date with vaccination and patients who are immunosuppressed regardless of vaccination status.</p> <p>Do not routinely use sotrovimab in patients who are up-to-date with vaccination unless immunosuppressed.</p>			

Note: This flowchart does not apply to people on home oxygen due to pre-existing conditions. Use clinical judgement in these cases.

[^] Refer to next page for a list of risk factors for disease progression.

[#] Casirivimab plus imdevimab should not routinely be used where Omicron is the dominant circulating variant.

^Δ Do not routinely use casirivimab plus imdevimab in pregnant or breastfeeding women who are up-to-date with vaccinations unless immunosuppressed.

* Not approved for use by TGA for this indication.

^{##} While the clinical evidence supports use of sotrovimab to treat mild COVID-19, there is no clinical evidence to evaluate its effectiveness against the Omicron variant or BA.1 or BA.2 sub-variants. The Taskforce is aware of in vitro data that suggest potentially reduced efficacy against these variants and while the clinical implications of this are not certain, given the availability of other treatments, where infection with Omicron BA.2 is confirmed or considered likely, use of sotrovimab should not be considered unless other treatments are unsuitable or unavailable. This advice applies to pregnant and breastfeeding women.

	Not requiring oxygen WITHOUT lower respiratory tract disease	Not requiring oxygen WITH lower respiratory tract disease	Requiring oxygen WITHOUT mechanical ventilation	Requiring invasive mechanical ventilation
CONDITIONAL RECOMMENDATION AGAINST	<p>DO NOT routinely use dexamethasone (or other systemic corticosteroid) to treat COVID-19 in pregnant or breastfeeding women who do not require oxygen.</p>			
NOT RECOMMENDED	<p>DO NOT use the following for the treatment of COVID-19:</p> <ul style="list-style-type: none"> • aspirin • azithromycin • colchicine • convalescent plasma • hydroxychloroquine • hydroxychloroquine plus azithromycin • interferon β-1a • interferon β-1a plus lopinavir-ritonavir • ivermectin • lopinavir-ritonavir 			
				<p>DO NOT start remdesivir in pregnant or breastfeeding women hospitalised with COVID-19 who require non-invasive or invasive ventilation.</p>
	<p>DO NOT use casirivimab plus imdevimab (Ronapreve) in seropositive pregnant or breastfeeding women who are hospitalised with moderate to critical COVID-19.</p>			
ONLY IN RESEARCH	<p>Do not use the following for the treatment of COVID-19 outside of randomised trials with appropriate ethical approval:</p> <ul style="list-style-type: none"> • anakinra • angiotensin 2 receptor agonist C21 • aprepitant • baloxavir marboxil • bamlanivimab • bamlanivimab plus etesevimab • baricitinib • bromhexine hydrochloride • camostat mesilate • chloroquine • combined metabolic activators (CMA) • darunavir-cobicistat • doxycycline • dutasteride • enisamium • favipiravir • fluvoxamine • human umbilical cord mesenchymal stem cells • immunoglobulin • immunoglobulin plus methylprednisone • inhaled interferon β-1a • interferon β-1b • interferon gamma • interferon kappa plus trefoil factor 2 (IFN-κ plus TFF2) • ivermectin plus doxycycline • lenzilumab • molnupiravir (Lagevrio) • N-acetylcysteine • nirmatrelvir plus ritonavir (Paxlovid) • nitazoxanide • peginterferon lambda • recombinant human granulocyte colony-stimulating factor (rhG-CSF) • regdanvimab • ruxolitinib • sarilumab • sofosbuvir-daclatasvir • sulodexide • telmisartan • tixagevimab plus cilgavimab (Evusheld) • tofacitinib • triazavirin • umifenovir • vitamin C • vitamin D analogues (calcifediol / cholecalciferol) • zinc • other disease-modifying treatments 			
^RISK FACTORS FOR DISEASE PROGRESSION	<p>Risk factors for disease progression</p> <ul style="list-style-type: none"> • Pre-gestational diabetes requiring medication • Obesity (BMI >30 kg/m²) • Renal failure • Cardiovascular disease, including hypertension • Respiratory compromise, including COPD, asthma requiring steroids, or bronchiectasis • Immunocompromising condition <p><i>Note: This list has been simplified based on the individual risk factors for each therapy option from clinical trial evidence. Refer to the Australian guidelines for the clinical care of people with COVID-19 for further information.</i></p>			
	<p>Refer to the Risk Classification Tool when making decisions about which individuals are most likely to benefit from treatment.</p>			
	<p>Immunocompromising conditions include:</p> <ul style="list-style-type: none"> • Primary or acquired immunodeficiency <ul style="list-style-type: none"> - Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes - Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months) - Immunocompromised due to primary or acquired (AIDS) immunodeficiency - Other significantly immunocompromising conditions • Immunosuppressive therapy (current or recent) <ul style="list-style-type: none"> - Chemotherapy, whole body radiotherapy or total lymphoid irradiation - High-dose corticosteroids (≥20 mg of prednisone per day, or equivalent) for ≥14 days - Selected other potent immunosuppressive therapies (refer to ATAGI advice) 			

The Taskforce recognises that individuals have diverse gender identities. When we use the terms *woman*, *mother* or *maternity*, it is not meant to exclude those who are pregnant or breastfeeding and do not identify as women.

Source
[National COVID-19 Clinical Evidence Taskforce](#) – Australian guidelines for the clinical care of people with COVID-19.