



Access criteria for medicines to treat COVID-19 that are part of the National Medical Stockpile

Access to stock requires completion of a WA Emergency COVID-19 Treatment Approval form (via an electronic REDCap form linked to [Formulary One](#)) and confirmation by the prescriber that the patient fulfils required criteria. Supply of COVID-19 therapeutics via the National Medical Stockpile (NMS) is uncertain and availability is expected to fluctuate with demand and constraints in the supply chain. To ensure equity of access and conserve therapy for those patients at the highest risk of progression, a tiered access criterion is in place to allocate stock based upon current supply. Even within the most restricted tiers, access may be limited and available only on a first-come-first-served basis.

- **Tier 1 - Limited supply, access restricted to Tier 1 category**
- **Tier 2 - Ready supply, access restricted to Tier 1 and 2 indications**
- **Tier 3 - Unlimited supply, all tiers of access open**

Vaccination status

As per Australian Technical Advisory Group on Immunisation ([ATAGI advice on vaccination status](#)).

Up to date status is defined as follows:

Individuals aged 16 years and over - after completing an appropriate primary course of a Therapeutic Goods Administration (TGA) approved or recognised vaccine.

To optimise protection from the Omicron SARS-CoV-2 variant, individuals should receive a booster dose 3 months after completion of their primary schedule.

A person will be considered '**overdue**' if a booster has not been received within 6 months of completing their primary schedule.

Children and adolescents aged 5-15 years - after completion of a primary course of vaccination.

A booster dose is not currently recommended for this age group.

Severely immunocompromised individuals aged 5 years and over after completion of a 3rd primary dose of a COVID-19 vaccine from 2 months (and no later than 6 months) after dose 2 to remain up-to-date.

Those who are aged 16 years and over are recommended a booster (4th) dose, 3 months after dose 3 of their primary vaccination course. However, for the purpose of being up-to-date in the Australian Immunisation Register [AIR] (which does not contain any information on medical conditions) only a total of 3 doses will be counted as being up-to-date in this subgroup.

Individuals who have had prior COVID-19, including asymptomatic SARS-CoV-2 infection, still require completion of the above vaccination schedule, but can defer receipt of the next dose for up to 4 months following their infection.

This recommendation has changed from the previous 6-month interval. Some people may choose to be vaccinated prior to 4 months. Refer to [ATAGI clinical guidance on people with a past SARS-CoV-2 infection](#).



Partially vaccinated – person has received part of the recommended course of a TGA approved, or recognised vaccine as recommended above.

Unvaccinated – person has not received a Therapeutic Goods Administration (TGA) approved or recognised vaccine.

Note: Patients are deemed to have developed protective antibody levels 14 days after a COVID-19 vaccination dose. Doses given within this 14-day period should be classified as not having received a vaccination for the purposes of treatment eligibility in this guideline

TIER	Criteria	Eligibility
TIER 1	<p>ADAPTED FROM COMET-ICE CRITERIA FOR UNVACCINATED ADULTS AND ADULTS AT HIGH RISK OF SEVERE DISEASE</p> <p>TIER system based on National Institutes of Health Statement on Patient Prioritisation for Outpatient Therapies</p>	<p>Unvaccinated and age equal or greater than 75 years</p> <p style="text-align: center;">OR</p> <p>Unvaccinated and age equal or greater than 65 years of age (or Aboriginal and Torres Straight Islanders [ASTI]) patients equal or greater than 35 year of age) with additional risk factors as below: -</p> <ul style="list-style-type: none"> • Diabetes (including gestational diabetes) requiring medication • Obesity (BMI > 30 kg/m²) • Chronic kidney disease (i.e. eGFR < 60 mL/minute) • Congestive heart failure (New York Heart Association [NYHA] class II or greater) • Moderate-to-severe asthma (requiring an inhaled steroid to control symptoms or prescribed a course of oral steroids in the previous 12 months) • Chronic obstructive pulmonary disease (history of chronic bronchitis, chronic obstructive lung disease, or emphysema with dyspnoea on physical exertion) • Down syndrome <p>There is a cumulative increase in risk of progression to severe disease with each additional risk factor, which may further impact eligibility at times of extreme product shortage.</p>
	<p>PREGNANT WOMEN IN SECOND OR THIRD TRIMESTER</p>	<p>Unvaccinated or partially vaccinated (not up to date)</p> <p style="text-align: center;">OR</p> <p>Full vaccination and severe immunocompromised</p>
	<p>SEVERE IMMUNO-COMPROMISED</p> <p>Subset of immunocompromised persons as per ATAGI Recommendations on the use of a 3rd primary dose of COVID-19 vaccine in individuals who are severely immunocompromised</p>	<p>Severe immunocompromised regardless of vaccination status:</p> <ul style="list-style-type: none"> • Patients who are within 1 year of receiving B-cell depleting therapies (e.g., rituximab, ocrelizumab, ofatumumab, alemtuzumab) • Patients receiving Bruton tyrosine kinase inhibitors • Chimeric antigen receptor T cell recipients • Post-hematopoietic stem cell transplant recipients who have chronic graft versus host disease or who are taking immunosuppressive medications for another indication • Patients with hematologic malignancies who are on active therapy • Lung transplant recipients • Patients who are within 1 year of receiving a solid-organ transplant (other than lung transplant) or haematopoietic stem cell transplant

		<ul style="list-style-type: none"> • Solid-organ transplant recipients with recent treatment for acute rejection with T or B cell depleting agents • Patients with certain primary immunodeficiencies <ul style="list-style-type: none"> ○ Primary Immunodeficiencies (PID) affecting cellular and humoral immunity (severe and other combined immunodeficiencies (https://doi.org/10.1007/s10875-019-00737-x)) ○ PIDs with profoundly decreased or absent B cell number or function ○ PIDs with impaired interferon responses • Patients with untreated HIV who have a CD4 T lymphocyte cell count <50 cells/mm³ • Patients on any of the following agents not already listed <ul style="list-style-type: none"> ○ Anti-CD20 antibodies rituximab, obinutuzumab, ocrelizumab, ofatumumab ○ Bruton's tyrosine kinase (BTK) inhibitors ibrutinib, acalabrutinib, zanubrutinib ○ Sphingosine 1- phosphate receptor modulators fingolimod, siponimod ○ Anti-CD52 antibodies alemtuzumab ○ Anti-complement antibodies eculizumab ○ Anti-thymocyte globulin
	PAEDIATRIC	Paediatric Infectious Diseases Specialist review required (Perth Children's Hospital (PCH) to determine appropriateness of adolescent risk factors. Within 2 years of Hematopoietic stem-cell transplantation (HSCT) or Solid Organ Transplant regardless of vaccination status will be prioritised.
TIER 2	FOR UNVACCINATED AND PARTIALLY VACCINATED ADULTS AT HIGH RISK OF SEVERE DISEASE	<p>Unvaccinated and age equal or greater than 55 years (or ATSI patients equal or greater than 35 year of age) OR</p> <p>Partially vaccinated (not up to date) and age equal or greater than 55 years (or ATSI patients equal or greater than 35 year of age) with one additional risk factor as outlined above in Tier 1 OR</p> <p>Unvaccinated or partially vaccinated (not up to date) AND moderate immunocompromised, as per the following criteria, regardless of age or clinical risk factors. Moderate immunocompromised:</p> <ul style="list-style-type: none"> ○ Primary immunodeficiency including combined immunodeficiency and syndromes, major antibody deficiency (e.g. common variable immune deficiency (CVID) or agammaglobulinemia), defects of innate immunity (including phagocytic cells), defects of immune regulation, complement deficiencies and phenocopies of primary immunodeficiencies ○ Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes ○ Greater than 12 months post-transplant: haematopoietic stem cell transplant. ○ Advanced or untreated HIV with CD4 counts <200/microL, or those with a higher CD4 count unable to be established on effective anti-retroviral therapy, recent (within 12 months) AIDS-defining condition, or persistent/recurrent viraemia OR not on antiretroviral therapy (excluding elite controllers).

		<ul style="list-style-type: none"> ○ Haemodialysis or peritoneal dialysis ○ Immunosuppressive therapy (current or recent) examples include: ○ Chemotherapy or radiotherapy ○ Janus kinase (JAK) inhibitors - tofacitinib, baricitinib, ruxolitinib ○ High-dose corticosteroids (≥ 20 mg of prednisone per day, or equivalent) for ≥ 14 days in a month, or pulse corticosteroid therapy. ○ Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate (>0.4 mg/kg/week), leflunomide, azathioprine (≥ 3mg/kg day), 6-mercaptopurine (≥ 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus). <p>NOTE – The following agents are not considered to impart risk</p> <ul style="list-style-type: none"> - Anti-integrins natalizumab, vedolizumab - Anti-TNF-α antibodies infliximab, adalimumab, etanercept, golimumab, certolizumab - Anti-IL1 antibodies anakinra - Anti-IL6 antibodies tocilizumab - Anti-IL17 antibodies secukinumab, ixekizumab - Anti-IL4 antibodies dupilumab Anti-IL23 antibodies ustekinumab - Immune checkpoint inhibitors nivolumab, pembrolizumab, ipilimumab, atezolizumab * <p>OR</p> <p>Solid organ transplant recipient regardless of vaccination status.</p>
	PREGNANCY	<p>Unvaccinated who do not meet Tier 1 criteria (strong recommendation for discussion with ID physician and/or Womens and Newborns Health Service obstetrician before consideration)</p> <p>OR</p> <p>Partially vaccinated (not up to date) and at least one of the following risk factors who do not meet Tier 1 criteria:</p> <ul style="list-style-type: none"> ○ Gestational diabetes requiring medication ○ Obesity (BMI > 30 kg/m² or for paediatric patients BMI $>95^{\text{th}}$ centile for age and gender based on Clinical Growth Chart [CDC] chart) ○ Chronic kidney disease (i.e. eGFR < 60 mL/minute) ○ Congestive heart failure (NYHA class II or greater) ○ Moderate-to-severe asthma (requiring an inhaled steroid to control symptoms or prescribed a course of oral steroids in the previous 12 months) ○ Chronic obstructive pulmonary disease (history of chronic bronchitis, chronic obstructive lung disease, or emphysema with dyspnoea on physical exertion)
	PAEDIATRIC	<p>Paediatric Infectious Diseases Specialist (PCH) review required and referral of unvaccinated or partially vaccinated adolescents with risk factors including:</p> <ul style="list-style-type: none"> ● paediatric chronic complex condition, ● obesity ($>95^{\text{th}}$ centile for age and gender based on CDC growth charts), ● severe asthma, ● chronic obstructive lung disease,

		<ul style="list-style-type: none"> • diabetes (on insulin), • severe cardiac disease, • end stage renal disease, • sickle cell disease, • immune deficiency
TIER 3	MODERATE RISK OF SEVERE DISEASE	<p>All other patients who do not meet Tier 1 and Tier 2 criteria but do meet recommendations for use as per the National COVID-19 Clinical Evidence Taskforce.</p> <ul style="list-style-type: none"> • Unvaccinated or partially vaccinated patients less 55 years of age with additional risk factors OR • Immunocompromised that do not meet criteria for Tier 1 and Tier 2 OR • Partially vaccinated and age equal or greater than 55 years of age (or ATSI patients equal or greater than 35 year of age) without risk factor. <p>Note: Patients that do not meet recommendations for use as per the National COVID-19 Clinical Evidence Taskforce are not included in any tier as they will not be considered to be eligible for treatment.</p>

NOTE: [Molnupiravir is PBS listed](#) for treatment of symptomatic COVID infection in certain at-risk groups.

Please refer to current PBS guidelines for detailed prescribing information in the following groups:

- a) patients over 65 years of age,
- b) moderately to severely immunocompromised patients and
- c) Aboriginal or Torres Strait Islander patients over 50 years of age

Version	Date	Comments
1.0	2/02/2022	EAG APPROVED PSCQ ED APPROVED
2.0	2/03/2022	EAG APPROVED PSCQ ED APPROVED
3.0	9/02/2022	EAG APPROVED PSCQ ED APPROVED
3.1	17/03/2022	EAG APPROVED removing molnupiravir from Tier 3 and creating a note at end of table.

This guidance is correct at the time of publishing. However, as it is subject to updates, please use the hyperlinks to confirm the information is accurate.

WA guidance may be amended as additional federal guidance is finalised and/or further information becomes available.

The latest version of this guidance will be made available on the [COVID-19 information for health professional](#) webpage.

This document can be made available in alternative formats on request for a person with disability.

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