Government of **Western Australia**
Department of **Health**

ACCESS CRITERIA FOR SOTROVIMAB

This medication is regulated by the National Medical Stockpile. Access to stock requires completion of the WA Emergency COVID-19 Treatment Approval form (via REDCap) form 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 sotrovimab 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 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 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.

TIER	Criteria	Eligibility
TIER 1	**ADAPTED FROM COMET-ICE CRITERIA FOR UNVACCINATED ADULTS AND ADULTS AT HIGH RISK OF SEVERE DISEASE** TIER system based on National Institutes of Health Statement on Patient Prioritisation for Outpatient Therapies	**Unvaccinated** and age greater than 75 years OR **Unvaccinated** and age greater than 65 years of age (or ATSI patients greater than 35 year of age) with additional risk factors as below: - • Diabetes (including gestational diabetes) requiring medication • Obesity (BMI > 30 kg/m^2) • 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) 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.
	PREGNANT WOMENT IN SECOND OR THIRD TRIMESTER	• **Unvaccinated or partially vaccinated (first dose only)** • Any vaccination status and immunocompromised as per full ATAGI criteria listed below

	SEVERE IMMUNO-COMPROMISED
	
	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
		Severe immunocompromise regardless of vaccination status:
		• 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
		• Solid-organ transplant recipients with recent treatment for acute rejection with T or B cell depleting agents
		• Patients with certain primary immunodeficiencies
		  ○ PIDs 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/mm^3
		• Patients on any of the following agents not already listed
		  ○ Anti-CD20 antibodies rituximab, obinutuzumab, ocrelizumab, ofatumumab
		  ○ BTK inhibitors ibrutinib, acalabrutinib, zanubrutinib
		  ○ Sphingosine 1- phosphate receptor modulators fingolimod, siponimod
		  ○ Anti-CD52 antibodies alemtuzumab
		  ○ Anti-complement antibodies eculizumab
		  ○ Anti-thymocyte globulin

	PAEDIATRIC PATIENTS	Paediatric Infectious Diseases Specialist review required (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		**TIER 1 +** **Unvaccinated** and age > 55 years OR **Partially vaccinated** and age > 55 years with one additional factor as outlined above OR **Partially vaccinated (**first or second dose only**) and moderate immunocompromise**, regardless of age or clinical risk factors.
	PREGNANT	• Any vaccination status and at least one risk factor o Gestational diabetes requiring medication o Obesity (BMI > 30 kg/m2 or for paediatric patients BMI >95th centile for age and gender based on CDC chart) o Chronic kidney disease (i.e. eGFR < 60 mL/minute) o Congestive heart failure (NYHA class II or greater) o Moderate-to-severe asthma (requiring an inhaled steroid to control symptoms or prescribed a course of oral steroids in the previous 12 months) o Chronic obstructive pulmonary disease (history of chronic bronchitis, chronic obstructive lung disease, or emphysema with dyspnoea on physical exertion)
	PAEDIATRIC PATIENTS	Paediatric Infectious Diseases Specialist (PCH) review required and referral of unvaccinated or partially vaccinated adolescents with risk factors including: • paediatric chronic complex condition, • obesity (>95th centile for age and gender based on CDC growth charts), • severe asthma, • chronic obstructive lung disease, • diabetes (on insulin), • severe cardiac disease, • end stage renal disease, • sickle cell disease, • immune deficiency
TIER 3	**Fully vaccinated moderate risk of severe disease**	**TIER 1 and TIER 2 + all persons who are up to date (fully vaccinated) including booster vaccination who fulfil the following:** • Moderate immunocompromise with additional clinical risk factors for progression, regardless of vaccination status as above as per ATAGI advice: o 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 o Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes o Solid organ transplant on immunosuppressive therapy o Greater than 12 months post-transplant: solid organ transplant (on immunosuppressive therapy) or haematopoietic stem cell transplant. o 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 ART (excluding elite controllers). ○ Haemodialysis or peritoneal dialysis ○ Immunosuppressive therapy (current or recent) examples include: ○ Chemotherapy or radiotherapy ○ 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 ○ Biologic and targeted therapies listed in Table 1 above that are anticipated to reduce the immune response to COVID-19 vaccine ○ 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). NOTE – The following agents are not considered to impart risk - 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 * • Any age and unvaccinated with a clinical risk factor.