

Request to Access: tixagevimab and cilgavimab (Evusheld®) – Children’s Health

(For prophylaxis or treatment of COVID-19 in paediatric patients)

Please email completed forms to CTWG@health.qld.gov.au and nominated pharmacy delegate at your hospital

Please note: this medication is regulated by the National Medical Stockpile. Access to stock requires completion of this form and confirmation by the prescriber that the patient fulfils required criteria.

Note:

1. Fulfilling eligibility criteria does not automatically result in the prescription of tixagevimab and cilgavimab in children and it is currently reserved for those at the very highest risk of infection and disease progression.
2. The use of tixagevimab and cilgavimab in children and adolescents requires the approval of a specialist Paediatric Infectious Diseases physician.
3. The use of tixagevimab and cilgavimab in children under the age of 12 and/or less than 40 kg is off-label and will be considered on a case-by-case basis after discussion with the multidisciplinary team with approval and dosing advice from a specialist Paediatric Infectious Diseases Physician.

PATIENT DETAILS

Patient initials:

URN:

Patient DOB:

Gender:

Patient age:

HHS:

Patient weight:

Hospital/Facility:

Is the patient pregnant?

Is the patient breastfeeding?

SEROLOGICAL STATUS

Has baseline COVID serology been performed?

Serology pathology provider:

Anti-IgG serology testing can be considered prior to administration of tixagevimab and cilgavimab (Evusheld®) but this is not a mandatory requirement.

ACCESS CRITERIA

The patient must meet ALL access criteria:

Age \geq 12 years (and weighing \geq 40 kg). ^{NOTE3 (above)}

Moderate to severely compromised immune system (as defined below)

Indication:

For prophylaxis

For treatment

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ADMINISTRATION

Date of administration:

For guidance, detailed definitions and risk stratification refer to the CHQ Paediatric Guideline

IMMUNOSUPPRESSION

Select all that apply:

Stem cell transplant (SCT)

Hematological malignancy on active therapy

Details:

Within 1 year of a solid organ transplant (other than lung transplant)

Date of transplant:

Organ:

Lung transplant recipient (any time frame)

Solid tumor on active highly invasive chemotherapy

Rituximab/infliximab/obintuzumab PLUS additional immunosuppressive agents within 6 months

Alemtuzumab within 3 months

Solid organ transplant (other than lung): > 1 year post transplant AND child unvaccinated

CAR-T cell therapy within 12 months

HIV with CD4 cell count < 50 cells/mm³

Primary immune deficiency (T/B cell)

Details:

Immunosuppressed patients without evidence of seroconversion who are at least two weeks post 3-dose primary vaccine course (i.e.; negative anti-spike IgG)

Dialysis dependent patients without evidence of seroconversion who are at least two weeks post 3-dose primary vaccine course (i.e.: negative anti-spike IgG)

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RISK FACTORS

Select applicable risk factors. Mandatory if patient not immunosuppressed

Complex life limiting neurodisability with respiratory involvement

Obesity (BMI \geq 95th [CDC] / \geq 97th [WHO] centile for age)

Chronic Lung disease, severe

Heart failure

Severe asthma

Diabetes (insulin dependent)

Moderate-severe asthma not fulfilling severe criteria

Chronic kidney disease (GFR $<$ 15 mL/min/1.73m²)

Sickle cell disease

Complex genetic disease

Complex metabolic disease

Complex chronic gastrointestinal disease

Multiple congenital anomalies

Trisomy 21

Provide any further details (e.g. results of MDT discussion, patient’s clinical picture and risk:

If the patient does not meet the above eligibility requirements, please justify rationale for use:

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PRESCRIBER DETAILS

Prescriber full name:

Email:

Position:

Phone:

APPROVER DETAILS (if required at your site)

Name of approving Infectious Diseases Physician/COVID delegate:

Email:

Position:

Phone:

Date of approval:

Name of pharmacist consulted:

ACKNOWLEDGEMENT

I declare that the information provided is accurate at the time of completion

I declare that I have discussed the risks and benefits of prophylaxis with the patient and/or their carer and provided a Evusheld® Patient Information Leaflet

I agree to report any adverse reactions via the ADR portal

I agree to provide patient outcome information when requested

For off label/off license use, I have requested and received approval from the local hospital/health service Medication Advisory Committee/ Executive Director of Medical services