Evusheld™ prescribing in primary care

November 2022

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VICTORIA State Government | Department of Health

Tixagevimab and cilgavimab (Evusheld™) overview

- Provisional approval from TGA for **pre-exposure prophylaxis**
- Monoclonal antibodies designed to block viral attachment and entry into cells
- Available through the NMS since April, community prescribing pathway since July
- PBAC review in September did not recommend for PBS – for future submission
- Treatment goal is to prevent COVID-19 infection in people who:
  - are moderately-severely immunocompromise or,
  - can not be vaccinated due to severe allergy
- **Supply available until 31 December 2022**

Evusheld™ eligibility - Victoria

- heart/lung transplant recipients
- STEM Cell Transplant recipients within **24 months** or STEM Cell recipients with GVHD or still requiring significant ongoing immunosuppression for other reasons
- CAR T-cell therapy recipients within 12 months
- kidney, pancreas/islet cell, or liver transplant recipients within 12 months, or requiring therapy for acute rejection, or still requiring significant ongoing suppression for other reasons
- individuals with primary immunodeficiency syndromes
- haematologic disorders that may affect B cell function for example, CLL, CMML, myelodysplastic syndrome, myeloma
- individuals unable to be immunised with **COVID-19 vaccines due to genuine, severe allergy** and not recently infected with COVID-19 within 3 months
- individuals who have haematological malignancies and are receiving active therapy
- individuals with HIV who have a **CD4 cell count < 250 cells/mm^3**

Evusheld™ eligibility - Victoria

- individuals who within the last 12 months received:
  - anti-CD20 antibodies (rituximab, obinutuzumab, ocrelizumab, ofatumumab)
  - BTK inhibitors (ibrutinib, acalabrutinib, zanubrutinib)
  - BLC2 inhibitor (venetoclax)
  - anti-CD38 (daratumumab)
  - anti-BCMA bi-specific antibody
  - sphingosine 1- phosphate receptor modulators (fingolimod, siponimod)
  - anti-CD52 antibodies (alemtuzumab)
  - anti-complement antibodies (eculizumab)
  - anti-thymocyte globulin
  - high dose (> 1 g/m^2) cyclophosphamide
  - **JAK inhibitors (ruxolitinib, baricitinib, tofacitinib, upadacitinib)**
  - **abatacept**

Evusheld™ eligibility - Victoria

ALL NEW:

- individuals who within the last 3 months received:
  - Selected csDMARDs including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (for example, cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (for example, cyclosporin, tacrolimus)
  - high-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy,
  - chemotherapy or whole body radiotherapy.

- Repeat doses at approximately 6 months, or earlier at clinician discretion

Evusheld™ prescribing considerations

Administration

- 2x IM sequential injections (1.5mL tixagevimab and 1.5mL cilgavimab)
- Observe for 15 minutes post

Contraindications

- COVID-19 infection within the last 30 days
- COVID-19 vaccination within the last 2 weeks
- Weighs < 40 kg
- Age < 12 years old
- Hypersensitivity to active ingredients or other components of the product

Evusheld™ prescribing considerations

Precautions

- Breastfeeding or pregnancy (category B2)
- Clinically significant bleeding disorders, such as thrombocytopenia and other coagulation disorders
- Aged 12-17 years old
- Cardiovascular history

Evusheld™ primary care pathway

- The department stocks doses of Evusheld™ in **selected** community (Supercare) and regional and rural hospital pharmacies
- GPs can prescribe Evusheld™ for eligible patients
- Patients are dispensed Evusheld™ for free at participating pharmacies
- Option for administration at Supercare pharmacies by onsite nurses (6-10pm) or patients return to prescriber's clinic for administration
- Requires **prescription** and completed **Request to Access form**

REQUEST TO ACCESS BY GPs AND NON-GP SPECIALISTS

TIXAGEVIMAB PLUS CILGAVIMAB (EVUSHELD) FOR COVID-19 PRE-EXPOSURE PROPHYLAXIS

This form is required to be completed and supplied alongside a prescription to enable dispensing of Evusheld™ from participating hospital and community pharmacies. **Evusheld™ is available until 31st December 2022.**

TO BE COMPLETED BY PRESCRIBER:

PATIENT DETAILS

Patient's Name _____ Patient DOB (dd/mm/yyyy) _____

Sex

☐ Male ☐ Non-binary ☐ Other

☐ Female ☐ Not disclosed

DOSE AND ROUTE

300mg (150mg of both tixagevimab plus cilgavimab) IM (2 X 1.5ml inj) ☐

First Dose ☐ **Second dose** ☐

ACCESS CRITERIA (tick each criterion that applies to confirm the access criteria have been met)

☐ Stem Cell Transplant recipient within 24 months

☐ Stem Cell recipient with GVHD, OR still requiring significant ongoing immunosuppression for other reasons

☐ CAR T-cell therapy recipient within 12 months

☐ Heart/lung transplant recipient

☐ Kidney, pancreas/islet cells or liver transplant recipient within 12 months

☐ Kidney, pancreas/islet cells or liver transplant recipient requiring therapy for acute rejection, OR stillrequiring significant ongoing suppression for other reasons

☐ Individual with primary immunodeficiency syndromes. Please specify _____

☐ B or T cell depleting therapy within the previous 12 months. Please specify _____

☐ Individual unable to be immunised with COVID-19 vaccines due to genuine, severe allergy and not recently infected with COVID-19 within 3 months

☐ Haematological malignancy on active therapy

☐ Haematologic disorders that may affect B cell function e.g. CLL, CMML, myelodysplastic syndrome,myeloma

☐ Individual with HIV who have a CD4 cell count < 250 cells/mm³

☐ Selected csDMARDs, high dose corticosteroids, chemotherapy or whole body radiotherapy in the last 3 months.
Please specify _____

TIXAGEVIMAB PLUS CILGAVIMAB (EVUSHELD) FOR COVID-19 PRE-EXPOSURE PROPHYLAXIS

If Administration is to be completed by Supercare Pharmacy Nurses (6pm-10pm), complete the following:

Nursing services are only available at Supercare Pharmacies. **Regional and rural hospital pharmacies do not havenursing services available.**

DATE OF ADMINISTRATION (Must be no later than 31st December 2022)

Within the Next month ☐ Other (dd/mm/yyyy) _____

PRESCRIBER DETAILS

Prescriber Full Name _____ Prescriber Email _____

Prescriber Job Title _____ Phone Number _____

☐ I declare that the above information is accurate at the time of completion and agree to provide patient outcome information when requested by the Victorian Department of Health.

☐ I declare that patient consent for treatment with Evusheld™ has been obtained.

DATE OF FORM COMPLETION _____

TO BE COMPLETED BY PHARMACIST:

Please email the completed request form to: PharmDist@alfred.org.au

OFFICIAL

OFFICIAL

Evusheld™ resources to support prescribing

- Evusheld™ community prescriber guide
- Evusheld™ FAQ for clinicians
- Evusheld™ patient fact sheet
- Dedicated community prescriber website with all of the above resources and locations of selected pharmacies
- Pharmacy helpline 7 days a week 8am-5pm (03) 8290 3801
- Consumer web content to support awareness

Evusheld™ evidence

- **PROVENT trial** 300mg IM dose as PrEP reduced the risk of developing symptomatic COVID-19 compared to placebo by 83% over 6 months
- Some studies looking at Evusheld™ as treatment – **TACKLE** and **ACTIV-3-TICO.** Treatment under review by TGA.
- Invitro data of reduced effectiveness in BA.4/5
- Invitro data of lack of neuralisation in BA.4.6, BA.2.75.2, XBB and BQ1.1

Summary

- Expanded eligibility, similar to PBS antiviral immunocompromised criteria
- 2nd doses at approximately 6 months, earlier at clinician discretion
- Available for use until 31 December 2022. Supply thereafter uncertain.
- Adjunct to vaccination for immunocompromised, or substitute for those who can not be vaccinated, as PrEP
- Use as treatment only in exceptional circumstances with specialist recommendation
- Updated advice as will be shared by DH

Further information

Department:

COVID-19 medications resources

Evusheld™ community prescribing pathway

Consumer information

covid+pathways@health.vic.gov.au

Other:

Australian guidelines for the clinical care of people with COVID-19

TGA product information