Position Statement - COVID-19 Prophylaxis in People with Immune Deficiencies

5 May 2022

The National (Australian) COVID-19 Clinical Evidence Taskforce (the Taskforce), has issued recommendations on the use of monoclonal antibodies tixagevimab plus cilgavimab (Evusheld) for COVID-19 prevention (prophylaxis). Evusheld is supplied by Astra Zeneca, and has provisional approval in Australia from the Therapeutic Goods Administration (TGA) since January 2022:

www.tga.gov.au/media-release/tga-grants-provisional-determination-astrazeneca-pty-ltd-covid-19-prophylaxis-and-treatment-tixagevimab-and-cilgavimab-evusheld

Product information is available at www.tga.gov.au/sites/default/files/evusheld-pi.pdf which includes the following details:

- Evusheld is administered by intramuscular (IM) injection, and should be given with caution to patients with thrombocytopenia or any coagulation disorder.
- Serious adverse events are rare, as listed in table 5.
- Efficacy and safety of Evusheld in children (less than 18 years) has not been established.
- Evusheld is not recommended as a substitute for vaccination.
- The trial of Evusheld included particpants who had moderate to severe immune compromise due to a medical condition or immunosuppressive medications/treatments, that made it likely that they will not mount an adequate immune response to COVID-19 vaccination.

Supply of Evusheld is currently limited, and is only available in Australia from the National Stockpile. Therefore Evusheld can only be considered for pre-exposure prophylaxis in exceptional circumstances, in people who are severely immunocompromised and at high risk of progression to severe COVID-19.

This includes people who are expected to have an inadequate response to vaccination, who have:

- Solid organ transplant, blood or bone marrow transplant.
- Primary immune deficiencies, also known as inborn errors of immunity.
- Secondary immune deficiencies, including patients on significant immunosuppressive medications and some people with HIV.

ASCIA recommends that allocation of Evusheld should be based on the severity of the underlying immune deficiency, the risk of acquiring coronavirus infection, and the risk of severe COVID, supported by the patient's specialist recommendation. It is noted that there is currently no clinical data regarding effectiveness of Evusheld specific to SARS-CoV-2 variants of concern.

The Taskforce recommendations on Evusheld for prophylaxis are available at:
https://app.magicapp.org/#/guideline/L4Q5An/section/j7Amwz