GUIDANCE FOR COVID-19 THERAPEUTIC - Evusheld® (tixagevimab and cilgavimab)

Background

As part of a commitment to providing therapeutic treatments for COVID-19, Pharmac and Medsafe have approved the use of Evusheld as the first Pre-exposure Prophylaxis (PrEP) medication in New Zealand.

Purpose

1. To provide guidance to the Health Sector for implementation of Evusheld, firstly through secondary care, then Primary Care ensuring coverage in rural remote New Zealand.
2. To clarify eligibility criteria for those who qualify.
3. To promote equity and accessibility for those eligible to receive Evusheld.

Key messages

- Evusheld is a Pre-exposure Prophylaxis (PrEP) therapeutic containing two long-acting monoclonal antibodies (tixagevimab and cilgavimab)
- Evusheld is not a replacement for COVID-19 vaccination. People are encouraged to be fully vaccinated, where they can be, and are encouraged to get the COVID-19 vaccine first
- It is intended for:
    - A small group of immunocompromised people, who would not (or do not) develop an antibody response to COVID-19 vaccination. It is expected this will be approximately 10,000 people, which equates to approximately two per 1,000 in the population.
    - or people who are unable to have the COVID-19 vaccine, however this is not for people who choose not to have the vaccine but for those people who are unable to have the covid-19 vaccine due to a medical contraindication.
- Given as sequential Intramuscular injections (IM) – dosage listed in inclusion criteria below
- In the first instance, it is expected that specialist services will be able to identify and contact those patients that meet criteria. It is anticipated that for most people it will be possible to receive this medicine in a specialist setting.
- To ensure equity and accessibility, in particular for people in rural, remote areas, we will work with local providers to develop mechanisms to make it as easy as possible for people to access the medicine.

Inclusion criteria

Must meet the following and the prescribing clinician must have endorsed the prescription accordingly as per Pharmac criteria – [Tixagevimab with cilgavimab (Evusheld) Access Criteria - Pharmac | New Zealand Government]

- All of the following:

1. Patient does not currently have SARS-CoV-2 infection

AND

2. Either:

2.1 Patient is severely immunocompromised and considered to be at risk of inadequate immune response to SARS-CoV-2 vaccination or infection due to **ANY** of the following clinical situations:

- heart or lung transplant recipient (any time frame)
- other solid-organ transplant recipient with any of the following:
  - transplant received within the last 12 months
  - receiving induction immunosuppressant treatment (any timeframe)
  - receiving maintenance immunosuppressant treatment that includes mycophenolate mofetil (any timeframe)
  - treated for graft rejection within the past 12 months
- allogenic haematopoietic stem cell transplant recipient with any of the following:
  - transplant received within last 12 months
  - has chronic graft versus host disease
  - requires significant ongoing immunosuppression for another reason
- autologous haematopoietic stem cell transplant received within the last 12 months
- multiple myeloma on active and/or maintenance treatment
- combined primary immunodeficiency syndromes (including Severe Combined Immunodeficiency (SCID))
- common variable immunodeficiency (CVID) with additional T-cell defects, past opportunistic infection or requiring immunosuppressive therapy
- diagnosed humoral immunodeficiency with baseline IgG < 3g/L
- HIV with a CD4 T lymphocyte cell count <200 cells/mm3
- person who is receiving:
  - potent B-cell or T-cell depleting therapy within the previous 12 months or planned to receive within two weeks of tixagevimab and cilgavimab administration*
  - a B-cell inhibitor (e.g. venetoclax or a Bruton tyrosine kinase inhibitor)
  - ruxolitinib
  - regular 3-4-weekly intravenous or subcutaneous immunoglobulin
  - sphingosine 1- phosphate receptor modulator therapy (eg fingolimod) within previous 12 months
  - high dose cyclophosphamide (>1g/m2) within previous 6 months.
- History of previous persistent SARS-CoV-2 infection (defined as a laboratory confirmed diagnosis of persistent SARS-CoV-2 infection persisting ≥20 days) that has since resolved

OR

2.2 Person is both

- not able to be vaccinated against COVID-19 due to medical contraindication (for example a history of severe adverse reaction to a COVID-19 vaccine or its components) **AND**
- is considered at high risk of severe illness from COVID-19 infection.

Notes:

* potent B-cell or T-cell depleting therapy such as rituximab, obinutuzumab, ocrelizumab, bendamustine, fludarabine, cladribine, alemtuzumab, anti-thymocyte globulin, CamPath antibody treatment, anti-B-cell bispecific antibody, CAR T-cells or BiTE antibody treatment.