Te Whatu Ora
Health New Zealand

Evusheld – FAQ

What is Evusheld?

- Evusheld is a combination of two long-acting anti-SARS-CoV-2 monoclonal antibodies (tixagevimab and cilgavimab). These antibodies target the SARS-CoV-2 spike protein and block viral attachment and entry into cells. It is currently licenced in New Zealand for Pre-exposure Prophylaxis (PrEP), and assessments are underway for future use as treatment.

How effective is Evusheld?

- A large ongoing Phase III, randomised, double-blind placebo-controlled clinical trial (PROVENT) in high-risk individuals assessed the safety and administration of Evusheld. This reported an 83% reduction of symptomatic COVID-19 in high-risk people during the six months after administration.
    - Over 75% of participants were high risk for severe COVID-19 due to co-morbidities, indicating this treatment is appropriate for very immunocompromised people.
    - Prior to unblinding, 0.2% of the treatment group reported symptomatic COVID-19 infections compared to 1.0% in the placebo: a relative risk reduction (RRR) of 76.7% for infections in the treatment group. Only primary endpoints that were prior to participants' vaccination were included in the study.

Is Evusheld effective against the Omicron variant?

- Data is still emerging on the efficacy of Evusheld against new emerging subvariants of Omicron, however some countries have switched to using a 600mg dose of Evusheld in response to concerns about reduced effectiveness. Several in-vitro studies suggest that the neutralising activity of Evusheld is likely to be lower for Omicron subvariants than for the Delta variant. Although some retention of neutralising ability of Evusheld is promising, the trend towards lower potency with new variants will need monitoring.

Can Evusheld be used in place of COVID-19 vaccination?

- 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.
- People who have recently received a COVID-19 vaccine should wait at least 2 weeks before receiving Evusheld.
- In rare situations, some very immunocompromised people do not mount an adequate immune response to the vaccine due to comorbidities or other health conditions. In these cases, Evusheld can provide additional protection to the individuals.

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Who is eligible for Evusheld?

- Refer to the Pharmac Eligibility

Is it necessary or desirable to check antibody status prior to administration?

- Serology testing is not required prior to administration of Evusheld.

What is the current recommended dose of Evusheld?

- Currently the licenced dose of Evusheld is 150mg of tixagevimab and 150mg of cilgavimab (300 mg total) administered as separate sequential intramuscular injections.
- Based on currently available information relating to effectiveness against new variants, Pharmac have taken the decision to fund 300mg tixagevimab + 300mg cilgavimab given intra muscularly (a 600 mg dose).
- Due to international evidence that a 600 mg dose is safe and providing better protection, the FDA and the manufacture (AstraZeneca) have amended their recommendation to this.

What models of care are currently being used to deliver Evusheld to eligible consumers?

- In the first instance, it is expected that specialist services will be able to identify and contact 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 and remote areas, we will work with local providers to develop mechanisms to make it as easy as possible for people to access the medicine.

Will there be funding to support recalling, assessing and administering Evusheld to patients in primary care?

- Our intention is to fund primary care for this work however funding arrangements are still being confirmed.

Is the timing between a patient receiving a COVID-19 vaccine and being administered Evusheld significant?

- If a patient is eligible for a COVID-19 dose, this should be prioritised prior to receiving Evusheld
- Patients who have received a COVID-19 vaccine should wait at least 2 weeks before receiving Evusheld

How will administration of Evusheld be recorded by specialist services?

- Hospital based clinicians will document and communicate Evusheld related activities with each other and GPs via existing clinical recording and referral systems.

What should I do if a patient contacts me in my general practice seeking Evusheld?

- If you believe the patient meets the eligibility criteria, you should refer them to their specialist via usual referral channels.

How long after a confirmed COVID-19 infection should Evusheld be administered?

- Eligible patients who have recently recovered from COVID-19 are less likely to be re-infected than similar uninfected patients. As such, the additional benefit of Evusheld might be lower in the months after recovery. For this reason, clinicians caring for patients recently recovered from COVID-19 should consider deferring Evusheld for 2-3 months after clinical recovery.

What is the recommended observation time for a patient after receiving Evusheld?

- Clinical observation of the patient is recommended for 15 minutes following injection.

Are patients required to obtain a negative PCR prior to receiving Evusheld?

- A negative PCR prior to the administration of Evusheld is not required, however, patients should follow testing guidelines as per usual process (e.g., getting tested if they have symptoms of COVID-19).

Can Evusheld be given if a person has previously had antiviral treatment (Paxlovid, Molnupiravir) for an active COVID-19 infection?

- Evusheld can still be given if a person has previously had antivirals for the treatment of COVID-19. If the patient has had a previous COVID-19 infection which required treatment, it is suggested to wait 2-3 months after the initial infection before administering Evusheld.

How is Evusheld given?

- Evusheld is supplied in a carton which contains two separate single-use vials that do not require reconstitution. Each carton contains one 300 mg dosage (150 mg of each antibody).
- To administer a 600 mg dose, two cartons need to be used. Each antibody should be administered as separate single injections i.e, 2 x 1.5 ml vials of tixagevimab solution into one syringe and 2 x 1.5 ml vials of cilgavimab solution into another single syringe. These are to be administered sequentially as intramuscular injections into different sites. The preferred injection site is the gluteal muscles.

What are side effects of Evusheld?

- In general, Evusheld is well tolerated, however common and uncommon side effects include:

- Common: may affect up to 1 in 10 people
    - hypersensitivity reaction (rash or hives - an itchy red rash or raised bumps)
    - injection site reaction (pain, redness, itching, swelling where the injection was given)
- Uncommon: may affect up to 1 in 100 people
    - injection related reaction (examples of these include headache, chills and redness, discomfort or soreness near where the injection was given)

Are there any medication related interactions with Evusheld?

- Evusheld is not renally excreted or metabolised by cytochrome P450 (CYP) enzymes; therefore, interactions with concomitant medications that are renally excreted or that are substrates, inducers, or inhibitors of CYP enzymes are unlikely and can be co-administered.

Is Evusheld being used in paediatric populations?

- Evusheld is licenced for use in children aged 12 and older and weighing at least 40 kg.

When should a consumer receive a second dose of Evusheld?

- Pharmac are not funding subsequent courses at the present time.
- Current evidence supports six-month efficacy with a single dose of Evusheld

If a patient contracts the virus causing COVID-19 after they have received Evusheld, are they still eligible for antiviral therapies?

- Yes, patients can still receive antiviral therapies for COVID-19 if they contract the virus after receiving Evusheld.