Supplemental Protocol
EVUSHELD Dosing and Administration

Authorized Use

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of the unapproved product EVUSHELD (tixagevimab co-packaged with cilgavimab) for the pre-exposure prophylaxis of Coronavirus disease 2019 (COVID-19) in adults and pediatric individuals (12 years of age and older weighing at least 40 kg):

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2, **and**
- Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination, **or**
- For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

Limitations of Authorized Use

- EVUSHELD is not authorized for use in individuals:
  - For treatment of COVID-19, or
  - For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2.
- Pre-exposure prophylaxis with EVUSHELD is not a substitute for vaccination.
- In individuals who have received a COVID-19 vaccine, EVUSHELD should be administered at least two weeks after vaccination.

Dosage

The dosage of EVUSHELD in adults and pediatric individuals (12 years of age and older weighing at least 40 kg) is 150 mg of tixagevimab and 150 mg of cilgavimab administered as two separate consecutive intramuscular (IM) injections.

Contraindications

EVUSHELD is contraindicated in individuals with previous severe hypersensitivity reactions, including anaphylaxis, to any component of EVUSHELD.

Fact Sheets

- Provide a copy of the Fact Sheet for Patients, Parents, and Caregivers for EVUSHELD and explain risks, benefits and alternatives to the patient, emphasizing that this therapy is not FDA approved but is under Emergency Use Authorization (EUA).
- Review the Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of EVUSHELD.

Resources

Refer to Vermont EMS Protocol for COVID-19 Monoclonal Antibody Administration for information on PPE, management of adverse reactions, and documentation.

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EVUSHELD Dose Preparation

Each EVUSHELD carton contains two vials, one of each antibody. Each vial contains an overfill to allow the withdrawal of 150 mg (1.5 mL).

Table 1. Dosage of Tixagevimab and Cilgavimab

EVUSHELD* (tixagevimab co-packaged with cilgavimab)	Antibody dose	Number of vials needed	Volume to withdraw from vial(s)
	tixagevimab 150 mg	1 vial (dark grey vial cap)	1.5 mL
	cilgavimab 150 mg	1 vial (white vial cap)	1.5 mL

* 150 mg of tixagevimab and 150 mg of cilgavimab are to be administered as separate, consecutive intramuscular injections

- Tixagevimab and cilgavimab are each supplied in individual single-dose vials. **Do not shake the vials.**
- Visually inspect the vials for particulate matter and discoloration. Tixagevimab and cilgavimab are clear to opalescent, colorless to slightly yellow solutions. Discard the vials if the solution is cloudy, discolored or visible particles are observed.
- Withdraw 1.5 mL of tixagevimab solution and 1.5 mL of cilgavimab solution into TWO separate syringes (see Table 1) using a 1 ½ inch 21-gauge transfer needle. Discard unused portion in vials.
- This product is preservative-free and therefore, the prepared syringes should be administered immediately. If immediate administration is not possible, and the prepared tixagevimab and cilgavimab syringes need to be stored, the total time from vial puncture to administration must not exceed 4 hours at room temperature up to 25ºC (77ºF) or in a refrigerator at 2ºC to 8ºC (36ºF to 46ºF).

EVUSHELD Dose Administration

- Administer the two components of EVUSHELD consecutively.
- Administer the IM injections at different injection sites, preferably one in each of the gluteal muscles, one after the other. Use a 1 to 1 ½ inch 25-gauge needle for IM injection.
- Clinically monitor individuals after injections and observe for at least 1 hour.

Storage

Refrigerate unopened vials at 2ºC to 8ºC (36ºF to 46ºF) in original carton. Do not freeze or shake. Protect from light.