

**Keeping Up With COVID  
Therapeutics Part 1 - Monoclonal Antibodies (mAbs)**

**Tixagevimab/cilagavimab (EVUSHELD)**

Mechanism of Action

- Long-acting recombinant human IgG1kappa mAb derived from B cells donated by patients after SARS-CoV-2 virus; bind to SARS-CoV-2 spike protein, thus blocking virus attachment

Indication

- **Pre-exposure prophylaxis** in adults and pediatrics ( $\geq 12$  years, weighing at least 40 kg)
  - Not currently infected and no known recent exposure
  - Moderate-severe immunocompromised
  - Those not able to mount adequate immune response from vaccination
  - **NOT a substitute for vaccination**

Dosage/Administration (adults and peds)

- Tixagevimab 150mg IM and cilgavimab 150mg IM administered as separate, consecutive injections
- **Administer at least 2 weeks after COVID-19 vaccination**
- PROVENT trial - indicates effectiveness for 6 months

Warnings/Precautions

- Monitor individuals after injection and observe for at least 1 hour
- Cardiovascular Serious Adverse Events (SAEs)
  - SAEs include myocardial infarction (1 fatality during trials) and cardiac failure – however these patients had underlying cardiac risk factors or history (relationship has not been established)
- Renal impairment unlikely; hepatic impairment unknown

Pregnancy/Lactation

- Insufficient data (IgG1 antibodies known to cross placenta, benefit/risk unknown)
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**Sotrovimab**

Mechanism of Action

- Recombinant human IgG1kappa mAb; binds to spike protein; inhibits an undefined step before fusion of virus to cell membrane

Indication

- **Treatment** of mild-moderate disease in adults and pediatrics ( $\geq 12$  years, weighing at least 40 kg) with positive COVID-19 test result, and those who are at high risk for severe disease progression (hospitalization or death)
- NOT authorized for: patients hospitalized with COVID-19, require oxygen therapy for COVID-19, require an increase in oxygen flow rate because of COVID-19 (were previously on oxygen)
  - Treatment benefit not observed in hospitalized patients with **severe** infection

#### Dosage/Administration (adults and peds)

- 500mg as a single IV infusion
- Administer ASAP after positive test result and within **10 days of symptom onset**

#### Warnings/Precautions

- Monitor individuals after injection and observe for at least 1 hour after infusion is complete
- Renal impairment unlikely; hepatic impairment unknown
- Infusion related reactions fever, chills, fatigue, chest pain, weakness, headache, difficulty breathing, arrhythmia, hypotension, altered mental status, difficulty breathing

#### Pregnancy/Lactation

- Insufficient data (IgG antibodies potential to cross placenta, benefit/risk unknown)
- Maternal IgG known to be present in breast milk

#### Unavailable mAbs

- FDA revised EUAs for bam/ete and REGEN-COV
  - Limits use to only patients who are likely to have been infected with or exposed to a variant susceptible to these treatments
  - Data show treatments unlikely to work against Omicron
  - Treatments not currently authorized for use in any US states, territories, jurisdictions
  - Products must be used in accordance with EUA guidance
- Alternative therapies remain: EVUSHELD, Sotrovimab

#### Implementations in Practice

##### Considerations for implementation:

1. Practice Model
  - a. Refer patients to administration sites
  - b. Administer directly at practice site
    - i. Appropriate space for administration
    - ii. Need to consider space for observation period
    - iii. Appropriate staff on-site to administer
  - c. Storage
2. Billing for administration
  - a. Coverage of Monoclonal Antibody Products to Treat COVID-19
  - b. CMS: Medicare Reimbursement for Monoclonal Antibody Administration

##### How to access these therapeutics as a provider:

1. Complete enrollment survey
2. Review compliance and reporting requirements
3. Order through VaMax

Resources
<a href="#"><u>VDH COVID-19 Therapeutics</u></a>
<a href="#"><u>VDH COVID-19 Treatment Locator Tool</u></a>
<a href="#"><u>EVUSHELD Fact Sheet for Healthcare Providers</u></a>
<a href="#"><u>Sotrovimab Fact Sheet for Healthcare Providers</u></a>
<a href="#"><u>Outpatient Therapeutics Decision Guide for Providers</u></a>