Tixagevimab & Cilgavimab
Quick Point-of-Care Reference

Last reviewed: 4/15/22

Tixagevimab and cilgavimab (brand name Evusheld™) has been FDA-authorized for emergency use as pre-exposure prophylaxis (PrEP) for prevention of COVID-19 in certain adults and pediatric patients since December 2021 with a dosing revision in February 2022.

CLINICAL INFORMATION

Eligibility: FDA's tixagevimab and cilgavimab EUA covers adults and pediatric patients 12 years of age and older weighing at least 40 kg (88 lbs) who are:

- Not currently infected with SARS-CoV-2 with no known recent exposure

AND

- May not mount an adequate immune response to COVID-19 vaccination

OR

- For whom vaccination with available approved or authorized COVID-19 vaccines is not recommended.

Dosing: A course of tixagevimab and cilgavimab consists of 300 mg tixagevimab and 300 mg cilgavimab administered as two consecutive intramuscular injections.

- Individuals who initially received the previously authorized dose of 150 mg tixagevimab and 150 mg of cilgavimab should receive a second dose of 150 mg tixagevimab and 150 mg cilgavimab as soon as possible.

Clinical Decision-Making: IDSA guidelines suggest PrEP with tixagevimab/cilgavimab rather than no tixagevimab/cilgavimab in moderately or severely immunocompromised individuals at increased risk for inadequate immune response to COVID-19 vaccine or for whom COVID-19 vaccine is not recommended due to a documented serious adverse reaction to the vaccine (conditional recommendation, low certainty of evidence).

NIH guidelines recommend tixagevimab and cilgavimab as PrEP for patients who are moderately to severely immunocompromised and may have inadequate immune response to COVID-19 vaccination (BIIa) or are not able to be fully vaccinated with any available COVID-19 vaccines due to a documented history of severe adverse reaction to a COVID-19 vaccine or any of its components (AIIa).

COVID-19 Real-Time Learning Network
Brought to you by CDC and IDSA

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SAFETY ISSUES

Although a full understanding of tixagevimab and cilgavimab's safety profile remains incomplete, according to FDA notable considerations include:

Hypersensitivity Including Anaphylaxis: Serious hypersensitivity reactions, including anaphylaxis, have been observed with monoclonal antibodies like tixagevimab and cilgavimab. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive therapy. Clinically monitor individuals after injections and observe for at least 1 hour.

Cardiovascular Events: A higher proportion of subjects who received tixagevimab and cilgavimab versus placebo reported myocardial infarction and cardiac failure serious adverse events. All of the subjects with events had cardiac risk factors and/or a prior history of cardiovascular disease, and there was no clear temporal pattern. A causal relationship between tixagevimab and cilgavimab and these events has not been established. Consider the risks and benefits prior to initiating tixagevimab and cilgavimab in individuals at high risk for cardiovascular events, and advise individuals to seek immediate medical attention if they experience any signs or symptoms suggestive of a cardiovascular event.

Clinically Significant Bleeding Disorders: As with any other intramuscular injection, tixagevimab and cilgavimab should be given with caution to individuals with thrombocytopenia or any coagulation disorder.

Interactions With Other Therapeutics: Tixagevimab and cilgavimab is not known to have adverse reactions with other therapeutics.

SUPPLY & ACCESS

Distribution: Tixagevimab and cilgavimab is currently available in limited quantities in the U.S. and is being allocated by the federal government to health departments in states, territories and jurisdictions as well as select community health centers.

For allocation details, refer to HHS's weekly distribution summaries; for information intended for health providers, see HHS's COVID-19 Therapeutics Locator; for provider-specific distribution information, view HHS's COVID-19 Public Therapeutics Locator. Contact your state, territorial or jurisdictional health department for further local information.

CODING, BILLING & REPORTING

Coding:

Drug Name	Dosage	Package Size	Package Components	NDC
Tixagevimab/ cilgavimab	300 mg tixagevimab and 300 mg cilgavimab administered as two consecutive IM injections	One carton (two vials per carton)	One vial tixagevimab for injection (NDC 0310-8895-01) One vial cilgavimab for injection (NDC 0310-1061-01)	00310-7442-02

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Billing: Providers may use HCPCS codes:

Q0221: Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40 kg) with no known SARS-CoV-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available COVID-19 vaccine is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s), 600 mg.

Q0220: Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40 kg) with no known SARS-CoV-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available COVID-19 vaccine is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s), 300 mg. **(Use for catch-up doses only.)**

M0220: Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40 kg) with no known SARS-CoV-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available COVID-19 vaccine is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s), includes injection and post-administration monitoring.

M0221: Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40 kg) with no known SARS-CoV-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available COVID-19 vaccine is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s), includes injection and post-administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the COVID-19 public health emergency.

Reporting: All serious adverse events and medication errors potentially related to tixagevimab/cilgavimab should be submitted to FDA's MedWatch adverse event report online or by calling 1-800-FDA-1088.

FURTHER INFORMATION

Real-Time Learning Network Tixagevimab/Cilgavimab Literature Reviews
FDA Tixagevimab/Cilgavimab Fact Sheet for Health Providers
FDA Tixagevimab/Cilgavimab Emergency Use Authorization Letter

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