



# THE PRESCRIBER e-LETTER

## Evusheld (tixagevimab copackaged with cilgavimab)

The MassHealth Pharmacy program continues to support prescribers and members in appropriate prevention and treatment strategies for COVID-19. As such, the program is using this edition of the E-letter to provide updated information regarding the current United States Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for Evusheld (tixagevimab copackaged with cilgavimab).

Evusheld (tixagevimab copackaged with cilgavimab) is a combination of two recombinant human IgG1κ monoclonal antibodies which are SARS-CoV-2 spike protein-directed attachment inhibitors. This agent was issued an EUA by the U.S. FDA for emergency use as pre-exposure prophylaxis for prevention of COVID-19 on December 8, 2021, for 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 to a COVID-19 vaccine(s) and/or COVID-19 vaccine components(s).

More recently on February 24, 2022, the EUA was revised to recommend an increased initial dose of 300 mg of tixagevimab and 300 mg of cilgavimab due to a concern about suboptimal activity against certain Omicron subvariants with original 150 mg dosing regimen.

MassHealth providers can find more detailed information on appropriate patient selection, warnings and precautions, availability and coverage for Evusheld in the reference section below.

### Dosing and Administration

Administer 300 mg (3 mL) of tixagevimab and 300 mg (3 mL) of cilgavimab as two separate intramuscular (IM) injections, per EUA package insert, preferably one in each of the gluteal muscles (each injection is comprised of 150 mg tixagevimab and 150 mg of cilgavimab).

- Individuals who received the previously authorized dose (150 mg tixagevimab and 150 mg of cilgavimab) should receive a second Evusheld dose (150 mg tixagevimab and 150 mg of cilgavimab) as soon as possible.
- Monitor individuals for adverse events at least one hour after injections.
- In individuals who have received a COVID-19 vaccine, Evusheld should be administered at least two weeks after vaccination.

### Adverse Reactions

Most common adverse events (all grades, incidence ≥ 3%) are headache, fatigue, and cough.

### Availability and Coverage

MassHealth will cover the administration of Evusheld (tixagevimab copackaged with cilgavimab) by providers enrolled in the MassHealth acute outpatient hospital, community health center, and physician programs for pre-exposure prophylaxis of COVID-19 only when the injections are administered in a manner fully compliant with the FDA's EUA. Prior authorization is not required for this product.

The appropriate billing Healthcare Common Procedure Coding System (HCPCS) are provided below for reference. Refer to MassHealth All Provider Bulletin 336 and 341 for full descriptions.

The *Prescriber e-Letter* is an update designed to enhance the transparency and efficiency of the MassHealth drug prior-authorization (PA) process and the MassHealth Drug List. Each issue **highlights** key clinical **information and updates** to the **MassHealth Drug List**. The Prescriber E-Letter was prepared by the MassHealth Drug Utilization Review Program and the MassHealth Pharmacy Program.

Code	Rate	Description
M0220	\$150.50	injection and post administration monitoring
M0221	\$250.50	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

References:

1. Coronavirus Update: FDA authorizes new long-acting monoclonal antibodies for pre-exposure prevention of COVID-19 in certain individuals [press release on the Internet]. U.S. Food & Drug Administration. 2021 Dec 8 [cited 2022 Feb 1]. Available from: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-new-long-acting-monoclonal-antibodies-pre-exposure>.
2. Fact sheet for healthcare providers: emergency use authorization for Evusheld (tixagevimab co-packaged with cilgavimab). U.S. Food and Drug Administration. 2022 Feb [cited 2022 Mar 18]. Available from: <https://www.fda.gov/media/154701/download>.
3. MassHealth All Provider Bulletin 336. Mass.gov. 2021 Dec [cited 2022 Mar 18]. Available from: <https://www.mass.gov/doc/all-provider-bulletin-336-coverage-of-and-payment-for-the-administration-of-1-tixagevimab-co-packaged-with-cilgavimab-and-2-remdesivir-in-an-outpatient-setting-corrected/download>.
4. MassHealth All Provider Bulletin 341. Mass.gov. 2022 Mar [cited 2022 Mar 18]. Available from: <https://www.mass.gov/doc/all-provider-bulletin-341-coverage-of-and-payment-for-the-administration-of-1-tixagevimab-co-packaged-with-cilgavimab-and-2-bebtelovimab-0/download>.
5. COVID-19 Public Therapeutic Locator. HealthData.gov. Cited 2022 Mar 18. Available from: <https://healthdata.gov/Health/COVID-19-Public-Therapeutic-Locator/rxn6-qnx8/data>.