Iowa Medicaid
IOWA HHS

INFORMATIONAL LETTER NO. 2445-MC-FFS-CVD

DATE: April 5, 2023

TO: All Iowa Medicaid Providers

APPLIES TO: Managed Care (MC), Fee-for-Service (FFS), Coronavirus Disease (CVD)

FROM: Iowa Department of Health and Human Services (HHS), Iowa Medicaid

RE: Monoclonal Antibodies Update

EFFECTIVE: Immediately

On January 26, 2023, the U.S. Food and Drug Administration (FDA) rescinded the emergency use authorization (EUA) for a monoclonal antibody treatment – Evusheld™ (tixagevimab co-packaged with cilgavimab), citing to limit its use to when the combined frequency of non-susceptible SARS-CoV-2 variants nationally is less than or equal to 90%. Data show Evusheld™ is highly unlikely to be active against certain SARS-CoV-2 variants.

As a result, the following monoclonal antibody is no longer authorized for use and may not be administered for treatment or pre-exposure prevention of COVID-19 under the EUA until further notice by the FDA. However, the U.S. Government recommends that facilities and providers with Evusheld™ retain all product in the event that SARS-CoV-2 variants which are neutralized by Evusheld™ become more prevalent in the U.S. in the future. Retained product must be appropriately held in accordance with storage conditions detailed in the authorized fact sheet for healthcare providers[1] and the letter of authorization[2]. The full FDA statement is available here[3].

AstraZeneca	
Code	**Description**
M0220	Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older) with no known SARS-CoV-2 exposure; includes injection and post administration monitoring

[1] https://www.fda.gov/media/154701/download
[2] https://www.fda.gov/media/154704/download
[3] https://www.fda.gov/drugs/drug-safety-and-availability/fda-announces-evusheld-not-currently-authorized-emergency-use-us

M0221	Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older) with no known SARS-CoV-2 exposure; includes injection and post administration monitoring in the home or residence
Q0220	Injection, tixagevimab and cilgavimab, 300 mg
Q0221	Injection, tixagevimab and cilgavimab, 600 mg

On November 30, 2022, the FDA rescinded the EUA for a monoclonal antibody treatment – Bebtelovimab, citing it is not expected to neutralize Omicron subvariants BQ.1 and BQ.1.1., according to data included in the fact sheet for healthcare providers[4].

The U.S. Government recommends all product be retained in the event that SARS-CoV-2 variants susceptible to bebtelovimab, which are currently circulating at lower prevalence, become more prevalent in the future in the United States. Retained product must be appropriately held in accordance with storage conditions detailed in the authorized fact sheet for healthcare providers[5] and the letter of authorization[6].

As a result, the following monoclonal antibody is no longer authorized for use and may not be administered for treatment of COVID-19 under the EUA until further notice by the FDA. Alternative monoclonal antibody therapies remain available under the EUA. Healthcare providers should use other approved or authorized products[7] as they choose appropriate treatment options for patients. The full FDA statement is available here[8].

Eli Lilly	
Code	**Description**
M0222	Intravenous injection, bebtelovimab, includes injection and post administration monitoring
M0223	Intravenous injection, bebtelovimab, 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

[4] https://www.fda.gov/media/156152/download
[5] https://www.fda.gov/media/156152/download
[6] https://www.fda.gov/media/156151/download
[7] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs
[8] https://www.fda.gov/drugs/drug-safety-and-availability/fda-announces-bebtelovimab-not-currently-authorized-any-us-region

Q0222	Injection, bebtelovimab, 175 mg

On April 5, 2022, the FDA rescinded the EUA for a monoclonal antibody treatment – Sotrovimab, citing estimates that the proportion of COVID-19 cases caused by the Omicron BA.2 variant is above 50% in all U.S. Department of Health and Human Services U.S. regions. Data included in the fact sheet for healthcare providers[9] show the authorized dose of sotrovimab is unlikely to be effective against the BA.2 sub-variant.

As a result, the following monoclonal antibody is no longer authorized for use and may not be administered for treatment of COVID-19 under the EUA until further notice by the FDA.

Alternative monoclonal antibody therapies remain available under the EUA. Healthcare providers should use other approved or authorized products[10] as they choose appropriate treatment options for patients. The full FDA statement is available here[11].

GlaxoSmithKline	
Code	**Description**
M0247	Intravenous infusion, sotrovimab, includes infusion and post administration monitoring
M0248	Intravenous infusion, sotrovimab, includes infusion 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
Q0247	Injection, sotrovimab, 500 mg

If you have questions, please contact Iowa Medicaid Provider Services or the appropriate MCO:

Iowa Medicaid Provider Services for FFS members:

- Provider services: 1-800-338-7909
- Provider email: imeproviderservices@dhs.state.ia.us

[9] https://www.fda.gov/media/149534/download
[10] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs
[11] https://www.fda.gov/drugs/drug-safety-and-availability/fda-announces-evusheld-not-currently-authorized-emergency-use-us

Amerigroup Iowa, Inc.:

- Provider services: 1-800-454-3730
- Provider email: iowamedicaid@amerigroup.com
- Website: https://providers.amerigroup.com/ia

Iowa Total Care:

- Provider services: 1-833-404-1061
- Provider email: Providers may send email using their account on the ITC website.
- Website: https://www.iowatotalcare.com