09-J3000-86

Original Effective Date: 01/15/21

Reviewed: 12/09/20

Revised: 07/01/22

Subject: SARS-CoV-2 Monoclonal Antibodies

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Monoclonal antibodies are laboratory-made versions of proteins naturally produced by the immune system in response to invading viruses or other pathogens. Neutralizing antibodies, whether natural or monoclonal, can bind directly to portions of viruses that they use to attach to and enter cells, preventing them from initiating the infection cycle. Monoclonal antibodies may provide short-term protection from SARS-CoV-2 and could serve as important components of the COVID-19 pandemic response until vaccines become available.

The following monoclonal antibodies have received a Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for the treatment or prophylaxis of COVID-19:

- Bamlanivimab – issued 11/9/20, revoked 4/16/21
- REGEN-COV (Casirivimab and Imdevimab) – issued 11/21/20, revised 7/30/21
- Bamlanivimab and Etesevimab – issued 2/9/21, revised 9/16/21
- Sotrovimab – issued 5/26/21, revised 4/5/22
- Evusheld (tixagevimab co-packaged with cilgavimab) – issued 12/8/21 (pre-exposure prophylaxis only)
- Bebtelovimab – issued 2/11/22

On July 30, 2021, FDA reissued the EUA for REGEN-COV to authorize emergency use as post-exposure prophylaxis in certain adults and pediatric individuals. Post-exposure prophylaxis with REGEN-COV (casirivimab with imdevimab) is not intended to be a substitute for vaccination against COVID-19. REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19. The EUA for combination bamlanivimab and etesevimab was revised on September 16, 2021 to allow for emergency use as post-exposure prophylaxis for COVID-19.

POSITION STATEMENT:

NOTE: SARS-CoV-2 monoclonal antibodies do not require prior authorization.

SARS-CoV-2 monoclonal antibodies **meet the definition of medical necessity** for the following indications when all associated criteria are met:

1. **Bebtelovimab only:** Indication for use is the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric individuals (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing
    a. Member is at high risk for progressing to severe COVID-19 and/or hospitalization or death (For additional information on medical conditions and factors associated with increased risk for progression to severe COVID-19, see the CDC website: https://www.cdc.gov/coronavirus/2019- ncov/need-extra-precautions/people-with-medical-conditions.html)
    b. Use will not be in a member hospitalized due to COVID-19
    c. Use will not be in a member who requires oxygen therapy due to COVID-19
    d. Use will not be in a member who requires an increase in baseline oxygen flow rate due to COVID-19 if on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity
    e. Product will be administered in a setting (including the home or residence) in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.
    f. Use will not be in geographic regions where infection is likely to have been caused by a non-susceptible SARS-CoV-2 variant, based on available information including variant susceptibility to these drugs and regional variant frequency.

    NOTE: FDA will monitor conditions to determine whether use in a geographic region is consistent with this scope of authorization, referring to available information, including information on variant susceptibility (see, e.g., section 12.4 of authorized Fact Sheet for Health Care Providers), and CDC regional variant frequency data available at: https://covid.cdc.gov/covid-data-tracker/#variant-proportions. FDA's determination and any updates will be available at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policyframework/emergency-use-authorization#coviddrugs

2. **Sotrovimab only**: Due to the high frequency of the Omicron BA.2 sub-variant, sotrovimab is not currently authorized in any U.S. region. Therefore, sotrovimab may not be administered for treatment of COVID-19 under the Emergency Use Authorization until further notice by the Agency.

3. **REGEN-COV, bamlanivimab/etesevimab only**: Due to the high frequency of the Omicron variant, bamlanivimab and etesevimab are not currently authorized in any U.S. region. Therefore, these drugs may not be administered for treatment or post-exposure prevention of COVID-19 under the Emergency Use Authorization until further notice by the Agency.

4. **Evusheld only**: Indication for use is pre-exposure prophylaxis for prevention of 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 either of the following:

a. Member has 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

b. Member 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)

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

Emergency Use Authorization

- The most current information regarding the authorized use of SARS-Cov-2 monoclonal antibodies can be found here: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs

PRECAUTIONS:

Boxed Warning

- None

Contraindications

- None

Precautions/Warnings

- Hypersensitivity

BILLING/CODING INFORMATION:

HCPCS Coding

J3490	Unclassified drug
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 40kg) 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
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 40kg) 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
Q0222	Injection, bebtelovimab, 175 mg
Q0240	Injection, casirivimab and imdevimab, 600 mg. **Note: This product is not currently authorized**
Q0243	Injection, casirivimab and imdevimab, 2400 mg. **Note: This product is not currently authorized**
Q0244	Injection, casirivimab and imdevimab, 1200 mg. **Note: This product is not currently authorized**
Q0245	Injection, bamlanivimab and etesevimab, 2100 mg. **Note: This product is not currently authorized**
Q0247	Injection, sotrovimab, 500 mg**. Note: This product is not currently authorized**
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 40kg) 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 40kg) 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
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
M0240	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring, subsequent repeat doses. **Note: This product is not currently authorized**
M0241	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or 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, subsequent repeat doses. **Note: This product is not currently authorized**

M0243	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring. **Note: This product is not currently authorized**
M0244	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring 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. **Note: This product is not currently authorized**
M0245	Intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring. **Note: This product is not currently authorized**
M0246	Intravenous infusion, bamlanivimab and etesevimab, 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. **Note: This product is not currently authorized**
M0247	Intravenous infusion, sotrovimab, includes infusion and post administration monitoring**. Note: This product is not currently authorized**
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**. Note: This product is not currently authorized**

ICD-10 Diagnosis Codes That Support Medical Necessity

U07.1	COVID-19

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline revised date.

DEFINITIONS:

None

RELATED GUIDELINES:

None

OTHER:

None

REFERENCES:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. Available at: www.clinicalpharmacilogy-ip.com. Accessed 11/25/20.
2. Micromedex Healthcare Series [Internet Database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed 11/25/20.
3. US Food and Drug Administration. Fact sheet for health care providers (c): Emergency use authorization (EUA) of bamlanivimab. Available at: https://www.fda.gov/media/143603/download.
4. US Food and Drug Administration. Fact sheet for health care providers (c): Emergency use authorization (EUA) casirivimab and imdevimab. Available at: https://www.fda.gov/media/143892/download.
5. US Food and Drug Administration. Letter of authorization: Emergency use authorization for use of bamlanivimab. Available at https://www.fda.gov/media/143602/download.
6. US Food and Drug Administration. Letter of authorization: Emergency use authorization for use of bamlanivimab and etesevimab. Available at https://www.fda.gov/media/145801/download
7. US Food and Drug Administration. Letter of authorization: Emergency use authorization for use of casirivimab and imdevimab. Available at https://www.fda.gov/media/145610/download.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 04/13/22.

GUIDELINE UPDATE INFORMATION:

01/15/21	New Medical Coverage Guideline.
07/01/21	Revised position statement, dosing, and coding.
09/01/21	Revised position statement and coding.
11/15/21	Revised position statement.
02/15/22	Revised position statement.
05/15/22	Revised position statement.
07/01/22	Revision: Added HCPCS code Q0221.