09-J3000-86

Original Effective Date: 01/15/21

Reviewed: 12/09/20

Revised: 10/01/25

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, revised
- 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), revised 1/26/23
- Bebtelovimab – issued 2/11/22, revised 11/30/22
- Pemivibart (Pemgarda) – issued 3/22/24

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:** Bebtelovimab is not currently authorized in any U.S. region.
2. **Sotrovimab only**: Sotrovimab is not currently authorized in any U.S. region.
3. **REGEN-COV, bamlanivimab/etesevimab only**: Bamlanivimab and etesevimab are not currently authorized in any U.S. region.
4. **Evusheld only**: Evusheld is not currently authorized in any U.S. region.
5. Pemivibart (Pemgarda) only: The U.S. FDA has issued an EUA for the emergency use of the unapproved product PEMGARDA (pemivibart), a SARS-CoV-2 spike protein-directed attachment inhibitor, for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and adolescents (12 years of age and older weighing at least 40 kg):
    a. 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 are unlikely to mount an adequate immune response to COVID-19 vaccination.
    b. PEMGARDA has been authorized by FDA for the emergency use described above. PEMGARDA is not FDA-approved for any use, including use for preexposure prophylaxis of COVID-19.

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

Q0224	Inj, pemivibart, 4500 mg
M0224	Intravenous infusion, pemivibart, for the pre-exposure prophylaxis only, for certain adults and adolescents (12 years of age and older weighing at least 40 kg) with no known SARS-CoV-2 exposure, who either have moderate-to-severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments, includes infusion and post administration monitoring
M0235	Intravenous infusion, monoclonal antibody products with an indication for post-exposure prophylaxis or treatment of covid-19, for hospitalized adults and/or pediatric patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, includes infusion and post administration monitoring, not otherwise classified, first dose
M0236	Intravenous infusion, monoclonal antibody products with an indication for post-exposure prophylaxis or treatment of covid-19, for hospitalized adults and/or pediatric patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, includes infusion and post administration monitoring, not otherwise classified, second dose
Q0235	Injection, monoclonal antibody products with an indication for post-exposure prophylaxis or treatment of covid-19, for hospitalized adults and/or pediatric patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, not otherwise classified, 1 mg

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.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

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 06/30/24.
2. Micromedex Healthcare Series [Internet Database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed 06/30/24.
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 07/10/24.

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.
08/15/24	Revised position statement and coding.
04/01/25	Revision: Deleted HCPCS codes retired by CMS for products no longer EUA approved [includes all products except pemivibart (Pemgarda)].
10/01/25	Revision: Added HCPCS codes M0235, M0236, and Q0235.