

Payment Policy | COVID-19 Monoclonal Antibody Treatment and Antiviral IV Medications



EFFECTIVE DATE: 01 | 01 | 2022

POLICY LAST REVIEWED: 05 | 01 | 2024

For dates of service on or after May 12, 2023, BCBSRI will cover FDA approved and authorized treatments of monoclonal antibodies and antiviral medications for COVID-19 in accordance with applicable Subscriber Agreement and/or Evidence of Coverage.

Commercial Products: Beginning with dates of service on or after **May 12, 2023**, representing the end of the COVID Public Health Emergency (PHE), the **cost share waiver** in this policy will no longer apply and cost share for the services in this policy will follow applicable Subscriber Agreement.

Medicare Advantage Plans: Beginning with dates of service on or after **July 1, 2023**, the **cost share waiver** in this policy will no longer apply and cost share for the services in this policy will follow applicable Evidence of Coverage.

OVERVIEW

Monoclonal antibodies are laboratory-made proteins that mimic the immune system's ability to fight off harmful antigens such as viruses. Monoclonal antibody products are considered COVID-19 vaccines per Centers for Medicare & Medicaid Services (CMS).

BCBSRI reserves the right to implement changes to this policy without the contractual sixty-day (60) notification that is normally required under BCBSRI contracts with its providers due to the urgent nature of a pandemic related service.

Note: This policy is NOT effective for any specific vaccine/antibody treatment during the time as the vaccine/antibody treatment is approved by the FDA. The effective date for any specific vaccine/antibody treatment shall align with the FDA approval date. As a result, each vaccine/antibody treatment may have a different effective date.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

Monoclonal antibody therapy, not limited to bamlanivimab, casirivimab and imdevimab for the treatment of mild-to-moderate COVID-19 is covered when all the following are met:

- positive COVID-19 test results AND
- over 12 years of age AND
- at high risk for progressing to severe COVID-19 and/or hospitalization AND
- given within 10 to 12 days of symptoms AND
- not hospitalized

For Medicare Advantage Plans, BCBSRI will adhere to Centers for Medicare & Medicaid (CMS) claims filing guidelines for monoclonal antibody therapy. See Coding section for details.

COVERAGE

BCBSRI will not impose any cost sharing (e.g., deductibles, copayments, and coinsurance) on monoclonal antibody drugs or administration related services for COVID-19 during the timeframe this policy is in effect.

BACKGROUND

On November 9, 2020, the U.S. Food and Drug Administration issued an EUA for the investigational monoclonal antibody therapy, bamlanivimab, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients with positive COVID-19 test results who are at high risk for progressing to severe COVID-19 and/or hospitalization. Bamlanivimab may only be administered in settings 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. Review the Fact Sheet for Health Care Providers EUA of Bamlanivimab regarding the limitations of authorized use.

On April 16, 2021, the FDA revoked the Emergency Use Authorization (EUA) for bamlanivimab, when administered alone, due to a sustained increase in COVID-19 viral variants in the U.S. that are resistant to this antibody therapy. The FDA determined that the known and potential benefits of bamlanivimab, when administered alone, no longer outweigh the known and potential risks.

Effective for services rendered on or after August 15, 2022, the United States Government (USG) is no longer purchasing and distributing Bebtelovimab. Bebtelovimab can now be purchased through typical purchasing channels, although distribution may be limited to the drug manufacturer's sole source distributor. Providers may bill only for products purchased commercially. Providers should not bill for USG purchased/supplied products that it may have on hand/in stock. For information regarding reimbursement, please see our policy titled "COVID-19 Diagnostic Testing, Vaccine and Antibody Treatment Administration Reimbursement"

Coverage for monoclonal antibodies is limited to the Emergency Use Authorization limitations set by the FDA and/or any guidelines on the medical conditions/indications and/or factors associated with increased risk for progression to severe COVID-19 issued and updated by the Centers for Disease Control and Prevention (CDC) website: *

**Please Note: BCBSRI reserves the right to request medical records retrospectively to ensure that all guidelines outlined by FDA's EUA and/or CDC were properly followed.*

Medicare Advantage Plans

In accordance with Center for Medicare and Medicaid Services (CMS) billing guidelines, codes for the vaccine and the administration of COVID-19 vaccines must be submitted to Original Medicare for all patients enrolled in Medicare Advantage in 2020 and 2021.

Effective 1/1/2022, providers should bill BCBSRI for any Medicare Advantage Plan services.

CODING

Medicare Advantage Plans and Commercial Products

Claims Filing/Reimbursement Information

Monoclonal Antibody Drugs

When monoclonal antibodies are purchased by provider, the provider should append modifier 22 to the monoclonal antibody code listed below to indicate the monoclonal antibody drug was purchased and not supplied by the USG.

Monoclonal antibody drugs supplied to providers at no cost will not have any reimbursement made if filed by a provider. If a provider elects to submit a claim for the monoclonal antibody drug code itself, the claim will

indicate a denial for the monoclonal antibody drug code/line item as a provider liability with no member liability as the member is not liable for any costs related to the actual monoclonal antibody drugs.

<u>Monoclonal Antibodies for COVID 19 and Administration CPT Codes</u>	<u>Medicare Advantage Plans</u>	<u>Commercial Products</u>
Administration		
M0220 administration of Tixagev and cilgav inj	Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22 - Covered and Separately Reimbursed Not Covered for DOS on or after 1/27/23	Covered and Separately Reimbursed Not Covered for DOS on or after 1/27/23
M0221 administration of Tixagev and cilgav inj	Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22 - Covered and Separately Reimbursed Not Covered for DOS on or after 1/27/23	Covered and Separately Reimbursed Not Covered for DOS on or after 1/27/23
M0222 Intravenous injection, bebtelovimab, includes injection and post administration monitoring	Effective 2/11/22-11/30/22 - Covered and Separately Reimbursed Not Covered for DOS on or after 12/1/22	Covered and Separately Reimbursed until 11/30/22 Not Covered for DOS on or after 12/1/22
M0224 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.	Effective 3/22/2024 - present	Covered and Separately Reimbursed
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	Effective 2/11/22-11/30/22 - Covered and Separately Reimbursed Not Covered for DOS on or after 12/1/22	Covered and Separately Reimbursed until 11/30/22 Not Covered for DOS on or after 12/1/22

<p>M0239 intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring</p>	<p>Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI 11/20/20 - 4/16/21</p> <p>Not Covered for DOS on or after 4/17/21</p>	<p>Covered and Separately Reimbursed 11/20/20 - 4/16/21</p> <p>Not Covered for DOS on or after 4/17/21</p>
<p>M0240 Intravenous infusion or subcutaneous injection, casirivimab and imdevimab, includes infusion or injection and post administration monitoring, subsequent repeat doses</p>	<p>Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI</p> <p>Effective 1/1/22-1/24/22 - Covered and Separately Reimbursed</p> <p>Not Covered for DOS on or after 1/25/22</p>	<p>Covered and Separately Reimbursed until 1/24/22</p> <p>Not Covered for DOS on or after 1/25/22</p>
<p>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</p>	<p>Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI</p> <p>Effective 1/1/22-1/24/22 - Covered and Separately Reimbursed</p> <p>Not Covered for DOS on or after 1/25/22</p>	<p>Covered and Separately Reimbursed until 1/24/22</p> <p>Not Covered for DOS on or after 1/25/22</p>
<p>M0243 intravenous infusion, casirivimab and imdevimab includes infusion and post administration monitoring</p>	<p>Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI</p> <p>Effective 1/1/22-1/24/22 - Covered and Separately Reimbursed</p> <p>Not Covered for DOS on or after 1/25/22</p>	<p>Covered and Separately Reimbursed until 1/24/22</p> <p>Not Covered for DOS on or after 1/25/22</p>
<p>M0244 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</p>	<p>Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI</p> <p>Effective 1/1/22-1/24/22 - Covered and Separately Reimbursed</p> <p>Not Covered for DOS on or after 1/25/22</p>	<p>Covered and Separately Reimbursed until 1/24/22</p> <p>Not Covered for DOS on or after 1/25/22</p>
<p>M0245 intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring</p>	<p>Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI</p> <p>Effective 1/1/22-1/24/22 - Covered and Separately Reimbursed</p> <p>Not Covered for DOS</p>	<p>Covered and Separately Reimbursed until 1/24/22</p> <p>Not Covered for DOS on or after 1/25/22</p>

	on or after 1/25/22	
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	Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22 - 1/24/22 - Covered and Separately Reimbursed Not Covered for DOS on or after 1/25/22	Covered and Separately Reimbursed until 1/24/22 Not Covered for DOS on or after 1/25/22
M0247 Intravenous infusion, sotrovimab, includes infusion and post administration monitoring	Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22-4/5/22 - Covered and Separately Reimbursed Not Covered for DOS on or after 4/6/22	Covered and Separately Reimbursed until 4/5/22 Not Covered for DOS on or after 4/6/22
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	Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22 -4/5/22- Covered and Separately Reimbursed Not Covered for DOS on or after 4/6/22	Covered and Separately Reimbursed until 4/5/22 Not Covered for DOS on or after 4/6/22
M0249 Intravenous infusion, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and older) with COVID-19 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, first dose	Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22 - Covered and Separately Reimbursed	Covered and Separately Reimbursed
M0250 Intravenous infusion, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and older) with COVID-19 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, second dose	Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22 - Covered and Separately Reimbursed	Covered and Separately Reimbursed

Monoclonal Antibodies		
Q0220 Tixagev and cilgav, 300 mg	Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22 - Covered and Separately Reimbursed Not Covered for DOS on or after 1/27/23	No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost Not Covered for DOS on or after 1/27/23
Q0221 Tixagevimab co-packaged with cilgavimab, administered as 2 separate consecutive intramuscular injections	Effective 2/24/22 - Covered and Separately Reimbursed Not Covered for DOS on or after 1/27/23	No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost Not Covered for DOS on or after 1/27/23
Q0222 Injection, bebtelovimab, 175 mg	Effective 2/11/22-11/30/22 - Covered and Separately Reimbursed Not Covered for DOS on or after 12/1/22	No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost Effective 8/15/2022-11/30/22 - Covered and Separately Reimbursed when purchased by a healthcare provider. Not Covered for DOS on or after 12/1/22
Q0224 Injection, pemivibart, 4500 mg	Effective March 22, 2024 - present	Covered and Separately Reimbursed
Q0239 Injection, bamlanivimab-xxxx, 700 mg	Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI 11/20/20 - 4/16/21 Not Covered for DOS on or after 4/17/21	No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost 11/20/20 - 4/16/21 Not Covered for DOS on or after 4/17/21
Q0240 Injection, casirivimab and imdevimab, 600 mg	Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22-1/24/22 - Covered and Separately Reimbursed	No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost Not Covered for DOS on or after 1/25/22

	Not Covered for DOS on or after 1/25/22	
Q0243 Injection, casirivimab and imdevimab, 2400 mg	Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22-1/24/22 - Covered and Separately Reimbursed Not Covered for DOS on or after 1/25/22	No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost Not Covered for DOS on or after 1/25/22
Q0244 Injection, casirivimab and imdevimab, 1200 mg	Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22-1/24/22 - Covered and Separately Reimbursed Not Covered for DOS on or after 1/25/22	No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost Not Covered for DOS on or after 1/25/22
Q0245 Injection, bamlanivimab and etesevimab, 2100 mg	Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22-1/24/22 - Covered and Separately Reimbursed Not Covered for DOS on or after 1/25/22	No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost Not Covered for DOS on or after 1/25/22
Q0247 Injection, sotrovimab, 500 mg	Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22 -4/5/22 - Covered and Separately Reimbursed Not Covered for DOS on or after 4/6/22	No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost Not Covered for DOS on or after 4/6/22
Q0249 Injection, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and older) with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) only, 1 mg	Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22 - Covered and Separately Reimbursed	No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost

Antiviral Medication Treatment		
J0248 Injection, remdesivir, 1 mg	Effective 12/23/21 - Covered and Separately Reimbursed	<p>No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost</p> <p>Covered and Separately Reimbursed when purchased by a healthcare provider.</p>

Commercial Products ONLY
State of RI Licensed Pharmacist Prescribing Assessment Services for Paxlovid

Pharmacist Assessment		
99211 Evaluation & Management Service	Effective 8/31/2022 until PHE ends	CVS charge \$60; reimbursed via paper claim click here

RELATED POLICIES

- COVID-19 Vaccinations
- COVID-19 Diagnostic Testing After Public Health Emergency End Date
- TEMPORARY Cost Share Waiver for Treatment of Confirmed Cases of COVID-19 During the COVID-19 Crisis (retired)
- TEMPORARY COVID-19 Diagnostic Testing (retired)
- TEMPORARY Encounter for Determination of Need for COVID-19 Diagnostic Testing (retired)

PUBLISHED

- Provider Update, May 2024
- Provider Update, July 2023
- Provider Communication sent May 3, 2023
- Provider Update, July 2023
- Provider Update, May 2023
- Provider Update, February 2023
- Provider Update, October 2022
- Provider Update, May 2022
- Provider Update, January 2022
- Provider Update, July 2021
- Provider Update, April 2021
- Provider Update, February 2021

REFERENCES:

1. U.S. Centers for Medicare & Medicaid Services. Monoclonal Antibody COVID-19 Infusion. Retrieved 12/6/22/20 from <https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies>
2. U.S. Food & Drug Administration. Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Monoclonal Antibody Bamlanivimab. Retrieved 4/20/21 from

<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-mono-clonal-antibody-bamlanivimab>

3. MLN Matters 2024-04-11-MLNC, <https://www.cms.gov/training-education/medicare-learning-network/newsletter/2024-04-11-mlnc>

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

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