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



## **EFFECTIVE DATE:** 01 | 01 | 2022 **POLICY LAST REVIEWED:** 04 | 01 | 2025

For dates of service on or after May12, 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 manufactures 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 antibodiesis 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 <u>must be submitted to Original Medicare</u> 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

# <u>Claims Filing/Reimbursement Information</u> 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.

Monoclonal Antibodies for COVID 19 and Administration CPT Codes	Medicare Advantage Plans	Commercial Products
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	Covered and Separately Reimbursed
	Effective 1/1/22 - Covered and Separately Reimbursed Not Covered for DOS on or after 1/27/23 deletion date is 12/12/2024	Not Covered for DOS on or after 1/27/23 deletion date is 12/12/2024
<b>M0221</b> 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	Covered and Separately Reimbursed
	Effective 1/1/22 - Covered and Separately Reimbursed	Not Covered for DOS on or after 1/27/23
	Not Covered for DOS on or after 1/27/23 deletion date is 12/12/2024	deletion date is 12/12/2024
<b>M0222</b> Intravenous injection, bebtelovimab, includes injection and post administration monitoring	Effective 2/11/22-11/30/22 - Covered and Separately Reimbursed	Covered and Separately Reimbursed until 11/30/22
	Not Covered for DOS on or after 12/1/22 deletion date is 12/12/2024	Not Covered for DOS on or after 12/1/22 deletion date is 12/12/2024
<b>M0223</b> 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	Covered and Separately Reimbursed until 11/30/22
	Not Covered for DOS on or after 12/1/22 deletion date is 12/12/2024	Not Covered for DOS on or after 12/1/22 deletion date is 12/12/2024
<b>M0239</b> intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring	Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI 11/20/20 - 4/16/21	Covered and Separately Reimbursed 11/20/20 - 4/16/21
	Not Covered for DOS on or after 4/17/21	Not Covered for DOS on or after 4/17/21

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<b>M0240</b> Intravenous infusion or subcutaneous injection, casirivimab and imdevimab, includes infusion or injection and post administration monitoring, subsequent repeat doses	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 deletion date is 12/12/2024	Covered and Separately Reimbursed until 1/24/22 Not Covered for DOS on or after 1/25/22 deletion date is 12/12/2024
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	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 deletion date is 12/12/2024	Covered and Separately Reimbursed until 1/24/22 Not Covered for DOS on or after 1/25/22 deletion date is 12/12/2024
<b>M0243</b> intravenous infusion, casirivimab and imdevimab 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 1/1/22-1/24/22 - Covered and Separately Reimbursed Not Covered for DOS on or after 1/25/22 deletion date is 12/12/2024	Covered and Separately Reimbursed until 1/24/22 Not Covered for DOS on or after 1/25/22 deletion date is 12/12/2024
<b>M0244</b> 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 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 deletion date is 12/12/2024	Covered and Separately Reimbursed until 1/24/22 Not Covered for DOS on or after 1/25/22 deletion date is 12/12/2024
<b>M0245</b> intravenous infusion, bamlanivimab and etesevimab, 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 1/1/22-1/24/22 - Covered and Separately Reimbursed Not Covered for DOS on or after 1/25/22 deletion date is 12/12/2024	Covered and Separately Reimbursed until 1/24/22 Not Covered for DOS on or after 1/25/22 deletion date is 12/12/2024

M0247 Intravenous infusion, sotrovimab, includes infusion and post administration monitoringCMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 11/122-4/5/22 Covered and Separately ReimbursedCovered and Separately ReimbursedCovered of DOS on or after 4/6/22 deletion date is 12/12/2024M0248 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 emergencyEffective 1/1/02/0-12/31/21 -Per Covered and Separately ReimbursedCovered and Separately ReimbursedCovered and Separately ReimbursedM0249 Intravenous infusion, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and olde) 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, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and olde/) with COVID-19 who are receiving systemic corticosteroids and require administration monitoring, first doseEffective 11/09/20-12/31/21 -Per CMS Biling guidelines, submit to Original Medicare Do Not Bil to BCBSRICovered and Separately ReimbursedM0250 Intravenous infusion, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and olde/) with COVID-19 who are receiving systemic corticosteroids and require audicinistration monitoring, first doseEffective 11/09/20-12/31/21 -Per CMS Biling guidelines, submit to Original Medicare Do Not Bil to BCBSRICovered and Separately <br< th=""><th><b>M0246</b> 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</th><th>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 deletion date is 12/12/2024</th><th>Covered and Separately Reimbursed until 1/24/22 Not Covered for DOS on or after 1/25/22 deletion date is 12/12/2024</th></br<>	<b>M0246</b> 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 deletion date is 12/12/2024	Covered and Separately Reimbursed until 1/24/22 Not Covered for DOS on or after 1/25/22 deletion date is 12/12/2024
M0248Intravenous 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 emergencyCMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRICovered and Separately ReimbursedNot Covered for DOS on or after 4/6/22 deletion date is 12/12/2024M0249Intravenous 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, 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, 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 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 doseEffective 11/09/20-12/31/21 -Per CON Bill to BCBSRI Effective 11/09/20-12/31/21 -Per CON	sotrovimab, includes infusion and post	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 deletion date is 12/12/2024	Reimbursed until 4/5/22 Not Covered for DOS on or after 4/6/22 deletion date is
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 doseEffective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRICovered and Separately ReimbursedM0250 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 doseEffective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRICovered and Separately Reimbursed	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	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	Reimbursed until 4/5/22 Not Covered for DOS on or after 4/6/22 deletion date is
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Monoclonal Antibodies	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	CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22 - Covered and	1 2

<b>Q0220</b> 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 deletion date is 12/12/2024	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 deletion date is 12/12/2024
<b>Q0221</b> 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 deletion date is 12/12/2024	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 deletion date is 12/12/2024
<b>Q0222</b> 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 deletion date is 12/12/2024	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 deletion date is 12/12/2024
<b>Q0239</b> 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
<b>Q0240</b> 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

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	Not Covered for DOS	deletion date is
	on or after 1/25/22	12/12/2024
	deletion date is 12/12/2024	
<b>Q0243</b> 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	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 deletion date is 12/12/2024	Not Covered for DOS on or after 1/25/22 deletion date is 12/12/2024
<b>Q0244</b> 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	No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost
	Reimbursed Not Covered for DOS on or after 1/25/22deletion date is 12/12/2024	Not Covered for DOS on or after 1/25/22 deletion date is 12/12/2024
<b>Q0245</b> 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 deletion date is 12/12/2024
<b>Q0247</b> Injection, sotrovimab, 500 mg	deletion date is 12/12/2024 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 deletion date is 12/12/2024	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 deletion date is 12/12/2024
<b>Q0249</b> 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	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

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

## **Commercial Products ONLY**

State of RI Licensed Pharmacist Prescribing Assessment Services for Paxlovid

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

## **RELATED POLICIES**

COVID-19 Vaccinations TEMPORARY Cost Share Waiver for Treatment of Confirmed Cases of COVID-19 During the COVID-19 Crisis TEMPORARY COVID-19 Diagnostic Testing TEMPORARY Encounter for Determination of Need for COVID-19 Diagnostic Testing

## PUBLISHED

Provider Update, June 2025 Provider Communication 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:**

- U.S. Centers for Medicare & Medicaid Services. Monoclonal Antibody COVID-19 Infusion. Retrieved 12/6/22/20 from
- 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-fdarevokes-emergency-use-authorization-monoclonal-antibody-bamlanivimab

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