

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



**EFFECTIVE DATE:** 01|01|2022

**POLICY LAST UPDATED:** 08|18|2022

### OVERVIEW

Monoclonal antibodies are laboratory-made proteins that mimic the immune system's ability to fight off harmful antigens such as viruses. Bamlanivimab is a monoclonal antibody that is specifically directed against the spike protein of SARS-CoV-2, designed to block the virus' attachment and entry into human cells. 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 until such 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. As FDA approval is issued, BCBSRI will include the effective date for each vaccine/antibody treatment in the BACKGROUND section of this Policy.**

### 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 Bebtelovimab 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.

<b><u>Monoclonal Antibodies for COVID 19 and Administration CPT Codes</u></b>	<b><u>Medicare Advantage Plans</u></b>	<b><u>Commercial Products</u></b>
<b>Administration</b>		
<b>M0220</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  Effective 1/1/22 - Covered and Separately Reimbursed	Covered and Separately Reimbursed
<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  Effective 1/1/22 - Covered and Separately Reimbursed	Covered and Separately Reimbursed
<b>M0222</b> Intravenous injection, bebtelovimab, includes injection and post administration monitoring	Effective 2/11/22 - Covered and Separately Reimbursed	Covered and Separately Reimbursed
<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 - Covered and Separately Reimbursed	Covered and Separately Reimbursed
<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  Not Covered for DOS on or after 4/17/21	Covered and Separately Reimbursed 11/20/20 - 4/16/21  Not Covered for DOS on or after 4/17/21
<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 - Covered and Separately Reimbursed	Covered and Separately Reimbursed
<b>M0241</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, 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 - Covered and Separately Reimbursed	Covered and Separately Reimbursed

<p><b>M0243</b> 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 - Covered and Separately Reimbursed</p>	<p>Covered and Separately Reimbursed</p>
<p><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</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 - Covered and Separately Reimbursed</p>	<p>Covered and Separately Reimbursed</p>
<p><b>M0245</b> 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 - Covered and Separately Reimbursed</p>	<p>Covered and Separately Reimbursed</p>
<p><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</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 - Covered and Separately Reimbursed</p>	<p>Covered and Separately Reimbursed</p>
<p><b>M0247</b> Intravenous infusion, sotrovimab, 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 - Covered and Separately Reimbursed</p>	<p>Covered and Separately Reimbursed</p>
<p><b>M0248</b> 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</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 - Covered and Separately Reimbursed</p>	<p>Covered and Separately Reimbursed</p>
<p><b>M0249</b> 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</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 - Covered and Separately Reimbursed</p>	<p>Covered and Separately Reimbursed</p>

<b>M0250</b> 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
<b>Monoclonal Antibodies</b>		
<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	No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost
<b>Q0221</b> Tixagevimab co-packaged with cilgavimab, administered as 2 separate consecutive intramuscular injections	Effective 2/24/22 - Covered and Separately Reimbursed	No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost
<b>Q0222</b> Injection, bebtelovimab, 175 mg	Effective 2/11/22 - Covered and Separately Reimbursed	No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost  Effective 8/15/2022 - Covered and Separately Reimbursed when purchased by a healthcare provider.
<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 - Covered and Separately Reimbursed	No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost
<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	No reimbursement for claims submitted to BCBSRI for products

	Effective 1/1/22 - Covered and Separately Reimbursed	health care providers receive at no cost
<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 - Covered and Separately Reimbursed	No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost
<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 - Covered and Separately Reimbursed	No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost
<b>Q0247</b> 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 - Covered and Separately Reimbursed	No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost
<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 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
<b>Antiviral Medication Treatment</b>		
<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

## 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, 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 11/9/20 from
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-monoclonal-antibody-bamlanivimab>

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