**Payment Policy |** COVID-19 Monoclonal Antibody Treatment

**EFFECTIVE DATE:** 01|01|2022
**POLICY LAST UPDATED:** 11|17|2021

## 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.

Bamlanivimab is not authorized for patients who are hospitalized due to COVID-19 or require oxygen therapy due to COVID-19. A benefit of bamlanivimab treatment has not been shown in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bamlanivimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

During the COVID-19 public health emergency (PHE), Medicare will cover and pay for these infusions the same way it covers and pays for COVID-19 vaccines (when furnished consistent with the EUA).

This would allow a broad range of providers and suppliers, including freestanding and hospital-based infusion centers, home health agencies, nursing homes, and entities with whom nursing homes contract for this, to administer this treatment in accordance with the EUA. Medicare will not pay for the monoclonal antibody products that providers receive for free. If providers begin to purchase monoclonal antibody products, Medicare anticipates setting the payment rate for the product, which will be 95% of the average wholesale price for many health care providers, consistent with usual vaccine payment methodologies. Monoclonal antibody products are considered COVID-19 vaccines per CMS. Additionally, Medicare anticipates establishing codes and rates for the administration of the product.

On April 16, 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.

**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 Supplied at No Cost to Provider**
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.

*Note: Providers should append modifier 22 to the monoclonal antibody drugs codes listed below, indicating the monoclonal antibody drug was purchased by the provider.*

| Monoclonal Antibodies for COVID 19 and Administration CPT Codes | Medicare Advantage Plans | Commercial Products |
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| **Administration** | | |
| **M0239** intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring | Per CMS billing guidelines, submit to Original Medicare<br>Do Not Bill to BCBSRI<br>11/20/20 - 4/16/21<br><br>Not Covered for DOS on or after 4/17/21 | Covered and Separately Reimbursed<br>11/20/20 - 4/16/21<br><br>Not Covered for DOS on or after 4/17/21 |
| **M0240** 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<br>Do Not Bill to BCBSRI<br><br>Effective 1/1/22 - Covered and Separately Reimbursed | Covered and Separately Reimbursed |
| **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<br>Do Not Bill to BCBSRI<br><br>Effective 1/1/22 - Covered and Separately Reimbursed | Covered and Separately Reimbursed |
| **M0243** 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<br>Do Not Bill to BCBSRI<br><br>Effective 1/1/22 - Covered and Separately Reimbursed | Covered and Separately Reimbursed |
| **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 | Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare<br>Do Not Bill to BCBSRI<br><br>Effective 1/1/22 - Covered and Separately Reimbursed | Covered and Separately Reimbursed |
| **M0245** 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<br>Do Not Bill to BCBSRI<br><br>Effective 1/1/22 - Covered and Separately Reimbursed | Covered and Separately Reimbursed |
| **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<br>Do Not Bill to BCBSRI<br><br>Effective 1/1/22 - Covered and Separately Reimbursed | Covered and Separately Reimbursed |

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| **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<br>Do Not Bill to BCBSRI<br><br>Effective 1/1/22 - Covered and Separately Reimbursed | Covered and Separately Reimbursed |
| **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<br>Do Not Bill to BCBSRI<br><br>Effective 1/1/22 - Covered and Separately Reimbursed | Covered and Separately Reimbursed |
| **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<br>Do Not Bill to BCBSRI<br><br>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<br>Do Not Bill to BCBSRI<br><br>Effective 1/1/22 - Covered and Separately Reimbursed | Covered and Separately Reimbursed |
| **Monoclonal Antibodies** | | |
| **Q0239** Injection, bamlanivimab-xxxx, 700 mg | Per CMS billing guidelines, submit to Original Medicare<br>Do Not Bill to BCBSRI<br>11/20/20 - 4/16/21<br><br>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<br>11/20/20 - 4/16/21<br><br>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<br>Do Not Bill to BCBSRI<br><br>Effective 1/1/22 - Covered and Separately Reimbursed | No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost |
| **Q0243** Injection, casirivimab and imdevimab, 2400 mg | Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare<br>Do Not Bill to BCBSRI | No reimbursement for claims submitted to BCBSRI for products |

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| | Effective 1/1/22 - Covered and Separately Reimbursed | health care providers receive at no cost |
| **Q0244** Injection, casirivimab and imdevimab, 1200 mg | Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare<br>Do Not Bill to BCBSRI<br><br>Effective 1/1/22 - Covered and Separately Reimbursed | No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost |
| **Q0245** Injection, bamlanivimab and etesevimab, 2100 mg | Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare<br>Do Not Bill to BCBSRI<br><br>Effective 1/1/22 - Covered and Separately Reimbursed | No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost |
| **Q0247** Injection, sotrovimab, 500 mg | Effective 11/09/20-12/31/21 -Per CMS billing guidelines, submit to Original Medicare<br>Do Not Bill to BCBSRI<br><br>Effective 1/1/22 - Covered and Separately Reimbursed | No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost |
| **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<br>Do Not Bill to BCBSRI<br><br>Effective 1/1/22 - 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, 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 https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion
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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