



EFFECTIVE DATE: 11|09|2020
POLICY LAST UPDATED: 02|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

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable immunization benefits/coverage.

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.

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.

As a result, providers should not bill BCBSRI for any Medicare Advantage Plan services.

CODING

Medicare Advantage Plans and Commercial Products

<u>Monoclonal Antibodies for COVID 19 and Administration CPT Codes</u>	<u>Medicare Advantage Plans</u>	<u>Commercial Products</u>
Administration		
M0239 intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring	Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI	Covered and Separately Reimbursed
M0243 intravenous infusion, casirivimab and imdevimab includes infusion and post administration monitoring	Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI	Covered and Separately Reimbursed

M0245 intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring	Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI	Covered and Separately Reimbursed
Monoclonal Antibodies		
Q0239 Injection, bamlanivimab-xxxx, 700 mg	Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI	No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost
Q0243 Injection, casirivimab and imdevimab, 2400 mg	Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI	No reimbursement for claims submitted to BCBSRI for products health care providers receive at no cost
Q0245 Injection, bamlanivimab and etesevimab, 2100 mg	Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI	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, April 2021

Provider Update, February 2021

REFERENCES:

<https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion>

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