



EFFECTIVE DATE: 11|09|2020
POLICY LAST UPDATED: 12|02|2020

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 and Medicaid Services(CMS).

BCBSRI reserves the right to implement and make changes to this policy without the contractual sixty-day (60) notification for a change in policy that is normally required, due to the urgent and emergent nature of a pandemic.

Notice of the implementation and changes to this policy may be communicated to BCBSRI providers via a notice on BCBSRI's provider website/portal under Alerts and Updates as well as other communication means.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

Monoclonal antibody therapy, bamlanivimab, 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 BlueCHiP for Medicare products, BCBSRI will adhere to Centers for Medicare and 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.

During the timeframe this policy is in effect, BCBSRI will not impose any cost sharing (e.g. deductibles, copayments, and coinsurance) requirements.

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.

CODING

BlueCHiP for Medicare

In accordance with CMS billing guidelines, the following code for the administration of bamlanivimab 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 the following code/service for any BlueCHiP for Medicare Subscribers.

M0239 intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring

BCBSRI will follow CMS guidelines which will not provide payment for the monoclonal antibody products that health care providers receive at no cost. Therefore, no payment will be made for the following code:

Q0239 Injection, bamlanivimab-xxxx, 700 mg

Commercial

The following administration code is covered and separately reimbursed:

M0239 intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring

There is no reimbursement for any product/services that health care providers receive at no cost. As a result, providers should not bill BCBSRI for the following code when administering bamlanivimab to Commercial Subscribers:

Q0239 Injection, bamlanivimab-xxxx, 700 mg

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, February 2021

REFERENCES:

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

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