Preemptive policy: This is a P&T approved policy and can be used until it is superseded by an updated policy.

CENTENE Corporation

Clinical Policy: Bamlanivimab + Etesevimab (LY-CoV555 + LY-CoV016)

Reference Number: CP.PHAR.532
Effective Date: 02.09.21
Last Review Date: 05.22
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Bamlanivimab + etesevimab (LY-CoV555 + LY-CoV016) is a combination neutralizing IgG1 monoclonal antibody product.

EUA Approved Indication(s)

Bamlanivimab and etesevimab when administered together are permitted by the FDA for emergency use in adults and pediatric patients, including neonates, for

- The treatment of mild to moderate coronavirus disease 2019 (COVID-19) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.
- Post-exposure prophylaxis of COVID-19 in individuals who are at high risk of progression to severe COVID-19, including hopitlization or death, and are:
  - Not fully vaccinated or who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (e.g., individuals with immunocompromising conditions including those taking immunosuppressive mediations), and:
    - Have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per Centers for Disease Control and Prevention (CDC), or
    - Who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (e.g., nursing homes, prisons)

Limitation(s) of authorized use:

- Bamlanivimab and etesevimab are not authorized for treatment of mild to moderate COVID-19 or for post-exposure prophylaxis of COVID-19 in geographic regions where infection is likely to have been caused by, or exposure is likely to have been to, a non-susceptible SARS-CoV-2 variant based on available information including variant susceptibility to these drugs and regional variant frequency.
  - FDA's determination and any updates are available at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatoryand-policy-framework/emergency-use-authorization#coviddrugs.
- Bamlanivimab and etesevimab are not authorized for use in patients 2 years and older who are hospitalized due to COVID-19.
- Bamlanivimab and etesevimab are not authorized for use in patients, regardless of age:
  - who require oxygen therapy and/or respiratory support due to COVID-19, or

  - who require an increase in baseline oxygen flow rate and/or respiratory support due to COVID-19 and are on chronic oxygen therapy due to underlying non-COVID-19-related comorbidity.
- Treatment with bamlanivimab and etesevimab has not been studied in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bamlanivimab and etesevimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.
- Post-exposure prophylaxis with bamlanivimab and etesevimab is not a substitute for a vaccination against COVID-19.
- Bamlanivimab and etesevimab are not authorized for pre-exposure prophylaxis for prevention of COVID-19.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that bamlanivimab and etesevimab administered together are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria*
**Criteria will mirror the clinical information from the prescribing information once FDA-approved*

A. COVID-19 Treatment (must meet all)**:**
1. Diagnosis of COVID-19 infection via a positive viral test for SARS-CoV-2 within the last 3 days;
2. Member has one or more mild to moderate COVID-19 symptoms;
3. Member is within 10 days of symptom onset;
4. Member meets at least one of the following criteria for being at high risk for progressing to severe COVID-19 and/or hospitalization (a-n):
   a. < 1 year of age;
   b. ≥ 65 years of age;
   c. Body mass index (BMI) ≥ 25 kg/m^2;
   d. Cardiovascular disease (including congenital heart disease) or hypertension;
   e. Chronic kidney disease;
   f. Chronic lung disease (e.g., chronic obstructive pulmonary disease [COPD], moderate-to-severe asthma, interstitial lung disease, cystic fibrosis, pulmonary hypertension);
   g. Currently receiving immunosuppressive treatment;
   h. Immunosuppressive disease;
   i. Medical-related technological dependence (e.g., tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19));
   j. Neurodevelopmental disorders (e.g., cerebral palsy);
   k. Other conditions that confer medical complexity (e.g., genetic or metabolic syndromes, severe congenital anomalies);
   l. Pregnant;
   m. Sickle cell disease;
   n. Type 1 or type 2 diabetes;

5. At the time of request, member meets all of the following (a, b, c, or d):
   a. Infection is not likely to have been caused by a non-susceptible SARS-CoV-2 variant based on available information including variant susceptibility to these drugs and regional variant frequency (FDA's determination and any updates are available at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs);
   b. For members aged 2 years or older: Member is not hospitalized due to COVID-19;
   c. Member does not require oxygen therapy due to COVID-19;
   d. For members on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity: Member does not require an increase in baseline oxygen flow rate due to COVID-19;
6. Bamlanivimab and etesevimab will be administered together as a single intravenous infusion;
7. Bamlanivimab and etesevimab will be administered to the member in a setting 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, as necessary;
8. Dose does not exceed one of the following (a, b, or c):
   a. Adults (≥ 18 years): bamlanivimab 700 mg (1 vial) with etesevimab 1,400 mg (2 vials) one time;
   b. Pediatrics (< 18 years and weighing at least 40 kg): bamlanivimab 700 mg (1 vial) with etesevimab 1,400 mg (2 vials) one time;
   c. Pediatrics (< 18 years and weighing < 40 kg) (i, ii, or iii):
      i. > 20 kg to < 40 kg: 350 mg bamlanivimab and 700 mg etesevimab;
      ii. > 12 kg to 20 kg: 175 mg bamlanivimab and 350 mg etesevimab;
      iii. 1 kg to 12 kg: 12 mg/kg bamlanivimab and 24 mg/kg etesevimab.

Approval duration: One time

B. Post-exposure Prophlyaxis of COVID-19 (must meet all):

1. Member meets one of the following (a or b):
   a. Member has been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per CDC (*see Appendix E*);
   b. Member is at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (e.g., nursing homes and prisons);
2. Documentation of one of the following (a or b):
   a. Member is not fully vaccinated;
   b. Member is not expected to mount adequate immune response to complete SARS-CoV-2 vaccination (e.g., individuals with immunocompromising conditions including those taking immunosuppressive medications);
3. Member meets at least one of the following criteria for being at high risk for progressing to severe COVID-19 and/or hospitalization (a-h):
   a. < 1 year of age;
   b. ≥ 65 years of age;

c. BMI ≥ 25 kg/m^2;
d. Cardiovascular disease (including congenital heart disease) or hypertension;
e. Chronic kidney disease;
f. Chronic lung disease (e.g., COPD, moderate-to-severe asthma, interstitial lung disease, cystic fibrosis, pulmonary hypertension);
g. Currently receiving immunosuppressive treatment;
h. Immunosuppressive disease;
i. Medical-related technological dependence (e.g., tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19);
j. Neurodevelopmental disorders (e.g., cerebral palsy);
k. Other conditions that confer medical complexity (e.g., genetic or metabolic syndromes, severe congenital anomalies);
l. Pregnant;
m. Sickle cell disease;
n. Type 1 or type 2 diabetes;

4. Bamlanivimab and etesevimab are not being used for pre-exposure prophylaxis for prevention of COVID-19;
5. At the time of request, member meets all of the following (a, b, c, or d):
   a. Exposure is not likely to have been to a non-susceptible SARS-CoV-2 variant based on available information including variant susceptibility to these drugs and regional variant frequency (FDA's determination and any updates are available at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs);
   b. For members aged 2 years or older: Member is not hospitalized due to COVID-19;
   c. Member does not require oxygen therapy due to COVID-19;
   d. For members on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity: Member does not require an increase in baseline oxygen flow rate due to COVID-19;
6. Bamlanivimab and etesevimab will be administered together as a single intravenous infusion;
7. Bamlanivimab and etesevimab will be administered to the member in a setting 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, as necessary;
8. Dose does not exceed one of the following (a, b, or c):
   a. Adults (≥ 18 years) bamlanivimab 700 mg (1 vial) with etesevimab 1,400 mg (2 vials) one time;
   b. Pediatric (< 18 years and weighing at least 40 kg): bamlanivimab 700 mg (1 vial) with etesevimab 1,400 mg (2 vials) one time;
   c. Pediatrics (< 18 years and weighing < 40 kg) (i, ii, or iii):
      i. > 20 kg to < 40 kg: 350 mg bamlanivimab and 700 mg etesevimab;
      ii. > 12 kg to 20 kg: 175 mg bamlanivimab and 350 mg etesevimab;
      iii. 1 kg to 12 kg: 12 mg/kg bamlanivimab and 24 mg/kg etesevimab.

Approval duration: One time

C. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy*

**Criteria will mirror the clinical information from the prescribing information once FDA-approved*

A. All Indications in Section I

1. Re-authorization is not permitted.

Approval duration: Not applicable

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BMI: body mass index
CDC: Centers for Disease Control and Prevention
COVID-19: coronavirus disease 2019
EUA: Emergency Use Authorization
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings [Pending]

- Contraindication(s): pending
- Boxed warning(s): pending

Appendix D: General Information

- The data supporting the EUA for bamlanivimab and etesevimab are based on analyses of data from the Phase 2/3 BLAZE-1 trial (NCT04427501) and the Phase 2 BLAZE-4 trial (NCT04634409). BLAZE-1 provides clinical efficacy data from subjects receiving 2,800 mg bamlanivimab and 2,800 mg of etesevimab together. BLAZE-4 provides comparative virologic outcome data from subjects receiving 700 mg bamlanivimab and 1,400 mg etesevimab (the authorized doses), subjects receiving 2,800 mg bamlanivimab and 2,800 mg of etesevimab, and placebo.

- BLAZE-1 is an ongoing randomized, double-blind, placebo-controlled clinical trial which enrolled subjects who were not hospitalized and had 1 or more mild or moderate COVID-19 symptoms. Treatment was initiated within 3 days of obtaining the first positive SARS-CoV-2 viral infection determination. In the Phase 2 portion of the trial, patients were treated with a single infusion of bamlanivimab 2,800 mg and etesevimab 2,800 mg (N = 112), bamlanivimab alone (at doses of 700 mg [N = 101], 2,800 mg [N = 107], or 7,000 mg [N = 101]) or placebo [N = 156]). The data are from an interim analysis after all enrolled subjects completed at least Day 29 of the trial. The pre-specified primary endpoint in this Phase 2 trial was change in viral load from baseline to Day 11 for 2,800 mg bamlanivimab and 2,800 mg etesevimab-treated subjects vs. placebo. Most subjects, including those receiving placebo, effectively cleared virus by Day 11. The most important evidence that bamlanivimab and etesevimab may be effective came from the predefined secondary endpoint of COVID-19-related hospitalizations or emergency room visits within 28 days after treatment. A lower proportion of bamlanivimab and etesevimab-treated subjects progressed to COVID-19-related hospitalization or emergency room visits compared to placebo-treated subjects (1% vs. 6%, respectively). No deaths occurred in any treatment arm. The median time to symptom improvement as recorded in a trial specific daily symptom diary was 6 days for bamlanivimab and etesevimab-treated subjects, as compared with 8 days for placebo-treated subjects.
- In one arm of the Phase 3 portion of the BLAZE-1 trial, subjects were treated with a single infusion of bamlanivimab 2,800 mg and etesevimab 2,800 mg (N = 518) or placebo (N = 517). All of the patients enrolled in these dose arms met the criteria for high-risk. The primary endpoint was the proportion of subjects with COVID-19 related hospitalization (defined as ≥ 24 hours of acute care) or death by any cause by Day 29. Events occurred in 36 subjects treated with placebo (7%) as compared to 11 events in subjects treated with bamlanivimab 2,800 mg and etesevimab 2,800 mg together (2%) [$p < 0.001$], a 70% reduction. There were 10 deaths in subjects treated with placebo and no deaths in subjects treated with bamlanivimab 2,800 mg and etesevimab 2,800 mg together ($p < 0.001$). At Day 7, 29% of subjects treated with placebo and 10% of subjects treated with bamlanivimab 2,800 mg and etesevimab 2,800 mg together had persistently high viral loads ($p < 0.000001$), which was defined as SARS-CoV-2 viral load > 5.27.
- In another arm of the Phase 3 portion of the BLAZE-1 trial, subjects were treated with a single infusion of bamlanivimab 700 mg and etesevimab 1,400 mg (N = 511) or placebo (N = 258). All subjects were high-risk patients aged 12 and older with mild to moderate COVID-19. There were four events (0.8%) in patients taking bamlanivimab with etesevimab and 15 events (5.8%) in patients taking placebo, representing an 87% risk reduction ($p < 0.0001$). Bamlanivimab and etesevimab together also demonstrated statistically significant improvements on key secondary endpoints. There were four deaths total, all of which were deemed related to COVID-19 and all of which occurred in patients taking placebo; no deaths occurred in patients receiving treatment with bamlanivimab and etesevimab together.
- BLAZE-4 is an ongoing Phase 2, randomized, double-blind, placebo-controlled clinical trial studying bamlanivimab and etesevimab for the treatment of non-hospitalized subjects with mild to moderate COVID-19. BLAZE-4 enrolled adult subjects who had at least 1 or more COVID-19 symptoms that were at least mild in severity, and excluded

subjects ≥ 65 years old or with BMI ≥ 35. Treatment was initiated within 3 days of obtaining the clinical sample for the first positive SARS-CoV-2 viral infection determination. Subjects were treated with a single infusion of bamlanivimab 700 mg and etesevimab 1,400 mg (N = 158), bamlanivimab 2,800 mg and etesevimab 2,800 mg (N = 101), bamlanivimab alone at a dose of 700 mg (N = 103), or placebo (N = 153). As of March 2021, results are not yet complete for additional arms in this trial. The pre-specified primary endpoint in this trial was the proportion of participants with SARS-CoV-2 viral load > 5.27 on Day 7 (+2 days). The rates were 31% for placebo, 14% for bamlanivimab 700 mg and etesevimab 1,400 mg together ($p < 0.001$ vs. placebo), and 10% for bamlanivimab 2,800 mg and etesevimab 2,800 mg together ($p < 0.001$ vs. placebo).

- A potential difference between bamlanivimab alone and bamlanivimab and etesevimab, administered together, is the difference in the risk for emergent resistant variants. Emergent variants were less frequently detected in patients who received bamlanivimab and etesevimab together compared to patients who received bamlanivimab alone or received placebo during the clinical trial development program. Although not yet evaluated in clinical trials, treatment with bamlanivimab and etesevimab together may protect against treatment failure, should a patient be infected with a SARS-CoV-2 viral variant that is resistant to bamlanivimab alone. It is recommended that sites use the monoclonal antibody product that is available.
- Per the EUA for bamlanivimab and etesevimab, these agents 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, as necessary.
- There is a potential for serious hypersensitivity reactions, including anaphylaxis, with administration of bamlanivimab both with and without etesevimab.
- Infusion-related reactions have been observed with administration of bamlanivimab and etesevimab together. Signs and symptoms of infusion-related reactions may include: fever, difficulty breathing, reduced oxygen saturation, chills, fatigue, arrhythmia (e.g., atrial fibrillation, sinus tachycardia, bradycardia), chest pain or discomfort, weakness, altered mental status, nausea, headache, bronchospasm, hypotension, hypertension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, dizziness, and diaphoresis.
- Based upon this low risk of reinfection and the estimated half-life of the monoclonal antibodies, the Advisory Committee on Immunization Practices (ACIP) recommends COVID-19 vaccination be deferred for at least 90 days after treatment with a monoclonal antibody for COVID-19. This is a precautionary measure to avoid interference of monoclonal antibody treatment specifically with vaccine-induced immune responses. Updates to this recommendation may be made as additional information on the interaction between prior monoclonal antibody treatment and vaccine response becomes available.
- The data supporting this EUA for post-exposure prophylaxis of COVID-19 are based on the final analysis of Part 1 of the Phase 3 trial BLAZE-2 (NCT04497987). BLAZE-2 Part 1 is a randomized, double-blind, placebo-controlled study evaluating bamlanivimab alone for prevention of COVID-19 in residents and staff of skilled nursing facilities following a confirmed reported case of SARS-CoV-2 infection at the facility. All participants in Part

1 were randomized and treated with a single infusion of bamlanivimab 4,200 mg or placebo. Results of baseline testing for SARS-CoV-2 were not known until after the therapy was administered. Those with a positive baseline SARS-CoV-2 RT-PCR test were included in the Treatment Population (N = 132) and those with a negative test were included in the Prevention Population (N = 966). Individuals in these populations were also required to have a baseline negative SARS-CoV-2 serology test; those who tested positive were only included in the overall safety population.

- The primary endpoint was assessed after 8 weeks of follow-up, and analysis were adjusted for facility, sex, and role within nursing facility. There were 114 cases of symptomatic COVID-19, with a lower frequency occurring in participants treated with bamlanivimab as compared to placebo (adjusted odds ratio 0.43; $p < 0.001$) reducing the risk of being infected with COVID-19 by up to 57%. Four COVID-19-related deaths were reported in the overall Prevention Population; all occurred in the placebo arm (0.8%). No COVID-19-related deaths occurred in the bamlanivimab arm.
- Use of bamlanivimab and etesevimab in pediatric patients is based on analyses of data from BLAZE-1 in subjects aged 10 months to 18 years of age. No dosage adjustment is recommended in pediatric patients 12-18 years of age who weigh at least 40 kg. Pediatric patients weighing less than 40 kg should be dosed on the basis of body weight. The recommended dosing regimen for pediatric patients ≤ 12 kg is predicted based on pharmacokinetic modeling and simulation. The youngest participant in the pediatric clinical trial for treatment was 10 months of age and weighed 8.6 kg. Safety in pediatric patients was similar to what was observed in adults. Children were not enrolled in the post-exposure prophylaxis trial, BLAZE-2.
- Warnings for use:
  - Hypersentivitiy including anaphylaxis: Serious hypersensitivity reactions, including anaphylaxis, have been observed with administration of bamlanivimab and etesevimab. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and inidiate appropriate medications and/ or supportive are.
  - Infusion- related reactions: Occurs during the infusion and up to 24 hours after the infusion. These reactions may be severe or life threatening.
  - Clinical worsening: Clinical worsening of COVID-19 after administration of bamlanivimab and etesevimab together has been reported and may include signs or symptoms of fever, hypoxia or increased respiratory difficulty, arrhythmia (e.g., atrial fibrillation, sinus tachycardia, bradycardia), fatigue, and altered mental status. Some of these events required hospitalization. It is not known if these events were related to bamlanivimab and etesevimab use or were due to progression of COVID-19.

Appendix E: CDC Close Contact Criteria

Close contact with an infected individual is defined as: being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (hugging or kissing, for example), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (sneezing or coughing, for example). See this website for additional details: https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
COVID-19 infection, treatment and post-exposure prophylaxis of COVID-19 in adults (≥ 18 years) and pediatric patients (< 18 years and weighing at least 40 kg)	Bamlanivimab 700 mg IV administered together with etesevimab 1,400 mg IV one time	Bamlanivimab 700 mg and etesevimab 1,400 mg
COVID-19 infection, treatment and post-exposure prophylaxis of COVID-19 for pediatric patients (< 18 years and weighing < 40 kg)	Varies depending on body weight: • > 20 kg to < 40 kg: 350 mg bamlanivimab and 700 mg etesevimab • > 12 kg to 20 kg: 175 mg bamlanivimab and 350 mg etesevimab • 1 kg to 12 kg: 12 mg/kg bamlanivimab and 24 mg/kg etesevimab	See regimen

VI. Product Availability

- Bamlanivimab vial: 700 mg/20 mL
- Etesevimab vial: 700 mg/20 mL

VII. References

1. Bamlanivimab and etesevimab EUA letter of authorization. January 2022. Available at: https://www.fda.gov/media/145801/download. Accessed February 13, 2022.
2. Fact sheet for health care providers Emergency Use Authorization (EUA) of bamlanivimab and etesevimab. Available at: https://www.fda.gov/media/145802/download. Accessed February 13, 2022.
3. Frequently Asked Questions on the EUA for bamlanivimab and etesevimab. Available at: https://www.fda.gov/media/145808/download. Accessed February 13, 2022.
4. Chen P, Nirula A, Heller B, et al. SARS-CoV-2 neutralizing antibody LY-CoV555 in outpatients with Covid-19. NEJM October 2020; DOI: 10.1056/NEJMoa2029849.
5. ClinicalTrials.gov. A study of LY3819253 (LY-CoV555) and LY3832479 (LY-CoV016) in participants with mild to moderate COVID-19 illness (BLAZE-1). Available at: https://clinicaltrials.gov/ct2/show/NCT04427501. Accessed December 27, 2021.
6. ClinicalTrials.gov. A study of immune system proteins in participants with mild to moderate COVID-19 illness (BLAZE-4). Available at: https://clinicaltrials.gov/ct2/show/NCT04634409. Accessed December 27, 2021.
7. ClinicalTrials.gov. A study of LY3819253 (LY-CoV555) and LY3832479 (LY-CoV016) in Preventing SARS-CoV-2 Infection and COVID-19 in Nursing Home Residents and Staff (BLAZE-2). Available at: https://clinicaltrials.gov/ct2/show/study/NCT04497987. Accessed December 27, 2021.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-

date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
Q0239	Injection, bamlanivimab, 700 mg
M0239	Intravenous infusion, bamlanivimab, includes infusion and post administration monitoring
Q0245	Injection, bamlanivimab and etesevimab, 2,100 mg
M0245	Intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Clinical policy created pre-emptively	03.10.21	05.21
RT4: added new EUA criteria of post-exposure prophylaxis for COVID-19.	10.07.21	11.21
RT4: added pediatric extension for neonates; reviewed and updated references.	12.27.21	
2Q 2022 annual review: added requirement for documentation that this product is not being used for pre-exposure prophylaxis; RT4: criteria added to reflect new FDA limitation of use against use in regions where infection or exposure is likely due to a non-susceptible SARS-CoV-2 variant; references reviewed and updated.	02.13.22	05.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.