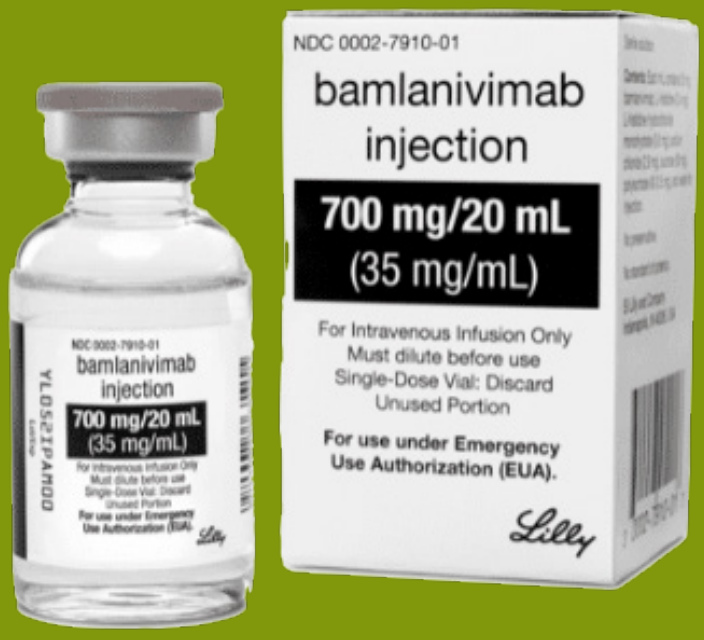
COVID-19: TREATMENT BILLING GUIDE

Bamlanivimab EUA

DEC 11th UPDATE

November 12, 2020.
Under an Executive Order from President Trump, the Federal Drug Administration (FDA) has granted Emergency Use Authorization (EUA) to Eli Lilly of Bamlanivimab infusion for COVID-19 treatment. Additionally, the FDA approved the funding and paid Eli Lilly $375M directly for the first 300,000 dosages. Due to this grant, facilities should not be separately charged under AWP or the charge model for the facility under contract with the supplier.

According to Eli Lilly, Bamlanivimab is intended to treat adults and pediatric patients 12 years of age and older who have been diagnosed with mild to moderate COVID-19 and are considered high-risk for developing severe infection that may require hospitalization. The company says the intravenous infusion should be administered as soon as possible after a positive COVID-19 test and within 10 days of symptom onset. Administration may only be done 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. To review the fact sheet for Health Care Providers EUA of Bamlanivimab regarding the limitations of authorized use, visit http://pi.lilly.com/eua/bamlanivimab-eua-factsheet-hcp.pdf



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Enrollment

Health care providers will follow the same enrollment process when administering Bamlanivimab infusion as those administering the other COVID-19 vaccines.

To review the provider enrollment information, visit **https://www.cms.gov/medicare/covid-19/enrollment**

Payment for Product

- 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 in accordance with Section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act).
- Medicare will not provide payment for the monoclonal antibody products that health care providers receive for free, as will be the case for the product's initial availability in response to the COVID-19 PHE.
- IF, health care providers begin to purchase these monoclonal antibody products (after the initial offering), CMS anticipates setting payment rates the same as it does for COVID-19 vaccines. Example: Medicare will pay 95% of the average wholesale price (AWP) for COVID-19 vaccines provided/furnished in physician office settings and pay hospital outpatient departments at reasonable cost for COVID-19 vaccines.
- Medicare Beneficiaries pay no cost sharing for these monoclonal antibody infusion:
    - o No co-payment/coinsurance
    - o No deductible

Payment for Infusion

- Initial payment rate for Bamlanivimab product infusion/administration is inclusive of the preparation time, one (1) hour infusion time and post-administration monitoring while in the hospital OP setting.
- Rates will be geographically adjusted. Currently, rate of payment is $309.60.

Billing for Infusion Administration

- Health care providers can bill for the administration of the monoclonal antibody infusion on a single claim for COVID-19, or, submit claims on roster bill according to the FDA EUA.
- Health care providers are expected to maintain appropriate and supportive documentation attesting to the medical necessity of the service. This to include:
    - o Support of the terms of the EUA are met,
    - o For the treatment of mild to moderate COVID-19,
    - o Patient is at high risk for progression to severe COVID-19, and/or hospitalization
    - o Name of the practitioner who ordered or made the decision to administer (this is also the case where claims are submitted on roster bills)
- Health care providers can only bill for the administration of the monoclonal antibody infusion when doses are provided by the government without charge.
- Health care providers should not include the monoclonal antibody codes on the claim when the product is provided for free.
- Health care providers participating in a Medicare Advantage Plan should submit claims for Bamlanivimab administration to Original Medicare for all patients enrolled in Medicare Advantage in 2020 and 2021.
- M0239 Intravenous infusion, Bamlanivimab includes infusion and post administration monitoring.

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Guidelines

- Bamlanivimab EUA is a monoclonal antibody; under CMS guidelines this drug falls under the Chemotherapy Hierarchy for administration:
  - o These patients present a high-risk population with mild to moderate symptomology for COVID-19
  - o These patients cannot be serviced in the same area with any other immunocompromised patients receiving Chemotherapy, due to the high potential of cross contamination of the environment regardless of the distance and life expectancy of the virus itself on surfaces
  - o Patients must be 12-years of age or older and weigh at least 40 kg
  - o The administration of Bamlanivimab must be done under direct physician supervision
    - ‣ This does not mean the physician administers the drug, however, must be present and immediately available to furnish assistance and direction throughout the performance of the procedure. The physician does not need to be present in the actual room. This is due to the high adverse reaction to the drug in the form of anaphylaxis.
  - o Generally, an emergency kit is available with the required medications to mitigate the reaction of anaphylaxis
  - o Any adverse reaction during the administration or observation period following must be reported to the FDA-SRP web page or via the FAERS Electronic Submissions web page. Either report must state "use of Bamlanivimab was under and EUA"; and in accordance with the Fact Sheet for Healthcare Providers. www.fda.gov/medwatch/report.htm

Charging

Facility with FREE drug: M0239 Infusion and Monitoring	Facility: If adverse reactions occur, can utilize CPT 96366, 96375 and 96376
Facility + Drug Cost: M0239 Infusion and Monitoring	Facility: if adverse reactions occur, can utilize CPT 96366, 96375 and 96376

Professional:
E&M New 99201 - 99205 | OR | E&M Est 99211 - 99215

E&Ms are based on intensity of service to severity of illness and are for either New or Established patients

CPT 99070 abd 99072 are a possible for supplies and time of staff to mitigate infection/disease transmission during the evaluation, treatment or procedural services. NOTE: These CPTs cannot be billed along with an E&M Level.

References

- FDA Letter of Authorization
- Fact Sheet for Patients, Parents and Caregivers (English and Spanish)
- Eli Lilly and Company's Antibody Bamlanivimab (LY-CoV555)
- Fact Sheet for Health Care Providers
- Bamlanivimab Antibody Playbook by Eli Lilly

**Above playbook can also be accessed directly from the EAU Letter for Authorization*

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Contact us to learn more at Solutions@EnsembleHP.com or 704-765-3715.