

Medicare Monoclonal Antibody COVID-19 Infusion Program Instruction

On November 9, 2020, the U.S. Food and Drug Administration (FDA) issued an emergency use authorization (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.

On November 21, 2020, the FDA issued an EUA for the investigational monoclonal antibody therapy, casirivimab and imdevimab, administered together, 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. As with the other monoclonal antibody infusion treatments, casirivimab and imdevimab 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 Casirivimab and Imdevimab](#) regarding the limitations of authorized use when administered together.

On February 9, 2021, the FDA issued an EUA for the investigational monoclonal antibody therapy, bamlanivimab and etesevimab, administered together, 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. As with the other monoclonal antibody infusion treatments, bamlanivimab and etesevimab 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 and Etesevimab](#) regarding the limitations of authorized use when administered together.

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

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 these treatments in accordance with the EUA. Medicare will not pay for the COVID-19 monoclonal antibody products that providers receive for free. If providers begin to purchase COVID-19 monoclonal antibody products, Medicare anticipates setting the payment rate for the products, which will be 95% of the average wholesale price (AWP) for many health care providers, consistent with usual vaccine payment methodologies. Additionally, Medicare anticipates establishing codes and rates for the administration of the products.

In order to facilitate the efficient administration of COVID-19 vaccines to SNF residents, CMS will exercise enforcement discretion with respect to certain statutory provisions as well as any associated statutory references and implementing regulations, including as interpreted in pertinent guidance (collectively, "SNF Consolidated Billing Provisions"). Through the exercise of that discretion, CMS will allow Medicare-enrolled immunizers including, but not limited to, pharmacies working with the United States, as well as infusion centers, and home health agencies to bill directly and receive direct reimbursement from the Medicare program for vaccinating Medicare SNF residents.

Health care providers administering the COVID-19 monoclonal antibody infusions will follow the same enrollment process as those administering the other COVID-19 vaccines. Review [provider enrollment](#) information.

Coding for Monoclonal Antibody COVID-19 Infusion

CMS identified specific code(s) for each COVID-19 monoclonal antibody product and specific administration code(s) for Medicare payment:

[Eli Lilly and Company's Antibody Bamlanivimab \(LY-CoV555\), EUA effective November 10, 2020](#), revised February 9, 2021

Q0239:

- Long descriptor: Injection, bamlanivimab-xxxx, 700 mg
- Short descriptor: bamlanivimab-xxxx

M0239:

- Long Descriptor: intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring
- Short Descriptor: bamlanivimab-xxxx infusion

[Regeneron's Antibody casirivimab and imdevimab \(REGN-COV2\) \(ZIP\)](#), EUA effective November 21, 2020

Q0243:

- Long descriptor: Injection, casirivimab and imdevimab, 2400 mg
- Short descriptor: casirivimab and imdevimab

M0243:

- Long Descriptor: intravenous infusion, casirivimab and imdevimab includes infusion and post administration monitoring
- Short Descriptor: casirivi and imdevi infusion

[Eli Lilly and Company's Antibody Bamlanivimab and Etesevimab](#), EUA effective February 9, 2021

Q0245:

- Long descriptor: Injection, bamlanivimab and etesevimab, 2100 mg
- Short descriptor: bamlanivimab and etesevima

M0245:

- Long Descriptor: intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring
- Short Descriptor: bamlan and etesev infusion

Get the most up to date [list of billing codes, payment allowances and effective dates](#).

Medicare Payment for Monoclonal COVID-19 Infusion

In order to ensure immediate access during the COVID-19 PHE, Medicare will cover and pay for these infusions in accordance with Section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). CMS intends to address potential refinements to payment for COVID-19 monoclonal antibody infusions and their administration through future notice and comment rulemaking.

Get the most up to date [list of billing codes, payment allowances and effective dates](#).

Payment for Infusion

Initially, for the infusion of bamlanivimab, casirivimab and imdevimab (administered together), and bamlanivimab and etesevimab (administered together), the Medicare national average payment rate for the administration will be approximately \$310. This payment rate is based on one hour of infusion and post-administration monitoring in the hospital outpatient setting. At a later date, we may use a similar methodology to determine the payment rate for the infusion of additional monoclonal antibody products based on the expected infusion time, consistent with the FDA EUA or FDA approval of such products.

Payment for Product

As noted above, Medicare will not provide payment for the COVID-19 monoclonal antibody products that health care providers receive for free, as will be the case upon the product's initial availability in response to the COVID-19 PHE. If health care providers begin to purchase these monoclonal antibody products, CMS anticipates setting the payment rate in the same way we set the payment rate for COVID-19 vaccines. For example, Medicare will pay 95% of AWP for COVID-19 vaccines furnished in the physician office setting, and pay hospital outpatient departments at reasonable cost for COVID-19 vaccines. Because COVID-19 monoclonal antibody products are considered COVID-19 vaccines, they are not eligible for the New COVID-19 Treatments Add-on Payment (NCTAP) under the Inpatient Prospective Payment System (IPPS).

Note: We also anticipate addressing coding and payment rates for administration of monoclonal antibody products through future notice-and-comment rulemaking.

Should there be additional products that come to market, get the most up to date [list of billing codes, payment allowances and effective dates](#).

People with Medicare pay no cost sharing for these COVID-19 monoclonal antibody infusion therapy products:

- No copayment/coinsurance
- No deductible

Billing for Monoclonal Antibody COVID-19 Infusion Administration

Health care providers can bill for the administration of the COVID-19 monoclonal antibody infusion on a single claim for COVID-19 monoclonal antibody administration or submit claims on a roster bill, in accordance with the FDA EUA for each product.

- The EUA for COVID-19 monoclonal antibody treatments contain specific requirements for administration that are considerably more complex than for other services that are billed using roster billing. CMS expects that health care providers will maintain appropriate medical documentation that supports the medical necessity of the service. This includes documentation that supports that the terms of the EUAs are met. The documentation should also include the name of the practitioner who ordered or made the decision to administer the infusion, even in cases where claims for these services are submitted on roster bills.
- When COVID-19 monoclonal antibody doses are provided by the government without charge, providers should only bill for the administration. Health care providers should not include the COVID-19 monoclonal antibody codes on the claim when the product is provided for free.

Health care providers who provide these services to enrollees in a Medicare Advantage Plan should submit claims for monoclonal antibodies to treat COVID-19 that are covered by Part B in accordance with Section 3713 of the CARES Act to Original Medicare for all patients enrolled in Medicare Advantage in 2020 and 2021.