Principio del formulario

Monoclonal Antibody COVID-19 Infusion

Monoclonal Antibody Products to Treat COVID-19

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CMS.gov
Centers for Medicare & Medicaid Services

Principio del formulario

Final del formulario

On June 25, 2021, the Federal Government is immediately pausing all distribution of bamlanivimab and etesevimab together and etesevimab alone (to pair with existing supply of bamlanivimab at a facility for use under EUA 094 (PDF) (ZIP) on a national basis until further notice. In addition, FDA recommends that health care providers nationwide use alternative authorized monoclonal antibody therapies, as described below, and not use bamlanivimab and etesevimab administered together at this time.

Review the Antiviral Resistance information in Section 15 of the authorized Fact Sheets for each monoclonal antibody therapy available under an EUA for details regarding specific variants and resistance. You should also refer to the CDC website (https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-proportions.html) and information from state and local health authorities regarding reports of viral variants of importance in their region to guide treatment decisions.

Review the infographic (PDF) on coverage of monoclonal antibody products to treat COVID-19.

The following investigational monoclonal antibody therapies are available under FDA emergency use authorization (EUA):

- Casirivimab and imdevimab, administered together (EUA issued November 21, 2020, latest update July 30, 2021)
- Bamlanivimab and etesevimab, administered together (EUA issued February 9, 2021)
- Sotrovimab (EUA issued May 26, 2021)
- Tocilizumab (EUA issued June, 24 2021)

The FDA authorized the use of these monoclonal antibody therapies to treat mild-to-moderate COVID-19 in adults and pediatric patients when both of these apply:

- The patient has a positive COVID-19 test result
- The patient is at high risk for progressing to severe COVID-19, hospitalization, or both

Health care providers may administer these monoclonal antibody therapies only in settings where they have both of these:

- Immediate access to medications to treat a severe infusion reaction, such as anaphylaxis
- The ability to activate the emergency medical system (EMS)

Note:

Under the terms of the EUA, health care providers may only administer tocilizumab to hospitalized patients with severe COVID-19 illness. See the FDA EUA for more information.

Note:

Under the terms of the EUA, casirivimab and imdevimab, administered together, are authorized in adult and pediatric individuals for treatment of COVID-19 and post-exposure prophylaxis for certain individuals who have been exposed to COVID-19 positive persons. See the FDA EUA for more information and further limitations.

Learn more about treatment guidelines and recommendations for using monoclonal antibody therapies.

For more information about the limits of authorized use for these monoclonal antibody therapies, including information about viral variants and antiviral resistance, review the following:

- Fact Sheet for Health Care Providers EUA of Casirivimab and Imdevimab (PDF)
- Fact Sheet for Health Care Providers EUA of Bamlanivimab and Etesevimab
- Fact Sheet for Health Care Providers EUA of Sotrovimab
- Fact Sheet for Health Care Providers EUA of Tocilizumab (ZIP)

Important Update about Viral Variants

On April 16, 2021, the FDA revoked the EUA for bamlanivimab, when administered alone, due to a sustained increase in COVID-19 viral variants in the U.S. that are resistant to the solo product.

Importantly, although the FDA revoked the EUA for bamlanivimab, when administered alone, alternative monoclonal antibody therapies remain available under EUA for the same uses as previously authorized for bamlanivimab alone. The FDA indicates that alternative monoclonal antibody therapies remain appropriate to treat COVID-19 patients, and health care providers may continue using these authorized therapies:

- Casirivimab and imdevimab, administered together
- Bamlanivimab and etesevimab, administered together (distribution paused on June 25, 2021)
- Sotrovimab
- Tocilizumab

The FDA indicates using these other therapies may reduce the risk of treatment failure for patients infected with a COVID-19 viral variant that's resistant to bamlanivimab when administered alone. For details about specific variants and resistance, review the Antiviral Resistance information in Section 15 of each of the Fact Sheets listed above.

Following your existing ordering and reporting procedures, you can still order the following from the authorized distributor:

- Casirivimab and imdevimab, to be administered together
- Bamlanivimab and etesevimab, to be administered together (distribution paused on June 25, 2021)

Sotrovimab and tocilizumab won't be purchased and distributed for free by the federal government. You may purchase these products through typical purchasing channels.

For more information about viral variants in your area to help you make treatment decisions:

- Visit the CDC's website on Variant Proportions in the U.S.
- Refer to information from your state and local health authorities

Medicare Coverage for Monoclonal Antibody Products to Treat COVID-19

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.

Note:

Medicare will only cover and pay for bamlanivimab (administered alone) if it was furnished, consiste with the terms of the EUA, between November 10, 2020 - April 16, 2021.

Our approach to paying for these products as COVID-19 vaccines during the PHE allows a broad range of providers and suppliers to administer these treatments, including but not limited to:

- Freestanding and hospital-based infusion centers
- Home health agencies
- Nursing homes
- Entities with whom nursing homes contract to administer treatment

To help skilled nursing facilities (SNFs) efficiently administer COVID-19 vaccines (including monoclonal antibody products to treat COVID-19) to residents, CMS has exercised enforcement discretion for certain statutory provisions and any associated statutory references and implementing regulations, including as interpreted in pertinent guidance (collectively, "SNF Consolidated Billing Provisions"). We allow Medicare-enrolled immunizers including, but not limited to, pharmacies working with the U.S., infusion centers, and home health agencies to bill directly and get direct payment from the Medicare Program for vaccinating Medicare SNF residents.

Health care providers administering the infusions of monoclonal antibody products to treat COVID-19 will follow the same enrollment process as those administering the COVID-19 vaccines. Get provider enrollment information.

Coding for Monoclonal Antibody Products to Treat COVID-19

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

Product	EUA Effective & Revocation Date(s)	Specific Code	Administration Code
Eli Lilly and Company's Antibody Bamlanivimab (LY-CoV555)	November 10, 2020 - April 16, 2021 **Note:** On April 16, 2021, the FDA revoked the EUA for bamlanivimab when administered alone.	Q0239 **Long descriptor:** Injection, bamlanivimab-xxxx, 700 mg **Short descriptor:** Bamlanivimab-xxxx	M0239 **Long Descriptor:** Intraveno infusion, bamlanivimab-xxxx, includes infusion and administration monitor **Short Descriptor:** Bamlaniv xxxx infusion
Regeneron's Antibody casirivimab and imdevimab (REGN-COV2) (ZIP) (ZIP)	November 21, 2020 - TBD **Note:** While the product EUA was originally issued on November 21, 2020, these product and administration codes are effective July 30, 2021	Q0240 (Code effective 07/30/2021 and reflects updated dosing regimen) **Long descriptor:** Injection, casirivimab and imdevimab, 600 mg **Short descriptor:** Casirivi and imdevi 600 mg	M0240 **Long Descriptor:** Intraveno infusion or subcutaneo injection, casirivimab a imdevimab includes infusion or injection, a post administration monitoring, subsequer repeat doses **Short Descriptor:** Ca and imdevi repeat
Regeneron's Antibody casirivimab and imdevimab (REGN-COV2) (ZIP) (ZIP)	November 21, 2020 - TBD **Note:** While the product EUA was	Q0240 (Code effective 07/30/2021 and reflects updated dosing regimen) **Long descriptor:** Injection,	M0241 **Long Descriptor:** Intraveno infusion or subcutaneo injection, casirivimab a imdevimab includes

	originally issued on November 21, 2020, these product and administration codes are effective July 30, 2021	casirivimab and imdevimab, 600 mg **Short descriptor:** Casirivi and imdevi 600 mg	infusion or injection, a post administration monitoring in the hom residence, this include beneficiary's home tha been made provider-b to the hospital during t covid-19 public health emergency, subseque repeat doses **Short Descriptor:** Ca and imdevi repeat hm
Regeneron's Antibody casirivimab and imdevimab (REGN-COV2) (ZIP) (ZIP)	November 21, 2020 - TBD	Q0243 **Long descriptor:** Injection, casirivimab and imdevimab, 2400 mg **Short descriptor:** Casirivimab and imdevimab Q0244 (Code effective 06/03/2021 and reflects updated dosing regimen) **Long descriptor:** Injection, casirivimab and imdevimab, 1200 mg **Short descriptor:** Casirivi and imdevi 1200 mg	M0243 **Long Descriptor:** Intraveno infusion or subcutaneo injection, casirivimab a imdevimab includes infusion or injection, a post administration monitoring **Short Descriptor:** Ca and imdevi inj
Regeneron's Antibody casirivimab and imdevimab (REGN-COV2) (ZIP)	November 21, 2020 – TBD **Note:** While the product EUA was issued on November 21, 2020, this administration	Q0243 **Long descriptor:** Injection, casirivimab and imdevimab, 2400 mg **Short descriptor:** Casirivimab and imdevimab	M0244 **Long Descriptor:** Intraveno infusion or subcutaneo injection, casirivimab a imdevimab includes infusion or injection, a post administration monitoring in the hom residence; this include

	code is effective May 6, 2021	Q0244 (Code effective 06/03/2021 and reflects updated dosing regimen) **Long descriptor:** Injection, casirivimab and imdevimab, 1200 mg **Short descriptor:** Casirivi and imdevi 1200 mg	beneficiary's home tha been made provider-b to the hospital during t COVID-19 public healt emergency[1] **Short Descriptor:** Ca and imdevi inj hm
Eli Lilly and Company's Antibody Bamlanivimab and Etesevimab, (ZIP)	February 9, 2021 - TBD	Q0245 **Long descriptor:** Injection, bamlanivimab and etesevimab, 2100 mg **Short descriptor:** Bamlanivimab and etesevima	M0245 **Long Descriptor:** Intraveno infusion, bamlanivimal etesevimab, includes infusion and post administration monitor **Short Descriptor:** Ba and etesev infusion
Eli Lilly and Company's Antibody Bamlanivimab and Etesevimab, (ZIP)	February 9, 2021 (reissued on February 25, 2021) – TBD **Note:** While the product EUA was issued on February 9, 2021, this administration code is effective May 6, 2021	Q0245 **Long Descriptor:** Injection, bamlanivimab and etesevimab, 2100 mg **Short Descriptor:** Bamlanivimab and etesevima	M0246 **Long Descriptor:** Intraveno infusion, bamlanivimal etesevimab, includes infusion and post administration monitor the home or residence includes a beneficiary' home that has been m provider-based to the hospital during the COVID-19 public healt emergency[1] **Short Descriptor:** Bamlan and etesev inf home
GlaxoSmithKline's Antibody Sotrovimab	May 26, 2021 - TBD	Q0247	M0247 **Long Descriptor:** Intraveno

		Long descriptor: Injection, sotrovimab, 500 mg **Short descriptor:** Sotrovimab	infusion, sotrovimab, includes infusion and administration monitor **Short Descriptor:** Sotrovima infusion
GlaxoSmithKline's Antibody Sotrovimab	May 26, 2021 - TBD	Q0247 **Long descriptor:** Injection, sotrovimab, 500 mg **Short descriptor:** Sotrovimab	M0248 **Long Descriptor:** Intraveno infusion, sotrovimab, includes infusion and administration monitor the home or residence includes a beneficiary' home that has been m provider-based to the hospital during the COVID-19 public healt emergency[1] **Short Descriptor:** Sotrovima inf, home admin
Genentech's Antibody Tocilizumab	June 24, 2021 – TBD	Q0249[2] **Long descriptor:** Injection, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and older) with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) only, 1 mg	M0249 **Long Descriptor:** Intraveno infusion, tocilizumab, f hospitalized adults an pediatric patients (2 ye of age and older) with covid-19 who are rece systemic corticosteroi and require suppleme oxygen, non-invasive invasive mechanical ventilation, or extracorporeal membr oxygenation (ECMO) includes infusion and

		Short descriptor: Tocilizumab for COVID-19	administration monitor first dose **Short Descriptor:** Ad Tocilizu COVID-19 1st
Genentech's Antibody Tocilizumab	June 24, 2021 – TBD	Q0249[2] **Long descriptor:** Injection, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and older) with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) only, 1 mg **Short descriptor:** Tocilizumab for COVID-19	M0250 **Long descriptor:** Intraveno infusion, tocilizumab, f hospitalized adults an pediatric patients (2 ye of age and older) with covid-19 who are rece systemic corticosteroi and require suppleme oxygen, non-invasive invasive mechanical ventilation, or extracorporeal membr oxygenation (ECMO) includes infusion and administration monitor second dose **Short descriptor:** Adr Tocilizu COVID-19 2nd

[1] These rates don't apply if Medicare pays you for preventive vaccines and their administration at reasonable cost (for example, federally qualified health centers, rural health clinics, and hospital-based renal dialysis facilities). Also, as indicated in the 2021 Medicare Physician Fee Schedule Final Rule, we continue to seek additional information from the public for further consideration as we review and establish payment rates for vaccine administration services during the PHE and on a longer term basis.

[2] Given the limited clinical situations allowed under the EUA, you should only bill for tocilizumab on a 12x type of bill (TOB).

Get the most current list of billing codes, payment allowances, and effective dates.

Medicare Payment for Administering Monoclonal Antibody Products to Treat COVID-19

To ensure immediate access during the COVID-19 PHE, Medicare covers and pays for these infusions in accordance with Section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). We'll address potential refinements to payment for administering monoclonal antibody products to treat COVID-19 through future notice-and-comment rulemaking.

Payment for Infusion

On May 6, 2021, CMS updated the Medicare payment rates for the administration of COVID-19 monoclonal antibody products. Effective for services furnished on or after May 6, 2021, the new Medicare payment rate for administering COVID-19 monoclonal antibody products, authorized or approved by the FDA, is approximately $450. This rate applies to all providers and suppliers not paid reasonable cost for furnishing these products. The new rate reflects updated information about the costs involved in administering monoclonal antibody products for different types of providers and suppliers, and the additional resources necessary to ensure providers administer the products safely and appropriately to COVID-19 positive patients. CMS geographically adjusts the rate based on where you furnish the service.

Note:

Under the terms of the EUA, health care providers can only administer tocilizumab to hospitalized patients in limited clinical situations. The Medicare payment rate of approximately $450 for the administration of COVID-19 monoclonal antibody products will apply for the administration of tocilizumab when you furnish it in accordance with the EUA.

The EUA for tocilizumab also allows for 2 infusions for the same patient in limited situations. Medicare will pay approximately $450 per infusion when 2 infusions are clinically necessary. As with payments for administering other COVID-19 monoclonal antibodies, the separate Medicare payment amount of $450 per infusion of tocilizumab applies to all hospitals not paid reasonable cost for furnishing these products consistent with the EUA. CMS geographically adjusts the rate based on where you furnish the service. Get the most current geographically adjusted rates.

Note:

The July 30, 2021 revised EUA for casirivimab and imdevimab allows for its use for post-exposure prophylaxis for certain patients who have been exposed to (or are at high risk of exposure to) a person with COVID-19. In these situations, use the following HCPCS codes to bill for casirivimab and imdevimab:

M0243 or M0244 when billing for the administration of the initial dose in a health care setting or the home

M0240 or M0241 when billing for the administration of any subsequent repeat doses in a health care setting or the home

Medicare also pays for treatment to address major complications:

- As needed and appropriate
- Consistent with existing payment methodologies for the care setting where you provide the treatment

For COVID-19 monoclonal antibody products administered before May 6, 2021, the Medicare payment rate is approximately $310.

Medicare will establish codes and rates for administering new products as the FDA approves or authorizes each product.

Get the most current list of billing codes, payment allowances, and effective dates for currently authorized monoclonal antibody products.

Payment for Infusion at Home

Beginning on May 6, 2021, Medicare established separate coding and payment for administering COVID-19 monoclonal antibody products in a patient's home or residence. Effective for services furnished on or after May 6, 2021, the Medicare payment rate for administering monoclonal antibody products in a patient's home or residence is approximately $750. This rate reflects updated information about the costs involved in furnishing these complex products in a patient's home. For many providers and suppliers, CMS also geographically adjusts this rate based on where you furnish the service.

Note:

These rates don't apply if Medicare pays you for preventive vaccines and their administration at reasonable cost (for example, federally qualified health centers, rural health clinics, and hospital-based renal dialysis facilities). Also, as indicated in the 2021 Medicare Physician Fee Schedule Final Rule, we continue to seek additional information from the public for further consideration as we review and establish payment rates for vaccine administration services during the PHE and on a longer term basis.

Providers and suppliers may bill for the higher home payment rate when they furnish a COVID-19 monoclonal antibody product in a "home or residence." This includes circumstances such as a Medicare patient's permanent residence, temporary lodging (for example, hotel or motel, hostel, or homeless shelter), and homes or residences that have been made provider-based to the hospital during the COVID-19 PHE.

If your Medicare patient's permanent residence is a setting that provides health care services, such as an intermediate care facility, nursing facility, or skilled nursing facility, that setting would also qualify as a "home or residence" for purposes of billing codes M0241, M0244, M0246, or M0248. However, if the patient is only in that location temporarily (such as if your patient has a permanent home but is in a post-acute stay in a skilled nursing facility), the setting isn't considered a patient's "home or residence" for this purpose, and you shouldn't bill for the higher "at home" HCPCS codes M0241, M0244, M0246, or M0248.

If you administer COVID-19 monoclonal antibodies to Medicare patients in traditional health care locations (for example, a hospital outpatient infusion clinic or freestanding infusion clinic), continue to bill HCPCS codes M0240, M0243, M0245, or M0247, as applicable. Inpatient locations, such as inpatient hospitals, inpatient psychiatric hospitals, long-term care hospitals, and inpatient rehabilitation hospitals, would never qualify as the "home or residence" for purposes of HCPCS codes M0241, M0244, M0246, or M0248.

Note:

Under the terms of the EUA, tocilizumab may only be infused in the hospital setting, in limited clinica situations. Providers may not furnish tocilizumab in the "home or residence," including homes or residences that have been made provider-based to the hospital during the COVID-19 PHE. As a result, Medicare hasn't created a separate HCPCS code for billing for the higher Medicare payment amount for administering tocilizumab in the home.

Get the most current list of billing codes, payment allowances, and effective dates for currently authorized monoclonal antibody products.

Payment for Product

In response to the COVID-19 PHE, the government initially purchased the monoclonal antibody products to treat COVID-19 and made them available for free. Medicare doesn't pay for the monoclonal antibody products to treat COVID-19 that providers get for free, including:

- Casirivimab and imdevimab, to be administered together
- Bamlanivimab and etesevimab, to be administered together

The government won't purchase sotrovimab or tocilizumab and make them available for free. Get the most current payment allowances and effective dates for the product.

Note:

CMS pays for tocilizumab based on the number of units administered, so you should include the tota number of units administered on the claim per day. For example, if you administer 200mg of tocilizumab in 1 infusion, you should add 200 as the number of units on the claim. If you give 2 infusions in the same day, you should include the total units for both infusions with the product code Q0249 on 1 line (per day).

CMS set the payment rate for COVID-19 monoclonal antibody products the same way we set the payment rate for COVID-19 vaccines. For example, Medicare will pay 95% of AWP for COVID-19 vaccines provided in the physician office setting, and pay hospital outpatient departments at reasonable cost for COVID-19 vaccines. Because CMS considers monoclonal antibody products to treat COVID-19 to be COVID-19 vaccines, they aren't eligible for the New COVID-19 Treatments Add-on Payment (NCTAP) under the Inpatient Prospective Payment System (IPPS).

There's No Cost for Your Patients

There's no cost sharing for people with Medicare for these monoclonal antibody products to treat COVID-19:

- No copayment/coinsurance
- No deductible

Billing for Administering Monoclonal Antibody Products to Treat COVID-19

Health care providers can bill on a single claim for administering monoclonal antibody products to treat COVID-19, or submit claims on a roster bill.

- The EUAs for monoclonal antibody products to treat COVID-19 contain specific requirements for administration that are considerably more complex than for other services that use roster billing. CMS expects health care providers to maintain appropriate medical documentation that supports the medical necessity of the service, including:
  - Documentation that supports that the provider met the terms of the EUAs
  - The name of the provider who ordered or decided to administer the infusion, even in cases where providers use roster billing to submit claims for these services
- When the government provides monoclonal antibody products to treat COVID-19 for free, providers should only bill for the administration. Don't include the monoclonal antibody product codes on these claims.
- To ensure access during the PHE, Medicare covers and pays for COVID-19 monoclonal antibodies under the COVID-19 vaccine benefit.
- If you're enrolled as a mass immunizer, you may be able to bill Medicare for administering monoclonal antibodies, consistent with the product's EUA and in accordance with state law and scope of practice.
- Mass immunizers may bill using a roster bill or a traditional claim form, such as a CMS-1500 (PDF) or the 837P electronic format. CMS systems will accept roster bills for 1 or more patients that get the same type of shot (or in the case of monoclonal antibodies, same type of infusion) on the same date of service.
- For patients enrolled in a Medicare Advantage Plan in 2020 and 2021, submit claims for monoclonal antibody products to treat COVID-19 to Original Medicare through your Medicare Administrative Contractor (MAC). Use your patients' Medicare Beneficiary Identifiers (MBI) to bill Original Medicare.
  - Ask your Medicare Advantage patients for their Original Medicare card. All Medicare patients have a red, white, and blue Medicare card with an MBI, including those enrolled in a Medicare Advantage Plan.
  - If your patients don't have their Original Medicare card or don't know their MBI, use the MBI look-up tool in your MAC's secure portal (PDF). You'll need your patients' first names, last names, dates of birth, and SSNs. You can use the MAC's secure portal to look up the MBI for your Medicare patients even if they're enrolled in a Medicare Advantage Plan.
  - For Part A claims, include Condition Code (CC) 78.