

# CORONAVIRUS DISEASE 2019 (COVID-19)

## COVID-19 Monoclonal Antibody Therapy Charging/Billing



**Audience:** Revenue Integrity, Patient Financial Services, MGPS, HIM, Integrity & Compliance Officers

**Revision Date:** 01/30/2023

**Version:** #22

**COVID-19 Response Team Owner:** Finance

**Date of Last Review:** 01/31/2023

**What's Changed:** On January 26, 2023 the FDA announced Evusheld is not currently authorized for use related to COVID-19 infections in any U.S. regions.

### COVID-19 Monoclonal Antibody Therapy

**Note:** As of January 26, 2023, there are no monoclonal antibodies with Emergency Use Authorization for outpatient use against COVID-19.

CMS has published documents containing coding and billing guidance for COVID-19 monoclonal antibody therapies once a monoclonal antibody product has been approved for outpatient setting (or not limited to the inpatient setting) and has FDA approval or emergency use authorization (EUA) approval and the product has been approved by the hospital's Pharmacy and Therapeutics Committee,

- On December 8, 2020, CMS updated their COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing document to include Q&As 5-22 in section BB. Drugs & Vaccines under Part B.
- On November 9, 2020 the first COVID-19 monoclonal antibody therapy, Bamlanivimab, was granted EUA approval by the FDA.
- On November 21, 2020 a two-drug monoclonal antibody therapy, Casirivimab/Imdevimab, was granted EUA approval by the FDA.
- On November 10, 2020, CMS issued a Medicare Monoclonal Antibody COVID-19 Infusion Program Instruction document which included specific guidance and coding for Bamlanivimab. This was updated on December 3, 2020 to include information on Casirivimab/Imdevimab.
- On February 3, 2021, the FDA updated EUA for Casirivimab/Imdevimab.
- On February 9, 2021, the FDA granted EUA approval for Etesevimab used with Bamlanivimab. On February 18, 2021, CMS published coding for combined Bamlanivimab and Etesevimab.
- On February 19, 2021, CMS updated their COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing document to include Q&As 23-30 to include instructions for Revenue Code, Condition Code and diagnosis code instructions when billing monoclonal antibodies.
- On April 16, 2021, the FDA revoked the EUA approval of Bamlanivimab when administered alone.
- On May 6, 2021, CMS revised reimbursement for COVID-19 monoclonal antibody therapy. The payment for this therapy provided on-site is increased to \$450. CMS is also establishing an even higher payment rate when the monoclonal antibody therapy is provided in the patient's home/residence. CMS created additional HCPCS codes to differentiate administration provided at homes/residences. CMS also updated their COVID-19 Frequently

Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing document to update most of the Q&As in section BB. Drugs & Vaccines under Part B.

- On May 26, 2021, the FDA granted EUA approval for Sotrovimab. On June 8<sup>th</sup>, CMS published coding for this drug.
- On June 3, 2021, the FDA issued a revised EUA for Casirivimab/Imdevimab updating the dosage and adding an additional route of administration. On June 16, 2021, CMS published an additional Casirivimab/Imdevimab drug HCPCS code.
- On June 24, 2021, the FDA EUA approved a new monoclonal antibody Actemra (tocilizumab) for inpatient use. On July 22, 2021, CMS created HCPCS codes and provided claim guidance.
- As of June 25, 2021, distribution of Etesevimab and Bamlanivimab has been paused due to COVID-19 variants.
- On July 30, 2021, The FDA expanded emergency authorized use of Casirivimab and Imdevimab (Regen-COV) as a prophylactic treatment in a lower dosage.
- On December 8, 2021, the FDA EUA approved a new monoclonal antibody combination Tixagevimab co-packaged with cilgavimab for prophylactic use in specified conditions. On December 23, 2021, CMS published coding for this monoclonal antibody.
- On January 24, 2022, due to the Omicron variant, the EUAs for combined Etesevimab with Bamlanivimab and for combined Casirivimab/Imdevimab have been revoked.
- On February 11, 2022, the FDA EUA approved a new monoclonal antibody Bebtelovimab. On February 18, 2022, CMS published coding for this monoclonal antibody.
- On February 24, 2022, the FDA EUA updated the initial dosage for Tixagevimab co-packaged with Cilgavimab (EVUSHELD) and created a new drug HCPCS code for this dosage.
- On April 5, 2022, due to the Omicron BA.2 variant, the EUA for Sotrovimab has been revoked.
- Beginning August 15, 2022, Bebtelovimab will begin commercial distribution which means facilities will be purchasing this monoclonal antibody.
- On September 26, 2022 the HHS announced a product replacement initiative if purchased Bebtelovimab is used on uninsured or underinsured.
- On November 30, 2022, the FDA paused the emergency use authorization of Bebtelovimab in all U.S. regions, until further notice by the Agency.
- On January 26, 2023, the FDA paused the emergency use authorization of Evusheld in all U.S. regions, until further notice by the Agency.

## Bamlanivimab

**On April 16, 2021, the FDA revoked the EUA for Bamlanivimab, when administered alone.** The increase viral variants that are resistant to Bamlanivimab alone is resulting in increased risk for treatment failure. The FDA has determined that the known and potential benefits of Bamlanivimab, when administered alone, no longer outweigh the known and potential risks for its authorized use

This monoclonal antibody product, created by Eli Lilly, was granted EUA approval by the FDA on November 9, 2020 for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients. Bamlanivimab is authorized for patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kilograms (about 88 pounds), and who are at high risk for progressing to severe COVID-19 and/or hospitalization. This includes those who are 65 years of age or older, or who have certain chronic medical conditions.

Per the FDA's EUA letter, Bamlanivimab is to be administered IV in an outpatient setting; distribution will be controlled by the US government, with Lilly supplying the drug to authorized distributors.

On November 10, 2020, CMS issued a Medicare Monoclonal Antibody COVID-19 Infusion Program Instruction document which included the following additional guidance and coding for Bamlanivimab.

This document notes that 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.

### Specific Coding

CMS created specific coding for both this product and its administration. The coding is covered only for dates of service November 10, 2020 through April 16, 2021.

- **Drug/Product:** Q0239 (Injection, bamlanivimab-xxxx, 700 mg)
  - Bill with revenue code 636 for outpatient
- **Drug/Product Administration Procedure:** M0239 (intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring)
  - CMS has established a payment of \$309.60, which will be geographically adjusted.
  - System Office recommends pricing this service the same as a first hour of chemotherapy (CPT 96413)
  - The full APC payment will be made even if this is provided in an off-campus provider-based department that bills with PN modifier.

### Etesevimab used with Bamlanivimab

**On January 24, 2022 the EUA was revoked for this therapy.** The combined use of these monoclonal antibody products, created by Eli Lilly, were granted EUA approval by the FDA on February 9, 2021 for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients. Etesevimab may only be administered together with Bamlanivimab. This drug combination is authorized for patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kilograms (about 88 pounds), and who are at high risk for progressing to severe COVID-19 and/or hospitalization. This includes those who are 65 years of age or older, or who have certain chronic medical conditions.

Per the FDA's EUA letter, Etesevimab with Bamlanivimab are to be administered IV in an outpatient setting; distribution will be controlled by the US government, with Lilly supplying the drug to authorized distributors.

On February 18, 2021, CMS updated that Medicare Monoclonal Antibody COVID-19 Infusion Program Instruction document to include the coding for this drug combination.

This document notes that this drug combination 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.

As of June 25, 2021, the Assistant Secretary for Preparedness and Response (ASPR) and FDA have paused distribution of Etesevimab and Bamlanivimab (either together or individually) until further notice. The use of Etesevimab and Bamlanivimab is not effective against some COVID-19 variants. FDA recommends use alternative authorized monoclonal antibody therapies at this time.

On January 24, 2022 the EUA for this drug combination was revoked as it is not effective against the Omicron variant.

### Specific Coding

CMS created specific coding for both this product and its administration:

- **Drug/Product:** Q0245 (Injection, bamlanivimab and etesevimab, 2100 mg)
  - Bill with revenue code 636 for outpatient
- **Drug/Product Administration Procedure:**
  - M0245 (Intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring) As of May 6, 2021, this code is used when provided in **on-site locations**.
  - M2046 (Intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring **in the home or residence**; this includes a beneficiary's home that has been made provider-based to the hospital during the covid-19 public health emergency)

### Casirivimab and Imdevimab

**On January 24, 2022 the EUA was revoked for this therapy.** This monoclonal antibody product, created by Regeneron, was granted EUA approval by the FDA on November 21, 2020 for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients. Casirivimab/Imdevimab drug combination is authorized for patients with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19 and/or hospitalization. Per the EUA, this drug combination is to be administered in an outpatient setting.

The FDA EUA letter issued November 21, 2020, approved a Casirivimab/Imdevimab drug combination dose of 2400 mg total. The FDA reissued the EUA letter on February 3, 2021.

On December 3, 2020, CMS updated the Medicare Monoclonal Antibody COVID-19 Infusion Program Instruction document which included the following additional guidance and coding for Casirivimab/Imdevimab.

On June 3, 2021, the FDA issued a revised EUA for Casirivimab/Imdevimab revising the dosage to 1200 mg total and added subcutaneous injection as an alternation route of administration. The EUA states: Intravenous infusion is strongly recommended. Subcutaneous injection is an alternative route of administration when intravenous infusion is not feasible and would lead to delay in treatment. On June 16, 2021, CMS published an additional Casirivimab/Imdevimab drug HCPCS code to reflect the revised dose and updated the administration codes to include subcutaneous injection.

On July 30, 2021, the FDA issued a revised EUA and approved emergency use of REGEN-COV as a prophylactic treatment for high-risk individuals that have been exposed to, or if they are at high-risk of exposure to (nursing home patients, prison inmates, etc.), persons infected with COVID-19 who are not fully vaccinated or are not expected to develop an adequate immune response to the vaccine because of immunocompromising conditions. This includes persons that are currently prescribed and taking immunosuppressive drugs. The initial dosage for REGEN-COV is at 600mg each Casirivimab/Imdevimab by infusion or subcutaneous injection, subsequent dosage can be lowered to 300mg each Casirivimab and Imdevimab, once every four weeks during ongoing exposure.

Casirivimab/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.

On January 24, 2022 the EUA for this drug combination was revoked as it is not effective against the Omicron variant.

#### Specific Coding

CMS created specific coding for both this product and its administration:

- **Drug/Product:**
  - ~~Q0243 (Injection, casirivimab and imdevimab, 2400 mg)~~
    - No Longer approved under the EUA as of June 3, 2021
  - Q0244 (Injection, casirivimab and imdevimab, 1200 mg) – effective June 3, 2021
  - Q0240 (Injection, casirivimab and imdevimab, 600mg) – effective July 30, 2021
  - Bill with revenue code 636 for outpatient
- **Drug/Product Administration Procedure:**
  - Provided in On-site Locations
    - M0243 (Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring) As of May 6, 2021, this code is used when provided in **on-site locations**.
    - M0240 (Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection and monitoring, subsequent repeat doses).
  - Provided in Home or Residence
    - M0244 (Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration **monitoring in the home or residence**; this includes a beneficiary's home that has been made provider-based to the hospital during the covid-19 public health emergency).
    - M0241 (Intravenous infusion or injection and post administration **monitoring in the home or residence**; this includes a home that has been made provider-based to the hospital during the covid-19 public health emergency, subsequent repeat doses)

#### Sotrovimab

**On April 5, 2022 the FDA revoked the EUA for Sotrovimab.** The use of this monoclonal antibody product, created by GlaxoSmithKline, was granted EUA approval by the FDA on May 26, 2021 for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients. This drug is authorized for patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kilograms (about 88 pounds), and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

Per the FDA's EUA letter, Sotrovimab is to be administered IV in an outpatient setting; distribution will be controlled by the US government, with GlaxoSmithKline supplying the drug to authorized distributors.

On June 8, 2021, CMS updated that Medicare Monoclonal Antibody COVID-19 Infusion Program Instruction document to include the coding for this drug.

This document notes that this drug 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.

**NOTE:** Per CMS MLN Connects published on June 17, 2021, the government will not provide this drug for free. On April 5, 2022, due to the Omicron BA.2 variant, the EUA for Sotrovimab has been revoked for all areas of the US. Data shows this monoclonal antibody is not effective to treat this variant.

#### Specific Coding

CMS created specific coding for both this product and its administration:

- **Drug/Product:** Q0247 (Injection, sotrovimab, 500 mg)
  - CMS has established payment of \$2394 for this code.
- **Drug/Product Administration Procedure:**
  - M0247 (Intravenous infusion, sotrovimab, includes infusion and post administration monitoring) This code is used when provided in **on-site locations**.
  - M0248 (Intravenous infusion, sotrovimab, includes infusion and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the covid-19 public health emergency)

#### Tixagevimab co-packaged with Cilgavimab

**On January 26, 2023, the FDA paused the EUA for Evusheld in all regions until further notice by the Agency.** The use of this combined monoclonal antibody product (EVUSHELD), created by AstraZeneca, was granted EUA approval by the FDA on December 8, 2021 for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and pediatric individuals (12 years of age and older weighing at least 40 kg):

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2, and,
  - Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination, or,
  - For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

Per the FDA's EUA letter, Tixagevimab co-packaged with Cilgavimab is to be administered by two consecutive IM injections in an outpatient setting. The U.S. Department of Health and Human Services (HHS) will oversee the allocation and distribution of this product.

On December 23, 2021, CMS updated that Medicare Monoclonal Antibody COVID-19 Infusion Program Instruction document to include the coding for this drug.

On February 24, 2022, the FDA EUA revised the initial dosage to 600 mg. On March 10, 2022, CMS released a new HCPCS code for this dose.



Specific Coding

CMS created specific coding for both this product and its administration:

- **Drug/Product:**

- Q0220 ( Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40kg) with no known sars-cov-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available covid-19 vaccine is not recommended due to a history of severe adverse reaction to a covid-19 vaccine(s) and/or covid-19 vaccine component(s), 300 mg)
  - This code **reflects the initial dose prior to February 24, 2022** and reflects 150mg of each drug.
  - Per the revised EUA, patients that received an initial 300mg dose, should receive another dose of 300mg as soon as possible.
  - Bill with revenue code 636 for outpatient
  - This drug will be provided free of charge by the government.
- Q0221 (Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40kg) with no known sars-cov-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available covid-19 vaccine is not recommended due to a history of severe adverse reaction to a covid-19 vaccine(s) and/or covid-19 vaccine component(s), 600 mg)
  - This code **reflects the initial dose on/after February 24, 2022** and reflects 300mg of each drug.
  - Bill with revenue code 636 for outpatient
  - This drug will be provided free of charge by the government.

- **Drug/Product Administration Procedure:**

- M0220 (Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40kg) with no known sars-cov-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available covid-19 vaccine is not recommended due to a history of severe adverse reaction to a covid-19 vaccine(s) and/or covid-19 vaccine component(s), includes injection and post administration monitoring)
  - Medicare payment for this code is \$150.50, subject to geographic adjustments.
- M0221 (Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40kg) with no known sars-cov-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available covid-19 vaccine is not recommended due to a history of severe adverse reaction to a covid-19 vaccine(s) and/or covid-19 vaccine component(s), includes injection and post administration monitoring **in the home or residence**; this includes a beneficiary's home that has been made provider-based to the hospital during the covid-19 public health emergency)
  - Medicare payment for this code is \$250.50, subject to geographic adjustments.

## Bebtelovimab

**The FDA revoked the Emergency Authorized Use declaration for the drug Bebtelovimab on November 30, 2022 in all U.S. regions.**

The use of this monoclonal antibody product, created by Eli Lilly, was granted EUA approval by the FDA on February 11, 2022 for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients. This drug is authorized for patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kilograms (about 88 pounds), and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

Per the FDA's EUA letter, Bebtelovimab is to be administered IV in an outpatient setting; distribution will be controlled by the US government, with Eli Lilly supplying the drug to authorized distributors.

This document notes that this drug 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.

On February 18, 2022, CMS updated that Medicare Monoclonal Antibody COVID-19 Infusion Program Instruction document to include the coding for this drug.

On August 15, 2022, Eli Lilly will begin commercial distribution of this MAB. CMS will reimburse \$2,394 for the product, which is 95% of AWP. The commercially distributed (purchased product) can be identified by the Batch # D534422. Eli Lilly will release more information about future batch numbers. Integrated Clinical Services Pharmacy provided the following NDC 0002-7589-01 which is the same for both the free and purchased product.

Sites might have both United States Government (USG)-obtained and commercial product in inventory. For dates of service on or after August 15, only bill Medicare if you use commercially purchased products; don't bill for USG-obtained products. Continue to bill for administering either type of product. The HCPCS codes noted below will continue to be used.

#### Actions Needed:

- New CDMs and TC Willow process will need to be created for the chargeable version of this monoclonal antibody.
- Sites will need to carefully monitor each dose and inventory to determine whether the USG-provided free product or the purchased product is administered to make sure the appropriate product CDM is used.

On September 26, 2022 the HHS announced a product replacement initiative if purchased Bebtelovimab is used on uninsured or underinsured. HHS estimates there are 60,000 doses available under this initiative expected to be available until September 2023. At this time, HHS has not provided details on how this initiative will work. [HHS Announces Initiative to Help Uninsured and Underinsured Americans Access COVID-19 Monoclonal Antibody Treatment | HHS.gov](#)

On November 30, 2022, the FDA revoked the Emergency Use Authorization for Bebtelovimab because it is ineffective against current prevalent infections with BQ.1 and BQ.1.1 subvariants of the COVID-19 virus. Subsequently, Eli Lilly has paused its distribution of commercially available products of Bebtelovimab and the Administration of Strategic Preparedness has paused the Bebtelovimab Product Replacement Initiative at this time because the product should no longer be administered for the treatment of COVID-19.

#### Specific Coding

CMS created specific coding for both this product and its administration:

- **Drug/Product:** Q0222 (Injection, bebtelovimab, 175 mg)
  - Bill with revenue code 636 for outpatient
  - This drug will be provided free of charge by the government.
- **Drug/Procedure Administration Procedure:**
  - M0222 (Intravenous injection, bebtelovimab, includes injection and post administration monitoring) This code is used when provided in **on-site locations**.
  - M0223 (Intravenous injection, bebtelovimab, includes injection and post administration monitoring in the **home or residence**; this includes a beneficiary's home that has been made provider-based to the hospital during the covid-19 public health emergency)

## COVID Monoclonal Antibody Therapy Reimbursement, Documentation and Billing Guidelines

#### Reimbursement

For COVID-19 monoclonal antibody administration, CMS initially established a payment rate of \$309.60 which would be geographically adjusted. Effective May 6, 2021, CMS updated reimbursement rates for this therapy:

- Reimbursement for administration provided on-site at a hospital/clinic location is updated to \$450, which will be geographically adjusted.
- CMS established a separate, higher reimbursement rate of \$750 when this service is provided to patients at their home/residence. (New separate HCPCS codes were created to differentiate this as noted above.) This includes not only a beneficiary's permanent residence but also temporary lodging (e.g., hotel/motel, cruise ship, hostel, or homeless shelter) and homes or residences that have been made provider-based to the hospital during the COVID-19 PHE.

System Office recommends pricing this service the same as a first hour of chemotherapy (CPT 96413). If the current price is below Medicare payment rates, an upward adjustment is recommended to exceed the Medicare reimbursement rates.

The full APC payment will be made even if this is provided in an off-campus provider-based department that bills with PN modifier

#### Documentation Requirements

CMS clarifies that documentation must include or support:

- Medical necessity of the service
- That terms of the EUA are met, including that it is being used for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) for a patient that is at high risk for progressing to severe COVID-19 and/or hospitalization
- The name of the practitioner who ordered or made the decision to administer the infusion

#### Billing for Outpatient Monoclonal Antibody Therapy

CMS states that when the product is provided free of charge by the government, the product should not be billed, only the administration would be billed.

- When the drug is provided free of charge, set CDM price to \$0.00 so the product is charged and is on the account but does not go to the claim.

Because these drugs are EUA approved, condition code 91 is also required for billing, effective with claims billed on or after February 1, 2021.

On February 19, 2021 CMS has provided the following coding and billing clarifications in their FAQs:

- A6 is a required condition code on claims when COVID-19 monoclonal antibody therapies are administered
- COVID-19 Monoclonal Antibody Products (when required to be reported, i.e., facilities incur a charge for the product) must be reported with revenue code 636
- COVID-19 Monoclonal Antibody Administration Codes should be reported with revenue code 771
- ICD-10-CM Diagnosis Code Z23, Vaccine Administration, should be reported on all COVID-19 monoclonal antibody therapy claims.

Because these drugs are related to the PHE and services provided under the waivers, condition code DR should be included on the claim.

There will be no cost-sharing for Medicare beneficiaries (through the year the COVID-19 PHE ends) and likely all payers.

Claims for Medicare Advantage Plan should be submitted to Original Medicare for all patients enrolled in Medicare Advantage in 2020 and 2021.

- **\*Exception:** For patients with Medicare Advantage coverage, in alignment with CMS guidance, Trinity Health colleagues are required to register the patient with the appropriate **Medicare FFS plan**. *We are waiting for additional guidance on the beneficiary ID number to be utilized with this plan.*
- Condition code 78 is needed when billing for an MA beneficiary to Medicare FFS.

Per CMS FAQ, #21 in the section BB. Drugs & Vaccines under Part B, for dual eligible beneficiaries, Medicare will be the primary payer.

CMS will allow roster billing for this therapy if provided by entities that do roster billing.

If given during an ED encounter that ends up as an inpatient admission:

- when the date of service is not the same as the admission date, the monoclonal antibody administration can remain on the outpatient TOB 13x.
- when given on the same date as the admission, the monoclonal antibody administration can be split off onto a TOB 12x. (This is similar to vaccines given during an inpatient stay.)

Since the monoclonal antibody therapy is not EUA approved for inpatient use, this should be rare.



Because CMS is treating these monoclonal antibody treatments as vaccines, these would not be subject to combining under the 3-Day Rule. The monoclonal antibody administration and any related charges can remain on the outpatient TOB 13x.

## CMS Monoclonal Antibody Therapy Charging and Billing Guidelines – New Drugs/Products Without Specific Coding/Guidance

In the December 8, 2020 update of CMS' COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing document, in section BB. Drugs & Vaccines under Part B question #8, CMS states that for future monoclonal antibody therapy claims should be held until CMS publishes product specific HCPCS codes.

CMS also notes that under the Hospitals without Walls Initiative, this could be provided to patients in their homes.

## COVID-19 Monoclonal Antibody Therapy Approved Only for Inpatient Use

### Actemra (tocilizumab)

The use of this monoclonal antibody product, created by Genentech, was EUA approved by the FDA on June 24, 2021 for inpatient use to treat COVID-19 in hospitalized adults and pediatric patients (2 years of age and older) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO.

This drug is supplied in single dose vials and may only be administered via intravenous infusion.

#### Specific Coding

The following ICD-10-PCS codes would be used to report use of this drug on inpatient claims:

- XW033H5 - Introduction of Tocilizumab into Peripheral Vein, Percutaneous Approach, New Technology Group 5
- XW043H5 - Introduction of Tocilizumab into Central Vein, Percutaneous Approach, New Technology Group 5

**NOTE:** Per CMS MLN Connects published on July 22, 2021, the government will not provide this drug for free.

On July 22, 2021, CMS released specific coding for both this product and its administration:

- **Drug/Product:** Q0249 (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)
  - CMS has established payment of \$6.572 per milligram for this code.
- **Drug/Product Administration Procedure:**
  - M0249 (Intravenous infusion, 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, includes infusion and post administration monitoring, **first dose**)
    - CMS has established payment of \$450
  - M0250 (Intravenous infusion, 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, includes infusion and post administration monitoring, **second dose**)
    - CMS has established payment of \$450

**BILLING NOTE:** CMS' Monoclonal Antibody Infusion webpage notes that because the COVID-19 monoclonal antibody treatments are treated as vaccines, that this drug would not qualify for the COVID-19 New Technology Add-on Payment. CMS instructs to bill this monoclonal antibody and the related administration codes on a TOB 12x when provided for EUA covered diagnosis to inpatients. Refer to the Billing for Outpatient Monoclonal Antibody Therapy section above for information on condition codes and diagnosis codes. CMS was silent related to MA plans; at this time the COVID Revenue Subcommittee does not think Medicare FFS should be billed if this drug is provided to patients with an MA plan.

## References

Frequently Asked Questions to Assist Medicare Providers (PDF) Refer to question #1-31 beginning on page 131

Bamlanivimab FDA EUA: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibody-treatment-covid-19>

FDA EUA Revoked: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-monoclonal-antibody-bamlanivimab>

Casirivimab/Imdevimab FDA EUA: <https://www.cms.gov/files/document/covid-medicare-monoclonal-antibody-infusion-program-instruction.pdf>; <https://www.fda.gov/media/145610/download> Revised Fact Sheet: [treatment-covid19-eua-fact-sheet-for-hcp.pdf \(regeneron.com\)](https://www.fda.gov/media/145610/download)

Etesevimab used with Bamlanivimab FDA EUA: <https://www.fda.gov/media/145801/download>; <https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab-etesevimab/Pages/bamlanivimab-etesevimab-distribution-pause.aspx>

Etesevimab used with Bamlanivimab and Casirivimab/Imdevimab FDA Revocation: [Coronavirus \(COVID-19\) Update: FDA Limits Use of Certain Monoclonal Antibodies to Treat COVID-19 Due to the Omicron Variant | FDA](https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-limits-use-certain-monoclonal-antibodies-treat-covid-19-due-omicron-variant)

Sotrovimab EUA: <https://www.cms.gov/files/document/2021-06-17-mlnc.pdf>; [GSK Sotrovimab Fact Sheet for HCP 05262021 \(fda.gov\)](https://www.fda.gov/media/145610/download); [Sotrovimab Emergency Use Authorization](https://www.fda.gov/media/145610/download)

FDA EUA Revoked: [GSK Sotrovimab Fact Sheet for HCP 03252022 \(fda.gov\)](https://www.fda.gov/media/145610/download)

Actemra (tocilizumab) EUA: <https://www.fda.gov/media/150319/download>

Tixagevimab co-packaged with cilgavimab: [Evusheld Healthcare Providers FS 12202021 \(fda.gov\)](https://www.fda.gov/media/145610/download); [Evusheld Healthcare Providers FS 02242022 \(fda.gov\)](https://www.fda.gov/media/145610/download); [Evusheld Letter of Authorization 01262023 \(fda.gov\)](https://www.fda.gov/media/145610/download)

Bebtelovimab FDA Revoked EUA: [Bebtelovimab Health Care Provider Fact Sheet 11042022 \(fda.gov\)](https://www.fda.gov/media/145610/download)

CMS Monoclonal Antibody Program Instruction and Coding: <https://www.cms.gov/files/document/covid-medicare-monoclonal-antibody-infusion-program-instruction.pdf>

CMS COVID-19 Vaccine and Monoclonal Antibody Coding and Payment: [COVID-19 Vaccines and Monoclonal Antibodies | CMS](https://www.cms.gov/files/document/covid-19-vaccine-and-monoclonal-antibody-coding-and-payment)

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

HHS Monoclonal Antibody: [Monoclonal Antibody COVID-19 Infusion | Guidance Portal \(hhs.gov\)](https://www.hhs.gov/coronavirus/monoclonal-antibody-covid-19-infusion-guidance)