Washington State Health Care Authority

Monoclonal Antibody Treatment for COVID-19

Medical policy no. 19.50.20

Background:

Distribution and use of monoclonal antibodies for the treatment of mild to moderate COVID-19, COVID-19 in hospitalized adults and pediatric children, or for post-exposure prophylaxis (PEP) is determined by the Washington State Department of Health (DOH). This policy describes the requirements that facilities, providers, and pharmacies must abide by to receive and use the monoclonal antibodies listed in this policy for the treatment of COVID-19. For general information about COVID-19, see HCA's Information about novel coronavirus (COVID-19) webpage.

During the PHE, a pharmacist may prescribe, administer, and bill for monoclonal antibodies for the treatment of mild to moderate COVID-19 when there is a standing order or a collaborative practice agreement in place. Pharmacies may bill for monoclonal antibodies for the treatment of mild to moderate COVID-19 or when used for post-exposure prophylaxis (PEP) and the pharmacist administers the product in the pharmacy.

The administration of these products must be billed as a HIPPA 837 transaction using the pharmacy billing taxonomy of 193200000X.

This policy applies to HCA fee-for-service and contracted managed care organizations

Billing information for Professional and Facility Claims:

Reimbursement information and billing guidance

The COVID monoclonal antibody and their specific administration codes listed, are covered by Apple Health (Medicaid) for the treatment of COVID-19.

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.

Please see the COVID-19 fee schedule for rates and effective dates.

Outpatient hospital facility

CMS established modifier "PN" (Non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital) to identify and pay non-excepted items and services billed on an institutional claim. For Monoclonal antibody treatment, non-excepted off-campus provider-based departments of a hospital are required to report this modifier on each claim line with a HCPCS for non-excepted items and services.

As of 1/1/21 claims billed with the PN modifier are paid at 46% EAPG rates.

Providers are subject to post pay review. If it found that modifier PN should have been used at the time of billing, recoupment of payment may occur.

Medical necessity

Drug	Medical Necessity
Casirivimab + Imdevimab	Casirivimab + imdevimab may be considered medically necessary when prescribed for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2, and who are at high risk, according to the Emergency Use Authorization (EUA), for progression to severe COVID-19, including hospitalization or death in accordance with DOH requirements. Casirivimab + imdevimab may be considered medically necessary when prescribed for post-exposure prophylaxis of COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) who are at high risk, according to the Emergency Use Authorization (EUA), for progression to severe COVID-19, including hospitalization or death in accordance with DOH requirements, and are: • Not fully vaccinated or who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications) **AND** • Meet one of the following criteria: ▪ Have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per Center for Disease Control and Prevention **OR** ▪ Who are at high risk of exposure to an infected individual with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes or prisons).
Bamlanivimab + Etesevimab	Bamlanivimab + etesevimab may be considered medically necessary when prescribed for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2, and who are at high risk, according to the Emergency Use Authorization (EUA), for progression to severe COVID-19, including hospitalization or death in accordance with DOH requirements. Bamlanivimab + etesevimab may be considered medically necessary when prescribed for post-exposure prophylaxis of COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) who are at high risk, according to the Emergency Use Authorization (EUA), for progression to severe COVID-19, including hospitalization or death in accordance with DOH requirements, and are:

	• Not fully vaccinated or who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications) **AND** • Meet one of the following criteria: ▪ Have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per Center for Disease Control and Prevention **OR** ▪ Who are at high risk of exposure to an infected individual with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes or prisons).
Sotrovimab	Sotrovimab may be considered medically necessary when prescribed for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2, and who are at high risk, according to the Emergency Use Authorization (EUA), for progression to severe COVID-19, including hospitalization or death in accordance with DOH requirements.
Tocilizumab	Tocilizumab may be considered medically necessary when prescribed for the treatment of coronavirus disease 2019 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 extracorporeal membrane oxygenation (ECMO), according to the Emergency Use Authorization (EUA), in accordance with DOH requirements.

Clinical policy:

Clinical Criteria	
Mild to moderate COVID-19 at high risk for progressing to severe COVID-19 or hospitalization Casirivimab + Imdevimab Bamlanivimab + Etesevimab Sotrovimab	Healthcare providers must document in the patient's medical record that the patient/caregiver has been: 1. Communicated information consistent with and provided the "Casirivimab plus Imdevimab Fact Sheet for Patients, Parents and Caregivers," "Bamlanivimab and Etesevimab Fact Sheet for Patients, Parents and Caregivers" or "Sotrovimab Fact Sheet for Patients, Parents, and Caregivers" prior to administering the medication; **AND** 2. Informed of alternatives prior to receiving these medications; **AND** 3. Informed that these medications are unapproved drugs that are authorized for use under Emergency Use Authorization; **AND** 4. Patient will be monitored for at least 1 hour after infusion or injection is complete.

COVID-19 in hospitalized adults and pediatric children Tocilizumab	Healthcare providers must document in the patient's medical record that the patient/caregiver has been: 1. Communicated information consistent with and provided the "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) for Actemra (tocilizumab)" prior to administering the medication. If providing this information will delay the administration of tocilizumab to a degree that would endanger the life of a patient, the information must be provided to the patient/caregiver as soon as feasible after tocilizumab administration; **AND** 2. Informed of alternatives prior to receiving these medications; **AND** 3. Informed that these medications are unapproved drugs that are authorized for use under Emergency Use Authorization
Post-Exposure Prophylaxis (PEP) Casirivimab + Imdevimab Bamlanivimab + Etesevimab	Healthcare providers must document in the patient's medical record that the patient/caregiver has been: 1. Communicated information consistent with and provided the "Casirivimab plus Imdevimab Fact Sheet for Patients, Parents and Caregivers" or "Bamlanivimab and Etesevimab Fact Sheet for Patients, Parents and Caregivers" prior to administering the medication; **AND** 2. Informed of alternatives prior to receiving these medications; **AND** 3. Informed that these medications are unapproved drugs that are authorized for use under Emergency Use Authorization; **AND** 4. Patient will be monitored for at least 1 hour after infusion or injection is complete.

Dosage and quantity limits

Drug	Dose and Quantity Limits
Casirivimab + Imdevimab	Mild-to-moderate COVID-19 at high risk for progressing to severe COVID-19 or hospitalization: • 600 mg casirivimab + 600 mg imdevimab Post-exposure prophylaxis: • Initial: 600 mg casirivimab + 600 mg imdevimab • Continued exposure after 4 weeks: 300 mg casirivimab + 300 mg imdevimab every 4 weeks
Bamlanivimab + Etesevimab	• 700 mg bamlanivimab + 1400 mg etesevimab
Sotrovimab	• 500 mg
Tocilizumab	• Patients less than 30 kg: 12 mg/kg, max 2 infusions • Patients at or above 30 kg: 8 mg/kg, max 800 mg per infusion, max 2 infusions

Coding:

HCPCS Code	*Description*
Q0240	Injection, casirivimab and imdevimab, 600 mg
Q0243	Injection, casirivimab and imdevimab, 2400 mg
Q0244	Injection, casirivimab and imdevimab, 1200 mg
M0240	Intravenous infusion of subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring, subsequent repeat doses
M0241	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, subsequent repeat doses
M0243	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring
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
Q0245	Injection, bamlanivimab and etesevimab, 2100 mg
M0245	Intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring
M0246	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
Q0247	Injection, sotrovimab, 500 mg
M0247	Intravenous infusion, sotrovimab, includes infusion and post administration monitoring
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
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
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
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

Providers

1. In accordance with the DOH requirements, healthcare providers must communicate to patients or parents/caregivers, as age appropriate, information consistent with the "Casirivimab plus Imdevimab Fact Sheet for Patients, Parents and Caregivers," "Bamlanivimab and Etesevimab Fact Sheet for Patients, Parents and Caregivers," "Sotrovimab Fact Sheet for Patients, Parents, and Caregivers" or "Tocilizumab Fact Sheet for Patients, Parents, and Caregivers" (and provide a copy of the Fact Sheet) prior to the patient receiving the medication (If delay in tocilizumab administration would endanger the life of the patient, the tocilizumab fact sheet must be provided to the patient/caregiver as soon as feasible after infusion), including:

   • FDA has authorized the emergency use of casirivimab plus imdevimab, bamlanivimab plus etesevimab, or sotrovimab for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk, according to the respective EUA, for progression to severe COVID-19, including hospitalization or death.

   • FDA has authorized the emergency use of tocilizumab for coronavirus disease 2019 in hospitalized adults and pediatric patients (2 years of age or older) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO), according to the Emergency Use Authorization (EUA).

   • FDA has authorized the emergency use of casirivimab plus imdevimab or bamlanivimab plus etesevimab for post-exposure prophylaxis of COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) who are at high risk, according to the Emergency Use Authorization (EUA), for progression to severe COVID-19, including hospitalization or death, and are:

      - Not fully vaccinated or who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications) AND
      - Have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per Center for Disease Control and Prevention OR
        - Who are at high risk of exposure to an infected individual with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes, prisons).
      - For casirivimab + imdevimab, repeat dosing may be appropriate for individuals with ongoing exposure to SARS-CoV-2 for longer than 4 weeks and who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination.

   • The patient or parent/caregiver has the option to accept or refuse casirivimab plus imdevimab, bamlanivimab + etesevimab, sotrovimab, or tocilizumab.

   • The significant known and potential risks and benefits of casirivimab plus imdevimab, bamlanivimab + etesevimab, sotrovimab, or tocilizumab and the extent to which such potential risks and benefits are unknown.

   • Information on available alternative treatments and the risks and benefits of those alternatives, including clinical trials.

   • Patients treated with casirivimab plus imdevimab, bamlanivimab + etesevimab, or sotrovimab should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and frequent handwashing) according to CDC guidelines.

   • Instructions for subcutaneous injection of casirivimab plus imdevimab is available. See "REGEN-COV: Subcutaneous Injection Instructions for Healthcare Providers."

2. • The prescribing health care provider and/or provider's designee are/is responsible for mandatory reporting of all medication errors and serious adverse events potentially related to casirivimab plus imdevimab, bamlanivimab and etesevimab, sotrovimab, or tocilizumab treatment within 7 calendar days from the onset of the event. These reports are to be submitted to FDA MedWatch. See "Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of REGEN-COV (casirivimab and imdevimab)," "Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of Bamlanivimab and Etesevimab," "Fact Sheet for Patients, Parents, and Caregivers Emergency Use Authorization (EUA) of Sotrovimab for the Treatment of Coronavirus Disease 2019 (COVID-19)," or "Fact Sheet for Patients, Parents, and Caregivers Emergency Use Authorization (EUA) of Tocilizumab for the Treatment of Coronavirus Disease 2019 (COVID-19)" for respective reporting requirements.
   • Bamlanivimab and etesevimab are **NOT** authorized for use in states, territories, and US jurisdictions in which the combined frequency of variants resistant to bamlanivimab and etesevimab exceeds 5%. A list of states, territories, and US jurisdictions in which bamlanivimab and etesevimab are **NOT** currently authorized is available on the following FDA website: "Bamlanivimab and Etesevimab Authorized States, Territories, and U.S. Jurisdictions"

   • Post-exposure prophylaxis with casirivimab and imdevimab or bamlanivimab and etesevimab is **NOT** a substitute for vaccination against COVID-19.

   • Casirivimab and imdevimab or bamlanivimab and etesevimab are **NOT** authorized for pre-exposure prophylaxis for prevention of COVID-19.

   • ACTEMA subcutaneous injection is **NOT** authorized for the treatment of COVID-19 patients.

   • Actemra for COVID-19 is **NOT** authorized to be used outside the hospital (i.e. for non-hospitalized patients).

References

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2. Information About Novel Coronavirus. Washington State Health Care Authority. https://www.hca.wa.gov/information-about-novel-coronavirus-covid-19.
3. Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of Casirivimab and Imdevimab. https://www.fda.gov/media/145611/download. Accessed 9/16/2021.
4. Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of Bamlanivimab and Etesevimab. https://www.fda.gov/media/145802/download. Accessed 9/22/2021.
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13. Frequently Asked Questions on the Emergency Use Authorization for Sotrovimab. https://www.fda.gov/media/149535/download. Accessed 9/22/2021.
14. Frequently Asked Questions on the Emergency Use Authorization for Actemra (Tocilizumab) for Treatment of COVID-19. https://www.fda.gov/media/150345/download. Accessed 9/22/2021.
15. Interim Guidance on Duration of Isolation and Precautions for Adults with COVID-19. https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html.
16. REGEN-COV: Subcutaneous Injection Instructions for Healthcare Providers. https://www.phe.gov/emergency/events/COVID19/therapeutics/Documents/REGEN-COV-SubQ-FactSheet-July2021-508.pdf. Accessed 9/22/2021.
17. Bamlanivimab and Etesevimab Authorized States, Territories, and U.S. Jurisdictions. https://www.fda.gov/media/151719/download. Accessed 9/22/2021.

History

Date	Action and Summary of Changes
9/22/2021	Updating policy to include use of casirivimab + imdevimab and bamlanivimab + etesevimab for post-exposure prophylaxis. Updating policy to include tocilizumab. Updated hyperlinks, provider requirements, and HCPCS codes. Added resource information for subcutaneous administration of casirivimab + imdevimab. Added information for providers for limitations of authorized use.
7/1/2021	Updating policy to include sotrovimab
4/20/2021	Removed bamlanivimab as emergency use authorization was revoked.
3/2/2021	Updating policy to include bamlanivimab + etesevimab
12/18/2020	New policy