Washington State Health Care Authority

Therapies for COVID-19

Medical policy no. 19.50.20

Background:

Distribution and use of COVID-19 therapies for the treatment of mild to moderate COVID-19, COVID-19 in hospitalized adults and pediatric children, pre-exposure prophylaxis (PrEP), 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 COVID-19 therapies 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 COVID-19 therapies 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 COVID-19 therapies for the treatment of mild to moderate COVID-19 or when used for PrEP or 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-19 therapies and their specific administration codes listed, are covered by Apple Health (Medicaid) for the treatment of COVID-19.

When COVID-19 therapy doses are provided by the government without charge, providers should only bill for the administration. Health care providers should not include the COVID-19 therapy 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 COVID-19 therapy 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 for progression to severe COVID-19, including hospitalization or death in accordance with the Emergency Use Authorization (EUA), National Institutes of Health (NIH) COVID-19 Treatment Guidelines, and 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 for progression to severe COVID-19, including hospitalization or death in accordance with the Emergency Use Authorization (EUA), National Institutes of Health (NIH) COVID-19 Treatment Guidelines, and 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, including neonates, with positive results of direct SARS-CoV-2, and who are at high risk for progression to severe COVID-19, including hospitalization or death in accordance with the Emergency Use Authorization (EUA), National Institutes of Health (NIH) COVID-19 Treatment Guidelines, and DOH requirements. Bamlanivimab + etesevimab may be considered medically necessary when prescribed for post-exposure prophylaxis of COVID-19 in adults and pediatric patients, including neonates who are at high risk for progression to severe COVID-19, including hospitalization or death in accordance with the Emergency Use Authorization (EUA), National Institutes of Health (NIH) COVID-19 Treatment Guidelines, and 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 for progression to severe COVID-19, including hospitalization or death in accordance with the Emergency Use Authorization (EUA), National Institutes of Health (NIH) COVID-19 Treatment Guidelines, and 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), in accordance with the Emergency Use Authorization (EUA), National Institutes of Health (NIH) COVID-19 Treatment Guidelines, and DOH requirements.
Remdesivir (Veklury)	Remdesivir may be considered medically necessary when prescribed for adults and pediatric patients (12 years of age and older and weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome 2 (SARS-CoV-2) viral testing who are: • Hospitalized; **OR** • Not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death. Remdesivir may be considered medically necessary when prescribed for the treatment of pediatric patients weighing 3.5 kg to less than 40 kg **or** pediatric patients less than 12 years of age weighing at least 3.5 kg, in accordance with the Emergency Use Authorization (EUA), National Institutes of Health (NIH) COVID-19 Treatment Guidelines, and DOH Requirements, who are: • Hospitalized; **OR** • Not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

Nirmatrelvir+ritonavir (Paxlovid)	Nirmatrelvir+ritonavir 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 or older weighing at least 40 kg) with positive results of direct SARS-CoV-2, and who are at high risk for progression to severe COVID-19, including hospitalization or death in accordance with the Emergency Use Authorization (EUA), National Institutes of Health (NIH) COVID-19 Treatment Guidelines, and DOH requirements.
Molnupiravir	Molnupiravir may be considered medically necessary when prescribed for the treatment of mild to moderate COVID-19 in adults with positive results of direct SARS-CoV-2, and who are at high risk for progression to severe COVID-19, including hospitalization or death in accordance with the Emergency Use Authorization (EUA), National Institutes of Health (NIH) COVID-19 Treatment Guidelines, and DOH requirements.
Tixagevimab+cilgavimab (Evusheld)	Tixagevimab+cilgavimab may be considered medically necessary when prescribed for pre-exposure prophylaxis of COVID-19 in adults and pediatric patients (12 years of age or older weighing at least 40 kg), in accordance with the Emergency Use Authorization (EUA), National Institutes of Health (NIH) COVID-19 Treatment Guidelines, and DOH requirements, 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 and/or COVID-19 vaccine component(s).
Bebtelovimab	Bebtelovimab may be considered medically necessary when prescribed for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg), in accordance with the Emergency Use Authorization (EUA), National Institutes of Health (NIH) COVID-19 Treatment Guidelines, and DOH requirements, who: • Have positive results of direct SARS-CoV-2 viral testing; AND • Are at high risk for progression to severe COVID-19, including hospitalization or death; AND • Alternative COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate.

Clinical policy:

Clinical Criteria	
Mild to moderate COVID-19 at high risk for progressing to severe COVID-19 or hospitalization Bebtevolimab Casirivimab + Imdevimab Bamlanivimab + Etesevimab Molnupiravir Nirmatrelvir+ritonavir Remdesivir Sotrovimab	Healthcare providers must document in the patient's medical record that the patient/caregiver has been: 1. For products authorized under EUA, 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," "Fact Sheet for Parents and Caregivers Emergency Use Authorization (EUA) of Veklury (remdesivir) for Hospitalized Children Weighing 8 pounds (3.5 kg) to Less than 88 Pounds (40 kg) or Hospitalized Children Less than 12 Years of Age Weighing at Least 8 Pounds (3.5 kg) with Coronavirus Disease 2019 (COVID-19)," "Molnupiravir Fact Sheet for Patients, Parents and Caregivers," "Nirmatrelvir+ritonavir Fact Sheet for Patients, Parents, and Caregivers," "Fact Sheet for Patients, Parents, and Caregivers Emergency Use Authorization (EUA) of Bebtevolimab for Coronavirus Disease 2019 (COVID-19)," 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. For products authorized under EUA, informed that these medications are unapproved drugs that are authorized for use under Emergency Use Authorization; **AND** 4. For molnupiravir and bevtevolimab, alternative COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate. 5. Patient will be monitored for at least 1 hour after infusion or injection is complete.

COVID-19 in hospitalized adults and pediatric children Tocilizumab Remdesivir	Healthcare providers must document in the patient's medical record that the patient/caregiver has been: 1. For products authorized under EUA, communicated information consistent with and provided the "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) for Actemra (tocilizumab)" or "Fact Sheet for Parents and Caregivers Emergency Use Authorization (EUA) of Veklury (remdesivir) for Hospitalized Children Weighing 8 pounds (3.5 kg) to Less than 88 Pounds (40 kg) or Hospitalized Children Less than 12 Years of Age Weighing at Least 8 Pounds (3.5 kg) with Coronavirus Disease 2019 (COVID-19)" prior to administering the medication. If providing this information will delay the administration of tocilizumab or remdesivir 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 or remdesivir 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.

Pre-exposure Prophylaxis (PrEP) Tixagevimab+Cilgavimab	Healthcare providers must document in the patient's medical record that the patient/caregiver has been: 1. Communicated information consistent with and provided the "Tixagevimab+Cilgavimab 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 (EUA); **AND** 4. Patient will be monitored for at least 1 hour after injections.

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	• Adults and pediatric patients (<18 years and weighing at least 40kg): 700 mg bamlanivimab + 1400 mg etesevimab • Pediatric patients >20kg to <40kg: 350 mg bamlanivimab and 700 mg etesevimab • Pediatric patients >12 kg to 20 kg: 175 mg bamlanivimab and 350 mg etesevimab • Pediatric patients 1kg to 12kg: 12 mg/kg bamlanivimab and 24 mg/kg 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
Remdesivir	Loading dose: • 3.5 kg to less than 40 kg: 5 mg/kg • 40 kg and higher: 200 mg Maintenance: • 3.5 kg to less than 40 kg: 2.5 mg/kg • 40 kg and higher: 100 mg
Nirmatrelvir+ritonavir	• 300 mg nirmatrelvir + 100 mg ritonavir twice daily for 5 days
Molnupiravir	• 800 mg every 12 hours for 5 days
Tixagevimab+cilgavimab	• 150 mg tixagevimab + 150 mg cilgavimab
Bebtelovimab	• 175 mg bebtevolimab

Coding:

HCPCS Code	*Description*
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
Q0222	Injection, bebtevolimab, 175 mg
Q0240	Injection, casirivimab and imdevimab, 600 mg
Q0243	Injection, casirivimab and imdevimab, 2400 mg
Q0244	Injection, casirivimab and imdevimab, 1200 mg
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
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
M0222	Intravenous injection, bebtelovimab, includes injection and post administration monitoring
M0223	Intravenous injection, bebtelovimab, includes injection and post administration monitoring in the home or residence; this includes beneficiary's home that has been made provider-based to the hospital during the COVID-19 public health emergency
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
J0248	Injection, remdesivir, 1 mg when administered in an outpatient setting

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," "Tocilizumab Fact Sheet for Patients, Parents, and Caregivers," "Remdesivir Fact Sheet for Parents and Caregivers," "Nirmatrelvir+ritonavir Fact Sheet for Patients, Parents, and Caregivers," "Molnupiravir Fact Sheet for Patients, Parents, and Caregivers," "Fact Sheet for Patients, Parents, and Caregivers Emergency Use Authorization (EUA) of Bebtevolimab for Coronavirus Disease 2019 (COVID-19)," or "Tixagevimab+cilgavimab 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 or remdesivir 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, sotrovimab, Paxlovid, molnupiravir, or bebeltovimab 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 (For bamlanivimab plus etesevimab: adults and pediatric patients, including neonates), and who are at high risk for progression to severe COVID-19, including hospitalization or death, in accordance with the Emergency Use Authorization (EUA).

• 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), in accordance with the Emergency Use Authorization (EUA).

• Remdesivir is approved for adults and pediatric patients (12 years of age and older and weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome 2 (SARS-CoV-2) viral testing who are:

- Hospitalized; **OR**
- Not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

• FDA has authorized the emergency use of Remdesivir for the treatment of pediatric patients weighing 3.5 kg to less than 40 kg **or** pediatric patients less than 12 years of age weighing at least 3.5 kg, in accordance with the Emergency Use Authorization (EUA) who are:

- Hospitalized; **OR**
- Not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

• 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 who are 12 years of age and older weighing at least 40 kg (For bamlanivimab plus etesevimab: adults and pediatric patients, including neonates) who are at high risk for progression to severe COVID-19, including hospitalization or death, in accordance with the Emergency Use Authorization (EUA), 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.

• FDA has authorized the emergency use of Evusheld for pre-exposure prophylaxis of COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg), in accordance with the Emergency Use Authorization (EUA), and:

- 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).

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

• The significant known and potential risks and benefits of casirivimab plus imdevimab, bamlanivimab + etesevimab, sotrovimab, tocilizumab, Paxlovid, molnupiravir, bebtelovimab, and Evusheld 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, sotrovimab, remdesivir, Paxlovid, molnupiravir or bebtelovimab 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 Healthcare Providers Emergency Use Authorization (EUA) of Sotrovimab," "Fact Sheet for Healthcare Providers Emergency Use Authorization (EUA) for Tocilizumab," "Fact Sheet for Health Care Providers Emergency Use Authorization of Veklury (remdesivir)," "Fact Sheet for Healthcare Providers Emergency Use Authorization (EUA) for Paxlovid," "Fact Sheet for Healthcare Providers Emergency Use Authorization (EUA) for Molnupiravir," "Fact Sheet for Health Care Providers: Emergency Use Authorization for Bebtelovimab," or "Fact Sheet for Healthcare Providers Emergency Use Authorization (EUA) for Evusheld (tixagevimab co-packaged with cilgavimab)" 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 in individuals for whom COVID-19 vaccination is recommended.

   • Pre-exposure prophylaxis with Evusheld is **NOT** a substitute for vaccination against COVID-19 in individuals for whom COVID-19 vaccination is recommended.

   • 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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15. Fact Sheet for Patients, Parents, and Caregivers Emergency Use Authorization (EUA) of Tocilizumab for the Treatment of Coronavirus Disease 2019 (COVID-19). https://www.fda.gov/media/150320/download. Accessed 1/4/2022.
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History

Date	Action and Summary of Changes
2/24/2022	Updating policy to include: • Updated FDA label for bebtelovimab
1/28/2022	Updating policy to include: • Updated FDA label for remdesivir Updated EUA for remdesivir

1/18/2022	Updating policy to include: • Use of Paxlovid and molnupiravir for mild to moderate COVID-19. • Use of Evusheld for pre-exposure prophylaxis. • Use of remdesivir for hospitalized patients with suspected or laboratory confirmed COVID-19. • Use of remdesivir for non-hospitalized patients from recent NIH treatment guidelines. Updated: • Hyperlinks, provider requirements, and HCPCS codes. • Bamlanivimab+etesevimab dosing. Title of policy from "Monoclonal antibody for treatment of COVID-19" to "Therapies for COVID-19".
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