Monoclonal Antibodies for the Treatment of COVID-19 for Utah Medicaid Members: Frequently Asked Questions (FAQs)

Utah Medicaid is committed to ensuring our members continue to receive products and services without interruptions or delays due to the novel coronavirus (COVID-19) outbreak. In response, Utah Medicaid is temporarily modifying certain policies. Providers are expected to provide only medically necessary services. All services rendered may be subject to post-payment review.

In November 2020, the U.S. Food and Drug Administration (FDA) issued emergency use authorizations for the investigational monoclonal antibody therapies, bamlanivimab and casirivimab, in combination with imdevimab for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients who are 12 years of age and older, weighing at least 40 kilograms (about 88 pounds), with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization. [1,2,6,9]

What is Emergency Use Authorization (EUA)?

Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological or nuclear (CBRN) threat agents when there are no adequate, approved, and available alternatives.[3]

Is there any FDA-approved treatment for COVID-19?

At the time of publication of this document remdesivir is the only FDA-approved treatment for COVID-19 for use in adult and pediatric patients 12 years of age and older and weighing at least 40 kilograms (about 88 pounds) for the treatment of COVID-19 requiring hospitalization.[4]

What is the definition of high risk for progressing to severe COVID-19?

High risk is defined as patients who meet at least one of the following criteria: [2,6]

- Have a body mass index (BMI) ≥ 35
- Have a chronic kidney disease
- Have diabetes
- Have an immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥ 65 years of age
- Are ≥ 55 years of age AND have:
  - Cardiovascular disease, OR
  - Hypertension, OR
  - Chronic obstructive pulmonary disease/other chronic respiratory disease
- Are 12-17 years of age AND have:

- BMI ≥ 85th percentile for their age and gender based on CDC growth charts, OR
- Sickle cell disease, OR
- Congenital or acquired heart disease, OR
- Neurodevelopmental disorders (e.g., cerebral palsy), OR
- A medical-related technological dependence (e.g., tracheostomy, gastrostomy, or positive pressure ventilation - not related to COVID-19), OR
- Asthma, reactive airway, or other chronic respiratory disease that requires daily medication for control

What are the limitations on bamlanivimab, casirivimab and imdevimab authorized use?

Benefits have not been assessed and is not authorized for use in patients who are: [2,6]

- Hospitalized due to COVID-19, OR
- Require oxygen therapy due to COVID-19, OR
- Require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity, OR
- Weigh less than 40 kg

How is bamlanivimab administered? What is the recommended dosing?

Providers can administer diluted bamlanivimab 700 mg once via intravenous (IV) infusion over at least 60 minutes via pump or gravity. Bamlanivimab should be administered as soon as possible after positive results of direct SARS-CoV-2 viral testing and within 10 days of symptom onset. [2]

No dosage adjustment is recommended based on age, sex, race, body weight, renal, or hepatic impairement. [2]

How is casirivimab and imdevmab administered? What is the recommended dosing?

Providers can administer diluted 1,200 mg of casirivimab and 1,200 mg of imdevimab together as a single intravenous (IV) infusion over at least 60 minutes via pump or gravity. Casirivimab and imdevimab should be administered as soon as possible after positive results of direct SARS-CoV-2 viral testing and within 10 days of symptom onset.[6]

No dosage adjustment is recommended based on age, sex, race, body weight, renal, or hepatic impairement.[6]

What are the side effects of bamlanivimab, casirivimab and imdevimab?

Most common side effects of bamlanivimab include nausea, diarrhea, dizziness, headache, pruritus, and vomiting. Most common side effects of casirivimab and imdevimab are infusion-related reactions and hypersensitivity reactions.

Severe hypersensitivity events were reported during clinical trials of these monoclonal antibodies. It is recommended to monitor patients during infusion and observe patients for at least 1 hour after infusion completion.[2,6]

Studies for bamlanivimab, casirivimab and imdevimab are ongoing. Therefore, not all the risks are known at this time. The completion of the FDA MedWatch Form to report all medication errors and adverse events occurring during bamlanivimab, casirivimab and imdivimab treatment is mandatory.[2,6]

Providers can find more information about the side effects on the Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) for:

- Bamlanivimab at: https://www.fda.gov/media/143603/download
- Casirivimab and imdevimab at: https://www.fda.gov/media/143892/download

What are potential drug-drug interactions with bamlanivimab, casirivimab and imdevimab?

Bamlanivimab, casirivimab and imdevimab are not renally excreted or metabolized by the cytochrome P450 enzyme. Drug-drug interactions with concomitant medications that are renally excreted or hepatically metabolized are unlikely.[2,6]

Can pregnant women receive bamlanivimab, casirivimab and imdevimab?

There is not sufficient data of bamlanivimab, casirivimab and imdevimab use in pregnant women. Human immunoglobulin G1 (IgG1) antibodies are known to cross the placental barrier. Monoclonal antibodies have the potential to be transferred from the mother to the developing fetus with unknown benefit and risk. Pregnant women should receive bamlanivimab, or casirivimab and imdevimab only if the potential benefit justifies the potential risk for the mother and the fetus.[2,6]

Can bamlanivimab, casirivimab and imdevimab be used in the pediatric population?

The safety and effectiveness of bamlanivimab, casirivimab and imdevimab have not been assessed in pediatric patients. They are FDA-approved in patients 12 years and older and weighing at least 40 kg.[2,6]

Can bamlanivimab, casirivimab and imdevimab be used in the geriatric population?

Bamlanivimab, casirivimab and imdevimab can be used in geriatric population, as they have been studied in patients 65 years and older. There was no difference in pharmacokinetics in geriatric patients compared to younger patients.[2,6]

How should bamlanivimab, casirivimab and imdevimab be stored?

Bamlanivimab injection is a sterile, preservative-free solution supplied as a single-dose vial. Providers need to discard any unused portion.

Casirivimab and imdevimab are also sterile, preservative-free solutions supplied as single-dose vials. Providers need to discard any unused portion.

Any unopened vials should be stored in the original carton in a refrigerator at 2 to 8 degrees Celsius (36 to 45 degrees Fahrenheit). Do not freeze, shake, or expose the vials to direct light.[2,6]

What should patients do after receiving bamlanivimab, or casirivimab and imdevimab?

Patients treated with bamlanivimab or casirivimab and imdevimab should continue to self-isolate and use infection control measures such as wearing masks, social distancing, avoid sharing personal items, etc., according to CDC guidelines.[2]
Patients and caregivers can find more information on this Fact Sheet for Patients, Parents and Caregiver Emergency Use Authorization (EUA) of:

- Bamlanivimab for Coronavirus Disease 2019 (COVID-19)[7]
- Casirivimab and imdevimab for Coronavirus Disease 2019 (COVID-19)[8]

Does Utah Medicaid cover bamlanivimab, casirivimab and imdevimab? What is the billing pathway?

Though unapproved investigational drugs bamalnivimab, casirivimab and imdevimab are qualified as prescribed drugs under 42 C.F.R. § 440.120.[1]
Pharmacies can bill bamlanivimab to Utah Medicaid through the Point-of-Sale system. Bamlanivimab can also be submitted using HCPCS M0239 for the administration fee and Q0239 for following NDC:[2,5]

- Bamlanivimab injection 700mg/20ml (35 mg/ml): 0002-7910-01

Pharmacies can bill casirivimab and imdevimab to Utah Medicaid through the Point-of-Sale system. Casirivimab and imdevimab can also be submitted using HCPCS M0243 for the administration fee, and Q0243 for following NDC:[5,6]

- Casirivimab 1332 mg/11.1 ml (120 mg/ml): 61755-024-01
- Casirivimab 300 mg/2.5 ml (120 mg/ml): 61755-026-01
- Imdevimab 1332 mg/11.1 ml (120 mg/ml): 61755-025-01
- Imdevimab 300 mg/2.5 ml (120 mg/ml): 61755-027-01

For more information, please visit: https://coronavirus.utah.gov/noveltherapeutics/.

References:

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