Dosage and Administration

Dosage of bebtelovimab in adults and pediatric patients (≥12 years of age and weighing at least 40 kg [88 lbs]) is 175 mg/2 mL. The medication should be administered as soon as possible after positive results of SARS-CoV-2 viral testing and within 7 days of symptom onset. The medication is administered as a single intravenous injection over at least 30 seconds. After the entire contents of the syringe has been administered, flush the injection line with 0.9% sodium chloride to ensure delivery of the required dose.

No dosage adjustment is recommended in pregnant or lactating individuals, geriatrics, individuals with renal impairment, or individuals with mild hepatic impairment. Bebtelovimab is not renally excreted or metabolized by the cytochrome P450 enzymes; therefore, interactions with concomitant medications that are renally excreted or that are substrates, inducers, or inhibitors of cytochrome P450 enzymes are unlikely. Bebtelovimab is clear to opalescent and colorless to slightly yellow to slightly brown solution. Do not shake the vial. Discard the vial if the solution is cloudy, discolored, or visible particles observed. Bebtelovimab should be allowed to equilibrate to room temperature for 20 minutes prior to use. The product is preservative-free. If immediate administration is not possible, the syringe can be stored up to 24 hours at refrigerated temperatures (2 °C to 8 °C [36 °F to 46 °F]).

Patients should be observed (waiting room acceptable) for 1 hour post-treatment.

Indications

Specific indications for bebtelovimab therapy include the following: (1) positive results (antigen or PCR) of direct SARS-CoV-2 viral testing within 7 days of symptom onset; (2) high risk of progression to severe COVID-19, including hospitalization or death (i.e., type 2 diabetes, obesity, hypertension); (3) authorized alternative COVID-19 treatments are not accessible or clinically appropriate.

Bebtelovimab is not authorized for use in patients hospitalized or requiring additional oxygen support from baseline requirements. Monoclonal antibodies such as bebtelovimab may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high-flow oxygen or mechanical ventilation.
Data supporting the EUA for bebtelovimab was based on the Phase 2 portion of the BLAZE-4 trial with both low- and high-risk subjects receiving 175 mg bebtelovimab alone or together with 700 mg bamlanivimab and 1400 mg etesevimab. The study was conducted prior to the emergence of the Omicron variant. Primary endpoint was the proportion with persistently high viral load (PHVL) by day 7 and was reduced from 21% with placebo to 14% in subjects treated with bebtelovimab 175 mg alone, a 34% (95% CI) relative reduction. The median time to sustained symptom resolution for subjects treated with betelovimab was 6 days compared to 8 days for the placebo group.

Based on the data from Blaze-4, bebtelovimab has been shown to improve symptoms and reduce viral load on day 5 in patients with mild-to-moderate COVID-19 and may be effective for the treatment of patients with mild-to-moderate COVID-19.