BEBTELOVIMAB INFORMATIONAL SHEET SUMMARY

LIVE WELL SAN DIEGO

Monoclonal Antibody for Treatment of COVID-19

A Prescription Guide for Providers

The U.S. Food and Drug Administration (FDA) issued Emergency Use Authorization (EUA) of intravenous bebtelovimab monoclonal antibody 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 [88 lbs]). Bebtelovimab is a human immunoglobulin G1 (IgG1 variant) monoclonal antibody composed of 449 amino acids produced by a cell culture or cell line. Bebtelovimab binds the spike protein of SARS-CoV-2 virus and blocks attachment to the human ACE2 receptor. Of significance, bebtelovimab is active against the BA.2 Omicron variant.

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. Bebtalovimab 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 ºC to 8 ºC [36 ºF to 46 ºF]).

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**.

Betelovimab 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.

Efficacy

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.

Additional Information & Resources

	Summary	Links
Pregnancy and Reproductive Health 	• There are insufficient data to evaluate the drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Bebtelovimab should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and fetus. • There is no available data on the presence of bebtelovimab in human or animal milk, the effects on the breastfed infants, or the effects on milk production. Maternal IgG is known to be present in human milk.	Healthcare Provider Fact Sheet
Efficacy 	• Blaze-4 Trial bebtelovimab group had a 34% relative reduction in persistently high viral load. • Rates of patients hospitalized was the same in treatment group and placebo (1.6%). • Symptomatic improvement in 6 days compared to 8 with placebo.	Blaze-4 Trial
Adverse Reactions	Slower administration over 1-2 minutes may lessen side effects of nausea, vomiting, chest pain, diaphoresis, difficulty breathing, pruritis, rash, potential myalgias and more serious infusion related hypersensitivity reactions. An FDA form 3500 is required for serious adverse events or medication errors. Infusion-related reactions may occur up to 24 hours post-injection.	Healthcare Provider Fact Sheet FDA Form 3500
Fact Sheet for Prescribers	**FDA Emergency Use Authorization for Bebtelovimab**	Healthcare Provider Fact Sheet
Fact Sheet for Patients/ Caregivers	**FDA Fact Sheet for Patient, Parents, and Caregivers**	FDA Fact Sheet (Spanish)
NIH Guidelines	**NIH Summary Recommendations for Prevention of SARS-CoV-2 Infection**	NIH Treatment Guidelines