

Zinplava™ (bezlotoxumab)

When requesting Zinplava™ (bezlotoxumab), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Zinplava is indicated to reduce recurrence of *Clostridioides difficile* infection (CDI) in adults and pediatric patients 1 year of age and older who are receiving antibacterial drug treatment for CDI and are at a high risk for CDI recurrence.

Coverage Guidelines

Clostridioides difficile infection

The individual must meet **all** of the following criteria for approval:

- Is currently receiving antibacterial drug treatment for *Clostridioides difficile* infection;
- Is at high risk for *Clostridioides difficile* infection recurrence;
- Has not previously received bezlotoxumab.

Approval duration: One dose

Dosing Recommendations

The recommended dosage is a single dose of 10 mg/kg administered as an intravenous infusion over 60 minutes. The safety and efficacy of repeat administration of Zinplava in patients with CDI have not been studied.

References

1. Zinplava™ prescribing information. Whitehouse Station, NJ: Merck and Company, Inc. May 2023.
2. Wilcox MH, Gerding DN, et al. Bezlotoxumab for Prevention of Recurrent *Clostridium difficile* Infection; *N Engl J Med*. 2017; 376:305-317.
3. McDonald LC, Gerding DN, et al. Clinical Practice Guidelines for *Clostridium difficile* Infection in Adults and Children: 2017 Update by the IDSA and SHEA. *Clin Infect Dis*. 2018; Volume 66, Issue 7:987-994.
4. Bezlotoxumab (Zinplava®). Lexi-Drugs. Wolters Kluwer Health, Inc. Riverwoods, IL. [Updated; April 15, 2024; Accessed June 28, 2024].
5. Bezlotoxumab (Zinplava®). DRUGDEX® System. Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com>. Accessed: June 28, 2024.
6. Johnson S, Lavergne V, Skinner AM, et al. Clinical Practice Guidelines by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of *Clostridioides difficile* Infection in Adults. *Clin Infect Dis*. 2021. [published online] June 2021. Accessed on June 28, 2024.