

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

To reduce the recurrence of *Clostridium difficile* infection (CDI) in individuals who are receiving antibacterial drug treatment for CDI and are at a high risk for CDI recurrence.

Coverage Guidelines

Clostridium difficile infection

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

- Receiving antibacterial drug treatment for *Clostridium difficile* infection;
- At high risk for *Clostridium difficile* infection recurrence; AND
- Has **not** previously received bezlotoxumab.

Approval duration: 1 dose

Dosing Recommendations

Approve up to a maximum dose of 10mg per kilogram, administered intravenously, once.

References

1. Zinplava™ prescribing information. Whitehouse Station, NJ: Merck and Company, Inc: Revised October 2016. [Accessed September 13, 2019].
2. Bezlotoxumab (Zinplava®). In: DRUGDEX® (electronic version) System Micromedex. Greenwood Village, CO. Revised August 22, 2018. [Accessed September 16, 2019].
3. Bezlotoxumab (Zinplava®). In: AHFS Drug Information Online Electronic Medical Library. Bethesda, Maryland: American Society of Health-System Pharmacists. Revised 8/8/2019. [Accessed September 16, 2019].
4. Wilcox MH, Gerding DN, et al. Bezlotoxumab for Prevention of Recurrent *Clostridium difficile* Infection; *N Engl J Med*. 2017; 376:305-317.
5. 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.