

Zinplava (bezlotoxumab)

Override(s)	Approval Duration
Prior Authorization	One time approval for one injection per authorization request

Medications
Zinplava (bezlotoxumab) 25 mg/mL intravenous solution for injection

APPROVAL CRITERIA

Requests for Zinplava (bezlotoxumab) may be approved if the following criteria are met:

- I. Individual has a *Clostridioides difficile* infection demonstrated by:
 - A. Passage of three or more loose stools within 24 hours or less; **AND**
 - B. Positive stool test for toxigenic *Clostridioides difficile* from a stool sample collected no more than 7 days prior to scheduled infusion; **AND**
 - II. Individual is currently receiving antibacterial therapy for *Clostridioides difficile* infection (including Difcid, metronidazole, or oral vancomycin;
- AND**
- III. Individual is at high risk of *Clostridioides difficile* infection recurrence meeting any one of the following:
 - A. 65 years of age or older; **OR**
 - B. History of *Clostridioides difficile* infection in the past 6 months; **OR**
 - C. Immunocompromised state; **OR**
 - D. Severe *Clostridioides difficile* infection at presentation*; **OR**
 - E. *Clostridioides difficile* ribotype 027.

***Note:** Severe *Clostridioides difficile* infection can be defined by one of the following:

- I. Infectious Disease Society of America (IDSA) definition (IDSA, 2017):
 - A. WBC $\geq 15,000$ cells/mL OR serum creatinine level >1.5 mg/dL;
- OR**
- II. ZAR score ≥ 2 (Zar, 2007):
 - A. Age >60 years old = 1 point;
 - B. Body temperature $>38.3^{\circ}\text{C}$ ($>100.9^{\circ}\text{F}$) = 1 point;
 - C. Albumin level <2.5 mg/dL = 1 point;
 - D. Peripheral white blood cell count $>15,000$ cells/mm³ within 48 hours = 1 point;
 - E. Endoscopic evidence of pseudomembranous colitis = 2 points
 - F. Treatment in Intensive Care Unit (ICU) = 2 points.

Zinplava (bezlotoxumab) may not be approved for the following:

- I. First-line treatment for *Clostridioides difficile* infection; **OR**

- II. Use in combination with Rebyota or Vowst during the same *Clostridioides difficile* infection episode; **OR**
- III. May not be approved when the above criteria are not met and for all other indications.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 10, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. 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;73(5):1029-1044.
4. Kelly CP, Lamont JT, Bakken JS. *Clostridioides difficile* infection in adults: Treatment and prevention. Updated: May 11, 2023. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: September 10, 2023.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
6. McDonald LC, Gerding DN, Johnson S, et al. Clinical Practice Guidelines for *Clostridium difficile* Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). *Clin Infect Dis*. 2018;66(7):987-994.
7. Wilcox MH, Gerding DN, Poxton IR, et al. Bezlotoxumab for the prevention of recurrent *Clostridium difficile* infection. *N Eng J Med*. 2017; 376(4):305-317.
8. Zar FA, Bakkanagari SR, et al. A comparison of vancomycin and metronidazole for the treatment of *Clostridium difficile*-associated diarrhea, stratified by disease severity. *Clin Infect Dis*. 2007; 45(3):302-307.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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