



## **MVP Health Care Medical Policy**

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### **Medicare Part B: Zinplava (bezlotoxumab)**

**Type of Policy:** **Drug Therapy**

**Prior Approval Date:** **01/01/2025**

**Approval Date:** **12/01/2025**

**Effective Date:** **02/01/2026**

**Related Policies:** **C. Difficile Drug Therapy**

**Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.**

**Refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available.**

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#### **Codes Requiring Prior Authorization (covered under the medical benefit)**

J0565 Zinplava (injection, bezlotoxumab 10mg)

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#### **Overview/Summary of Evidence**

C. difficile is the most common cause of infectious diarrhea in hospitalized members. About 1/3 of members have recurrent C. difficile infection (CDI) after completing their initial antibiotic therapy. Recurrent C. difficile is more difficult to treat and leads to more severe outcomes and greater treatment costs.

Zinplava is a human monoclonal antibody that is indicated to reduce recurrence of C. difficile infection (CDI) in adult and pediatric members 1 year and older who are receiving antibacterial therapy and are at a high risk for CDI recurrence. Zinplava is not an

antibacterial drug and should not be used as monotherapy. It is meant to be used in combination with standard C. Difficile treatment. It works by binding and neutralizing the effect of C. difficile toxin B.

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## **Indications/Criteria**

- Prescribed by or in consultation with infectious disease or gastroenterologist
- Member must be diagnosed with C-difficile
  - defined as diarrhea ( $\geq 3$  unformed bowel movements [5 to 7 on the Bristol stool scale] in 24hrs)
  - stool test result that was positive for toxigenic C. difficile
- Member should be receiving standard C. diff therapy (vancomycin, fidaxomicin (preferred therapy), or metronidazole)
- Must be at high risk of CDI recurrence or at high risk for CDI-related adverse outcome as defined by having **at least one** of the following risk factors:
  - Age  $\geq 65$
  - Prior episode of C. difficile Infection within the past 6 months
  - Clinically severe C. difficile infection (Zar Score of greater than or equal to 2)
  - Immunocompromised state
  - Disease states that represent an increased risk such as solid organ transplant, stem cell transplant, chronic kidney disease, end stage renal disease, Inflammatory Bowel Disease, cancer
  - Prolonged antibiotic therapy
- If the member has a history of congestive heart failure (CHF), the provider must attest that the benefits outweigh the risk.

**Initial coverage** will be for a **single dose** of 10mg/kg IV infused over 60 minutes.

**Requests for continuation: see exclusions**

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## **Exclusions**

- Any repeat dose is considered experimental or investigational

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.
- Zinplava monotherapy used to treat C-difficile infection
  - Must be used in conjunction with antibacterial drug treatment for CDI
- Combined with fecal transplantation

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## References

1. Wilcox M.H. Poxton. I.R et al. Bezlotoxumab for Prevention of Recurrent Clostridium difficile Infection. *The New England Journal of Medicine*. January 2017; 376: 306-17 Available at :  
<http://www.nejm.org/doi/pdf/10.1056/NEJMoa1602615>
2. Zinplava (Bezlotoxumab) Injection. Prescribing Information. Whitehouse Station, NJ: Merck Co.INC ; 2016. Revised May 2023.
3. McDonald, L.C., Gerdin D., et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Disease Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). *Clinical Infectious Diseases*, Volume 66, Issue 7; March 2018; e1-e48. Available at: <https://academic.oup.com/cid/article/66/7/e1/4855916>
4. Infectious Disease Society of America. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America. *Clinical Infectious Diseases*, Volume 66, Issue 7. April 2018; pages e1-e48. Available at: [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 \(SHEA\) \(idsociety.org\)](https://www.idsociety.org/guidelines/clostridium-difficile-infection-adults-children-2017)
5. Stuart Johnson, Valéry Lavergne, Andrew M Skinner. Clinical Infectious Diseases. Clinical Practice Guidelines for the Management of Clostridioides difficile Infection in Adults: 2021 Update by SHEA/IDSA. Published 06/14/2021