MVP Health Care Medical Policy

Medicare Part B: Zinplava (bezlotoxumab)

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**N/A**
Approval Date:	**1/01/2024**
Effective Date:	**01/01/2024**
Related Policies:	**C. Difficile Drug Therapy**

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

Codes Requiring Prior Authorization (covered under the medical benefit)

J0565 Zinplava (injection, bezlotoxumab 10mg)

Overview/Summary of Evidence

C. difficile is the most common cause of infectious diarrhea in hospitalized patients. About 1/3 of patients 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 patients 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.

Indications/Criteria

- Prescribed by or in consultation with infectious disease or gastroenterologist
- Patient must be diagnosed with C-difficile
    - defined as diarrhea (≥3 unformed bowel movements [5 to 7 on the Bristol stool scale] in 24hrs)
    - stool test result that was positive for toxigenic C. difficile
- Patient should be receiving standard C. diff therapy (vancomycin, fidoxomicin, 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 ≥ 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 patient has a history of congestive heart failure (CHF), the provider must acknowledge that the benefits outweigh the risk.
- Zinplava single dose of 10mg/kg IV infused over 60 minutes

Exclusions

- Any repeat dose is considered experimental or investigational
- Dose or duration outside of the FDA approved package label
- Zinplava monotherapy used to treat C-difficile infection (Zinplava should only be used in conjunction with antibacterial drug treatment for CDI)
- Combined with fecal transplantation

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., Gerding 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)