PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Zinplava (bezlotoxumab)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Zinplava is a human monoclonal antibody indicated to reduce recurrence of *Clostridioides difficile* infection (CDI) in patients 18 years and older who are receiving standard of care antibacterial treatment for CDI and are at high risk for CDI recurrence. Zinplava acts by binding to *C. difficile* toxin B and neutralizing its effects. Zinplava is administered as a one-time 60-minute intravenous infusion during antibacterial treatment for CDI.

Zinplava (bezlotoxumab) will be considered for coverage when the following criteria are met:

Reduce recurrence of *Clostridioides difficile* infection (CDI)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication is prescribed by or in consultation with a gastroenterologist or infectious disease specialist; AND
3. Member has documentation of 3 or more loose stools or liquid stools within 24 hours; AND
4. Member has a positive stool test for the presence of *Clostridioides difficile* within the past 7 days; AND
5. Member is receiving standard of care antibacterial drug treatment for CDI (i.e., vancomycin, fidaxomicin, or metronidazole); AND
6. Member will receive Zinplava (bezlotoxumab) before completing antibacterial treatment for CDI; AND
7. Member meets one or more of the following criteria:
    a. Member has documentation of one or more CDI episodes within the last 6 months in addition to the current episode
    b. Member is ≥ 65 years of age
    c. Member is immunocompromised (i.e., history or use of immunosuppressive therapy)
    d. Member has documentation of severe CDI (i.e., WBC > 15,000 cells/mL or serum creatinine ≥ 1.5 mg/dL); AND
8. **Dosage allowed/Quantity limit**: Administer a single dose of 10 mg/kg during antibacterial treatment for CDI.

If all the above requirements are met, one dose of the medication will be approved.

For **reauthorization**:

1. Medication will not be reauthorized.

CareSource considers Zinplava (bezlotoxumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
04/25/2023	New policy for Zinplava created.

References:

1. Zinplava. Package Insert, Merck & Co. Inc.; 2016. Accessed April 25, 2023.
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3. Wilcox MH, Gerding DN, Poxton IR, et al. Bezlotoxumab for Prevention of Recurrent Clostridium difficile Infection. N Engl J Med. 2017;376(4):305-317. doi:10.1056/NEJMoa1602615
4. Gerding DN, Kelly CP, Rahav G, et al. Bezlotoxumab for Prevention of Recurrent Clostridium difficile Infection in Patients at Increased Risk for Recurrence. Clin Infect Dis. 2018;67(5):649-656. doi:10.1093/cid/ciy171
5. de la Villa S, Herrero S, Muñoz P, et al. Real-world Use of Bezlotoxumab and Fecal Microbiota Transplantation for the Treatment of Clostridioides difficile Infection. Open Forum Infect Dis. 2023;10(2):ofad028. Published 2023 Jan 25. doi:10.1093/ofid/ofad028
6. Birch T, Golan Y, Rizzardini G, et al. Efficacy of bezlotoxumab based on timing of administration relative to start of antibacterial therapy for Clostridium difficile infection. J Antimicrob Chemother. 2018;73(9):2524-2528. doi:10.1093/jac/dky182
7. Basu A, Prabhu VS, Dorr MB, et al. Bezlotoxumab Is Associated With a Reduction in Cumulative Inpatient-Days: Analysis of the Hospitalization Data From the MODIFY I and II Clinical Trials. Open Forum Infect Dis. 2018;5(11):ofy218. Published 2018 Nov 15. doi:10.1093/ofid/ofy218
8. Kelly CR, Fischer M, Allegretti JR, et al. ACG Clinical Guidelines: Prevention, Diagnosis, and Treatment of Clostridioides difficile Infections [published correction appears in Am J Gastroenterol. 2022 Feb 1;117(2):358]. Am J Gastroenterol. 2021;116(6):1124-1147. doi:10.14309/ajg.0000000000001278

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