



Montana Healthcare Programs
Physician-Administered Drug Coverage Criteria

ZINPLAVA® (bezlotoxumab)

I. Medication Description

Zinplava® is a human monoclonal antibody that binds to *Clostridium difficile* toxin B that is indicated to:

- Reduce recurrence of *Clostridium difficile* infection (CDI) in patients 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at high risk for CDI recurrence

II. Position Statement

Coverage is determined through a prior authorization process **that must include** supporting clinical documentation for each request.

III. Initial Coverage Criteria

Member must meet all the following criteria:

- Zinplava™ is being prescribed by a gastroenterology or infectious disease specialist.
- Member is 18 years of age or older.
- Member has a confirmed diagnosis of CDI, defined as diarrhea (passage of 3 or more loose bowel movements in 24 or fewer hours) and a positive stool test for toxigenic *Clostridium difficile* (*C. difficile*) from a stool sample collected within the past 7 days.
- Member is receiving concomitant standard of care antibacterial drugs for treatment of CDI (metronidazole, vancomycin or fidaxomicin).
- Member has no history of congestive heart failure (CHF) or provider states benefit outweighs risk.
- Member is at a high risk for CDI recurrence, defined as **any** of the following:
 - Age of 65 years or older
 - History of CDI in the past 6 months
 - Immunocompromised state
 - Hypervirulent strain of *C. difficile* (ribotypes 027, 078, or 244)
 - Clinically severe CDI at presentation (Zar score ≥ 2)
 - Zar score ≥ 2 points:
 - Age >60 years old (1 point)
 - Body temperature $>38.3^{\circ}\text{C}$ ($>100^{\circ}\text{F}$) (1 point)
 - Albumin level <2.5 mg/dl (1 point)
 - Peripheral WBC count $>15,000$ cells/mm³ (1 point)
 - Endoscopic evidence of pseudomembranous colitis (2 points)
 - Treatment in intensive care unit (2 points)

IV. Renewal Coverage Criteria

Zinplava™ is only indicated as a single infusion. Subsequent doses will not be approved.

V. Quantity Limitations

Max of 10 mg/kg IV over 60 minutes as a single infusion.

VI. Coverage Duration

Initial approval duration: one single infusion

Renewal approval duration: N/A