

MONTANA HEALTHCARE PROGRAMS
Prior Authorization Criteria

Version 1, 12-17-17

Zinplava (bezlotoxumab)

Zinplava is a human monoclonal antibody

Indications¹, Zinplava is used for:

Reducing the 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 a high risk for CDI recurrence

Criteria for Approval¹:

- A) Member has a confirmed diagnosis of CDI defined as diarrhea and a positive stool test for toxigenic *C. difficile* from a stool sample collected within the past 7 days.
- B) Member is receiving concomitant standard of care antibacterial drugs (metronidazole, vancomycin, or fidaxomicin)
- C) Member is at high risk for CDI recurrence. Risk factors include age of 65 years or older, history of CDI in the past 6 months, immunocompromised state, severe CDI at presentation, or *C. difficile* ribotype 027.
- D) Member is 18 years of age or older
- E) Member is not pregnant or breastfeeding
- E) Member has no history of CHF or provider states that benefit outweighs the risk.

Administration

Zinplava is administered by intravenous infusion over 60 minutes

Quantity Limit:

A single dose of 10mg/kg

Subsequent doses will not be approved. The safety and efficacy of repeat administration of Zinplava have not been studied

References:

1. Zinplava [package insert]. Whitehouse Station, NJ: Merck & Co.,Inc.; 10/2016, Accessed December 13, 2017.