MONTANA HEALTHCARE PROGRAMS
Prior Authorization Criteria

Version 1, 12-17-17

Zinplava® (bezlotoxumab)

Zinplava is a human monoclonal antibody

Indications[1], 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 Approval[1]:

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.