

**SOUTH DAKOTA MEDICAID
PRIOR AUTHORIZATION CRITERIA**

Physician Administered Drugs, Vaccines, and Immunizations

Bezlotoxumab (Zinplava)– PA Criteria

HCPC: J0565

Zinplava is a fully human, monoclonal antibody indicated for the secondary prevention of *Clostridioides difficile* infection (CDI) in adults and pediatric patients who are one year of age and older. It is covered by South Dakota Medicaid following prior authorization when the patient meets the following criteria:

****Retrospective authorization will be accepted for this medication (when all below criteria are met) in efforts to prevent delay of care if the patient is hospitalized during CDI treatment****

- **Initial Therapy (must meet all):**
 - The recipient is \geq 12 months of age
 - Therapy is prescribed by or in consultation with a gastroenterologist or infectious disease specialist
 - The recipient has a confirmed diagnosis of CDI as evidenced by **both** of the following:
 - Passage of 3 or more loose bowel movements in 24 or fewer hours
 - A positive stool test for toxigenic *Clostridium difficile* collected no more than 10 days prior to scheduled infusion
 - The recipient is starting or is currently receiving appropriate antibiotic treatment for CDI for at least 10 days
 - Zinplava will be administered during antibacterial drug treatment for recipient's CDI
 - The recipient meets therapy qualifications as evidenced by **one** of the following classifications:
 - Recipient has had one or more previous CDIs requiring treatment in the past 6 months
 - Recipient is \geq 65 years of age
 - Recipient is immunocompromised
 - Severe CDI (WBC $>$ 15,000 cells/mL OR Serum creatinine \geq 1.5 mg/dL)
 - Approval duration: 1 dose
- **Continuation of Therapy: not authorized**