SmartHealth

Ascension

Bezlotoxumab

(Zinplava®) J0565

Covered with prior authorization

Bezlotoxumab (Zinplava®) may be authorized when the following criteria are met:

- Individual has a Clostridiodes difficile infection (CDI) confirmed by:
    - Passage of three or more loose stools within 24 or fewer consecutive hours; **AND** Positive stool test for toxigenic Clostridiodes difficile from a stool sample collected no more than 14 days prior to scheduled infusion; **AND**
- Individual is currently receiving antibacterial therapy for CDI (standard of care 14 days therapy); **AND**
- Individual is at high risk of CDI recurrence meeting any **one** of the following:
    - 65 years of age or older; **OR**
    - History of CDI in the past 6 months; **OR**
    - Immunocompromised state; **OR**
    - Severe CDI at presentation; **OR**
    - Clostridiodes difficile ribotype 027; **AND**
- Individual >18 years of age; **AND**
- Dosing is 10mg/kg IV **once** up to day 14 of standard of care (SOC) antibiotic therapy.

Exclusion criteria:

- Individuals outside the 14 day standard of care antibiotic therapy for recent CDI;
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk;
- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.

Initial authorization is limited to one dose.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Clinical documentation provided must be from within the most recent 12 months.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage

Developed by: Medical Specialty Prior Authorization Team, April 2022
Approved by: Ambulatory Care Expert Review Panel, April 2022; Therapeutic Affinity Group, May 2022

Zinplava® is a human monoclonal antibody that binds to Clostridium difficile toxin B, 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 a high risk for CDI recurrence

References:

Ascension. (2021, November). *CDI Management SBAR*. Ascension TAG INITIATIVES - PSWP

Johnson, S., & Laverge, V. (2021, June 14). *Clinical Practice Guideline by the Infectious Diseases Society of America*. IDSA. Retrieved April 22, 2022, from https://www.idsociety.org/practice-guideline/clostridioides-difficile-2021-focused-update/

Zinplava® (bezlotoxumab) label. (2016, October). Accessdata.fda.gov. Retrieved April 22, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/761046s000lbl.pdf

Criteria History/ Revision Information:

Date	Summary of Changes
2018	Approved by Therapeutic Affinity Group
October 2021	Revision Ascension Management of CDI SBAR
November 2021	Approved by Therapeutic Affinity Group
April 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
May 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.