Clinical Policy Title:	bezlotoxumab
Policy Number:	RxA.330
Drug(s) Applied:	Zinplava™
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Clostridium difficile Infection (must meet all):

1. Diagnosis of CDI confirmed by documentation of positive Clostridium difficile test;
2. Age ≥ 1 years;
3. Member will receive or is currently receiving concomitant antibacterial drug treatment for CDI (e.g., metronidazole, vancomycin, fidaxomicin);
4. Member has had at least one episode of CDI recurrence (total 2 episodes) in the previous 6 months and has been treated with appropriate treatment for CDI (e.g., metronidazole, vancomycin, fidaxomicin), including a pulsed vancomycin regimen;
   *Treatment failure for CDI may be declared in as little as 48 hours in patients with severe disease who fail to improve.
5. Dose does not exceed 10 mg/kg once.

Approval Duration

Commercial: 3 months (1 dose only)

Medicaid: 3 months (1 dose only)

II. Continued Therapy Approval

A. Clostridium difficile Infection:

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval Duration

Not applicable

References

1. Antimicrobial Drugs Advisory Committee. Bezlotoxumab injection briefing document (BLA 761046). Published June 9, 2016. Available at: https://www.fda.gov/media/98714/download. Accessed June 28, 2023.
2. Zar FA, Bakkanagari SR, Moorthi KM, Davis MB. A comparison of vancomycin and metronidazole for the treatment of Clostridium difficile-associated diarrhea, stratified by disease severity. Clin Infect Dis 2007;45(3):302-7. Available at: https://pubmed.ncbi.nlm.nih.gov/17599306/. Accessed June 28, 2023.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established	01/2020	02/07/2020

Policy was reviewed: 1. Policy title table was updated 2. References were updated	07/02/2020	09/14/2020
Policy was reviewed: 1. References were reviewed and updated.	05/28/2021	9/14/2021
Policy was reviewed: 1. References were reviewed and updated.	02/08/2022	04/18/2022
Policy was reviewed: 1. Initial Approval Criteria I.A.4: Updated from two episodes to one episode and a total of three episodes to total of two episodes. 2. References were reviewed and updated.	01/18/2023	04/13/2023
Policy was reviewed: 1. Initial Approval Criteria, I.A.2: Updated age criteria from Age ≥ 18 years to Age ≥ 1 years. 2. References were reviewed and updated.	06/28/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023