

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

Zinplava (bezlotoxumab)

Override(s)	Approval Duration
Prior Authorization	One time approval for one injection per authorization request

Medications
Zinplava (bezlotoxumab) 25 mg/mL intravenous solution for injection

APPROVAL CRITERIA

Requests for Zinplava (bezlotoxumab) may be approved if the following criteria are met:

- I. Individual has a *Clostridiodes difficile* infection confirmed by :
 - A. Passage of three or more loose stools within 24 hours or less; **AND**
 - B. Positive stool test for toxigenic *Clostridiodes difficile* from a stool sample collected no more than 7 days prior to scheduled infusion; **AND**
- II. Individual is currently receiving antibacterial therapy for *Clostridiodes difficile* infection; **AND**
- III. Individual is at high risk of *Clostridiodes difficile* infection recurrence meeting any one of the following:
 - A. 65 years of age or older; **OR**
 - B. History of *Clostridiodes difficile* infection in the past 6 months; **OR**
 - C. Immunocompromised state; **OR**
 - D. Severe *Clostridiodes difficile* infection at presentation*; **OR**
 - E. *Clostridiodes difficile* ribotype 027.

***Note:** Severe *Clostridiodes difficile* infection can be defined by one of the following:

- I. American College of Gastroenterology (ACG) definition (Surawicz, 2013)
 - A. Albumin < 3 g/dl AND one of the following:
 1. White blood cell (WBC) \geq 15,000 cells/mm³;**OR**
 2. Abdominal tenderness;
- OR
- II. Infectious Disease Society of America (IDSA) definition (IDSA, 2017):
 - A. WBC \geq 15,000 cells/mL OR serum creatinine level >1.5 mg/dL;

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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OR

- III. ZAR score ≥ 2 (Zar, 2007):
- A. Age >60 years old = 1 point;
 - B. Body temperature $>38.3^{\circ}\text{C}$ ($>100.9^{\circ}\text{F}$) = 1 point;
 - C. Albumin level <2.5 mg/dL = 1 point;
 - D. Peripheral white blood cell count $>15,000$ cells/mm³ within 48 hours = 1 point;
 - E. Endoscopic evidence of pseudomembranous colitis = 2 points
 - F. Treatment in Intensive Care Unit (ICU) = 2 points.

Zinplava (bezlotoxumab) may not be approved for the following:

- I. All other indications not included above; **OR**
- II. First-line treatment for *Clostridioides difficile* infection.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 6, 2019.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Kelly CP, Lamont JT, Bakken JS. Clostridioides (formerly Clostridium) difficile infection in adults: Treatment and prevention. Updated: September 5, 2019. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: September 6, 2019.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. McDonald LC, Gerding DN, Johnson S, et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clin Infect Dis. 2018;66(7):987-994.
6. Surawicz CM, Brandt LJ, Binion DG, et al. Guidelines for diagnosis, treatment, and prevention of clostridium difficile infections. Am J Gastroenterol. 2013; 108:478-498.
7. Wilcox MH, Gerding DN, Poxton IR, et al. Bezlotoxumab for the prevention of recurrent Clostridium difficile infection. N Eng J Med. 2017; 376(4):305-317.
8. Zar FA, Bakkanagari SR et al. A comparison of vancomycin and metronidazole for the treatment of Clostridium difficile-associated diarrhea, stratified by disease severity. Clin Infect Dis. 2007; 45(3):302-307.

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