Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Zinplava (bezlotoxumab)

DRUG.00090

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

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

APPROVAL CRITERIA

A *single* injection of Zinplava (bezlotoxumab) may be approved to reduce recurrence of *Clostridium difficile* infection in individuals 18 years of age or older when the following criteria are met:

A. Individual has a confirmed *Clostridium difficile* infection when **both** of the criteria below are met:
   1. Passage of three or more loose stools within 24 hours or less; **AND**
   2. Positive stool test for toxigenic *Clostridium difficile* from a stool sample collected not more than 7 days prior to scheduled infusion; **AND**

B. Individual is currently receiving antibacterial therapy for *Clostridium difficile* infection; **AND**

C. Individual is at high risk of *Clostridium difficile* infection recurrence meeting any one of the following:
   1. Individual is 65 years of age or older, with a history of *Clostridium difficile* infection in the past 6 months; **OR**
   2. Immunocompromised state; **OR**
   3. Severe *Clostridium difficile* infection at presentation (meeting any one of the three definitions of severe *Clostridium difficile* in the definitions section*); **OR**
   4. *Clostridium difficile* ribotype 027.

*Clinically severe *Clostridium difficile* infection (CDI): As defined by one of the following:

I. American College of Gastroenterology (ACG) definition (Christina, 2013)-
   A. Albumin < 3g/dl plus one of the following:
      1. White blood cell (WBC) > or equal to 15,000 cells/mm3
      2. Abdominal tenderness

Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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II. Infectious Disease Society of America (IDSA) definition (Cohen, 2010):
   A. WBC > or equal to 15,000 cells/mm3 and serum Cr level > 1.5x baseline creatine level

III. ZAR score ≥ 2 (Zar, 2007):
   A. Age >60 years old (1 point);
   B. Body temperature >38.3°C (>100°F) (1 point);
   C. Albumin level <2.5 mg/dL (1 point);
   D. Peripheral white blood cell count >15,000 cells/mm^3 within 48 hours (1 point);
   E. Endoscopic evidence of pseudomembranous colitis (2 points); and
   F. Treatment in Intensive Care Unit (2 points)

The use of bezlotoxumab may not be approved when the above criteria are not met, and for all other conditions, including but not limited to first-line therapy.

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

Key References:

1. Bezlotoxumab Monograph. Lexicomp® Online, American Hospital Formulary Services® (AHFS®) Online, Hudson, Ohio, Lexi-Comp., Inc. Last revised November 4 2016. Accessed on January 5, 2017.
2. Bezlotoxumab (systemic). In: DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated October 2016. Available at: http://www.micromedexsolutions.com. Accessed on January 5, 2017.
3. Christina M, Surawicz MD, Lawrence J, et al. Guidelines for diagnosis, treatment, and prevention of clostridium difficile infections. Am J Gastroenterol. 2013; 108:478-498.
4. Cohen SH, Gerding DN, Johnson S, et al. Clinical practice guidelines for clostridium difficile infection in adults: 2010 update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Disease Society of America (IDSA). Infect Control Hosp Epidemiol. 2010; 31(5):431-455.
5. Merck Sharp & Dohme Corp. A study of MK-3415, MK-6072, and MK-3415A in participants receiving antibiotic therapy for clostridium difficile infection (MK-3415A-001) (MODIFY I). NLM Identifier: NCT01241552. Last updated October 24, 2016. Available at: https://www.clinicaltrials.gov/ct2/show/NCT01241552?term=NCT01241552&rank=1. Accessed on January 5, 2017.
6. Merck Sharp & Dohme Corp. A study of MK-6072 and MK-3415A in participants receiving antibiotic therapy for clostridium difficile infection (MK-3415A-002) (MODIFY 11). NLM Identifier: NCT01513239. Last updated October 29, 2015. Available at: https://www.clinicaltrials.gov/ct2/show/NCT01513239?term=NCT01513239&rank=1. Accessed on January 5, 2017.
7. Surawicz CM, Brandt LJ, Binion DG, et al. Guidelines for diagnosis, treatment, and prevention of clostridium difficile infections. Am J Gastroenterol. 2013; 108(4):478-498.
8. ZINPLAVA [Product Information]. Whitehouse Station, NJ. Merck Sharp & Dohme Corp.; October 21, 2016. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/761046s000lbl.pdf. Accessed on January 5, 2017.

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.