RX.PA.056.CCH ZINPLAVA (BEZLOTOXUMAB)

The purpose of this policy is to define the prior authorization process for Zinplava™ (bezlotoxumab).

Zinplava™ (bezlotoxumab) is a fully human monoclonal (mAb) IgG1/κ antibody indicated for reducing the recurrence of Clostridium difficile infection (CDI) in patients ≥18 years of age who are receiving antibacterial drug treatment of CDI and are at a high risk for CDI recurrence.

Zinplava™ (bezlotoxumab) is not indicated for the treatment of CDI as it is not an antibacterial drug. Zinplava™ (bezlotoxumab) should only be used in conjunction with antibacterial drug treatment of CDI.

DEFINITIONS

Clostridium difficile infection (CDI) – a bacterium causing symptoms ranging from diarrhea to more serious intestinal conditions such as colitis.

CDI recurrence – the development of a new episode of diarrhea associated with a positive stool test for C. difficile toxin following clinical cure of the initial CDI episode.
Human monoclonal antibody (mAb) – an antibody produced by a single clone of human cells consisting of identical antibody molecules.

IgG1/κ – an antibody subclass of the immunoglobulin G (IgG) subtype which is found in the serum and provides protection from infections caused by bacteria, fungi, and viruses.

POLICY
It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The drug, Zinplava™ (bezlotoxumab), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

A single injection of Zinplava™ (bezlotoxumab) is approved when all the criteria listed below are met:

1. **Enterocolitis due to Clostridium difficile:**
   - ≥18 years
   - Prescribed by or in consultation with a practitioner specializing in Infectious Disease
   - Confirmed Clostridium difficile infection (CDI) as defined by both below:
     - Passage of three or more loose stools within 24 hours or less
     - Positive stool test for toxigenic CDI from a stool sample collected not more than 7 days prior to scheduled infusion
   - The patient is concurrently receiving antibacterial drug treatment of CDI
   - The patient is at high risk of CDI recurrence as defined by at least one factor below:
     - 65 years of age or older with a history of CDI in the past 6 months
     - immunocompromised state
     - C. difficile ribotype 027
   - Dosing of Zinplava™ is appropriate for weight at 10 mg/kg
   - The patient has no history of previous treatment with Zinplava™

Reauthorization Criteria:

N/A - Repeat doses of Zinplava™ (bezlotoxumab) have not been studied.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	One dose
Reauthorization	N/A
Quantity Level Limit	
Zinplava	1 dose per lifetime

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

HCPCS Code

Code	Brand	Description
J0565	**ZINPLAVA**	INJECTION BEZLOTOXUMAB 10 MG

REFERENCES

1. Bezlotoxumab Monograph. Lexicomp® Online, American Hospital Formulary Services® (AHFS®) Online, Hudson, Ohio, Lexi-Comp., Inc. Accessed on January 10, 2017.
2. 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.
3. ZINPLAVA [Product Information]. Whitehouse Station, NJ. Merck Sharp & Dohme Corp; Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/761046s000lbl.pdf. Accessed on January 10, 2017.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Initial Review	3/22