

EVH Clinical Guideline 5055.CC for Zinplava (bezlotoxumab)

Guideline Number: EVH_CG_5055.CC	<u>Applicable Codes</u>	
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Original Date: March 2022	Last Revised Date: July 2026	Implementation Date: October 2026

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STATEMENT

General Information

- *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.*
- *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.*

Purpose

The purpose of this guideline is to define the prior authorization process for the following drug: Zinplava (bezlotoxumab).

Scope

This guideline applies to all practitioners who are involved in providing the requested drug. This guideline is specific to the Health Plan's medical benefit.

INITIAL REVIEW CRITERIA

The request must meet all of the criteria listed below for approval of a single injection.

Enterocolitis due to *Clostridium difficile*:

- Must be 1 year of age or older
- 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
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

- The patient has no history of previous treatment with Zinplava

REAUTHORIZATION CRITERIA

Zinplava is not eligible for reauthorization as repeat doses of Zinplava (bezlotoxumab) have not been studied.

APPROVAL DURATIONS

Initial Authorization	Up to 6 months
Reauthorization	N/A

CODING AND STANDARDS

Codes

Code	Brand	Description
J0565	Zinplava	Injection, bezlotoxumab, 10mg

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☐	Commercial
☐	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

BACKGROUND

Zinplava™ (bezlotoxumab) is a fully human monoclonal (mAb) IgG1/k 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/k – 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 HISTORY

Date	Summary
July 2026	• Updated approval duration to 6 months • Added dosing criterion
October 2024	Updated age requirement to 1 year and older
March 2022	New guideline

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Administrative Services Medical Policy Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or



drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

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 (bezlotoxumab) [prescribing information]. Rahway, NJ; Merck & Co Inc: May 2023.