

Drug Therapy Guidelines

Zinplava™ (bezlotoxumab)

Applicable*

Medical Benefit	x	Effective: 8/15/18
Pharmacy- Formulary 1		Next Review: 6/19
Pharmacy- Formulary 2		Date of Origin: 1/17
Pharmacy- Formulary 3/Exclusive		Review Dates: 12/16, 6/17, 6/18
Pharmacy- Formulary 4/AON		

I. Medication Description

Zinplava is a human monoclonal antibody that binds *C. difficile* toxin B and neutralizes its effects. Zinplava is not an antibiotic and should be used in conjunction with appropriate antibacterial medications.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation.

III. Policy

Coverage of Zinplava is provided when one of the following conditions is met:

- Zinplava is prescribed by, or in consultation with, a practitioner specializing in Infectious Disease **AND**
- The member is currently receiving antibacterial drug treatment of *Clostridium difficile* infection (CDI) **AND**
- There is a high risk for recurrence of CDI **AND**
- Member is at least 18 years of age

IV. Quantity Limitations

Coverage is authorized for a quantity sufficient to provide 10 mg/kg once.

V. Coverage Duration

Coverage is provided for one time administration of Zinplava and cannot be renewed.

VI. Coverage Renewal Criteria

The safety and efficacy of repeat administration have not been studied.

VII. Billing/Coding Information

Available as 1,000 mg/40 mL solution in a single-dose vial.

- J0565: 1 billable unit = 10 mg

VIII. Summary of Policy Changes

- 1/1/17: new policy
- 6/21/17: no policy changes
- 1/1/18: billing/coding information updated
- 8/15/18: added member age to coverage criteria

IX. References

1. Clinical Pharmacology online. Accessed 4/2018.
2. Zinplava™ (Product Information). Whitehouse Station, NJ: Merck & co., Inc. Revised 10/2016.
3. 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 \(SHEA\)](#) [published online February 15, 2018]. *Clin Infect Dis*. doi: 10.1093/cid/cix1085.
4. Centers for Medicare and Medicaid Services. Medicare Benefit Policy Manual: Chapter 15. (CMS Publication No. 100-02). Retrieved from <http://www.cms.hhs.gov>.

**These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section 50 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual.*

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.