Medical Policy:

Zinplava® (bezlotoxumab) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.184	January 2, 2025	September 2017

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Ziplava is a human monoclonal antibody. It binds to Clostridium difficile toxin B, which prevents toxin B from binding to and affecting mammalian cells. It is approved to reduce recurrence of CDI in patients 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at high risk for CDI recurrence. Zinplava is not indicated for the treatment of CDI. Zinplava is not an antibacterial drug and should only be used in conjunction with antibacterial drug treatment of CDI.

Length of Authorization

Coverage will be provided for 1 dose.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

- 10 mg/kg for 1 dose

Guideline

I. Initial Approval Criteria

Zinplava *may be considered medically necessary if the below condition is met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

1. **Clostridium difficile infection (CDI), recurrent**
   A. Patient is 1 year of age or older; **AND**
   B. Member has a confirmed diagnosis of *Clostridium difficile* infection (CDI) with documentation of the following: diarrhea (passage of 3 or more loose bowel movements in 24 or fewer hours) and a positive stool test for toxigenic *C. difficile* from a stool sample collected no more than 7 days prior; ***AND***
   C. Member is at high risk of CDI recurrence, defined as *any* of the following:
      i. Age greater than or equal to 65 years; **OR**
      ii. Long term use of systemic antibacterial drugs (excluding standard of care antibiotics); **OR**
      iii. History of 1 or more prior episodes of CDI within the previous 6 months; **OR**
      iv. Immunocompromised (defined as having an active hematologic malignancy, using an antineoplastic or immunomodulating agent, using corticosteroids, having received a prior solid organ transplant, being asplenic, being neutropenic/pancytopenic, or having AIDS/immunodeficient condition); **OR**
      v. Clinically severe CDI (as defined by a Zar score of greater than or equal to 2); **OR**
      vi. Hypervirulent strain (ribotypes 027, 078 or 244); ***AND***
   D. Bezlotoxumab will be given in conjunction with standard of care antibiotics (Infusion will be given during the antibiotic treatment course)

Limitations/Exclusions

1. Zinplava should be used only in conjunction with antibacterial drug treatment of CDI.
2. The use of Zinplava is considered investigational when the above criteria are not met, and for all other conditions, including but not limited to first-line therapy.

II. Renewal Criteria

Repeat administration of Zinplava is considered experimental and investigational.

Dosage/Administration

Indication	Dose
Clostridium difficile infection (CDI), recurrent	10 mg/kg administered as an intravenous infusion over 60 minutes as a single dose.

Applicable Procedure Codes

Code	Description
J0565	Injection, bezlotoxumab, 10 mg, 1 billable unit = 10 mg

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Applicable NDCs

Code	Description
00006-3025-xx	Ziplava single use vial; 25 mg/1 ml solution

ICD-10 Diagnoses

Code	Description
A04.71-A04.72	Enterocolitis due to Clostridium difficile

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/2/2025	Annual Review: No Criteria changes
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: Initial Criteria: Removed “Patient is 18 years of age or older; AND” Replaced with “Patient is 1 year of age or older; AND”
EmblemHealth & ConnectiCare	3/6/2023	Annual Review: No revisions
EmblemHealth & ConnectiCare	10/13/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	09/2017	New Policy

References

1. Product Information: ZINPLAVA™ IV injection, bezlotoxumab IV injection. Merck Sharp & Dohme Corp (per manufacturer), Whitehouse Station, NJ, 2016.

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