



Original Effective Date: 08/01/2018
 Current Effective Date: 04/06/2024
 Last P&T Approval/Version: 01/31/2024
 Next Review Due By: 01/2025
 Policy Number: C14821-A

Zinplava (bezlotoxumab)

PRODUCTS AFFECTED

Zinplava (bezlotoxumab)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:

Reduce recurrence of Clostridioides difficile infection (CDI) when receiving antibacterial drug treatment for CDI and at high risk for CDI recurrence

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. PREVENTION OF RECURRENCE OF CDI:

1. Documented diagnosis of Clostridioides difficile (C. diff) infection (CDI)
- AND

Drug and Biologic Coverage Criteria

2. Currently receiving antibacterial drug treatment for CDI
AND
3. Member has documented high risk for CDI recurrence as evidenced by ONE of the following:
≥65 years of age, received one or more systemic antibacterial drugs (during the 12-week follow-up period), One or more episodes of CDI within the six months prior to the episode under treatment, Immunocompromised, OR Clinically severe CDI (as defined by a Zar score of ≥2; scores range from 1 to 8, with higher scores indicating more severe infection)

CONTINUATION OF THERAPY:

NA

DURATION OF APPROVAL:

Initial authorization: Single dose, Continuation of Therapy: NA

NOTE: The safety and efficacy of repeat administration of ZINPLAVA in members with CDI have not been studied

PRESCRIBER REQUIREMENTS:

No requirements

AGE RESTRICTIONS:

QUANTITY:

10 mg/kg IV as a single dose

PLACE OF ADMINISTRATION:

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Intravenous Infusion

DRUG CLASS:

Bacterial Monoclonal Antibodies

FDA-APPROVED USES:

Indicated to reduce recurrence of Clostridioides difficile infection (CDI) in adults and pediatric patients 1 year of age and older who are receiving antibacterial drug treatment of CDI and are at a high risk for CDI recurrence.

Limitations of Use: Zinplava is not indicated for the treatment of CDI. Zinplava is not an antibacterial drug. Zinplava should only be used in conjunction with antibacterial drug treatment of CDI.

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

APPENDIX:

None

BACKGROUND AND OTHER CONSIDERATIONS**BACKGROUND:**

None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Zinplava (bezlotoxumab) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Zinplava (bezlotoxumab) include: No labeled contraindications.

OTHER SPECIAL CONSIDERATIONS:

None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J0565	Injection, bezlotoxumab, 10 mg

AVAILABLE DOSAGE FORMS:

Zinplava SOLN 1000MG/40ML

REFERENCES

1. ZINPLAVA™ (bezlotoxumab) [package insert]. Whitehouse Station, NJ: Merck and Co, Inc. May 2023.
2. Wilcox, M. H., Gerding, D. N., Poxton, I. R., Kelly, C., Nathan, R., Birch, T., ... Kartsonis, N. (2017). Bezlotoxumab for Prevention of Recurrent Clostridium difficile Infection. *New England Journal of Medicine*, 376(4), 305–317. <https://doi.org/10.1056/nejmoa1602615>
3. Johnson, S., & Gerding, D. N. (2018). Bezlotoxumab. *Clinical Infectious Diseases*, 68(4), 699–704. <https://doi.org/10.1093/cid/ciy577>
4. Johnson, S., Lavergne, V., Skinner, A. M., Gonzales-Luna, A. J., Garey, K. W., Kelly, C. P., & Wilcox, M. H. (2021). Clinical Practice Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of Clostridioides difficile Infection in Adults. *Clinical Infectious Diseases*, 73(5). <https://doi.org/10.1093/cid/ciab549>

Drug and Biologic Coverage Criteria

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Duration of Approval Age Restrictions FDA-Approved Uses Contraindications/Exclusions/Discontinuation Available Dosage Forms References	Q1 2024
ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q1 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy References	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file