Original Effective Date: 08/01/2018
Current Effective Date: 02/25/2023
Last P&T Approval/Version: 01/25/2023
Next Review Due By: 01/2024
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 clostridium difficile infection (CDI) in members who are receiving antibacterial drug treatment of CDI and are at a 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.

A. CLOSTRIDIUM DIFFICILE INFECTION (CDI) RECURRENCE PREVENTION:
1. Currently receiving antibacterial drug treatment of CDI
   AND
2. High risk for CDI recurrence by ONE (1) 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, (The safety and efficacy of repeat administration of ZINPLAVA in members with CDI have not been studied)

PRESCRIBER REQUIREMENTS:
No requirements

AGE RESTRICTIONS:
18 years of age or older

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:
Reduce recurrence of clostridium difficile infection (CDI) in patients 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at a high risk for CDI recurrence

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
Limitation 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.

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, 10mg

AVAILABLE DOSAGE FORMS:
Zinplava Sol 25MG/ML

REFERENCES

1. ZINPLAVA™ (bezlotoxumab) [package insert]. Whitehouse Station, NJ: Merck and Co, Inc. October 2016

SUMMARY OF REVIEW/REVISIONS	DATE
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