Original Effective Date: 11/23/2023
Current Effective Date: 03/08/2025
Last P&T Approval/Version: 01/29/2025
Next Review Due By: 01/2026
Policy Number: C26183-A

Rezzayo (rezafungin)

PRODUCTS AFFECTED

Rezzayo (rezafungin)

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:
Candidemia, Invasive candidiasis

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. ALL INDICATIONS:
   1. Documentation member has as infection caused by or strongly suspected to be caused by a type of pathogen and site of infection within the FDA label or compendia supported
      AND

2. Documentation of inadequate treatment response, serious side effects, contraindication, or non-susceptibility to an antifungal treatment – PREFERRED oral fluconazole, IV voriconazole, IV amphotericin (if diagnostically appropriate)
   AND
3. Documentation the member has limited or no alternative options for treatment of the infection

CONTINUATION OF THERAPY:
N/A: Each new infection treatment should be a new review

DURATION OF APPROVAL:
Initial authorization: 4 weeks, Continuation of Therapy: N/A

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified infectious disease specialist [If prescribed in consultation, consultation notes must be submitted with initial request]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
400 mg once (loading dose) followed by 200 mg once weekly thereafter

Maximum Quantity Limits – 4 weekly doses (including the loading 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

DRUG CLASS:
Antifungal - Glucan Synthesis Inhibitors (Echinocandins)

FDA-APPROVED USES:
Indicated in patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis. Approval of this indication is based on limited clinical safety and efficacy data for Rezzayo.
Limitations of Use: Rezzayo has not been studied in patients with endocarditis, osteomyelitis, and meningitis due to Candida.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Rezzayo (rezafungin) is an echinocandin antifungal indicated in patients who have limited or no alternative options for the treatment of candidemia and invasive candidiasis. It is the first new FDA approved treatment option for candidiasis in 10 years.

Safety and efficacy was established in the Phase 3 ReSTORE trial and supported by the Phase 2 STRIVE trial. The ReSTORE trial met both primary efficacy endpoints - 30-day all-cause mortality and global cure at Day 14. The STRIVE trial also met the primary endpoint of overall response at Day 14. Both clinical trials demonstrated noninferiority of once-weekly Rezzayo to the current once-daily standard of care, caspofungin.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Rezzayo (rezafungin) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Rezzayo (rezafungin) include: known hypersensitivity to rezafungin or other echinocandins.

OTHER SPECIAL CONSIDERATIONS:
If a scheduled dose is missed (not taken on the assigned day), administer the missed dose as soon as possible.

- If the missed dose is administered within 3 days of the assigned day, the next weekly dose may be given on schedule.
- If the missed dose is administered more than 3 days after the assigned day, revise the dosing schedule to ensure there are at least 4 days before the next dose.
- If restarting after at least 2 weeks of missed dosing, the dosing should be started again at the 400 mg loading dose.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J0349	Injection, rezafungin, 1 mg

AVAILABLE DOSAGE FORMS:
Rezzayo SOLR 200MG single-dose vial

REFERENCES

1. Rezzayo (rezafungin for injection), for intravenous use [prescribing information]. Lincolnshire, IL: Melinta Therapeutics LLC; March 2023.
2. Pappas, P. G., Kauffman, C. A., Andes, D. R., Clancy, C. J., Marr, K. A., Ostrosky-Zeichner, L., . . .

Sobel, J. D. (2015). Clinical practice guideline for the management of candidiasis: 2016 update by the Infectious Diseases Society of America. Clinical Infectious Diseases, 62(4). doi:10.1093/cid/civ933

SUMMARY OF REVIEW/REVISIONS	DATE
ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q1 2025
REVISION- Notable revisions: Background References	Q1 2024
NEW CRITERIA CREATION	Q4 2023