

Rylaze (asparaginase erwinia chrysanthemi (recombinant)-rywn)



Pharmacy Coverage Policy

Effective Date: September 15, 2021

Revision Date: July 26, 2023

Review Date: July 19, 2023

Line of Business: Medicare, Commercial, Medicaid - South Carolina, Medicaid - Ohio

Policy Type: Prior Authorization

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Products Affected

Rylaze intramuscular solution

Listed Indications

[Acute Lymphoblastic Leukemia \(ALL\) or Lymphoblastic Lymphoma \(LBL\)](#)

Acute Lymphoblastic Leukemia (ALL) or Lymphoblastic Lymphoma (LBL)

Does the member meet all of the following criteria?

Criteria #1	The member has a diagnosis of acute lymphoblastic leukemia (ALL) or Lymphoblastic lymphoma (LBL)
Criteria #2	The member has documented, Grade 2 - 4 hypersensitivity (based on Common Terminology Toxicity Criteria) as a result of prior treatment with Oncaspar (pegaspargase)
Criteria #3	The member is using Rylaze (asparaginase Erwinia chrysanthemi-rywn) as a component of a multi-agent chemotherapeutic regimen

Does the member have any of the following exclusions? If yes, approval may not be appropriate.

NOTE: Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

Exclusion #1	Members with a history of serious pancreatitis with prior asparaginase based therapy
Exclusion #2	Members with a history of serious thrombosis with prior asparaginase based therapy
Exclusion #3	Members with a history of serious hemorrhagic events with prior asparaginase based therapy
Exclusion #4	Members that have experienced disease progression while on asparaginase based therapy

Approval Duration

Initial	Rylaze (asparaginase Erwinia chrysanthemi-rywn) will be approved in six month durations or as determined through clinical review.
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Background

This is a prior authorization policy about Rylaze (asparaginase *Erwinia chrysanthemi*-recombinant-rywn)

Warnings and Precautions:

- Hypersensitivity: Monitor for signs or symptoms. Discontinue RYLAZE for serious reaction.
- Pancreatitis: Monitor for symptoms. Discontinue if pancreatitis occurs.
- Thrombosis: Discontinue RYLAZE for severe or life-threatening thrombosis. Provide anticoagulation therapy as indicated.
- Hemorrhage: Discontinue RYLAZE for severe or life-threatening hemorrhage.
- Hepatotoxicity: Discontinue RYLAZE for grade 4 increases of bilirubin.

Most common adverse reactions (incidence > 20%) are abnormal liver test, nausea, musculoskeletal pain, fatigue, infection, headache, pyrexia, drug hypersensitivity, febrile neutropenia, decreased appetite, stomatitis, bleeding, and hyperglycemia.

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Rylaze (asparaginase *Erwinia chrysanthemi recombinant-rywn*) catalyzes the deamidation of asparagine to aspartic acid and ammonia, resulting in a reduction in circulating levels of asparagine. The mechanism of action of Rylaze (asparaginase *Erwinia chrysanthemi recombinant-rywn*) is thought to be based on the inability of leukemic cells to synthesize asparagine due to lack of asparagine synthetase activity, resulting in cytotoxicity specific for leukemic cells that depend on an exogenous source of the amino acid asparagine for their protein metabolism and survival.

Rylaze (asparaginase *Erwinia chrysanthemi recombinant-rywn*) is an asparagine-specific enzyme indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia (ALL) or Lymphoblastic Lymphoma (LBL) who have developed hypersensitivity to E. coli-derived asparaginase.

Asparaginase *Erwinia chrysanthemi recombinant-rywn* is available as Rylaze in 10 mg/ 0.5 mL vials.

Provider Claim Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Rylaze; asparaginase *Erwinia chrysanthemi recombinant-rywn*; ALL; Acute Lymphoblastic Leukemia; LBL; Lymphoblastic Lymphoma; intramuscular; pharmacy

References

Rylaze (asparaginase *Erwinia chrysanthemi recombinant-rywn*) Prescribing Information. EUSA Pharma Inc. Lanhorne, PA. November 2022. Clinical Pharmacology [online database]. Tampa, FL: Gold Standard, Inc. URL: <http://www.clinicalpharmacology.com>. Updated periodically. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. NCCN Drug and Biologics Compendium. Fort Washington, PA: National Comprehensive Cancer Network (NCCN); Updated periodically.

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