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Section	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	July 23, 2021
Subject:	Rylaze	**Page:**	1 of 3

Last Review Date: December 8, 2023

Rylaze

Description

Rylaze (asparaginase erwinia chrysanthemi (recombinant)-rywn)

Background
Rylaze (asparaginase erwinia chrysanthemi (recombinant)-rywn) is an enzyme that catalyzes the conversion of the amino acid L-asparagine into aspartic acid and ammonia. The pharmacologic effect of Rylaze is based on the killing of leukemic cells due to depletion of plasma asparagine. Leukemic cells with low expression of asparagine synthetase have a reduced ability to synthesize asparagine, and therefore depend on an exogenous source of asparagine for survival (1).

Regulatory Status
FDA-approved indications: Rylaze is an asparagine specific enzyme indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) in adult and pediatric patients 1 month or older who have developed hypersensitivity to *E. coli*-derived asparaginase (1).

Rylaze is contraindicated in patients with a history of pancreatitis, thrombosis, hemorrhagic events, or anaphylaxis with prior asparaginase therapy (1).

Patients taking Rylaze should have bilirubin, transaminases, and glucose monitored (1).

Rylaze has warnings regarding hypersensitivity reactions, pancreatitis, thrombosis, hemorrhage, and hepatotoxicity (1).

Related policies
Asparlas, Erwinaze, Oncaspar

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Rylaze may be considered **medically necessary** if the conditions indicated below are met.

Rylaze may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Acute lymphoblastic leukemia (ALL)
2. Lymphoblastic lymphoma (LBL)

AND ALL of the following:

a. Hypersensitivity to *E. coli*-derived asparaginase
b. Prescriber agrees to monitor bilirubin, liver function tests (LFTs), and glucose

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Rylaze is an asparagine specific enzyme indicated for the treatment of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) who have developed hypersensitivity to *E. coli*-derived asparaginase. Patients should have bilirubin, transaminases, and glucose monitored while on therapy (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Rylaze while maintaining optimal therapeutic outcomes.

References

1. Rylaze [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; November 2022.
2. NCCN Drugs & Biologics Compendium® Asparaginase erwinia chrysanthemi (recombinant)-rywn 2023. National Comprehensive Cancer Network, Inc. Accessed on October 13, 2023.

Policy History

Date	Action
July 2021	Addition to PA
September 2021	Annual review and reference update
September 2022	Annual review and reference update
September 2023	Annual review and reference update
December 2023	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.