



Commercial/Healthcare Exchange PA Criteria Effective: September 14, 2021

Prior Authorization: Rylaze

Products Affected: Rylaze (asparaginase erwinia chrysanthemi (recombinant)-rywn) injection

Medication Description: 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.

Covered Uses:

1. Acute lymphoid leukemia, in combination with other chemotherapy agents; in patients who have developed E. coli-derived asparaginase hypersensitivity.
2. Diffuse non-Hodgkin's lymphoma, lymphoblastic, in combination with other chemotherapy agents; in patients who have developed E. coli-derived asparaginase hypersensitivity.

Exclusion Criteria:

1. Serious hypersensitivity reactions to Rylaze, including anaphylaxis.
2. Serious pancreatitis during previous L-asparaginase therapy.
3. Serious thrombosis during previous L-asparaginase therapy.
4. Serious hemorrhagic events during previous L-asparaginase therapy.

Required Medical Information:

1. Diagnosis
2. Documented allergy/Hypersensitivity to E. coli derived Asparaginase products.

Age Restrictions:

1. Pediatric patients \geq 1 month

Prescriber Restrictions: Prescribed by, or in consultation with an oncologist

Coverage Duration: 12 months

Other Criteria:

I. Initial Approval Criteria

1. **Acute lymphoblastic leukemia (ALL)/lymphoblastic lymphoma (LBL):** Approve Rylaze if the patient meets the following criteria:
 - A. Patient has a diagnosis of ALL or LBL; AND
 - B. Patient has a systemic allergic reaction or anaphylaxis to a pegylated asparaginase product

II. Continued Therapy

1. **Acute lymphoblastic leukemia (ALL)/lymphoblastic lymphoma (LBL):**

Last Rev. September 2021



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- A. Member is responding positively to therapy, as determined by the prescriber; AND
- B. Member has not experienced unacceptable toxicity from the drug (e.g. systemic hypersensitivity reactions)

References:

1. Rylaze ® [package insert]. Jazz Pharmaceuticals Inc. Palo Alto, CA 2021.
2. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2021.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	9/14/2021

Last Rev. September 2021



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