

PRIOR AUTHORIZATION POLICY

- POLICY:** Oncology (Injectable) – Rylaze Prior Authorization Policy
- Rylaze™ (asparaginase erwinia chrysanthemi [recombinant]-rywn – Jazz Pharmaceuticals)

REVIEW DATE: 07/07/2021

OVERVIEW

Rylaze, asparaginase erwinia chrysanthemi (recombinant), is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) in adults and pediatric patients ≥ 1 month who have developed hypersensitivity to *E. coli*-derived asparaginase.¹

Guidelines

The National Comprehensive Cancer Network ALL (version 2.2021 – July 19, 2021) and Pediatric ALL (version 3.2021 – July 19, 2021) guidelines recommend Rylaze for the second-line treatment of patients who develop a systemic allergic reaction or anaphylaxis to *E. coli*-derived asparaginase.²⁻⁴

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Rylaze. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Rylaze as well as the monitoring required for adverse events and long-term efficacy, approval requires Rylaze to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Rylaze is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Acute Lymphoblastic Leukemia/Lymphoblastic Lymphoma.** Approve for 1 year if the patient meets the following criteria (A and B):
 - A) Patient has a systemic allergic reaction or anaphylaxis to a pegylated asparaginase product; AND
 - B) Rylaze is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Rylaze is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.
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REFERENCES

1. Rylaze intramuscular injection [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals; June 2021.
2. The NCCN Drugs and Biologics Compendium. © 2021 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on July 20, 2021. Search term: asparaginase erwinia chrysanthemi (recombinant)-rywn.
3. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 2.2021 – July 19, 2021). © 2021 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on July 20, 2021.
4. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 3.2021 – July 19, 2021). © 2021 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on July 20, 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	07/07/2021
Update	07/20/2021. Updated the Guidelines section with National Comprehensive Cancer Network guideline recommendations.	NA