PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 04/24/2024

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 (NCCN) has addressed Rylaze:
- **ALL** (version 4.2023 – February 5, 2024) and **Pediatric ALL** (version 5.2024 – April 3, 2024) guidelines recommend Rylaze for patients who develop a systemic allergic reaction or anaphylaxis to pegaspargase.[2-4]
- **T-Cell Lymphomas:** NCCN guidelines (version 3.2024 – April 11, 2024) recommend Rylaze for patients with extranodal NK/T-Cell lymphoma who develop a systemic allergic reaction or anaphylaxis to pegaspargase.[2,5]

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:

FDA-Approved Indication

1. **Acute Lymphoblastic Leukemia/Lymphoblastic Lymphoma.** Approve for 1 year if the patient meets BOTH of the following (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.

Other Uses with Supportive Evidence

2. Extranodal NK/T-Cell Lymphoma. Approve for 1 year if the patient meets BOTH of the following (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.

REFERENCES

1. Rylaze intramuscular injection [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals; November 2022.
2. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 16, 2024. Search term: asparaginase erwinia chrysanthemi (recombinant)-rywn.
3. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 4.2023 – February 5, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 16, 2024.
4. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 5.2024 – April 3, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 16, 2024.
5. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 3.2024 – April 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 16, 2024.