UTILIZATION MANAGEMENT MEDICAL POLICY

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

REVIEW DATE: 03/26/2025

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 adult 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 3.2024 – December 20, 2024) and **Pediatric ALL** (version 3.2025 – March 17, 2025) guidelines recommend Rylaze for patients who develop a systemic allergic reaction or anaphylaxis to pegaspargase.[2-4]
- **T-Cell Lymphomas:** NCCN guidelines (version 1.2025 – November 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 medical benefit coverage of Rylaze. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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 one of the following criteria:

FDA-Approved Indication

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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.

   Dosing. Approve ONE of the following dosing regimens (A or B):

A) Once every 48 hour administration: Approve 25 mg/m^2 administered by intramuscular injection no more frequently than once every 48 hours for a total of up to 11 doses in each treatment cycle; OR

B) Monday, Wednesday, and Friday administration: Approve 25 mg/m^2 administered on Monday and Wednesday, and 50 mg/m^2 administered on Friday by intramuscular injection for a total of up to 9 doses in each treatment cycle.

Other Uses with Supportive Evidence

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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.

Dosing. Approve ONE of the following dosing regimens (A or B):

A) Once every 48 hour administration: Approve 25 mg/m^2 administered by intramuscular injection no more frequently than once every 48 hours for a total of up to 11 doses in each treatment cycle; OR

B) Monday, Wednesday, and Friday administration: Approve 25 mg/m^2 administered on Monday and Wednesday, and 50 mg/m^2 administered on Friday by intramuscular injection for a total of up to 9 doses in each treatment cycle.

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; April 2024.
2. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 17, 2025. Search term: asparaginase erwinia chrysanthemi (recombinant)-rywn.
3. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 3.2024 – December 20, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 17, 2025.
4. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 3. 2025 – March 17, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 17, 2025.
5. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 1.2025 – November 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 17, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Extranodal NK/T-Cell Lymphoma:** New condition of approval added.	06/28/2023
Early Annual Revision	**Acute Lymphoblastic Leukemia/Lymphoblastic Lymphoma.** Added descriptor "Once every 48 hour administration" to dosing regimen. Removed "up to" before 25 mg/m^2 and revised 6 doses to "up to 11 doses" in each treatment cycle. Added Monday, Wednesday, and Friday administration dosing regimen. **Extranodal NK/T-Cell Lymphoma.** Added descriptor "Once every 48 hour administration" to dosing regimen. Removed "up to" before 25 mg/m^2 and revised 6 doses to "up to 11 doses" in each treatment cycle. Added Monday, Wednesday, and Friday administration dosing regimen.	04/24/2024
Annual Revision	No criteria changes.	03/26/2025