Utilization Review Policy 258

POLICY: Oncology (Injectable) – Rylaze Utilization Management Medical Policy

- Rylaze™ (asparaginase erwinia chrysanthemi [recombinant]-rywn – Jazz Pharmaceuticals)

EFFECTIVE DATE: 12/01/2021
REVIEW DATE: 06/29/2022

COVERAGE CRITERIA FOR: All UCare Plans

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 ALL (version 1.2022 – April 4, 2022) and Pediatric ALL (version 1.2022 – October 1, 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 medical benefit coverage of Rylaze. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. 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 the following criteria:

FDA-Approved Indication

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.

   Dosing. Approve up to 25 mg/m^2 administered by intramuscular injection no more frequently than once every 48 hours for a total of 6 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; June 2021.
2. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 21, 2022. Search term: asparaginase erwinia chrysanthemi (recombinant)-rywn.
3. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 1.2022 – April 4, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 21, 2022.
4. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 1.2022 – October 1, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 21, 2022.

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
Annual Revision	No criteria changes.	06/29/2022