

SPECIALTY GUIDELINE MANAGEMENT

RYLAZE (asparaginase erwinia chrysanthemi (recombinant)-rywn)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

Rylaze 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 or older who have developed hypersensitivity to E. coli-derived asparaginase.

B. Compendial Uses

1. Extranodal Natural Killer/T-cell lymphoma/ Aggressive NK-cell Leukemia (ANKL)

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. **Acute Lymphoblastic Leukemia (ALL) and Lymphoblastic Lymphoma (LBL)**

Authorization of 12 months may be granted for treatment of ALL or LBL in members 1 month or older who have developed hypersensitivity to E. coli-derived asparaginase (e.g., pegaspargase) and the requested medication will be used in conjunction with multi-agent chemotherapy.

B. **Extranodal Natural Killer/T-cell Lymphoma / Aggressive NK-cell Leukemia (ANKL)**

Authorization of 12 months may be granted for treatment of ENKL or ANKL when both of the following criteria are met:

1. The member has previously received and developed hypersensitivity to an E. coli-derived asparaginase (e.g., pegaspargase).
2. The requested medication will be used in conjunction with multi-agent chemotherapy.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Rylaze [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; November 2022.
2. The NCCN Drugs & Biologics Compendium® ©2023 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed May 31, 2023.

Reference number
4812-A

3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: T-Cell Lymphomas. Version 1.2023. [https:// www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf](https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf). Accessed May 31, 2023.
4. Rylaze. Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed May 31, 2023.