Reference number(s)
4812-A

Specialty Guideline Management
Rylaze

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Rylaze	asparaginase erwinia chrysanthemi (recombinant)-rywn

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.

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.

Compendial Uses

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

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

Coverage Criteria

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.

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:

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

Continuation of Therapy

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

References

1. Rylaze [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; April 2024.
2. The NCCN Drugs & Biologics Compendium® ©2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed May 28, 2024.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: T-Cell Lymphomas. Version 4.2024. https:// www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed May 28, 2024.
4. Rylaze. Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed May 28, 2024.