Asparaginase erwinia chrysanthemi [recombinant]-rywn (Rylaze™)	Place of Service Office Administration Infusion Center Administration Outpatient Facility Infusion Administration HCPCS: J9021 per 0.1 mg

Condition(s) listed in policy (*see criteria for details*)

- Acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LBL)
- Extranodal NK/T-cell lymphoma

AHFS therapeutic class: Antineoplastic

Mechanism of action: Rylaze is produced by a genetically engineered bacterium containing the DNA which encodes for *Erwinia chrysanthemi*. The antineoplastic mechanism of action of asparaginase is proposed to be based on selective killing of leukemic cells due to depletion of plasma asparagine.

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Rylaze™ (asparaginase erwinia chrysanthemi [recombinant]-rywn) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LBL)

1. Patient has developed hypersensitivity to E. coli-derived asparaginase (e.g., Asparlas, Oncaspar), **AND**
2. Being used as a component of a multi-agent chemotherapeutic regimen

Covered Doses

When administered every 48 hours: 25 mg/m^2 intramuscularly every 48 hours
When administered Monday/Wednesday/Friday: 25 mg/m^2 intramuscularly on Monday morning and Wednesday morning, and 50 mg/m^2 intramuscularly on Friday afternoon.

Coverage Period

Cover for the duration of multi-agent chemotherapeutic regimen

ICD-10:

C83.50-C83.59, C91.00-C91.02

Extranodal NK/T-cell lymphoma

1. Patient has developed hypersensitivity to E. coli-derived asparaginase (e.g., Asparlas, Oncaspar), **AND**
2. Being used as a component of a multi-agent chemotherapeutic regimen

Covered Doses
When administered every 48 hours: 25 mg/m^2 intramuscularly every 48 hours
When administered Monday/Wednesday/Friday: 25 mg/m^2 intramuscularly on Monday morning and Wednesday morning, and 50 mg/m^2 intramuscularly on Friday afternoon.

Coverage Period
Cover for the duration of multi-agent chemotherapeutic regimen

ICD-10:
C84.90-C84.99, C84.Z0, C84.Z1, C84.Z2, C84.Z3, C84.Z4, C84.Z5, C84.Z6, C84.Z7, C84.Z8, C84.Z9, C86.0

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Rylaze™ (asparaginase erwinia chrysanthemi [recombinant]-rywn) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
10 mg/0.5 mL (single-use vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Rylaze (asparaginase erwinia chrysanthemi [recombinant]-rywn) [Prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals; 2022.
- National Comprehensive Cancer Network Drugs & Biologics Compendium. Rylaze (2023). Available by subscription at: www.nccn.org.
- National comprehensive cancer network. Acute Lymphoblastic Leukemia (Version 4.2021). Available at: www.nccn.org
- National comprehensive cancer network. Pediatric Acute Lymphoblastic Leukemia (Version 2.2023). Available at: www.nccn.org.
- National comprehensive cancer network. T-Cell Lymphoma (Version 1.2023). Available at: www.nccn.org.

(7) Policy Update

Date of last review: 2Q2023
Date of next review: 2Q2024
Changes from previous policy version:

- New indication in Section (2): Added coverage for extranodal NK/T-cell lymphoma
  Rationale: NCCN category 2A support

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee