Clinical Policy Title:	asparaginase erwinia chrysanthemi (recombinant)-rywn
Policy Number:	RxA.703
Drug(s) Applied:	Rylaze™
Original Policy Date:	08/17/2021
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Rylaze™ is an asparagine specific enzyme 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
asparaginase erwinia chrysanthemi (recombinant)-rywn (Rylaze™)	Acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL)	When replacing a long-acting asparaginase product, the recommended dosage of Rylaze™ is 25 mg/m^2 administered intramuscularly every 48 hours.	25 mg/m^2 Intra muscularly

Dosage Forms

- Injection: 10 mg/0.5 mL solution in a single-dose vial.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) (must meet all):

1. Diagnosis of one of the followings (a or b):
   a. ALL;
   b. LBL;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Member's age ≥ 1 month;
4. Prescribed as a component of a multi-agent chemotherapeutic regimen;
5. Clinical documentation indicating that member has developed hypersensitivity to an E. coli derived asparaginase;

6. Request meets one of the following (a or b):
   a. Dose does not exceed 25 mg/m^2 once every 48 hours;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) (must meet all):
1. Member is currently receiving medication that has been authorized by RxAdvance or documentation supports that member is currently receiving Rylaze™ for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. Request meets one of the following (a or b):
   a. Dose does not exceed 25 mg/m^2 once every 48 hours;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval Duration
Commercial: 6 months
Medicaid: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
ALL: Acute Lymphoblastic Leukemia
LBL: Lymphoblastic Lymphoma
FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives
None

APPENDIX C: Contraindications/Boxed Warnings
- Contraindication(s):
  - Serious hypersensitivity reactions to Rylaze™, including anaphylaxis;
  - Serious pancreatitis during previous L-asparaginase therapy;
  - Serious thrombosis during previous L-asparaginase therapy;
  - Serious hemorrhagic events during previous L-asparaginase therapy.

- Boxed Warning(s):
  - None

APPENDIX D: General Information
- Hypersensitivity: Monitor for signs or symptoms. Discontinue Rylaze™ for serious reaction.
- Pancreatitis: Monitor for symptoms. Discontinue if pancreatitis occurs.
- Thrombosis: Discontinue Rylaze™ for severe or life-threatening thrombosis. Provide anticoagulation therapy as indicated.

- Hemorrhage: Discontinue Rylaze™ for severe or life-threatening hemorrhage.
- Hepatotoxicity: Discontinue Rylaze™ for grade 4 increases of bilirubin.

References

1. Rylaze™ prescribing information. Palo Alto, CA, Jazz Pharmaceuticals, Inc.; June 2021. Available at: https://pp.jazzpharma.com/pi/rylaze.en.USPI.pdf. Accessed August 17, 2021.
2. National Comprehensive Cancer Network. Pediatric Acute lymphoblastic leukemia Version 3.2021. Available https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf . Accessed August 17, 2021.
3. National Comprehensive Cancer Network. Acute lymphoblastic leukemia Version 2.2021. Available https://www.nccn.org/professionals/physician_gls/pdf/all.pdf . Accessed August 17, 2021.
4. Rylaze™ Lexi drugs; Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: https://online.lexi.com/lco/action/search?q=Rylaze&t=name&va=Rylaze. Accessed August 17, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	8/17/2021	9/14/2021