

Clinical Policy: Erwinia Asparaginase (Erwinaze, Rylaze)

Reference Number: LA.PHAR.301

Effective Date:

Last Review Date: 08.22

Line of Business: Medicaid

Coding Implications

Revision Log

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Asparaginase *Erwinia chrysanthemi* (Erwinaze®) and asparaginase *Erwinia chrysanthem* (recombinant)-rywn (Rylaze™) are asparagine specific enzymes.

FDA Approved Indication(s)

Erwinaze is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia (ALL) who have developed hypersensitivity to *E. coli*-derived asparaginase.

Rylaze is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of ALL and lymphoblastic lymphoma (LBL) in adult and pediatric patients 1 month or older who have developed hypersensitivity to *E. coli*-derived asparaginase.

Policy/Criteria

Prior authorization is required. Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections that Erwinaze and Rylaze are medically necessary when the following criteria are met:

I. Initial Approval Criteria

A. Acute Lymphoblastic Leukemia (must meet all):

1. Diagnosis of ALL;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Prescribed as a component of a multi-agent chemotherapeutic regimen;
4. Member meets (a or b):
 - a. Member has developed hypersensitivity to an *E. coli* derived asparaginase product (Elspar® - off-market) or pegaspargase (Oncaspar®);
 - b. For Erwinaze, age ≥ 65 years and prescribed as combination induction therapy;
5. Request meets one of the following (a, b, or c):*
 - a. Erwinaze: dose does not exceed 25,000 International Units/m² administered three times per week;
 - b. Rylaze: dose does not exceed 25 mg/ m² every 48 hours;
 - c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

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**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration:

Medicaid – 3 months

B. Lymphoblastic Lymphoma (must meet all):

1. **Diagnosis of LBL;**
2. **Request is for Rylaze;**
3. **Prescribed by or in consultation with an oncologist or hematologist;**
4. **Prescribed as a component of a multi-agent chemotherapeutic regimen;**
5. **Member has developed hypersensitivity to an *E. coli* derived asparaginase product (Elspar - off-market) or pegaspargase (Oncaspar);**
6. **Request meets one of the following (a or b):***
 - a. **Dose does not exceed 25 mg/ m² 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:

Medicaid – 3 months

C. Other diagnoses/indications

1. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

II. Continued Therapy

A. All Indications in Section I (must meet all):

1. **Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Erwinaze or Rylaze for a covered indication and has received this medication for at least 30 days;**
2. **Member is responding positively to therapy;**
3. **If request is for a dose increase, request meets one of the following (a, b, or c):***
 - a. **Erwinaze: new dose should not exceed 25,000 International Units per m² administered three times per week;**
 - b. **Rylaze: new dose does not exceed 25 mg/ m² every 48 hours;**
 - c. **New 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:

Medicaid – 6 months

B. Other diagnoses/indications (must meet 1 or 2):

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1. Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy –LA.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALL: acute lymphoblastic leukemia

FDA: Food and Drug Administration

LBL: lymphoblastic lymphoma

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may require prior authorization.

<u>Drug Name</u>	<u>Dosing Regimen</u>	<u>Dose Limit/Maximum Dose</u>
<u>Oncaspar (pegaspargase)</u>	<ul style="list-style-type: none"> • <u>Administered IM or IV no more frequently than every 14 days.</u> • <u>Patients ages 21 years and younger: 2,500 International Units/m².</u> • <u>Patients ages over 21 years: 2,000 International Units/m².</u> 	<u>Varies</u>

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): History of 1) serious hypersensitivity reactions to Erwinaze/Rylaze, including anaphylaxis, 2) serious pancreatitis with prior L-asparaginase therapy, 3) serious thrombosis with prior L-asparaginase therapy, 4) serious hemorrhagic events with prior L-asparaginase therapy.
- Boxed warning(s): None reported.

V. Dosage and Administration

<u>Drug Name</u>	<u>Indication</u>	<u>Dosing Regimen</u>	<u>Maximum Dose</u>
<u>Erwinaze</u>	<u>ALL</u>	<u>To substitute for pegaspargase: the recommended dose for each planned dose of</u>	<u>25,000 IU/m²/dose</u>

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<u>Drug Name</u>	<u>Indication</u>	<u>Dosing Regimen</u>	<u>Maximum Dose</u>
		<u>pegaspargase is 25,000 International Units/m² administered IM or IV TIW (Monday/Wednesday/Friday) for six doses.</u>	
<u>Rylaze</u>	<u>ALL, LBL</u>	<u>To substitute for pegaspargase: 25 mg/m² IM every 48 hours to complete the intended duration of pegaspargase therapy</u>	<u>25 mg/m²/dose</u>

VI. Product Availability

<u>Drug Name</u>	<u>Availability</u>
<u>Erwinaze</u>	<u>10,000 International Units lyophilized powder per vial</u>
<u>Rylaze</u>	<u>10 mg/0.5 ml solution in single-dose vial</u>

VII. References

1. Erwinaze Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; December 2019. Available at <https://pp.jazzpharma.com/pi/erwinaze.en.USPI.pdf>. Accessed November 10, 2021.
2. Rylaze Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; June 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761179s000lbl.pdf. Accessed November 10, 2021.
3. Oncaspar Prescribing Information. Boston, MA: Servier Pharmaceuticals LLC.; June 2020. Available at https://www.oncaspar.com/prescribing_information.pdf. Accessed November 10, 2021.
4. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed November 10, 2021.
5. Acute Lymphoblastic Leukemia Version 2.2021. National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed November 10, 2021.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

<u>HCPCS Codes</u>	<u>Description</u>
<u>J9019</u>	<u>Injection, asparaginase, (Erwinaze), 1,000 IU</u>
<u>J9020</u>	<u>Injection, asparaginase, not otherwise specified, 10,000 units</u>

<u>Reviews, Revisions, and Approvals</u>	<u>Date</u>	<u>LDH Approval Date</u>
<u>Converted corporate to local policy.</u>	<u>09.22</u>	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

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through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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