

## **Clinical Policy: Erwinia Asparaginase (Erwinaze)**

Reference Number: CP.PHAR.301

Effective Date: 02.01.2017

Last Review Date: 02.19

Line of Business: HIM, 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<sup>®</sup>) is an asparagine specific enzyme.

### **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.

### **Policy/Criteria**

*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 health plans affiliated with Centene Corporation<sup>®</sup> that Erwinaze is **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 has developed hypersensitivity to an *E. coli* derived asparaginase product (Elspar<sup>®</sup> - off-market) or pegaspargase (Oncaspar<sup>®</sup>);
5. Request meets one of the following (a, b, or c):
  - a. Dose should not exceed 25,000 International Units per m<sup>2</sup> administered three times per week;
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 3 months**

### **B. Other diagnoses/indications**

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

## **II. Continued Therapy**

### **A. Acute Lymphoblastic Leukemia (must meet all):**

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1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Erwinaze 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. New dose should not exceed 25,000 International Units per m<sup>2</sup> administered three times per week;
  - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 6 months**

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

1. Currently receiving medication via Centene 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 for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace, and CP.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 – HIM.PHAR.21 for health insurance marketplace, and CP.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

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Oncaspar (pegaspargase)	2,500 International Units/m <sup>2</sup> IM or IV, administered no more frequently than every 14 days, as part of a multi-agent chemotherapeutic regimen.	Varies

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.*

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#### Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): History of 1) serious hypersensitivity reactions to Erwinaze, 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

Indication	Dosing Regimen	Maximum Dose
ALL	To substitute for pegaspargase: The recommended dose for each planned dose of pegaspargase is 25,000 International Units/m <sup>2</sup> administered IM or IV TIW (Monday/Wednesday/Friday) for six doses.	25,000 IU/m <sup>2</sup> /dose

#### VI. Product Availability

10,000 International Units lyophilized powder per vial

#### VII. References

1. Erwinaze Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; March 2016. Available at <http://www.erwinaze.com>. Accessed October 17, 2018.
2. Oncaspar Prescribing Information. Gaithersburg, MD: Sigma-Tau Pharmaceuticals, Inc.; May 2014. Available at [https://www.shirecontent.com/PI/PDFs/ONCASPAR\\_USA\\_ENG.pdf](https://www.shirecontent.com/PI/PDFs/ONCASPAR_USA_ENG.pdf). Accessed October 23, 2018.
3. Asparaginase Erwinia chrysanthemi. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at [www.nccn.org](http://www.nccn.org). Accessed October 17, 2018.
4. Acute lymphoblastic leukemia (Version 1.2018). National Comprehensive Cancer Network Guidelines. Available at [www.nccn.org](http://www.nccn.org). Accessed October 17, 2018.

#### 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.

HCPCS Codes	Description
J9019	Injection, asparaginase, (Erwinaze), 1,000 IU

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created.	02.01.17	02.17
1Q18 annual review: -No significant changes -Converted to the new template and added dosing	12.11.17	02.18

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
-Combined FDA approved criteria and NCCN recommendations, FDA indication covers both -References reviewed and updated		
1Q 2019 annual review; HIM line of business added; specialist added; per Recordati Rare Diseases, who acquired Elspar from Lundbeck in January 2013, Elspar was discontinued in 2012, there are currently no plans to reintroduce Elspar, there is no residual Elspar supply remaining on the current market, and Recordati Rare Diseases has not provided Elspar to any other territory within the global market; references reviewed and updated.	11.13.18	02.19

**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. The Health Plan 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. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**For Health Insurance Marketplace members**, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.

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