

Clinical Policy: Erwinia Asparaginase (Erwinaze)

Reference Number: PA.CP.PHAR.301

Effective Date: 01/18

Last Review Date: 07/18

[Coding Implications](#)

[Revision Log](#)

Description

The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness[®] clinical policy for asparaginase *Erwinia chrysanthemi* (Erwinaze[®]).

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

It is the policy of Pennsylvania Health and Wellness[®] 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 acute lymphoblastic leukemia (ALL);
2. Prescribed with a multi-agent chemotherapeutic regimen;
3. Meets a or b:
 - a. Member has developed hypersensitivity to E. coli-derived asparaginase.
 - b. Member has experienced a pegaspargase-associated allergic reaction (pegaspargase is an E. coli.-derived pegylated form of asparaginase available as Oncaspar);
4. Dose does not exceed (a or b):
 - a. Substitute for a dose of pegaspargase: 25,000 International Units/m² three times a week;
 - b. Substitute for a dose of native E. coli asparaginase: 25,000 International Units/m² intramuscularly or intravenously for each scheduled dose of native E. coli asparaginase.

Approval duration: 3 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Acute Lymphoblastic Leukemia (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed (a or b):

- a. Substitute for a dose of pegaspargase: 25,000 International Units/m² three times a week;
- b. Substitute for a dose of native E. coli asparaginase: 25,000 International Units/m² intramuscularly or intravenously for each scheduled dose of native E. coli asparaginase.

Approval duration: 6 months

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.CP.PMN.53

Background

Description/Mechanism of Action:

Erwinaze (asparaginase *Erwinia chrysanthemi*) contains an asparagine specific enzyme derived from *Erwinia chrysanthemi*. Asparaginase *Erwinia chrysanthemi* catalyzes the deamidation of asparagine to aspartic acid and ammonia, resulting in a reduction in circulating levels of asparagine. The mechanism of action of Erwinaze is thought to be based on the inability of leukemic cells to synthesize asparagine due to lack of asparagine synthetase activity, resulting in cytotoxicity specific for leukemic cells that depend on an exogenous source of amino acid asparagine for their protein metabolism and survival.

Formulations:

Erwinaze is a lyophilized powder supplied in a clear 3 mL glass vial.

- Each carton of Erwinaze contains 5 vials.
- Each single vial contains 10,000 International Units asparaginase *Erwinia chrysanthemi*.

Appendices

Appendix A: Abbreviation Key

ALL: Acute lymphocytic leukemia

CTCAE: Common terminology criteria for adverse events

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.

CLINICAL POLICY
Erwinia Asparaginase



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

Reviews, Revisions, and Approvals	Date	Approval Date
Combined FDA approved criteria and NCCN recommendations, FDA indication covers both. References reviewed and updated	02/18	

References

- i. Erwinaze prescribing information. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; March 2016. Available at <http://www.erwinaze.com>. Accessed December 11, 2017.
- ii. Asparaginase Erwinia chrysanthemi. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed January 26, 2017.
- iii. Acute lymphoblastic leukemia (Version 5.2017). In: National Comprehensive Cancer Network Guidelines. Available at www.NCCN.org. Accessed December 11, 2017.