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5.21.017

Section	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	February 28, 2012
Subject:	Erwinaze	**Page:**	1 of 4

Last Review Date: March 8, 2024

Erwinaze

Description

Erwinaze (asparaginase *Erwinia chrysanthemi*)

Background
Erwinaze (asparaginase *Erwinia chrysanthemi*) is an asparagine-specific enzyme. L-asparaginase is a tetrameric enzyme consisting of four identical subunits, each having a molecular weight of about 35 kDa. 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 the amino acid asparagine for their protein metabolism and survival (1).

Erwinaze (asparaginase *Erwinia chrysanthemi*) is indicated for the treatment of patients with acute lymphoblastic leukemia (ALL) who have developed hypersensitivity to *E. coli*-derived asparaginase as a component of a multi-agent chemotherapeutic regimen (1).

Regulatory Status
FDA-approved indication: 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 (1).

Erwinaze is contraindicated in patients with a history of pancreatitis, thrombosis, hemorrhagic events, or anaphylaxis reaction with prior L-asparaginase therapy. Discontinue Erwinaze in the event of serious hypersensitivity reactions, including anaphylaxis, and severe or hemorrhagic

pancreatitis. Glucose intolerance can occur and, in some cases, may be irreversible. Perform appropriate monitoring and treat hyperglycemia with insulin, as necessary. If thrombosis or hemorrhage occurs discontinue Erwinaze until resolved. Use in pregnant women only if clearly needed. Do not use in lactating women (1).

Related policies
Asparlas, Oncaspar, Rylaze

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Erwinaze may be considered **medically necessary** if the conditions indicated below are met.

Erwinaze may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnosis

Patient must have the following:

1. Acute lymphoblastic leukemia (ALL)
    a. Hypersensitivity to *E. coli*-derived asparaginase
    b. Prescriber agrees to monitor bilirubin, liver function tests (LFTs), and glucose

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Erwinaze (asparaginase *Erwinia chrysanthemi)* can be used as a component of a multi-agent chemotherapeutic regimen for the treatment of pediatric and adult patients with acute lymphoblastic leukemia (ALL) who have developed hypersensitivity to native or pegylated *Escherichia coli (E. coli)*-derived asparaginase. Erwinaze is contraindicated in patients with a history of pancreatitis, thrombosis, hemorrhagic events or anaphylaxis reaction with prior L-asparaginase therapy. Erwinaze therapy should be discontinued if the above conditions occur during therapy. Glucose intolerance could occur and may be irreversible (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Erwinaze while maintaining optimal therapeutic outcomes.

References

1. Erwinaze [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; December 2019.
2. NCCN Drugs & Biologics Compendium® Asparaginase Erwinia chrysanthemi 2024. National Comprehensive Cancer Network, Inc. Accessed on January 31, 2024.

Policy History

Date	Action
February 2012	New Policy
March 2013	Annual editorial and reference update
March 2014	Annual review
March 2015	Annual editorial review and reference update
June 2016	Annual editorial review and reference update Policy number changed from 5.04.17 to 5.21.17
June 2017	Annual review
June 2018	Annual editorial review
June 2019	Annual review
September 2019	Annual review. Added requirement to monitor bilirubin, LFTs, and glucose per FEP

June 2020	Annual review and reference update
March 2021	Annual review
September 2021	Annual review and reference update
March 2022	Annual review and reference update
March 2023	Annual review and reference update. Changed policy number to 5.21.017
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.