

POLICY: Oncology – Erwinaze® (asparaginase *Erwinia chrysanthemi* injection for intramuscular or intravenous use – Jazz Pharmaceuticals)

DATE REVIEWED: 06/03/2020

OVERVIEW

Erwinaze is *Erwinia chrysanthemi*-derived L-asparaginase.¹ Asparaginase reduces the plasma levels of asparagine by catalyzing the breakdown of asparagine to aspartic acid and ammonia. Leukemia cells have a deficiency of asparagine synthetase activity and rely on exogenous sources of L-asparagine for survival. Erwinaze depletes plasma L-asparagine levels leading to leukemia cell death.

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 *Escherichia coli*-derived asparaginase.¹

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for ALL (Version 1.2020 – January 15, 2020) recommend *E. chrysanthemi*-derived asparaginase for patients who have systemic allergic reactions or anaphylaxis due to pegaspargase hypersensitivity, and for induction therapy for ALL in patients ≥ 65 years of age.^{2,3}

The NCCN guidelines for Pediatric ALL (Version 2.2020 – November 25, 2019) recommend *E. chrysanthemi*-derived asparaginase for patients who have systemic allergic reactions or anaphylaxis due to pegaspargase hypersensitivity.^{3,4}

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Erwinaze. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Erwinaze as well as the monitoring required for adverse events and long-term efficacy, approval requires Erwinaze to be prescribed by or in consultation with a physician who specializes in the condition being treated.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Erwinaze is recommended in those who meet the following criteria:

FDA-Approved Indications

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- 1. Acute Lymphoblastic Leukemia.** Approve for 1 year if the patient meets the following criteria (A and B):
 - A)** Erwinaze is used for one of the following (i or ii):
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- i. The patient has a systemic allergic reaction or anaphylaxis to a pegylated asparaginase product;
OR
 - ii. Induction therapy in adults ≥ 65 years of age; AND
- B) Erwinaze is prescribed by or consultation with an oncologist.

Dosing. Approve the following dosing regimen: Each individual dose must not exceed 25,000 International Units/m² administered intravenously or intramuscularly no more frequently than three times a week.¹

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Erwinaze has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Erwinaze® injection for intramuscular or intravenous use [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals; December 2019.
2. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (Version 1.2020 – January 15, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed May 26, 2020.
3. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on May 26, 2020. Search term: asparaginase Erwinia chrysanthemi .
4. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (Version 2.2020 – November 25, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed May 26, 2020.

HISTORY

Type of Revision	Summary of Changes	Date Reviewed
New Policy	--	06/05/2019
Annual Revision	No change to criteria.	06/03/2020