Utilization Review Policy 158

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

EFFECTIVE DATE: 1/1/2020
LAST REVISION DATE: 05/31/2023

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

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

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for **ALL** (version 1.2022 – April 4, 2022) and for **Pediatric ALL** (version 2.2023 – March 10, 2023) 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.[2-4]

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 indications. 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

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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. 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 up to 25,000 International Units/m^2 administered intravenously or intramuscularly no more frequently than three times a week.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Erwinaze is not recommended in the following situations.

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® intramuscular or intravenous injection [prescribing information]. Palo Alto, CA: Jazz; December 2019.
2. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 1.2022 – April 4, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 11, 2022.
3. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 8, 2023. Search term: asparaginase Erwinia chrysanthemi.
4. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 2.2023 – March 10, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 8, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Extranodal NK/T-Cell Lymphoma:** Added new condition of approval.	05/18/2022
Annual Revision	**Extranodal NK/T-Cell Lymphoma:** Condition of approval removed.	05/31/2023