PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Erwinaze Prior Authorization Policy
- Erwinaze® (asparaginase *Erwinia chrysanthemi* intramuscular or intravenous injection – Jazz)

REVIEW DATE: 05/18/2022

OVERVIEW
Erwinaze, *Erwinia chrysanthemi*-derived L-asparaginase, 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
Erwinaze is addressed in National Comprehensive Cancer Network (NCCN) guidelines:
- **ALL:** The NCCN guidelines for **ALL** (version 1.2022 – April 4, 2022) and for **Pediatric ALL** (version 1.2022 – October 1, 2021) 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]
- **T-Cell Lymphomas:** Guidelines (version 2.2022 – March 7, 2022) recommend *E. chrysanthemi*-derived asparaginase for patients who have systemic allergic reactions or anaphylaxis due to pegaspargase hypersensitivity in patients with extranodal NK/T-cell lymphomas.[3,5]

POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of Erwinaze. 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

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):
     - **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.

Other Uses with Supportive Evidence

2. **Extranodal NK/T-Cell Lymphoma.** Approve for 1 year if the patient meets the following criteria (A and B):
   A) Patient has a systemic allergic reaction or anaphylaxis to a pegylated asparaginase product; AND
   B) Erwinaze is prescribed by or consultation with an oncologist.

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. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 11, 2022. Search term: asparaginase Erwinia chrysanthemi.
4. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 1.2022 – October 1, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 11, 2022.
5. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 2.2022 – March 7, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 11, 2022.