Reference number(s)
4199-A

STANDARD MEDICARE PART B MANAGEMENT

ERWINAZE (asparaginase *Erwinia chrysanthemi*)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

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.

B. Compendial Uses

1. Extranodal natural killer/T-cell lymphoma: as a component of multi-agent chemotherapeutic regimen
2. Lymphoblastic lymphoma (managed in the same manner as ALL)
3. Acute lymphoblastic leukemia (ALL) as induction therapy for adults aged 65 years and older as a component of multi-agent chemotherapeutic regimen, or as a substitute for pegaspargase in cases of systemic allergic reaction or anaphylaxis due to pegaspargase hypersensitivity
4. Pediatric acute lymphoblastic leukemia (ALL) as a substitute for pegaspargase in cases of systemic allergic reaction or anaphylaxis due to pegaspargase hypersensitivity
5. Acute myeloid leukemia
6. Chronic myeloid leukemia
7. Cutaneous T-cell lymphoma

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

A. Acute Lymphoblastic Leukemia (ALL) and Lymphoblastic Lymphoma

Authorization of 12 months may be granted for the treatment of ALL or lymphoblastic lymphoma when the requested medication will be used in conjunction with multi-agent chemotherapy and any of the following criteria is met:

1. The member has previously received and developed hypersensitivity to an E. coli-derived asparaginase (e.g. pegaspargase).

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2. The requested medication will be used as induction therapy for members age 65 years and older.

B. Extranodal Natural Killer/T-cell Lymphoma
Authorization of 12 months may be granted for the treatment of extranodal natural killer/T-cell lymphoma when both of the following criteria are met:
1. The member has previously received and developed hypersensitivity to an E. coli-derived asparaginase (e.g., pegaspargase).
2. The requested medication is used in conjunction with multi-agent chemotherapy.

C. Acute Myeloid Leukemia (AML)
Authorization of 12 months may be granted for the treatment of AML

D. Chronic Myeloid Leukemia (CML)
Authorization of 12 months may be granted for the treatment of CML

E. Cutaneous T-cell lymphoma
Authorization of 12 months may be granted for the treatment of positive Epstein-Barr virus, multidrug resistant cutaneous T-cell lymphoma.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with Erwinaze
B. Erwinaze is being used to treat an indication enumerated in Section II.
C. The member is receiving benefit from therapy. Benefit is defined as:
   1. No evidence of unacceptable toxicity while on the current regimen or
   2. No evidence of disease progression while on the current regimen

IV. REFERENCES

1. Erwinaze [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; December 2019.
2. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. http://www.nccn.org. Accessed June 2, 2022.
3. Erwinaze. Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed June 2, 2022.