SPECIALTY GUIDELINE 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, nasal type: 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

All other indications are considered experimental/investigational and are not medically necessary.

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

B. Extranodal Natural Killer/T-cell Lymphoma, nasal type

Authorization of 12 months may be granted for the treatment of extranodal natural killer/T-cell lymphoma, nasal type when the requested medication is used in conjunction with multi-agent chemotherapy.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of disease progression or an unacceptable toxicity while on the current regimen.

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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 30, 2020.
- 3. Erwinaze. Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed June 30, 2020.

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