OVERVIEW

Oncaspar is a conjugate of *Escherichia coli*-derived L-asparaginase and monomethoxypolyethylene glycol (mPEG). L-asparaginase catalyzes the breakdown of L-asparagine into aspartic acid and ammonia. Leukemia cells have a deficiency of asparagine synthetase and rely on exogenous sources of L-asparagine for survival. Oncaspar depletes plasma L-asparagine levels leading to leukemia cell death.

Oncaspar is indicated as a component of a multi-agent chemotherapy regimen for:

- The first-line treatment of pediatric and adult patients with acute lymphoblastic leukemia (ALL), and
- The treatment of pediatric and adult ALL patients with hypersensitivity to native forms of L-asparaginase.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for ALL (version 1.2019 – April 5, 2019) recommend pegaspargase as a component of a multiagent chemotherapeutic regimen for induction/consolidation therapy for Philadelphia chromosome-negative ALL, for induction therapy in Philadelphia chromosome-negative ALL in patients ≥ 65 years of age, for relapsed/refractory Philadelphia chromosome-negative ALL, and relapsed/refractory Philadelphia chromosome-positive ALL.

The NCCN guidelines for T-cell lymphomas (version 2.2019 – December 17, 2018) recommend pegaspargase as a component of induction or additional therapy for extranodal NK/T-cell lymphoma, nasal type.

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Oncaspar. 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 Oncaspar as well as the monitoring required for adverse events and long-term efficacy, approval requires Oncaspar to be prescribed by or in consultation with a physician who specializes in the condition being treated.
RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Oncaspar is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Acute Lymphoblastic Leukemia.** Approve for 1 year if Oncaspar is prescribed by or in consultation with an oncologist.

   **Dosing.** Approve one of the following dosing regimens (A or B):
   - **A)** Patients ≤ 21 years of age: Administer intravenously or intramuscularly up to 2,500 International Units/m² no more frequently than once every 14 days; OR
   - **B)** Patients > 21 years of age: Administer intravenously or intramuscularly up to 2,000 International Units/m² no more frequently than once every 14 days.¹

Other Uses with Supportive Evidence

2. **Extranodal NK/T-cell Lymphoma, Nasal Type.** Approve for 1 year if the patient meets the following (A and B):

   - **A)** Oncaspar is used for one of the following (i, ii, or iii):
     - i. Induction therapy; OR
     - ii. Additional therapy for patients with a positive biopsy and no response to induction therapy; OR
     - iii. Additional therapy for patients with a positive biopsy and partial response to induction therapy; AND
   - **B)** Oncaspar is prescribed by or in consultation with an oncologist.

   **Dosing.** Approve one of the following dosing regimens (A or B):
   - **A)** Patients ≤ 21 years of age: Administer intravenously or intramuscularly up to 2,500 International Units/m² no more frequently than once every 14 days; OR
   - **B)** Patients > 21 years of age: Administer intravenously or intramuscularly up to 2,000 International Units/m² no more frequently than once every 14 days.¹

   Limited dosing information is available. Single doses up to 2,500 International Units/m² administered no more frequently than once every 14 days are recommended in the product labeling for approved uses.

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Oncaspar 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


HISTORY

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<th>Type of Revision</th>
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<tr>
<td>New Policy</td>
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