POLICY: Oncology – Oncaspar® (pegaspargase injection for intramuscular or intravenous use – Servier)

DATE REVIEWED: 06/03/2020

OVERVIEW

Oncaspar is a conjugate of *Escherichia coli*-derived L-asparaginase and monomethoxypolyethylene glycol (mPEG).[1] 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.[1]

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for ALL (version 1.2020 – January 15, 2020) and the NCCN guidelines for Pediatric ALL (version 2.2020 – November 25, 2019) recommend pegaspargase as a component of a multiagent chemotherapeutic regimen for induction/consolidation therapy for 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.[2,3,5]

The NCCN guidelines for T-cell lymphomas (version 1.2020 – January 6, 2020) recommend pegaspargase as a component of therapy for extranodal NK/T-cell lymphoma, nasal type and as an alternative induction regimen if no response or progressive disease after primary treatment for hepatosplenic gamma-delta T-cell lymphoma.[3,4]

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: Each individual dose must not exceed 2,500 International Units/m^2 administered intravenously or intramuscularly no more frequently than once every 14 days; OR
   B) Patients > 21 years of age: Each individual dose must not exceed 2,000 International Units/m^2 administered intravenously or intramuscularly no more frequently than once every 14 days.[1]

Other Uses with Supportive Evidence

2. **Acute Lymphoblastic Extranodal NK/T-cell Lymphoma, Nasal Type.** 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: Each individual dose must not exceed 2,500 International Units/m^2 administered intravenously or intramuscularly no more frequently than once every 14 days; OR
   B) Patients > 21 years of age: Each individual dose must not exceed 2,000 International Units/m^2 administered intravenously or intramuscularly no more frequently than once every 14 days.[1]

3. **Hepatosplenic Gamma-Delta T-cell Lymphoma.** Approve for 1 year if the patient meets the following criteria (A and B):
   A) The patient had no response or progressive disease after primary treatment; 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: Each individual dose must not exceed 2,500 International Units/m^2 administered intravenously or intramuscularly no more frequently than once every 14 days; OR
   B) Patients > 21 years of age: Each individual dose must not exceed 2,000 International Units/m^2 administered intravenously or intramuscularly no more frequently than once every 14 days.[1]

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

1. Oncaspar® injection for intramuscular and intravenous use [prescribing information]. Boston, MA: Servier Pharmaceuticals; August 2019.
2. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (Version 1.2020 – January 15, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 27, 2020.
3. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 27, 2020. Search term: pegaspargase.

4. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (Version 1.2020 – January 6, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 27, 2020.
5. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (Version 2.2020 – November 25, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 27, 2020.

HISTORY

Type of Revision	Summary of Changes	Date Reviewed
New Policy	--	06/05/2019
Annual Revision	Extranodal NK/T-cell Lymphoma, Nasal Type: Removed "Oncaspar is used for one of the following (i, ii, or iii)" criteria. Added criteria for Hepatosplenic Gamma-Delta T-cell Lymphoma.	06/03/2020