Utilization Review Policy 175

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

EFFECTIVE DATE: 1/1/2020
LAST REVISION DATE: 05/31/2023

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Oncaspar, a conjugate of *Escherichia coli*-derived L-asparaginase and monomethoxypolyethylene glycol (mPEG), is indicated as a component of a multi-agent chemotherapy regimen for first-line treatment of **acute lymphoblastic leukemia** (ALL) in pediatric and adult patients and in patients with ALL with hypersensitivity to asparaginase.[1]

Guidelines

Oncaspar 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 2.2023 – March 10, 2023) recommend pegaspargase as a component of a multi-agent 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]
- **T-Cell Lymphomas:** The NCCN guidelines (version 1.2023 – January 5, 2023) recommend pegaspargase as a component of therapy for extranodal NK/T-cell lymphoma and as an alternative induction regimen if no response or progressive disease after primary treatment for hepatosplenic 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 indications. 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Oncaspar 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 BOTH of the following criteria (A and B):
   a. Patient is ≥ 1 month of age; AND
   b. Oncaspar is prescribed by or in consultation with an oncologist.

   Dosing. Approve one of the following dosing regimens (A or B):
   A) Patient ≤ 21 years of age: Approve 2,500 International Units/m^2 administered intravenously or intramuscularly no more frequently than once every 14 days; OR
   B) Patient > 21 years of age: Approve 2,000 International Units/m^2 administered intravenously or intramuscularly no more frequently than once every 14 days.

Other Uses with Supportive Evidence

2. Extranodal NK/T-cell Lymphoma. Approve for 1 year if the patient meets BOTH of the following criteria (A and B):
   a. Patient is ≥ 8 years of age; AND
   b. Oncaspar is prescribed by or in consultation with an oncologist.

   Dosing. Approve one of the following dosing regimens (A or B):
   A) Patient ≤ 21 years of age: Approve 2,500 International Units/m^2 administered intravenously or intramuscularly no more frequently than once every 14 days; OR
   B) Patient > 21 years of age: Approve 2,000 International Units/m^2 administered intravenously or intramuscularly no more frequently than once every 14 days.

3. Hepatosplenic T-cell Lymphoma. Approve for 1 year if the patient meets ALL of the following criteria (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient had no response or progressive disease after primary treatment; AND
   C) Oncaspar is prescribed by or in consultation with an oncologist.

   Dosing. Approve one of the following dosing regimens (A or B):
   A) Patient ≤ 21 years of age: Approve 2,500 International Units/m^2 administered intravenously or intramuscularly no more frequently than once every 14 days; OR
   B) Patient > 21 years of age: Approve 2,000 International Units/m^2 administered intravenously or intramuscularly no more frequently than once every 14 days.

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Coverage of Oncaspar 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. Oncaspar® intramuscular and intravenous injection [prescribing information]. Boston, MA: Servier; December 2022.
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 16, 2022.
3. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 9, 2023. Search term: pegaspargase.
4. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 1.2023 – January 5, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 9, 2023.
5. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 2.2023 – March 10, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 9, 2023.
6. Zhao Q, Fan S, Chang Y, et al. Clinical efficacy of cisplatin, dexamethasone, gemcitabine and pegaspargase (DDGP) in the initial treatment of advanced stage (stage III-IV) extranodal NK/T-cell lymphoma, and its correlation with Epstein-Barr virus. *Cancer Manag Res*. 2019;11:3555-3564.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Acute Lymphoblastic Leukemia:** Added requirement that the patient is ≥ 1 month of age. Removed "up to" qualifier from dosing regimens. **Extranodal NK/T-Cell Lymphoma:** Removed nasal type from condition of approval. Added requirement that the patient is ≥ 8 years of age. Removed "up to" qualifier from dosing regimens. **Hepatosplenic T-Cell Lymphoma:** Added requirement that the patient is ≥ 18 years of age. Removed "up to" qualifier from dosing regimens.	05/18/2022
Annual Revision	No criteria changes.	05/31/2023