Utilization Review Policy 175

POLICY: Oncology (Injectable) – Oncaspar Utilization Management Medical Policy

- Oncaspar® (pegaspargase intramuscular or intravenous injection – Servier)

EFFECTIVE DATE: 1/1/2021
LAST REVISION DATE: 09/16/2024

COVERAGE CRITERIA FOR: All Aspirus Medicare 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 4.2023 – February 5, 2024) and for **Pediatric ALL** (version 5.2024 – April 3, 2024) 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 4.2024 – May 28, 2024) recommend pegaspargase as a component of therapy for extranodal NK/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 (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 (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.

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; March 2024.

2. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 4.2023 – February 5, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 31, 2024.
3. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 31, 2024. Search term: pegaspargase.
4. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 4.2024 – May 28, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 31, 2024.
5. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 5.2024 – April 3, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 31, 2024.
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	No criteria changes.	05/31/2023
Annual Revision	**Hepatosplenic T-Cell Lymphoma**: Removed condition of approval, the National Comprehensive Cancer Network no longer recommends Oncaspar for this indication.	06/05/2024
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/16/2024