CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Asparlas Utilization Management Medical Policy
- Asparlas® (calaspargase pegol-mknl intravenous infusion – Servier)

REVIEW DATE: 01/29/2025

OVERVIEW

Asparlas is indicated as a component of a multi-agent chemotherapy regimen for the treatment of **acute lymphoblastic leukemia** (ALL) in pediatric and young adults, age 1 month to 21 years.[1]

Asparlas is a conjugate of L-asparaginase, produced by *E. coli*, and monomethoxypolyethylene glycol (mPEG) with a succinimidyl carbonate linker.[1] The succinimidyl carbonate linker forms a stable chemical bond between mPEG and L-asparaginase. Asparlas catalyzes the conversion of L-asparagine into aspartic acid and ammonia. Leukemia cells with low expression of asparagine synthetase cannot make L-asparagine and require exogenous sources for survival. Asparlas kills leukemia cells by depleting the plasma of exogenous L-asparagine.

Guidelines

The National Comprehensive Cancer Network clinical practice guidelines for ALL (version 3.2024 – December 20, 2024) state that Asparlas can be substituted for pegaspargase in patients ≤ 21 years of age.[2,3] The Pediatric ALL (version 2.2025 – December 16, 2024) guidelines state that Asparlas can be used for induction and consolidation therapy, and for the treatment of relapsed or refractory B-cell and T-cell ALL.[2,4]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Asparlas. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. 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 Asparlas as well as the monitoring required for adverse events and long-term efficacy, approval requires Asparlas to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Asparlas is recommended in those who meet 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 to 21 years of age; AND
   - **B)** Asparlas is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 2,500 units/m^2 administered intravenously no more frequently than once every 21 days.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Asparlas 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. Asparlas® intravenous infusion [prescribing information]. Boston, MA: Servier Pharmaceuticals; November 2023.
2. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 21, 2025. Search term: calaspargase.
3. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 3.2024 – December 20, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 21, 2025.
4. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 2.2025 – December 16, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 21, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	01/10/2024
Annual Revision	No criteria changes.	01/29/2025