PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Asparlas Prior Authorization Policy
- Asparlas® (calaspargase pegol-mknl intravenous infusion – Servier)

REVIEW DATE: 01/10/2024

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 3.2023 – October 9, 2023) state that Asparlas can be substituted for pegaspargase in patients ≤ 21 years of age.[2,3] The Pediatric ALL (version 3.2024 – October 31, 2023) 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 prescription benefit coverage of Asparlas. 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 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.

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® [prescribing information]. Boston, MA: Servier Pharmaceuticals; November 2023.
2. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 3, 2024. Search term: calaspargase.
3. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 3.2023 – October 9, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 3, 2024.
4. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 3.2024 – October 31, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 3, 2024.