

POLICY: Oncology – Asparlas™ (calaspargase pegol mknl injection, for intravenous use)

DATE REVIEWED: 12/11/2019

OVERVIEW

Asparlas is a conjugate of L-asparaginase, produced by *E. coli*, and monomethoxypolyethylene glycol (mPEG) with a succinimidyl carbonate (SC) linker.¹ The SC 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.

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

Guidelines

The National Comprehensive Cancer Network (NCCN) clinical practice guidelines for ALL (version 2.2019 – May 15, 2019) and Pediatric ALL (version 2.2020 – November 25, 2019) state that Asparlas can be substituted for pegaspargase in patients aged 1 month to 21 years for more sustained asparaginase activity.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(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 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.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Asparlas is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. Acute Lymphoblastic Leukemia. Approve for 1 year if the patient meets the following criteria (A and B):

- A) The patient is aged 1 month to 21 years; AND
- B) Asparlas is prescribed by or in consultation with an oncologist.

Dosing. Approve the following dosing regimen (A and B):

- A) Each individual dose must not exceed 2,500 units/m² administered intravenously; AND
- B) The dose is administered no more frequently than once every 21 days.¹

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Asparlas 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. Asparlas™ [prescribing information]. Boston, MA: Servier Pharmaceuticals LLC; September 2019.
2. The NCCN Drugs & Biologics Compendium. © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on December 3, 2019. Search term: calaspargase.
3. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (Version 2.2019 – May 15, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on December 3, 2019.
4. 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 on December 3, 2019.

HISTORY

Type of Revision	Summary of Changes	Date Reviewed
New policy	--	01/03/2019
Annual revision	No change to the criteria	12/11/2019