Reference number(s)
4616-A

STANDARD MEDICARE PART B MANAGEMENT

ASPARLAS (calaspargase pegol-mknl)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication

Asparlas is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia in pediatric and young adult patients age 1 month to 21 years.

B. Compendial Uses

1. Lymphoblastic lymphoma (managed in the same manner as ALL)
2. Acute lymphoblastic leukemia (ALL) as a substitute for pegaspargase in patients 21 years and younger for more sustained asparaginase activity
3. Pediatric acute lymphoblastic leukemia (ALL) as a substitute for pegaspargase in patients age 1 month to 21 years for more sustained asparaginase activity

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

Acute lymphoblastic leukemia/lymphoma

Authorization of 12 months may be granted for treatment of acute lymphoblastic leukemia or lymphoblastic lymphoma when all of the following criteria are met:

A. The requested medication will be used in conjunction with multi-agent chemotherapy
B. The member is 21 years of age or younger

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

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A. The member is currently receiving therapy with Asparlas
B. Asparlas is being used to treat an indication enumerated in Section II
C. The member is receiving benefit from therapy. Benefit is defined as:
    1. No evidence of unacceptable toxicity while on the current regimen AND
    2. No evidence of disease progression while on the current regimen

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Asparlas.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. NCCN Guideline: Acute lymphoblastic leukemia
4. NCCN Guideline: Pediatric lymphoblastic leukemia

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Asparlas are covered in addition to the following:

1. Lymphoblastic lymphoma (managed in the same manner as ALL)
2. Acute lymphoblastic leukemia (ALL) as a substitute for pegaspargase in patients 21 years and younger for more sustained asparaginase activity
3. Pediatric acute lymphoblastic leukemia (ALL) as a substitute for pegaspargase in patients age 1 month to 21 years for more sustained asparaginase activity

V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Asparlas to treat lymphoblastic lymphoma and acute lymphoblastic leukemia (used as a substitute for pegaspargase) can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

VI. REFERENCES

1. Asparlas [package insert]. Boston, MA: Servier Pharmaceuticals LLC; December 2021.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 2, 2022.
3. Int J Radiat Oncol Biol Phys. (2018). *Lymphoblastic Lymphoma: Guidelines From the International Radiation Oncology Group (ILROG)*. 2018 Nov 1; 102(3):508-514.