

Asparlas™ (calaspargase pegol-mknl) (Intravenous)

Document Number: IC-0425

Last Review Date: 10/28/2019

Date of Origin: 02/04/2019

Dates Reviewed: 02/2019, 11/2019

I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Asparlas 3,750 units per 5 mL single-use vial: 2 vials every 21 days

B. Max Units (per dose and over time) [Medical Benefit]:

- 750 billable units (2 vials) per 21 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient must not have a history of serious hypersensitivity, pancreatitis, severe hepatic impairment, thrombosis, or hemorrhagic events with prior L-asparaginase* therapy; **AND**

Acute lymphoblastic leukemia (ALL) †

- Patient age is 1 month up to 21 years old; **AND**
- Must be used as a component of multi-agent chemotherapy; **AND**
- Patient has B-cell lineage acute lymphoblastic leukemia

* *Note: Elspar (asparaginase) was discontinued in 2012*

† FDA Approved Indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include allergic reactions (including anaphylaxis), thrombosis, coagulopathy, severe hepatotoxicity, pancreatitis, etc.; **AND**

Acute lymphoblastic leukemia (ALL)

- Disease stabilization or improvement as evidenced by a complete response [CR] (i.e. morphologic, cytogenetic or molecular complete response CR), complete hematologic response or a partial response by CBC, bone marrow cytogenetic analysis, QPCR, or FISH

V. Dosage/Administration

Indication	Dose
All indications	Administer 2,500 units/m ² intravenously given no more frequently than every 21 days.*

**Store refrigerated at 2 to 8° C*

VI. Billing Code/Availability Information

HCPCS code:

- J9118 – Injection, calaspargase pegol-mknl, 10 units: 1 billable unit = 10 units (effective 10/1/2019)
- J9999 – Not otherwise classified, antineoplastic drugs

NDC(s):

- Asparlas 3,750 units/5 mL single-use vial: 72694-0515-XX

VII. References

1. Asparlas [package insert]. Boston, MA; Servier Pharmaceuticals Inc.; December 2018. Accessed October 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for calaspargase pegol-mknl. National Comprehensive Cancer Network, 2019. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed October 2019.
3. Silverman LB, Blonquist TM, Hunt SK, et al. Randomized Study of Pegasparagase (SS-PEG) and Calaspargase Pegol (SC-PEG) in Pediatric Patients with Newly Diagnosed Acute Lymphoblastic Leukemia or Lymphoblastic Lymphoma: Results of DFCC ALL Consortium Protocol 11-001. Blood 2016;128:175.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C83.50	Lymphoblastic (diffuse) lymphoma, unspecified site
C83.51	Lymphoblastic (diffuse) lymphoma, lymph nodes of head, face, and neck
C83.52	Lymphoblastic (diffuse) lymphoma, intrathoracic lymph nodes
C83.53	Lymphoblastic (diffuse) lymphoma, intra-abdominal lymph nodes
C83.54	Lymphoblastic (diffuse) lymphoma, lymph nodes of axilla and upper limb
C83.55	Lymphoblastic (diffuse) lymphoma, lymph nodes of inguinal region and lower limb
C83.56	Lymphoblastic (diffuse) lymphoma, intrapelvic lymph nodes
C85.57	Lymphoblastic (diffuse) lymphoma, spleen
C83.58	Lymphoblastic (diffuse) lymphoma, lymph nodes of multiple sites
C83.59	Lymphoblastic (diffuse) lymphoma, extranodal and solid organ sites
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC