Asparlas® (calaspargase pegol-mknl)
(Intravenous)

Document Number: IC-0425

Last Review Date: 12/3/2024
Date of Origin: 02/04/2019
Dates Reviewed: 02/2019, 11/2019, 11/2020, 11/2021, 04/2022, 11/2022, 11/2023, 12/2024

I. Length of Authorization

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

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 750 billable units (2 vials) per 21 days

III. Initial Approval Criteria [1,2]

Coverage is provided in the following conditions:

- Patient is at least 1 month and less than 21.5 years of age; **AND**
- Patient must not have a history of serious hypersensitivity reactions **§** with pegylated L-asparaginase therapy; **AND**
- Patient must not have a history of serious pancreatitis, thrombosis, or hemorrhagic events with prior L-asparaginase therapy; **AND**

Universal Criteria [1]

- Patient must not have severe hepatic impairment; **AND**
- Used as a component of a multi-agent chemotherapy regimen; **AND**
- Patient will receive premedication prior to administration of Asparlas to decrease the risk and severity of both infusion and hypersensitivity reactions**§** (e.g., acetaminophen, an H-1 receptor blocker [such as diphenhydramine], and an H-2 receptor blocker [such as famotidine]); **AND**

Acute Lymphoblastic Leukemia (ALL) † ‡ Φ [1,2]

§ Definition of Hypersensitivity Reactions (CTCAE v5.0) [4,5]
Allergic Reaction – Grade 1: Systemic intervention not indicated – Grade 2: Oral intervention indicated – Grade 3: Bronchospasm; hospitalization indicated for clinical sequelae; IV intervention indicated – Grade 4: Life-threatening consequences; urgent intervention indicated – Grade 5: Death **Anaphylaxis** – Grade 1 or 2: N/A

- Grade 3: Symptomatic bronchospasm, with or without urticaria; parenteral intervention indicated; allergy-related edema/angioedema; hypotension
- Grade 4: Life-threatening consequences; urgent intervention indicated
- Grade 5: Death

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,2]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and indication-specific criteria as identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hypersensitivity reactions (including anaphylaxis), pancreatitis, serious thrombotic events, hemorrhage, severe hepatotoxicity including hepatic veno-occlusive disease, etc.; **AND**
- Disease stabilization or improvement as evidenced by a complete response [CR] (e.g., morphologic, cytogenetic or molecular complete response CR), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

V. Dosage/Administration [1]

Indication	Dose
Acute Lymphoblastic Leukemia	Administer 2,500 units/m^2 intravenously given no more frequently than every 21 days
Note: Premedicate patients 30-60 minutes prior to administration of therapy. Because of the risk of serious allergic reactions (e.g., life-threatening anaphylaxis), administer in a clinical setting with resuscitation equipment and other agents necessary to treat anaphylaxis (e.g., epinephrine, oxygen, intravenous steroids, antihistamines) and observe patients for 1 hour after administration.	

VI. Billing Code/Availability Information

HCPCS Code:

- J9118 – Injection, calaspargase pegol-mknl, 10 units: 1 billable unit = 10 units

NDC:

- Asparlas 3,750 units/5 mL single-dose vial: 72694-0515-xx

VII. References

1. Asparlas [package insert]. Boston, MA; Servier Pharmaceuticals Inc.; November 2023. Accessed October 2024.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for calaspargase pegol-mknl. National Comprehensive Cancer Network, 2024.

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 2024.

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 DFCI ALL Consortium Protocol 11-001. Blood 2016;128:175.
4. Stock W, Douer D, DeAngelo DJ, et al. Prevention and management of asparaginase/pegasparaginase-associated toxicities in adults and older adolescents: recommendations of an expert panel. Leuk Lymphoma 2011:52;2237-2253.
5. Common Terminology Criteria for Adverse Events (CTCAE) v5.0. NIH National Cancer Institute: Division of Cancer Treatment & Diagnosis – Cancer Therapy Evaluation Program. Available at: https://ctep.cancer.gov/protocoldevelopment/electronic_applications/ctc.htm#ctc_50
6. Angiolillo AL, Schore RJ, Devidas M, et al. Pharmacokinetic and pharmacodynamic properties of calaspargase pegol Escherichia coli L-asparaginase in the treatment of patients with acute lymphoblastic leukemia: results from Children's Oncology Group study AALL07P4. J Clin Oncol. 2014;32(34):3874-3882.

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
C83.57	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)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): 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 GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC