Oncaspar® (pegaspargase)
(Intramuscular/Intravenous)

Document Number: IC-0290

Last Review Date: 04/04/2022
Date of Origin: 12/20/2016
Dates Reviewed: 12/2016, 10/2017, 11/2018, 02/2019, 11/2019, 11/2020, 11/2021, 04/2022

I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Oncaspar 3,750 IU per 5 mL single-use vial: 2 vials every 14 days

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

- 2 billable units per 14 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 1 month of age; **AND**
- Patient must not have a history of serious thrombosis or hemorrhagic events with prior L-asparaginase therapy; **AND**
- Patient must not have a history of pancreatitis, including pancreatitis related to prior L-asparaginase therapy; **AND**

Universal Criteria [1,2]

- Patient must not have severe hepatic impairment (i.e., Child-Pugh class C); **AND**
- Used as a component of a multi-agent chemotherapy; **AND**
- Patient will receive premedication prior to administration of Oncaspar 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]

- Patient has a hypersensitivity to native forms of L-asparaginase †; **OR**
- Used as first line/induction therapy †; **OR**

- Used as consolidation therapy; **AND**
    - Patient has Philadelphia chromosome (Ph)-positive B-ALL; **AND**
        - Treatment regimen includes a tyrosine kinase inhibitor (i.e., bosutinib, dasatinib, imatinib, nilotinib, or ponatinib); **OR**
    - Patient has Ph chromosome-negative B-ALL; **OR**
    - Patient has Ph chromosome-like B-ALL; **OR**
    - Patient has T-ALL; **OR**
- Used for relapsed/refractory disease ‡; **AND**
    - Patient has Ph chromosome-negative B-ALL or T-ALL; **OR**
    - Patient has Ph chromosome-positive B-ALL; **AND**
        - Patient is refractory to tyrosine kinase inhibitor therapy; **OR**
        - Used in combination with a tyrosine kinase inhibitor (i.e., bosutinib, dasatinib, imatinib, nilotinib, ponatinib, etc.) as part of a regimen not previously given; **OR**
- Used as systemic CNS-directed therapy ‡

T-Cell Lymphomas ‡ [2]

- Patient has Extranodal NK/T-Cell Lymphoma; **AND**
    - Used for relapsed or refractory disease if not previously used; **OR**
    - Used for induction therapy for nasal or extra-nasal disease; **OR**
    - Used as additional therapy, if not previously used, in patients with a positive biopsy following a partial or no response to induction therapy; **OR**
- Patient has aggressive NK-cell leukemia (ANKL); **OR**
- Used for Hepatosplenic T-Cell Lymphoma as additional therapy if no response or progressive disease after first-line therapy

§Definition of Hypersensitivity Reactions (CTCAE v5.0)[5,6]
Allergic Reaction – Grade 1: Systemic intervention not indicated – Grade 2: Oral intervention indicated – Grade 3: Bronchospasm; hospitalization 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 other indication-specific relevant criteria as identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: anaphylaxis and serious hypersensitivity reactions, serious thrombotic events, pancreatitis, glucose intolerance, hemorrhage, hepatotoxicity, 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 cytogenic analysis, QPCR, or FISH

T-Cell Lymphoma

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

V. Dosage/Administration [1]

Indication	Dose
All indications	Patients ≤ 21 years of age: 2,500 International Units/m^2 intramuscularly or intravenously administered no more frequently than every 14 days. Patients > 21 years of age: 2,000 International Units/m^2 intramuscularly or intravenously administered no more frequently than every 14 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 :

- J9266 – Injection, pegaspargase, per single-dose vial; 1 billable unit = 1 vial

NDC(s):

- Oncaspar 3,750 IU/5 mL solution in a single-dose vial: 72694-0954-XX

VII. References

1. Oncaspar [package insert]. Boston, MA; Servier Pharmaceuticals LLC; November 2021. Accessed March 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for pegaspargase. National Comprehensive Cancer Network, 2022. 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 March 2022.
3. Avramis VI, Sencer S, Periclou AP, et al. A randomized comparison of native Escherichia coli asparaginase and polyethylene glycol conjugated asparaginase for treatment of children with newly diagnosed standard-risk acute lymphoblastic leukemia: a Children's Cancer Group study. Blood. 2002 Mar 15;99.
4. Kurtzberg J, Asselin B, Bernstein M, et al. Polyethylene Glycol-conjugated L-asparaginase versus native L-asparaginase in combination with standard agents for children with acute lymphoblastic leukemia in second bone marrow relapse: a Children's Oncology Group Study (POG 8866). J Pediatr Hematol Oncol. 2011;33(8):610-616. doi:10.1097/MPH.0b013e31822d4d4e.
5. 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.
6. 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.

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

ICD-10	ICD-10 Description
C83.59	Lymphoblastic (diffuse) lymphoma, extranodal and solid organ sites
C84.90	Mature T/NK-cell lymphomas, unspecified, unspecified site
C84.91	Mature T/NK-cell lymphomas, unspecified, lymph nodes of head, face, and neck
C84.92	Mature T/NK-cell lymphomas, unspecified, intrathoracic lymph nodes
C84.93	Mature T/NK-cell lymphomas, unspecified, intra-abdominal lymph nodes
C84.94	Mature T/NK-cell lymphomas, unspecified, lymph nodes of axilla and upper limb
C84.95	Mature T/NK-cell lymphomas, unspecified, lymph nodes of inguinal region and lower limb
C84.96	Mature T/NK-cell lymphomas, unspecified, intrapelvic lymph nodes
C84.97	Mature T/NK-cell lymphomas, unspecified, spleen
C84.98	Mature T/NK-cell lymphomas, unspecified, lymph nodes of multiple sites
C84.99	Mature T/NK-cell lymphomas, unspecified, extranodal and solid organ sites
C84.Z0	Other mature T/NK-cell lymphomas, unspecified site
C84.Z1	Other mature T/NK-cell lymphomas, lymph nodes of head, face, and neck
C84.Z2	Other mature T/NK-cell lymphomas, intrathoracic lymph nodes
C84.Z3	Other mature T/NK-cell lymphomas, intra-abdominal lymph nodes
C84.Z4	Other mature T/NK-cell lymphomas, lymph nodes of axilla and upper limb
C84.Z5	Other mature T/NK-cell lymphomas, lymph nodes of inguinal region and lower limb
C84.Z6	Other mature T/NK-cell lymphomas, intrapelvic lymph nodes
C84.Z7	Other mature T/NK-cell lymphomas, spleen
C84.Z8	Other mature T/NK-cell lymphomas, lymph nodes of multiple sites
C84.Z9	Other mature T/NK-cell lymphomas, extranodal and solid organ sites
C86.0	Extranodal NK/T-cell lymphoma, nasal type
C86.1	Hepatosplenic T-cell lymphoma
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),Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/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/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, 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.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC