

Oncaspar® (pegaspargase) (Intramuscular/Intravenous)

Document Number: IC-0290

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Date of Origin: 12/20/2016

Dates Reviewed: 12/2016, 10/2017, 11/2018, 02/2019, 11/2019, 11/2020

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 old; **AND**

Universal Criteria ^{1,2}

- Patient must not have a history of serious pancreatitis, thrombosis, or hemorrhagic events with prior L-asparaginase therapy; **AND**
- Patient must not have severe hepatic impairment (i.e., Child-Pugh class C); **AND**
- Used as a component of a multi-agent chemotherapy; **AND**

Acute Lymphoblastic Leukemia (ALL) † Φ

- Used as first line therapy †; **OR**
- Used to treat patients with a hypersensitivity to native forms of L-asparaginase †; **OR**
- Used as systemic CNS-directed therapy †; **OR**
- Used in relapsed/refractory disease †; **AND**
 - Patient is Ph chromosome-negative; **OR**
 - Patient is Ph chromosome-positive; **AND**
 - Patient is refractory to tyrosine kinase inhibitor therapy; **OR**

- Used in combination with a tyrosine kinase inhibitor as part of a regimen not previously given

T-Cell Lymphomas †

- Patient has Extranodal NK/T-Cell Lymphoma nasal type disease; **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

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

IV. Renewal Criteria ^{1,2}

Coverage can be renewed based upon the following criteria:

- Patient continues to meet 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 allergic reactions (including anaphylaxis), thrombosis (including sagittal sinus thrombosis, cerebral thrombosis, ischemia, stroke), coagulopathy, severe hyperglycemia, pancreatitis, bleeding (including intracranial hemorrhage) 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)

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

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

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 per 5 mL single-use vial: 57665-0002-XX

VII. References

1. Oncaspar [package insert]. Cambridge, MA; Baxalta US Inc.; August 2019. Accessed October 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for pegaspargase. National Comprehensive Cancer Network, 2020. 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 2020.
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.

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
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

ICD-10	ICD-10 Description
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:

<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/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