



Oncaspar® (pegaspargase)

Document Number: IC-0290

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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]:

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

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

- 2 billable units per 14 days

III. Initial Approval Criteria

- Patient is 1 year or older; **AND**
- Patient must not have a history of serious pancreatitis, thrombosis, or hemorrhagic events with prior L-asparaginase* therapy; **AND**
- Must be used as a component of multi-agent chemotherapy; **AND**

Coverage is provided in the following conditions:

Acute lymphoblastic leukemia (ALL) †

- Used as first line therapy †; **OR**
- May be used to treat patients with a hypersensitivity to native forms of L-asparaginase †; **OR**
- Used in relapsed/refractory disease ‡; **AND**
 - Patient is Ph chromosome-negative; **OR**
 - Patient is Ph chromosome-positive; **AND**
 - Refractory to tyrosine kinase inhibitor therapy or used in conjunction with a TKI (if not used previously)

Extranodal NK/T-Cell Lymphoma ‡

- Patient has nasal disease

* *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**
- Stabilization of disease and/or absence of progression of disease; **AND**
- Absence of unacceptable toxicity from the drug (e.g., allergic reactions (including anaphylaxis), central nervous system (CNS) thrombosis, coagulopathy, elevated transaminases, hyperbilirubinemia, hyperglycemia, and pancreatitis, etc.)

V. Dosage/Administration

Indication	Dose
All indications	2,500 International Units/m ² IM or IV administered no more frequently than every 14 days.

*Store refrigerated at 2 to 8° C

VI. Billing Code/Availability Information

Jcode:

- J9266 – Injection, pegaspargase, per single dose vial

NDC(s):

- Oncaspar 3,750 IU per 5 mL single-use vial: 54482-0301-XX

VII. References

1. Oncaspar [package insert]. Cambridge, MA; Baxalta US Inc.; March 2016. Accessed September 2017.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for pegaspargase. National Comprehensive Cancer Network, 2017. 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 September 2017.
3. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD) for Chemotherapy Drugs and their Adjuncts (L35053). Centers for Medicare & Medicaid Services, Inc. Revised on 05/16/2017 with effective date 06/01/2017. Accessed September 2017.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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
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):

Jurisdiction(s): 5, 8	NCD/LCD Document (s): L35053
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L35053&bc=gAAAAAAAAAAAAA==	

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	Cahaba 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.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC