



## Oncaspar® (pegaspargase) (Intramuscular/Intravenous)

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Last Review Date: 10/28/2019

Date of Origin: 12/20/2016

Dates Reviewed: 12/2016, 10/2017, 11/2018, 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]:

- 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

Coverage is provided in the following conditions:

- Patient is 1 year or older; **AND**
- Patient must not have a history of serious hypersensitivity to pegaspargase or to any of the excipients, pancreatitis, severe hepatic impairment, thrombosis or hemorrhagic events with prior L-asparaginase\* therapy; **AND**
- Must be used as a component of multi-agent chemotherapy; **AND**

#### 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 as systemic CNS-directed therapy ‡; **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)

#### Acute Myeloid Leukemia (AML)

- Patient has diagnosis of Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN); **AND**
  - Used as treatment induction in candidates for intensive remission therapy; **OR**
  - Used for relapsed/refractory disease (if not already used) as a component of AspaMetDex (pegaspargase, methotrexate, dexamethasone)

#### **Extranodal NK/T-Cell Lymphoma ‡**

- Patient has nasal type disease; **AND**
  - Used as induction therapy; **OR**
  - Used as additional therapy (if regimen not previously used) in patients with a positive biopsy following a partial or no response to induction therapy

\* *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 (including sagittal sinus thrombosis), coagulopathy, severe hyperglycemia, 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)

#### **Acute Myeloid Leukemia (AML) - Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)**

- 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)

#### **Extranodal NK/T-Cell Lymphoma**

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread

## **V. Dosage/Administration**

| <b>Indication</b> | <b>Dose</b>   |
|-------------------|---|
| All indications   | <u>Patients &lt; 21 years old:</u>  |
|                   | 2,500 International Units/m <sup>2</sup> intramuscularly or intravenously administered no more frequently than every 14 days. |
|                   | <u>Patients &gt; 21 years old:</u>  |

|  |   |
|--|---|
|  | 2,000 International Units/m <sup>2</sup> intramuscularly or intravenously 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. 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.; January 2019. Accessed October 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for pegaspargase. 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.

## 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    |
| C84.92 | Mature T/NK-cell lymphomas, unspecified, intrathoracic lymph nodes              |

| ICD-10 | ICD-10 Description   |
|--------|--|
| 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  |
| C86.4  | Blastic NK-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) 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 |

### Medicare Part B Administrative Contractor (MAC) Jurisdictions

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