

Erwinaze® (asparaginase Erwinia chrysanthemi) (Intramuscular/Intravenous)

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Date of Origin: 12/20/2016

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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) [NDC Unit]:

- Erwinaze 10,000 IU lyophilized powder per single-dose vial: 18 vials per 7 days

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

- 190 billable units per week

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

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

Universal Criteria ^{1,2}

- Used as a component of multi-agent chemotherapy; **AND**

Acute Lymphoblastic Leukemia (ALL) † ‡ ^{1,2}

- Used as a substitute for pegaspargase ‡ or E. coli-derived asparaginase † in cases of systemic allergic reaction or anaphylaxis §; **OR**
- Used as induction therapy in patients at least 65 years of age **OR** who have substantial comorbidities ‡; **AND**
 - Patient has Philadelphia chromosome (Ph)-negative ALL; **OR**
 - Patient has Philadelphia chromosome (Ph)-positive B-ALL; **AND**
 - Treatment regimen includes a tyrosine kinase inhibitor (i.e., bosutinib, dasatinib, imatinib, nilotinib, or ponatinib)

T-Cell Lymphomas ‡²

- Patient has Extranodal NK/T-Cell Lymphoma; **AND**
- Used as a substitute for pegaspargase in cases of systemic allergic reaction or anaphylaxis §

§ 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 indication-specific criteria as identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity reactions (including anaphylaxis), glucose intolerance/hyperglycemia, pancreatitis, serious thrombotic or hemorrhagic events, 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>To substitute for a dose of pegaspargase (Oncaspar®):</u> The recommended dose for each planned dose of pegaspargase is 25,000 IU/m ² administered IM or IV 3 times a week (Mon/Wed/Fri) for six doses |

ERWINAZE® (asparaginase Erwinia chrysanthemi)

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| | |
|--|---|
| | <p>To substitute for a dose of native <i>E. coli</i> asparaginase:</p> <p>The recommended dose is 25,000 IU/m² administered IM or IV for each scheduled dose of native <i>E. coli</i> asparaginase</p> |
|--|---|

VI. Billing Code/Availability Information

HCP/CS Code:

- J9019 – Injection, asparaginase (Erwinaze), 1,000 IU; 1 billable unit = 1,000 IU

NDC(s):

- Erwinaze 10,000 IU lyophilized powder per single-dose vial: 57902-0249-xx

VII. References

1. Erwinaze [package insert]. Palo Alto, CA; Jazz Pharmaceuticals, Inc.; December 2019. Accessed October 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Asparaginase *Erwinia chrysanthemi*. 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 October 2022.
3. Pieters R, Hunger SP, Boos J, et al. L-asparaginase treatment in acute lymphoblastic leukemia: a focus on *Erwinia* asparaginase. *Cancer*. 2011 Jan 15; 117(2): 238–249.
4. Raetz EA, Salzer WL. Tolerability and Efficacy of L-Asparaginase Therapy in Pediatric Patients With Acute Lymphoblastic Leukemia, *Journal of Pediatric Hematology/Oncology*: October 2010 - Volume 32 - Issue 7 - p 554-563 doi: 10.1097/MPH.0b013e3181e6f003.
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 |

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| ICD-10 | ICD-10 Description |
|--------|--|
| 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 |
| 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), 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 |

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- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

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Minneapolis, MN 55459-0212
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

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