

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

Document Number: IC-0288

Last Review Date: 10/26/2020

Date of Origin: 12/20/2016

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

- Erwinaze 10,000 IU lyophilized powder 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 ¹⁻³

Coverage is provided in the following conditions:

- Patient is at least 1 year of age; **AND**

Universal Criteria

- Patient must not have a history of serious pancreatitis, thrombosis, or hemorrhagic events with prior L-asparaginase therapy; **AND**

Acute lymphoblastic leukemia (ALL) †

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

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

IV. Renewal Criteria ¹

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and indication-specific criteria as identified in section III; **AND**
- 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; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe hypersensitivity reactions including anaphylaxis, hyperglycemia, pancreatitis, thrombosis (including cerebral thrombosis, ischemia, and stroke), bleeding (including intracranial hemorrhage), etc.

V. Dosage/Administration

Indication	Dose
All indications	To substitute for a dose of pegaspargase (Oncaspar®):
	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
	To substitute for a dose of native <i>E. coli</i> asparaginase*:
	The recommended dose is 25,000 IU/m ² administered IM or IV for each scheduled dose of native <i>E. coli</i> asparaginase

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC(s):

- Erwinaze 10,000 IU lyophilized powder per single use vial: 57902-249-XX

VII. References

1. Erwinaze [package insert]. Palo Alto, CA; Jazz Pharmaceuticals, Inc.; December 2019. Accessed September 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Asparaginase *Erwinia chrysanthemi*. 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 September 2020.

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. Palmetto GBA, LLC. Local Coverage Article: Billing and Coding: Chemotherapy (A56141). Centers for Medicare & Medicaid Services, Inc. Updated on 05/26/2020 with effective date 04/30/2020. Accessed October 2020.

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
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):

Jurisdiction(s): J,M	NCD/LCD/Article Document (s): A56141
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56141&bc=gAAAAAAAAAAAA	

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