

## Erwinaze (asparaginase *Erwinia chrysanthemi*) (Intramuscular/Intravenous)

Document Number: IC-0288

Last Review Date: 10/30/2018

Date of Origin: 12/20/2016

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

### 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]:

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

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

- 190 billable units per week

### III. Initial Approval Criteria

Coverage is provided in the following conditions:

Acute lymphoblastic leukemia (ALL) †

- 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
  - Used as a substitute for pegaspargase or E. coli-derived asparaginase in cases of systemic allergic reaction or anaphylaxis ‡

† 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
- 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 cytogenic 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, bleeding, 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 <sup>2</sup> administered IM or IV 3 times a week
	To substitute for a dose of native E. coli asparaginase <sup>†</sup> :
	The recommended dose is 25,000 IU/m <sup>2</sup> administered IM or IV for each scheduled dose of native E. coli asparaginase

\*Note: Elspar (asparaginase) was discontinued in 2012

## VI. Billing Code/Availability Information

Jcode:

- 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.; March 2016. Accessed September 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Asparaginase Erwinia chrysanthemi. National Comprehensive Cancer Network, 2018. 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 2018.
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.

## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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
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