

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date:	October 12, 2011
Revision Date:	November 28, 2011, April 26, 2012, November 16, 2015, April 12, 2024

Erwinaze® (asparaginase erwinia chrysanthemi) and Rylaze® (asparaginase erwinia chrysanthemi [recombinant]-rywn)

LENGTH OF AUTHORIZATION: Up to one year

REVIEW CRITERIA:

Erwinaze

- Patient must be ≥ 1 year of age; **AND**
- Patient must have a diagnosis of Acute Lymphoblastic Leukemia verified by progress notes, discharge notes, or diagnosis code(s); AND
- Medication must be prescribed by an oncologist; AND
- Patient must have a history of serious hypersensitivity reaction (e.g., Grade 3 or higher angioedema, urticaria, rash or erythema, hypotension, bronchospasm, dyspnea, pruritus, etc.) to E. coli-derived asparaginase (e.g., pegaspargase [Oncaspar®]). (Must be clearly documented in official medical records.)

Rylaze

- Patient must be ≥ 1 month old; **AND**
- Patient must have a diagnosis of Acute Lymphoblastic Leukemia or Lymphoblastic Lymphoma verified by progress notes, discharge notes, or diagnosis code(s), **AND**
- Medication must be prescribed by an oncologist; AND
- Patient must have a history of serious hypersensitivity reaction (e.g., Grade 3 or higher angioedema, urticaria, rash or erythema, hypotension, bronchospasm, dyspnea, pruritus, etc.) to E. coli-derived asparaginase (e.g., pegaspargase [Oncaspar®]). (Must be clearly documented in official medical records.)

CONTINUATION OF THERAPY:

- Patient met initial review criteria; AND
- Documentation of a positive clinical response; AND
- Patient has not experienced any treatment-restricting adverse effects; AND
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING & ADMINISTRATION:

• Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/