# Medical Policy and Prior Authorization Notice

## Asparaginase Erwinia (recombinant)-rywn (Rylaze®)

Effective Date-9/6/24
Renewal Date-12/17/25

**PURPOSE:**

The goal of this policy is to establish standards and recommendations for the proper use of Erwinia asparaginase in the Parkland Community Health Plan for the best possible member care, safety, and resource management.

**SCOPE:**

All Parkland Community Health Plan members of STAR, and CHIP.

**POLICY:**

### 1. Descriptions

Asparaginase Erwinia (recombinant)-rywn (Rylaze®) is specific to asparagine specific enzymes

### 2. Initial Approval Indication(s)

Asparaginase Erwinia (recombinant)-rywn is recommended for the treatment of patients with acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) in adults and pediatric patients 1 month or older who have developed hypersensitivity to *E.coli*-derived asparaginase.

I. A) **Initial Approval Criteria:** Rylaze will be considered as medically necessary when all the following criteria are met:
   a. Prescribing is limited to a hematologist-oncologist.
   b. Diagnosis of ALL or LBL
   c. At least 1 month of age
   d. Has hypersensitivity to *E.coli*-derived asparaginase product or pegaspargase (Oncaspar®)
   e. Has no contraindications/boxed warnings such as
      i. history of serious hypersensitivity reactions (including anaphylaxis) to asparaginase (*Erwinia*) or any component of the formulation

ii. history of serious pancreatitis, serious thrombosis, or serious hemorrhagic events with prior asparaginase treatment
iii. severe hepatic impairment.

f. Member should be monitored according per FDA-approved labeling and best practices.

B) **Approval duration:** maximum of 6 months

J. II. A) **Continued Therapy:** Rylaze will be considered as medically necessary when all the following criteria are met:
   a. All indications from section I
   b. Has shown improvement from therapy
   c. Member should be monitored per FDA-approved labeling and best practices.

B) **Approval duration:** maximum of 6 months

**REGULATORY REFERENCES:**

Centene Corporation: Clinical policy: Erwinia asparaginase (Erwinaze, Rylaze). https://ambetter.pshpgeorgia.com/content/dam/centene/policies/pharmacy-policies/CP.PHAR.301.pdf

Lexicomp (2024). Recombinant Erwinia asparaginase: Drug information. *UpToDate*. Retrieved May 1, 2024.

U.S. Food and Drug Administration, https://nctr-crs.fda.gov/fdalabel/services/spl/set-ids/857e53aa-1098-4dad-b654-0276cdd43e03/spl-doc?hl=Rylaze