

# STANDARD MEDICARE PART B MANAGEMENT

## RYLAZE (asparaginase erwinia chrysanthemi (recombinant)-rywn)

### POLICY

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indications

Rylaze is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) in adult and pediatric patients 1 month or older who have developed hypersensitivity to *E. coli*-derived asparaginase.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

#### II. CRITERIA FOR INITIAL APPROVAL

##### **Acute Lymphoblastic Leukemia (ALL) and Lymphoblastic Lymphoma (LBL)**

Authorization of 12 months may be granted for treatment of ALL or LBL in patients 1 month or older who have developed hypersensitivity to *E. coli*-derived asparaginase (e.g., pegaspargase) and the requested medication will be used in conjunction with multi-agent chemotherapy.

#### III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- A. The member is currently receiving therapy with Rylaze
- B. Rylaze is being used to treat an indication enumerated in Section II.
- C. The member is receiving benefit from therapy. Benefit is defined as:
  1. No evidence of unacceptable toxicity while on the current regimen and
  2. No evidence of disease progression while on the current regimen.

#### IV. REFERENCES

1. Rylaze [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; June 2021.

Reference number(s)
4824-A