**Reference number** 

# SPECIALTY GUIDELINE 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 are considered experimental/investigational and not medically necessary.

#### **II. CRITERIA FOR INITIAL APPROVAL**

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

Authorization of 12 months may be granted for the treatment of ALL or LBL in members 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**

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

#### IV. REFERENCES

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

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