

## Medical Policy:

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

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.341	January 9, 2024	September 14, 2021

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

## Definitions

Rylaze, asparaginase erwinia chrysanthemi (recombinant), is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) in adults and pediatric patients ≥ 1 month who have developed hypersensitivity to E. coli-derived asparaginase.

## Length of Authorization

Coverage will be provided for 1 year and may be renewed.

## Dosing Limits [Medical Benefit]

Approve up to 25 mg/m<sup>2</sup> administered by intramuscular injection no more frequently than once every 48 hours for a total of 6 doses in each treatment cycle. (2,500 billable units (250 mg) per week)

## Guideline

### I. INITIAL APPROVAL CRITERIA

1. **Acute lymphoblastic leukemia (ALL)/lymphoblastic lymphoma (LBL):**

Approve if the patient meets all the following criteria:

- A. Patient has a diagnosis of ALL or LBL; **AND**
- B. Patient has a systemic allergic reaction or anaphylaxis to a pegylated asparaginase product

### II. Renewal Criteria:

1. **Acute lymphoblastic leukemia (ALL)/lymphoblastic lymphoma (LBL):**

- A. Patient has experienced a clinical response as determined by the prescribing physician; **AND**
- B. Patient has not experienced unacceptable toxicity from the drug.

## Applicable Procedure Codes

Code	Description
J9021	Injection, asparaginase, recombinant, (Rylaze), 0.1 mg

## Applicable NDCs

Code	Description
68727-0900-01	Solution, Intramuscular; 10 mg/0.5 mL (0.5 mL)
68727-0900-03	Solution, Intramuscular; 10 mg/0.5 mL (3 vials)

## ICD-10 Diagnoses

Code	Description
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse
C83.50	Lymphoblastic (diffuse) lymphoma, unspecified site
C83.51	Lymphoblastic (diffuse) lymphoma, lymph nodes of head, face, and neck
C83.52	Lymphoblastic (diffuse) lymphoma, intrathoracic lymph nodes
C83.53	Lymphoblastic (diffuse) lymphoma, intra-abdominal lymph nodes
C83.54	Lymphoblastic (diffuse) lymphoma, lymph nodes of axilla and upper limb
C83.55	Lymphoblastic (diffuse) lymphoma, lymph nodes of inguinal region and lower limb
C83.56	Lymphoblastic (diffuse) lymphoma, intrapelvic lymph nodes
C83.57	Lymphoblastic (diffuse) lymphoma, spleen
C83.58	Lymphoblastic (diffuse) lymphoma, lymph nodes of multiple sites
C83.59	Lymphoblastic (diffuse) lymphoma, extranodal and solid organ sites

## Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/9/2024	Annual Review: No criteria changes

EmblemHealth & ConnectiCare	5/9/2023	Annual Review: no criteria updates
EmblemHealth & ConnectiCare	1/11/2023	Transfer to New Template, Updated J code from C9399 and J9999 (unclassified) to J9021
EmblemHealth & ConnectiCare	9/14/2021	New Policy

## References

1. Rylaze® [package insert]. Jazz Pharmaceuticals Inc. Palo Alto, CA 2021.
2. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2021.