Asparaginase Erwinia chrysanthemi (recombinant)-rywn (Rylaze™)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

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.

A. 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.

B. Compendial Uses
1. Extranodal Natural Killer/T-cell lymphoma/ Aggressive NK-cell Leukemia (ANKL)

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. 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.

B. Extranodal Natural Killer/T-cell Lymphoma/ Aggressive NK-cell Leukemia (ANKL)
Authorization of 12 months may be granted for the treatment of ENKL or ANKL when both of the following criteria are met:
1. The member has previously received and developed hypersensitivity to an E. coli-derived asparaginase (e.g., pegaspargase).
2. 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.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Rylaze [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; November 2022.
2. The NCCN Drugs & Biologics Compendium® ©2023 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed May 31, 2023.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: T-Cell Lymphomas. Version 1.2023. https:// www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed May 31, 2023.
4. Rylaze. Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed May 31, 2023.

EFFECTIVE DATE 5/31/2024

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