Romidepsin [Istodax®; Romidepsin (liquid)]

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

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
Istodax is indicated for the treatment of cutaneous T-cell lymphoma (CTCL) in adult patients who have received at least one prior systemic therapy

Compendial Uses
Mycosis fungoides (MF)/Sézary syndrome (SS)
Peripheral T-Cell Lymphoma (PTCL)

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

COVERAGE CRITERIA

Cutaneous T-Cell Lymphoma (CTCL)

Authorization of 12 months may be granted for treatment of CTCL (e.g., mycosis fungoides, Sézary syndrome, primary cutaneous anaplastic large cell lymphoma, subcutaneous panniculitis-like T-cell lymphoma).

Peripheral T-Cell Lymphoma (PTCL) (See Appendix)

Authorization of 12 months may be granted for treatment of PTCL.

CONTINUATION OF THERAPY

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

APPENDIX: PTCL Subtypes

- Peripheral T-cell lymphoma not otherwise specified (PTCL-NOS)
- Angioimmunoblastic T-cell lymphoma (AITL)
- Anaplastic large cell lymphoma (ALCL)
- Breast Implant-Associated anaplastic large cell lymphoma (BIA-ALCL)

- Enteropathy-associated T-cell lymphoma (EATL)
- Monomorphic epitheliotropic intestinal T-cell lymphoma (MEITL)
- Nodal peripheral T-cell lymphoma with TFH phenotype (PTCL, TFH)
- Follicular T-cell lymphoma (FTCL)
- Extranodal NK/T-cell lymphoma (ENKL)
- Hepatosplenic T-cell lymphoma (HSTCL)

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. Istodax [package insert]. Summit, NJ: Celgene Corp.; January 2023.
2. Romidepsin [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; December 2021.
3. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed November 14, 2024.

EFFECTIVE DATE 9/30/2025

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