

SPECIALTY GUIDELINE MANAGEMENT

ISTODAX (romidepsin) romidepsin (generic)

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

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

B. Compendial Uses

1. Mycosis fungoides (MF)/Sézary syndrome (SS)
2. Peripheral T-Cell Lymphoma (PTCL)

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

II. CRITERIA FOR INITIAL APPROVAL

A. **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).

B. **Peripheral T-cell lymphoma (PTCL)** (see Appendix)

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

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. APPENDIX: PTCL subtypes

1. Peripheral T-cell lymphoma not otherwise specified (PTCL-NOS)
2. Angioimmunoblastic T-cell lymphoma (AITL)
3. Anaplastic large cell lymphoma (ALCL)
4. Breast Implant-Associated anaplastic large cell lymphoma (BIA-ALCL)
5. Enteropathy-associated T-cell lymphoma (EATL)
6. Monomorphic epitheliotropic intestinal T-cell lymphoma (MEITL)

Reference number
1859-A

7. Nodal peripheral T-cell lymphoma with TFH phenotype (PTCL, TFH)
8. Follicular T-cell lymphoma (FTCL)
9. Extranodal NK/T-cell lymphoma (ENKL)
10. Hepatosplenic T-cell lymphoma (HSTCL)

V. 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 January 5, 2024.