

Reference number
1859-A

SPECIALTY GUIDELINE MANAGEMENT

ISTODAX (romidepsin)

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

1. Cutaneous T-cell lymphoma (CTCL) in patients who have received at least one prior systemic therapy
2. Peripheral T-cell lymphoma (PTCL) in patients who have received at least one prior therapy

1. Compendial Uses Mycosis fungoides (MF)
2. Sézary syndrome (SS)

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

II. EXCLUSIONS

Coverage will not be provided for members with the following exclusion: Concomitant use of romidepsin with vorinostat (Zolinza).

III. 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.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III who have not experienced disease progression or an unacceptable toxicity.

V. 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), anaplastic lymphoma kinase (ALK)+/ALK-
4. Enteropathy-associated T-cell lymphoma (EATL)

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5. Monomorphic epitheliotropic intestinal T-cell lymphoma (MEITL)
6. Nodal peripheral T-cell lymphoma with TFH phenotype (PTCL, TFH)
7. Follicular T-cell lymphoma (FTCL)
8. Extranodal NK/T-cell lymphoma, nasal type (ENKL)
9. Hepatosplenic gamma-delta-T-cell lymphoma (HSGDTCL)

VI. REFERENCES

1. Istodax [package insert]. Summit, NJ: Celgene Corp.; November 2018.
2. The NCCN Drugs & Biologics Compendium™ © 2019 National Comprehensive Cancer Network, Inc. <https://www.nccn.org> Accessed September 11, 2019.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Primary Cutaneous Lymphomas (Version 2.2019). <https://www.nccn.org>. Accessed September 11, 2019.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: T-Cell Lymphomas (Version 2.2019). <https://www.nccn.org>. Accessed September 11, 2019.