

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

B. Compendial Uses

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

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR APPROVAL

A. **Cutaneous T-cell lymphoma (CTCL)**

Authorization of 12 months may be granted for the treatment of CTCL (e.g., mycosis fungoides, Sézary syndrome).

B. **Peripheral T-cell lymphoma (PTCL)**(see Appendix for examples of PTCL subtypes)

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

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

IV. APPENDIX: Examples of 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. Primary cutaneous anaplastic large cell lymphoma (PC-ALCL)
5. Enteropathy-associated T-cell lymphoma (EATL)
6. Adult T-cell leukemia/lymphoma (ATLL)
7. Monomorphic epitheliotropic intestinal T-cell lymphoma (MEITL)
8. Nodal peripheral T-cell lymphoma with TFH phenotype (PTCL, TFH)

Reference number
1859-A

9. Follicular T-cell lymphoma (FTCL)
10. Extranodal NK/T-cell lymphoma, nasal type (ENKL)
11. Hepatosplenic gamma-delta-T-cell lymphoma (HSGDTCL)

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 January 28, 2019.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Primary Cutaneous Lymphomas (Version 2.2019). <https://www.nccn.org>. Accessed January 28, 2019.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: T-Cell Lymphomas (Version 2.2019). <https://www.nccn.org>. Accessed January 28, 2019.