Reference number(s)
1859-A

Specialty Guideline Management romidepsin - Istodax

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Istodax	romidepsin
romidepsin (all brands)	romidepsin

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[1,2]

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[3]

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

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

Reference number(s)
1859-A

Coverage Criteria

Cutaneous T-Cell Lymphoma (CTCL)[1-3]

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

Peripheral T-Cell Lymphoma (PTCL)[3] (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[3]

- 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)

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.