

Romidepsin (Istodax)

Override	Approval Duration
Prior Authorization	1 year

Medication
Istodax (romidepsin) Romidepsin

APPROVAL CRITERIA

Requests for Istodax (romidepsin) or Romidepsin may be approved if the following criteria are met:

- I. Individuals has a diagnosis of cutaneous T-cell lymphoma; **AND**
- II. Individual is using for relapsed or refractory disease following at least one prior systemic therapy;

OR

- III. Individual has a diagnosis of Primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions; **AND**
 - A. Individual has relapsed or refractory disease; **AND**
 - B. Using romidepsin as monotherapy;

OR

- IV. Individual has a diagnosis of cutaneous ALCL with regional node (N1); **AND**
 - C. Individual has relapsed or refractory disease; **AND**
 - D. Using romidepsin as monotherapy;

OR

- V. Individual has a diagnosis of Mycosis Fungoides or Sézary Syndrome (NCCN 2A).

Requests for Istodax (romidepsin) or Romidepsin may not be approved when the above criteria are not met and for all other indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 30, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.

5. Coiffier B, Pro B, Prince HM, et al. Results from a Pivotal, Open-Label, Phase II Study of Romidepsin in Relapsed or Refractory Peripheral T-Cell Lymphoma after Prior Systemic Therapy. *J Clin Oncol* 2012; 30: 631-636.
6. Bachy E, Camus V, Thieblemont C, et al. Romidepsin Plus CHOP Versus CHOP in Patients with Previously Untreated Peripheral T-Cell Lymphoma: Results of the Ro-CHOP Phase III Study (Conducted by LYSA). *J Clin Oncol* 2022; 40:242-251.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on June 30, 2023.
8. Primary Cutaneous Lymphomas. V1.2023. Revised January 5, 2023.
9. T-Cell Lymphomas. V1.2023. Revised January 5, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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