CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – Histone Deacetylase Inhibitor) – Romidepsin Products Utilization Management Medical Policy
- Istodax® (romidepsin intravenous infusion – Celgene, generic)

REVIEW DATE: 06/12/2024

OVERVIEW

Romidepsin, a histone deacetylase inhibitor, is indicated for the treatment of **cutaneous T-cell lymphoma** in patients who have received at least one prior systemic therapy.[1]

Guidelines

Romidepsin is addressed in National Comprehensive Cancer Network (NCCN) guidelines:

- **Primary Cutaneous Lymphomas:** Guidelines (version 2.2024 – May 6, 2024) recommend romidepsin as systemic therapy for mycosis fungoides/Sezary syndrome with or without skin-directed therapy and as a single agent for relapsed or refractory primary cutaneous CD30+ T-cell lymphoproliferative disorders.[2,3]
- **T-Cell Lymphomas:** Guidelines (version 4.2024 – May 28, 2024) recommend romidepsin as a single agent for the second-line or subsequent therapy of relapsed or refractory peripheral T-cell lymphomas including anaplastic large cell lymphoma; peripheral T-cell lymphoma not otherwise specified, angioimmunoblastic T-cell lymphoma, enteropathy-associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, and nodal peripheral T-cell lymphoma with T-follicular helper (TFH) phenotype; follicular T-cell lymphoma; breast implant-associated anaplastic large cell lymphoma; extranodal NK/T-cell lymphoma; and hepatosplenic T-cell lymphoma.[3,4]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of romidepsin. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with romidepsin as well as the monitoring required for adverse events and long-term efficacy, approval requires romidepsin to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of romidepsin is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Cutaneous CD30+ T-Cell Lymphoproliferative Disorders.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has relapsed or refractory disease; AND
   - **C)** Patient has one of the following diagnoses (i or ii):
     - **i.** Primary cutaneous anaplastic large cell lymphoma with multifocal lesions; OR
     - **ii.** Cutaneous anaplastic large cell lymphoma with regional nodes; AND
   - **D)** Romidepsin is used as a single agent; AND
   - **E)** Romidepsin is prescribed by or in consultation with an oncologist.

   Dosing. Approve up to 14 mg/m^2 administered intravenously on Days 1, 8, and 15 of each 28-day cycle.

2. **Mycosis Fungoides/Sezary Syndrome.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication is prescribed by or in consultation with an oncologist or dermatologist.

   Dosing. Approve up to 14 mg/m^2 administered intravenously on Days 1, 8, and 15 of each 28-day cycle.

Other Uses with Supportive Evidence

3. **Breast Implant-Associated Anaplastic Large Cell Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has relapsed or refractory disease; AND
   - **C)** Romidepsin is used as a single agent; AND
   - **D)** Romidepsin is prescribed by or in consultation with an oncologist.

   Dosing. Approve up to 14 mg/m^2 administered intravenously on Days 1, 8, and 15 of each 28-day cycle.

4. **Extranodal NK/T-Cell Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has relapsed/refractory disease following combination asparaginase-based chemotherapy; AND

     Note: Examples of asparaginase-based chemotherapy include modified SMILE (steroid [dexamethasone], methotrexate, ifosfamide, pegaspargase, and etoposide), P-GEMOX (gemcitabine, pegaspargase, and oxaliplatin), and DDGP (dexamethasone, cisplatin, gemcitabine, pegaspargase).
   - **C)** Romidepsin is used as a single agent; AND
   - **D)** Romidepsin is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 14 mg/m^2 administered intravenously on Days 1, 8, and 15 of each 28-day cycle.

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5. Hepatosplenic T-Cell Lymphoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

A) Patient is ≥ 18 years of age; AND

B) Romidepsin is used as subsequent therapy after two primary treatment regimens; AND
Note: Examples of primary treatment regimens include ICE (ifosfamide, carboplatin, etoposide), DHAP (dexamethasone, cytarabine, cisplatin), DHAX (dexamethasone, cytarabine, oxaliplatin), IVAC (ifosfamide, etoposide, cytarabine).

C) Romidepsin is used as a single agent; AND

D) Romidepsin is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 14 mg/m^2 administered intravenously on Days 1, 8, and 15 of each 28-day cycle.

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6. T-Cell Lymphoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
Note: Examples of peripheral T-cell lymphoma include anaplastic large cell lymphoma, enteropathy-associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, angioimmunoblastic T-cell lymphoma, peripheral T-cell lymphoma not otherwise specified.

A) Patient is ≥ 18 years of age; AND

B) Patient has peripheral disease; AND

C) Patient has relapsed or refractory disease; AND

D) Romidepsin is used as a single agent; AND

E) Romidepsin is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 14 mg/m^2 administered intravenously on Days 1, 8, and 15 of each 28-day cycle.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of romidepsin is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Istodax® intravenous infusion [prescribing information]. Summit, NJ: Celgene; July 2021.
2. The NCCN Primary Cutaneous Lymphomas Clinical Practice Guidelines in Oncology (version 2.2024 – May 6, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 4, 2024.
3. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 4, 2024. Search term: romidepsin.
4. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 4.2024 – May 28, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 4, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	06/14/2023
Annual Revision	No criteria changes.	06/12/2024
Update	04/08/2025: The policy name was changed from "Oncology (Injectable) – Romidepsin Products UM Medical Policy" to "Oncology (Injectable – Histone Deacetylase Inhibitor) – Romidepsin Products UM Medical Policy".	N/A