Subject to: ☐Site of Care
☐Medication Sourcing

Romidepsin:
Istodax®; Romidepsin (liquid)
(Intravenous)

Document Number: IC-0217

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 1200 billable units every 28 days

III. Initial Approval Criteria [1-2]

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**

Cutaneous Lymphomas † ‡ [1-3,7]

- Cutaneous T-Cell Lymphoma (CTCL) **† Φ**
  (Including: Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders [primary cutaneous anaplastic large cell lymphoma], Mycosis Fungoides/Sezary Syndrome)
  - Used as single agent systemic therapy; **AND**
    - Member has failed prior systemic therapy **†**; **OR**
    - Used as primary therapy for Mycosis Fungoides/Sezary Syndrome, including generalized cutaneous or extracutaneous lesions with large cell transformation (*excluding use in stage IA disease*) **‡**
- Subcutaneous Panniculitis-Like T-Cell Lymphoma (SPTCL) **‡**
  - Member has hemophagocytic lymphohistiocytosis, systemic disease, or high tumor burden (widespread subcutaneous disease); **AND**

        - Used as single agent maintenance therapy following complete or partial response to first-line therapy; **OR**
        - Used as a single agent or in combination with prednisone for one of the following:
            - First-line therapy
            - Additional treatment for inadequate response to first-line therapy (if not previously used)
            - Retreatment for relapse after first-line therapy
            - Additional treatment for relapsed disease (if not previously used); **OR**
    - Member has SPTCL without hemophagocytic lymphohistiocytosis and has low tumor burden (localized or limited subcutaneous disease); **AND**
        - Used as a single agent or in combination with prednisone following inadequate response to first-line therapy

T-Cell Lymphomas ‡ [3,10]

- Peripheral T-Cell Lymphomas (PTCL)

  (*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; Nodal peripheral T-cell lymphoma with TFH phenotype; Follicular T-cell lymphoma)*
    - Used as a single agent as initial palliative intent therapy; **OR**
    - Used as subsequent therapy for relapsed/refractory OR progressive disease; **AND**
        - Used as a single agent; **OR**
        - Used in combination with duvelisib in members with intention to proceed to transplant *(**Note**: Does not apply to anaplastic large cell lymphoma)*
- Extranodal NK/T-Cell Lymphomas
    - Used as single agent therapy; **AND**
    - Used for relapsed/refractory disease following additional therapy with an alternate combination chemotherapy regimen (asparaginase-based) not previously used
- Hepatosplenic T-Cell Lymphoma
    - Used for refractory disease after two (2) first-line therapy regimens; **AND**
        - Used as a single agent; **OR**
        - Used in combination with duvelisib in members with intention to proceed to transplant
- Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)
    - Used as subsequent therapy for relapsed/refractory disease; **AND**
        - Used as a single agent; **OR**

- Used in combination with duvelisib in members with intention to proceed to transplant

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria

Prior authorization validity may be renewed based on the following criteria:

- Member continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: myelosuppression (e.g., neutropenia, lymphopenia, anemia, leukopenia, thrombocytopenia, etc.), serious infections (e.g., pneumonia, sepsis, viral reactivation of Epstein Barr or hepatitis B, etc.), tumor lysis syndrome (TLS), electrocardiographic (ECG) changes (e.g., T-wave, ST-segment changes, etc.), etc.

V. Dosage/Administration [1,2,8,9-10]

Indication	Dose
All Indications	Administer up to 14 mg/m² intravenously on days 1, 8, and 15 of a 28-day cycle. Repeat cycles until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS Code(s):

- J9319 – Injection, romidepsin, lyophilized, 0.1 mg; 1 billable unit = 0.1 mg
- J9318 – Injection, romidepsin, non-lyophilized, 0.1 mg; 1 billable unit = 0.1 mg Ψ

NDC(s):

- Istodax Kit (10 mg single-dose vial): 59572-0984-xx §
- Romidepsin 27.5 mg/5.5 mL single-dose vial solution for injection: 00703-4004-xx Ψ *
- Romidepsin 10 mg/2 mL single-dose vial solution for injection: 00703-3071-xx Ψ *

– * *No longer commercially available*
– § *Also available as an ANDA generic*
– Ψ *Designated products approved by the FDA as a 505(b)(2) NDA of the innovator product. These products may be available from several different manufacturers. For a complete list of all available products and NDCs please reference the FDA website at National Drug Code Directory for Romidepsin. These products are not rated as therapeutically equivalent to their reference listed drug in the Food and Drug Administration's (FDA) Orange Book and*

are therefore considered single source products based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Act. For a complete list of all approved 505(b)(2) NDA products please reference the latest edition of the Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book | FDA

VII. References

1. Istodax [package insert]. Princeton, NJ; Celgene Corporation; January 2023. Accessed March 2026.
2. Romidepsin [package insert]. North Wales, PA; Teva Pharmaceuticals USA, Inc.; December 2021. Accessed March 2026.
3. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) romidepsin. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2026.
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8. 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 Feb 20;30(6):631-6. doi: 10.1200/JCO.2011.37.4223.
9. Coiffier B, Pro B, Prince HM, et al. Romidepsin for the treatment of relapsed/refractory peripheral T-cell lymphoma: pivotal study update demonstrates durable responses. J Hematol Oncol. 2014 Jan 23;7:11. doi: 10.1186/1756-8722-7-11.
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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C84.00	Mycosis fungoides, unspecified site
C84.01	Mycosis fungoides, lymph nodes of head, face, and neck
C84.02	Mycosis fungoides, intrathoracic lymph nodes
C84.03	Mycosis fungoides, intra-abdominal lymph nodes
C84.04	Mycosis fungoides, lymph nodes of axilla and upper limb
C84.05	Mycosis fungoides, lymph nodes of inguinal region and lower limb
C84.06	Mycosis fungoides, intrapelvic lymph nodes
C84.07	Mycosis fungoides, spleen
C84.08	Mycosis fungoides, lymph nodes of multiple sites
C84.09	Mycosis fungoides, extranodal and solid organ sites
C84.10	Sézary disease, unspecified site
C84.11	Sézary disease, lymph nodes of head, face, and neck
C84.12	Sézary disease, intrathoracic lymph nodes
C84.13	Sézary disease, intra-abdominal lymph nodes
C84.14	Sézary disease, lymph nodes of axilla and upper limb
C84.15	Sézary disease, lymph nodes of inguinal region and lower limb
C84.16	Sézary disease, intrapelvic lymph nodes
C84.17	Sézary disease, spleen
C84.18	Sézary disease, lymph nodes of multiple sites
C84.19	Sézary disease, extranodal and solid organ sites
C84.40	Peripheral T-cell lymphoma, not classified, unspecified site
C84.41	Peripheral T-cell lymphoma, not classified, lymph nodes of head, face, and neck

ICD-10	ICD-10 Description
C84.42	Peripheral T-cell lymphoma, not classified, intrathoracic lymph nodes
C84.43	Peripheral T-cell lymphoma, not classified, intra-abdominal lymph nodes
C84.44	Peripheral T-cell lymphoma, not classified, lymph nodes of axilla and upper limb
C84.45	Peripheral T-cell lymphoma, not classified, lymph nodes of inguinal region and lower limb
C84.46	Peripheral T-cell lymphoma, not classified, intrapelvic lymph nodes
C84.47	Peripheral T-cell lymphoma, not classified, spleen
C84.48	Peripheral T-cell lymphoma, not classified, lymph nodes of multiple sites
C84.49	Peripheral T-cell lymphoma, not classified, extranodal and solid organ sites
C84.60	Anaplastic large cell lymphoma, ALK-positive, unspecified site
C84.61	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of head, face, and neck
C84.62	Anaplastic large cell lymphoma, ALK-positive, intrathoracic lymph nodes
C84.63	Anaplastic large cell lymphoma, ALK-positive, intra-abdominal lymph nodes
C84.64	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of axilla and upper limb
C84.65	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of inguinal region and lower limb
C84.66	Anaplastic large cell lymphoma, ALK-positive, intrapelvic lymph nodes
C84.67	Anaplastic large cell lymphoma, ALK-positive, spleen
C84.68	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of multiple sites
C84.69	Anaplastic large cell lymphoma, ALK-positive, extranodal and solid organ sites
C84.70	Anaplastic large cell lymphoma, ALK-negative, unspecified site
C84.71	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of head, face, and neck
C84.72	Anaplastic large cell lymphoma, ALK-negative, intrathoracic lymph nodes
C84.73	Anaplastic large cell lymphoma, ALK-negative, intra-abdominal lymph nodes
C84.74	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of axilla and upper limb
C84.75	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of inguinal region and lower limb
C84.76	Anaplastic large cell lymphoma, ALK-negative, intrapelvic lymph nodes
C84.77	Anaplastic large cell lymphoma, ALK-negative, spleen
C84.78	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of multiple sites
C84.79	Anaplastic large cell lymphoma, ALK-negative, extranodal and solid organ sites
C84.7A	Anaplastic large cell lymphoma, ALK-negative, breast
C84.90	Mature T/NK-cell lymphomas, unspecified, unspecified site
C84.91	Mature T/NK-cell lymphomas, unspecified, lymph nodes of head, face, and neck
C84.92	Mature T/NK-cell lymphomas, unspecified, intrathoracic lymph nodes
C84.93	Mature T/NK-cell lymphomas, unspecified, intra-abdominal lymph nodes
C84.94	Mature T/NK-cell lymphomas, unspecified, lymph nodes of axilla and upper limb
C84.95	Mature T/NK-cell lymphomas, unspecified, lymph nodes of inguinal region and lower limb
C84.96	Mature T/NK-cell lymphomas, unspecified, intrapelvic lymph nodes
C84.97	Mature T/NK-cell lymphomas, unspecified, spleen
C84.98	Mature T/NK-cell lymphomas, unspecified, lymph nodes of multiple sites

ICD-10	ICD-10 Description
C84.99	Mature T/NK-cell lymphomas, unspecified, extranodal and solid organ sites
C84.Z0	Other mature T/NK-cell lymphomas, unspecified site
C84.Z1	Other mature T/NK-cell lymphomas, lymph nodes of head, face, and neck
C84.Z2	Other mature T/NK-cell lymphomas, intrathoracic lymph nodes
C84.Z3	Other mature T/NK-cell lymphomas, intra-abdominal lymph nodes
C84.Z4	Other mature T/NK-cell lymphomas, lymph nodes of axilla and upper limb
C84.Z5	Other mature T/NK-cell lymphomas, lymph nodes of inguinal region and lower limb
C84.Z6	Other mature T/NK-cell lymphomas, intrapelvic lymph nodes
C84.Z7	Other mature T/NK-cell lymphomas, spleen
C84.Z8	Other mature T/NK-cell lymphomas, lymph nodes of multiple sites
C84.Z9	Other mature T/NK-cell lymphomas, extranodal and solid organ sites
C86.00	Extranodal NK/T-cell lymphoma, nasal type not having achieved remission
C86.10	Hepatosplenic T-cell lymphoma not having achieved remission
C86.20	Enteropathy-type (intestinal) T-cell lymphoma not having achieved remission
C86.30	Subcutaneous panniculitis-like T-cell lymphoma not having achieved remission
C86.31	Subcutaneous panniculitis-like T-cell lymphoma, in remission
C86.50	Angioimmunoblastic T-cell lymphoma not having achieved remission
C86.60	Primary cutaneous CD30-positive T-cell proliferations not having achieved remission

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC