Medical Policy

Istodax®; Romidepsin (liquid)	
MEDICAL POLICY NUMBER	MED_Clin_Ops-111
ORIGINAL EFFECTIVE DATE	5/24/2022
CURRENT VERSION NUMBER	2
CURRENT VERSION EFFECTIVE DATE	01/01/2024
APPLICABLE PRODUCT AND MARKET	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Istodax®; Romidepsin (liquid) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Istodax; Romidepsin (liquid) will be provided for 6 months and may be renewed.

- Max Units (per dose and over time):
    - Maintenance Dose: 400 billable units on days 1, 8, and 15 of a 28-day cycle

Initial

A. Patient is at least 18 years of age; **AND**
B. Requested drug will be used as single-agent therapy; **AND**

T-Cell Lymphoma

A. Peripheral T-cell Lymphoma (PTCL) (Non-Cutaneous)
(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)
    a. Patient has failed prior systemic therapy; **OR**
    b. Requested drug will be used as initial palliative intent therapy

B. Cutaneous T-cell Lymphoma (CTCL)
(Including: Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders [primary cutaneous anaplastic large cell lymphoma], Mycosis Fungoides/Sezary Syndrome)
    a. Patient has failed prior systemic therapy; **OR**
    b. Requested drug will be used as primary treatment for Mycosis Fungoides/Sezary Syndrome in patients without stage IA-IIA disease with B1 blood involvement

C. Extranodal NK/T-Cell Lymphoma (nasal type)
    a. Requested drug will be used for relapsed/refractory disease following additional therapy with an alternate combination chemotherapy regimen (asparaginase-based) not previously used

D. Hepatosplenic T-Cell Lymphoma
    a. Requested drug will be used for refractory disease after two first-line therapy regimens

E. Breast Implant Associated Anaplastic Large Cell Lymphoma (ALCL)
    a. Requested drug will be used as subsequent therapy for relapsed/refractory disease

Renewal

A. Patient continues to meet initial criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc.; **AND**
B. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hematological abnormalities (e.g., neutropenia, lymphopenia, anemia, leukopenia, thrombocytopenia, etc.), severe infections (e.g., pneumonia, sepsis, viral reactivation of Epstein Barr or hepatitis B), severe tumor lysis syndrome, and ECG T-wave and/or ST segment changes, etc; **AND**
C. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

CODING

Applicable NDC Codes	
59572-0984-xx	Istodax kit (single-use 10 mg vial)
00703-4004-xx	Romidepsin 27.5 mg/5.5 mL solution for injection
00703-3071-xx	Romidepsin 10 mg/2 mL solution for injection

Applicable Procedure Code	
J9315	Injection, romidepsin, 1 mg; 1 billable unit = 1 mg ***(Discontinue use on 10/01/2021)***
J9318	Injection, romidepsin, lyophilized, 0.1 mg; 1 billable unit = 0.1 mg
J9319	Injection, romidepsin, non-lyophilized, 0.1 mg; 1 billable unit = 0.1 mg

Applicable ICD-10 Codes	
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

Applicable ICD-10 Codes	
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
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
C84.90	Mature T/NK-cell lymphomas, unspecified, unspecified site

Applicable ICD-10 Codes	
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
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
C86.0	Extranodal NK/T-cell lymphoma, nasal type
C86.1	Hepatosplenic T-cell lymphoma
C86.2	Enteropathy-type (intestinal) T-cell lymphoma
C86.5	Angioimmunoblastic T-cell lymphoma
C86.6	Primary cutaneous CD30-positive T-cell proliferations

EVIDENCE BASED REFERENCES

1. Istodax [package insert]. Summit, NJ; Celgene, July 2021. Accessed March 2022.
2. Romidepsin [package insert]. North Wales, PA; Teva Pharmaceuticals. March 2020. Accessed March 2022.

POLICY HISTORY

Original Effective Date	5/24/2022
Revised Date	
P&T Committee Endorsement	5/24/2022
Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan	01/01/2024

Approved by Pharmacy and Therapeutics Committee