Romidepsin (Istodax®)

Place of Service

Office Administration
Home Infusion Administration
Outpatient Facility Administration
Infusion Center Administration

HCPCS

- **J9318** per 0.1 mg, romidepsin non-lyophilized
- **J9319** per 0.1 mg, romidepsin lyophilized

Condition(s) listed in policy (*see criteria for details*)

- Anaplastic large cell lymphoma, non-systemic
- Breast implant-associated anaplastic large cell lymphoma
- Extranodal NK/T-cell lymphoma, nasal type
- Hepatosplenic gamma-delta T-cell lymphoma
- Mycosis fungoides or Sezary syndrome (cutaneous T-cell lymphoma)
- Peripheral T-cell lymphoma

AHFS therapeutic class: Antineoplastic; Histone Deacetylase (HDAC) Inhibitor

Mechanism of action: a HDAC inhibitor and a bicyclic depsipeptide that catalyzes the removal of acetyl groups from acetylated lysine residues in histone, resulting in the modulation of gene expression. HDACs also deacetylate nonhistone proteins, such as transcription factors.

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Istodax® (romidepsin) NOT listed in section 3 must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Anaplastic large cell lymphoma - cutaneous, non-systemic

1. Disease is associated with multifocal lesions or regional node, AND
2. Patient has received prior systemic therapy, AND
3. Being used as a single agent

Covered Doses

Up to 14 mg/m^2 IV on days 1, 8, and 15 of a 28-day cycle. Cycles repeat every 28 days as tolerated.

Coverage Period

Cover yearly based on continued response to therapy

ICD-10:
C86.6

Breast implant-associated anaplastic large cell lymphoma

Covered Doses
Up to 14 mg/m^2 IV on days 1, 8, and 15 of a 28-day cycle. Cycles repeat every 28 days as tolerated.

Coverage Period
Cover yearly based on continued response to therapy

ICD-10:
C84.7A

Extranodal NK/T-cell lymphoma, nasal type

Covered Doses
Up to 14 mg/m^2 IV on days 1, 8, and 15 of a 28-day cycle. Cycles repeat every 28 days as tolerated.

ICD-10: C84.90-C84.99, C84.Z0-C84.Z9, C86.0

Hepatosplenic gamma-delta T-cell lymphoma

Covered Doses
Up to 14 mg/m^2 IV on days 1, 8, and 15 of a 28-day cycle. Cycles repeat every 28 days as tolerated.

ICD-10: C84.90-C84.99, C84.Z0-C84.Z9, C86.1

Mycosis fungoides or Sezary syndrome (cutaneous T-cell lymphoma)

1. Not being used in combination with other systemic therapies

Covered Doses
Up to 14 mg/m^2 IV on days 1, 8, and 15 of a 28-day cycle. Cycles repeat every 28 days as tolerated.

Coverage Period
Cover yearly based on continued response to therapy

ICD-10:

C84.00-C84.09, C84.10-C84.19

Peripheral T-cell lymphoma (PTCL) - angioimmunoblastic T-cell lymphoma, systemic anaplastic large cell lymphoma, enteropathy-associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma (MEITL), nodal peripheral T-cell lymphoma with TFH phenotype, peripheral T-cell lymphoma not otherwise specified, or follicular T-cell lymphoma

Covered Doses
Up to 14 mg/m^2 IV on days 1, 8, and 15 of a 28-day cycle. Cycles repeat every 28 days as tolerated.

ICD-10:
C84.40-C84.49, C84.60-C84.69, C84.70-C84.79, C86.2, C86.5

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Istodax® (romidepsin) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
Istodax / romidepsin, lyophilized: 10 mg (single-use vial)
romidepsin, non-lyophilized: 27.5 mg/5.5 mL (single-use vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com
- Istodax® (Romidepsin) [Prescribing information]. Summit, NJ: Celgene Corporation; 7/2021.
- National Comprehensive Cancer Network Drugs & Biologics Compendium. Romidepsin (2022). Available by subscription at: www.nccn.org.
- National Comprehensive Cancer Network. Primary Cutaneous Lymphomas (Version 2.2022). Available at: www.nccn.org.
- National Comprehensive Cancer Network. T-Cell Lymphomas (Version 2.2022). Available at: www.nccn.org.

(7) Policy Update

Dates of last revision: 3Q2023

Date of next review: 1Q2024

- No clinical change to policy following revision.