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Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	April 3, 2015
Subject:	Romidepsin	**Page:**	1 of 4

Last Review Date: September 6, 2024

Romidepsin

Description

Istodax (romidepsin), Romidepsin

Background
Romidepsin is used in the treatment of cutaneous T-cell lymphoma in patients that the cancer comes back or does not respond to other cancer treatment. T-cell lymphoma occurs when T-cells of the immune system called lymphocytes, a type of white blood cell, grows uncontrollably. These cancerous cells then travel to other parts of the body and form masses called tumors. Romidepsin helps inhibit the growth of affected cells and often leads to cell death of the cancer cells (1-2).

Regulatory Status
FDA-approved indication: Romidepsin is a histone deacetylase (HDAC) inhibitor indicated for the treatment of cutaneous T-cell lymphoma (CTCL) in patients who have received at least one prior systemic therapy (1-2).

Romidepsin can cause thrombocytopenia, leukopenia (neutropenia and lymphopenia), and/or anemia. Physicians are cautioned to monitor blood counts during treatment in order to determine whether dosage modification is necessary (1-2).

Serious and sometimes fatal infections, including pneumonia and sepsis, have occurred with Romidepsin (1-2).

Romidepsin also has warnings for electrocardiographic (ECG) changes, tumor lysis syndrome and embryo-fetal toxicity (1-2).

The safety and effectiveness of Romidepsin in pediatric patients under the age of 18 have not been established (1-2).

Related policies
Beleodaq, Zolinza

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Romidepsin may be considered **medically necessary** if the conditions indicated below are met.

Romidepsin may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Cutaneous T-cell lymphoma (CTCL)

AND the following:

1. Disease must have relapsed or progressed after one prior therapy

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Cutaneous T-cell lymphoma (CTCL)

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits
Same as above

Rationale

Summary
Romidepsin is used in the treatment of cutaneous T-cell lymphoma in patients that the cancer comes back or does not respond to other cancer treatment. Romidepsin helps inhibit the growth of affected cells and often leads to cell death of the cancer cells. Romidepsin has warnings for the following: myelosuppression, infections, electrocardiographic (ECG) changes, tumor lysis syndrome and embryo-fetal toxicity. The safety and effectiveness of Romidepsin in pediatric patients under the age of 18 have not been established (1-2).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Romidepsin while maintaining optimal therapeutic outcomes.

References
1. Istodax [package insert]. Summit, NJ: Celgene Corporation; July 2021.
2. Romidepsin [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; December 2021.
3. NCCN Drugs & Biologics Compendium® Romidepsin 2024. National Comprehensive Cancer Network, Inc. Accessed on July 18, 2024.

Policy History

Date	Action

April 2015	Addition to PA
June 2016	Annual editorial review and reference update Policy changed from 5.04.57 to 5.21.57
July 2017	Annual editorial review and reference update
July 2018	Annual editorial review
June 2019	Annual review
May 2020	Addition of Romidepsin. Renamed policy Romidepsin
June 2020	Annual review and reference update
August 2021	Removed peripheral T-cell lymphoma indication per PI update
September 2021	Annual review and reference update
September 2022	Annual review and reference update
September 2023	Annual review and reference update
September 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.