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## **ROMIDEPSIN**

### **Istodax (romidepsin), Romidepsin**

#### **RATIONALE FOR INCLUSION IN PA PROGRAM**

##### **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).

##### **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



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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.