Istodax

Description

Istodax (romidepsin)

Background
Istodax is used in the treatment of peripheral T-cell lymphoma and 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 white blood cell, grows uncontrollably. These cancerous cells then travel to other parts of the body and form masses called tumors. Istodax helps inhibit the growth of affected cells and often leads to cell death of the cancer cells (1).

Regulatory Status
FDA-approved indications: Istodax is a histone deacetylase inhibitor indicated for (1):
1. Treatment of cutaneous T-cell lymphoma (CTCL) in patients who have received at least one prior systemic therapy
2. Treatment of peripheral T-cell lymphoma (PTCL) in patients who have received at least one prior therapy

Istodax 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).

Serious and sometimes fatal infections, including pneumonia and sepsis, have occurred with Istodax (1).
The safety and effectiveness of Istodax in pediatric patients under the age of 18 have not been established (1).

**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.*

Istodax may be considered **medically necessary** in patients 18 years of age and older with relapsed or refractory peripheral T-cell lymphoma (PTCL) or cutaneous T-cell lymphoma; disease must have relapsed or progressed after one prior therapy.

Istodax is considered **investigational** in patients less than 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age**
18 years of age or older

**Diagnoses**

Patient must have **ONE** of the following:

1. Cutaneous T-cell lymphoma (CTCL)
2. Peripheral T-cell lymphoma (PTCL)

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

**Diagnoses**
Patient must have the following:

1. Cutaneous T-cell lymphoma (CTCL)
2. Peripheral T-cell lymphoma (PTCL)

**Policy Guidelines**

**Pre - PA Allowance**

None

**Prior - Approval Limits**

Duration 12 months

**Prior – Approval Renewal Limits**

Duration 12 months

**Rationale**

**Summary**

Istodax is used in the treatment of peripheral T-cell lymphoma and cutaneous T-cell lymphoma in patients that the cancer comes back or does not respond to other cancer treatment. Istodax helps inhibit the growth of affected cells and often leads to cell death of the cancer cells (1).

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

**References**


**Policy History**

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<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>April 2015</td>
<td>Addition to PA</td>
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<tr>
<td>June 2016</td>
<td>Annual editorial review and reference update</td>
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<tr>
<td></td>
<td>Policy changed from 5.04.57 to 5.21.57</td>
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<tr>
<td>July 2017</td>
<td>Annual editorial review and reference update</td>
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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.