Zolinza

Description

Zolinza (vorinostat)

Background
Zolinza is a histone deacetylase inhibitor approved in the treatment of cutaneous manifestations in patients with cutaneous T-cell lymphoma. Cutaneous T-cell lymphomas (CTCLs) are the largest group of cutaneous lymphomas, with mycosis fungoides (MF) and Sézary syndrome representing ~60% and ~5% of CTCL cases, respectively. A group of non-Hodgkin’s lymphomas (1, 5), MF is characterized by primary cutaneous involvement, whereas Sézary syndrome is characterized by significant blood and lymph node involvement. Initial treatment for patients with patch/plaque disease consists of skin-directed therapies (e.g., topical corticosteroids) with the addition of systemic therapy for refractory or progressive disease (1-2).

Regulatory Status
FDA-approved indication: Zolinza is FDA-approved for the treatment of cutaneous manifestations in patients with cutaneous T cell lymphoma (CTCL) who have progressive, persistent or recurrent disease on or following two systemic therapies (3).

The drug has the potential for serious side effects, including pulmonary embolism, deep vein thrombosis, and gastrointestinal disturbances. Zolinza may cause dose-related thrombocytopenia and anemia, which could require dose reduction or discontinuation. Patients receiving Zolinza may experience hyperglycemia, especially patients with diabetes. Zolinza requires careful monitoring of blood cell counts, electrolytes, glucose and serum creatinine. Testing should be repeated every two weeks during the first two months of therapy and monthly thereafter. Baseline and periodic ECG are also recommended since QT prolongation has been observed. Hypokalemia and hypomagnessemia should be corrected prior to starting Zolinza. It is
important that adequate hydration be maintained during treatment. Any pre-existing nausea, vomiting and diarrhea should be adequately controlled before implementation of therapy (3-4).

The safety and effectiveness of Zolinza has not been established in patients less than 18 years of age (3).

Related policies
Beleodaq, Istodax

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

Zolinza may be considered medically necessary in patients 18 years of age or older for the treatment of cutaneous T-cell lymphomas (CTCL) and if the conditions indicated below are met.

Zolinza may be 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

Diagnosis

Patient must have the following:

Cutaneous T-Cell Lymphoma (CTCL)

AND the following:
1. Previous or concurrent treatment with two systemic therapies
2. Baseline ECG, blood cell counts, electrolytes, serum glucose and serum creatinine
3. Able to maintain adequate hydration (at least 2L/day)

Prior-Approval Renewal Requirements

Same as above

Policy Guidelines
Pre – PA Allowance
None

Prior - Approval Limits
Quantity 100 mg 360 capsules per 90 days
Duration 12 months

Prior – Approval Renewal Limits
Same as above

Rationale
Summary
Zolinza (vorinostat) is considered medically necessary for the treatment of cutaneous T-cell lymphoma (CTCL) in patients who have progressive, persistent or recurrent disease during or following treatment with two systemic therapies. The drug has the potential for serious side effects, including pulmonary embolism, deep vein thrombosis, gastrointestinal disturbances, hyperglycemia, hypokalemia, hypomagnesemia, and dose-related thrombocytopenia and anemia, which could require dose reduction or discontinuation. Zolinza requires careful monitoring of blood cell counts, electrolytes, glucose and serum creatinine. Testing should be repeated every two weeks during the first two months of therapy and monthly thereafter. It is important that adequate hydration be maintained during treatment (1-4).

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

References

Policy History
Date Action
September 2011 New Policy
September 2012 Annual editorial and reference update
<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
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<tbody>
<tr>
<td>March 2013</td>
<td>Annual editorial and reference update</td>
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<tr>
<td>March 2014</td>
<td>Annual review and reference update. Addition of baseline serum creatinine levels.</td>
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<tr>
<td>December 2014</td>
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<tr>
<td>June 2016</td>
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<tr>
<td>June 2017</td>
<td>Policy number changed from 5.04.15 to 5.21.15</td>
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<tr>
<td>June 2018</td>
<td>Annual editorial review and reference update. Addition of quantity limits to criteria</td>
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**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective July 1, 2019.