Farydak

Description

Farydak (panobinostat)

Background
Farydak is the first HDAC inhibitor approved to treat multiple myeloma in patients who have received at least two prior standard therapies, including bortezomib and an immunomodulatory agent. Farydak is to be used in combination with bortezomib, a type of chemotherapy, and dexamethasone, an anti-inflammatory medication. Multiple myeloma causes plasma cells to rapidly multiply and crowd out other healthy blood cells from the bone marrow. When the bone marrow has too many plasma cells, the cells may move to other parts of the body. Farydak works by inhibiting the activity of enzymes, known as histone deacetylases (HDACs). The inhibition of these enzymes may slow the over-development of plasma cells in multiple myeloma patients or cause these dangerous cells to die (1).

Regulatory Status
FDA-approved indication: Farydak, a histone deacetylase inhibitor, in combination with bortezomib and dexamethasone, is indicated for the treatment of patients with multiple myeloma who have received at least 2 prior regimens, including bortezomib and an immunomodulatory agent (2).

Farydak carries a boxed warning alerting patients and health care professionals that severe diarrhea and severe and fatal cardiac events, arrhythmias and electrocardiogram (ECG) changes have occurred in patients receiving Farydak. Arrhythmias may be exacerbated by electrolyte abnormalities. The most common laboratory abnormalities were low levels of phosphorus in the blood (hypophosphatemia), low potassium levels in the blood (hypokalemia),
low levels of salt in the blood (hyponatremia), increased creatinine, low platelets (thrombocytopenia), low white blood cell counts (leukopenia) and low red blood cell counts (anemia). Healthcare professionals should also inform patients of the risk of bleeding in the gastrointestinal tract and the lungs, and liver damage (hepatotoxicity) (2).

The safety and efficacy of Farydak in pediatric patients have not been established (2).

Related policies

Policy

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

Farydak may be considered medically necessary in patients 18 years of age or older for the treatment of patients with multiple myeloma and if the conditions indicated below are met.

Farydak is considered investigational for patients that are 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:

Multiple myeloma

AND ALL of the following:

1. Used in combination with Velcade (bortezomib) and dexamethasone

2. Received at least 2 prior regimens, including Velcade (bortezomib) and an immunomodulatory agent

3. Baseline monitoring of electrocardiogram (ECG) and serum electrolytes, including potassium and magnesium
   a. Agreement to monitor levels prior to the start of each cycle
Prior-Approval *Renewal* Requirements
None

**Policy Guidelines**

**Pre - PA Allowance**
None

**Prior - Approval Limits**
Duration  48 weeks

**Prior-Approval *Renewal* Limits**
None

**Rationale**

**Summary**
Farydak is a histone deacetylase inhibitor, in combination with bortezomib and dexamethasone, is indicated for the treatment of patients with multiple myeloma who have received at least 2 prior regimens, including bortezomib and an immunomodulatory agent. Farydak carries a Boxed Warning alerting patients and health care professionals that severe diarrhea and severe and fatal cardiac events, arrhythmias and electrocardiogram (ECG) changes have occurred in patients receiving Farydak. The safety and efficacy of Farydak in children have not been established (2).

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

**References**

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 2015</td>
<td>Addition to PA</td>
</tr>
</tbody>
</table>
### Prescription Drugs

**Effective Date:** July 1, 2019

### Antineoplastic Agents

**Original Policy Date:** March 13, 2015

### Farydak

**Page:** 4 of 4

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 2015</td>
<td>Annual Review and addition of monitoring ECG and electrolytes prior to start of each cycle per SME</td>
</tr>
<tr>
<td>September 2015</td>
<td>Annual review</td>
</tr>
<tr>
<td>July 2016</td>
<td>Annual review and reference update</td>
</tr>
<tr>
<td>September 2016</td>
<td>Policy number change from 5.04.56 to 5.21.56</td>
</tr>
<tr>
<td>June 2017</td>
<td>Annual review and reference update</td>
</tr>
<tr>
<td>July 2018</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>June 2019</td>
<td>Annual review and reference update</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 on July 1, 2019.