Clinical Pharmacy Program Guidelines for Farydak

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<th>Program</th>
<th>Prior Authorization</th>
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<tr>
<td>Medication</td>
<td>Farydak (panobinostat)</td>
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<td>Markets in Scope</td>
<td>Arizona, California, Florida- CHIP, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Ohio, Pennsylvania, Rhode Island</td>
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<tr>
<td>Issue Date</td>
<td>6/2015</td>
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<tr>
<td>Pharmacy and Therapeutics Approval Date</td>
<td>3/2019</td>
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<td>Effective Date</td>
<td>5/2019</td>
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1. **Background:**

Farydak® (panobinostat), a histone deacetylase inhibitor, in combination with Velcade® (bortezomib) and dexamethasone, is indicated for the treatment of patients with multiple myeloma who have received at least 2 prior regimens, including Velcade and an immunomodulatory agent [e.g., Revlimid® (lenalidomide), Thalomid® (thalidomide)].

The National Cancer Comprehensive Network (NCCN) also recommends use of Farydak in combination with Kyprolis (carfilzomib) or in combination with Revlimid and dexamethasone for treatment of multiple myeloma in patients who have received at least 2 prior regimens including Velcade and an immunomodulatory agent.³

2. **Coverage Criteria:**

**A. Multiple Myeloma**

1. **Initial Authorization**

   a. **Farydak** will be approved based on all of the following criteria:

      (1) Diagnosis of multiple myeloma

      -AND-

      (2) Used in combination with one of the following:

      (a) **Both** of the following:

          i. Velcade (bortezomib)
ii. Dexamethasone

-OR-

(b) Kyprolis (carfilzomib)

-OR-

(c) **Both** of the following:

i. Revlimid (lenalidomide)

ii. Dexamethasone

-AND-

(3) Has received at least 2 prior treatment regimens which included **both** of the following:

(a) Velcade (bortezomib)

(b) Immunomodulatory agent [e.g., Revlimid (lenalidomide), Thalomid (thalidomide)]

**Authorization will be issued for 12 months.**

2. **Reauthorization**

a. **Farydak** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Farydak therapy

**Authorization will be issued for 12 months.**

B. **NCCN Recommended Regimens**

1. **Initial Authorization**

a. **Farydak** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

**Authorization will be issued for 12 months.**

2. **Reauthorization**
a. **Farydak** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Farydak therapy

Authorization will be issued for 12 months.

3. **References:**