Commercial/Healthcare Exchange PA Criteria

Effective: November 2, 2016

Prior Authorization: Farydak

Products Affected: Farydak (panobinostat) 10 mg, 15 mg, and 20 mg oral capsules

Medication Description:

Farydak is a histone deacetylase (HDAC) inhibitor that inhibits the enzymatic activity of HDACs at nanomolar concentrations. HDACs catalyze the removal of acetyl groups from the lysine residues of histones and some non-histone proteins. Inhibition of HDAC activity results in increased acetylation of histone proteins, an epigenetic alteration that results in a relaxing of chromatin, leading to transcriptional activation. *In vitro*, Farydak caused the accumulation of acetylated histones and other proteins, inducing cell cycle arrest and/or apoptosis of some transformed cells. Increased levels of acetylated histones were observed in xenografts from mice that were treated with Farydak. Farydak shows more cytotoxicity towards tumor cells compared to normal cells.

Farydak is part of a Risk Evaluation and Mitigation Strategy (REMS) program to mitigate the risks of severe diarrhea and cardiac toxicities (severe and fatal cardiac ischemic events, severe arrhythmias, and ECG changes associated with Farydak treatment). The Farydak REMS program consists of a communication plan to inform healthcare professionals of risks of cardiotoxicity and diarrhea and how to minimize these events.

Covered Uses:

1. Multiple myeloma
    a. Used in combination with bortezomib and dexamethasone; AND
    b. Received 2 prior regimens, including bortezomib and an immunomodulatory agent

*Approved under accelerated approval based on progression free survival. Continued approval is contingent upon verification and description of clinical benefit in confirmatory trials.

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis
2. Previous therapies tried
3. Dose and frequency

Age Restrictions:18 years of age or older

Prescriber Restrictions: Prescribed by or in consultation with a hematologist/oncologist

Coverage Duration: 12 months

Other Criteria:

Multiple myeloma.

1. Approve if the patient meets the following criteria (a and b):

a. The patient will be taking Farydak in combination with Velcade and dexamethasone; AND
b. Patient has received at least two prior therapies including Velcade and an immunomodulatory agent (Thalomid, Revlimid, or Pomalyst)

References:

1. Farydak [prescribing information]. New York, NY: Novartis Pharmaceuticals Corporation. Revised June 2016. Accessed October 2019.
2. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (Version 3.2016). © 2015 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on August 15, 2016

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	8/15/2016
2	Policy Update	CCI Adoption of EH Policy, removed from CCI Oncology Policy Specified Covered Uses Removed Exclusion Criteria Addition of Age Restriction Addition of Prescriber Restriction	Covered Uses Exclusion Criteria Age Restriction Prescriber Restriction	10/15/2019