UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Farydak

Program	Prior Authorization
Medication	Farydak (panobinostat)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	6/2015
Pharmacy and Therapeutics Approval Date	3/2020
Effective Date	5/2020

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. <u>Multiple Myeloma</u>

1. <u>Initial Authorization</u>

a. **Farydak** will be approved based on **<u>all</u>** of the following criteria:

(1) Diagnosis of multiple myeloma

-AND-

(2) Used in combination with **<u>one</u>** of the following:

(a) **<u>Both</u>** 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:

1. Farydak [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp.; September 2019.
2. San-Miguel JF, Hungria VT, Yoon SS, et al. Panobinostat plus bortezomib and dexamethasone versus placebo plus bortezomib and dexamethasone in patients with relapsed or relapsed and refractory multiple myeloma: a multicentre, randomised, double-blind phase 3 trial. Lancet Oncol. 2014 Oct;15(11):1195-206.
3. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed February 3, 2020.

Program	Prior Authorization –Farydak (panobinostat)
Change Control	
Date	Change
6/18/2015	New Policy
10/2016	Updated clinical criteria to align with Employer and Individual's notification policy and updated policy template
3/2017	Annual review. Updated background, references, and template.
3/2018	Annual review. Revised criteria to include combination therapy with Revlimid/dexamethasone as recommended by NCCN. Added NCCN recommended review criteria. Updated background and references.
3/2019	Annual review. Updated references.
3/2020	Annual review. Updated references.