

Farydak (panobinostat)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Farydak (panobinostat)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Farydak (panobinostat) may be approved if the following criteria are met:

- I. Individual has a diagnosis of multiple myeloma; **AND**
- II. Individual has had trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to at least two (2) prior regimens, including bortezomib and an immunomodulatory agent (such as but not limited to, thalidomide or lenalidomide) (Label, NCCN 2A); **AND**
- III. Individual is using in combination with any of the following therapies:
 - A. Dexamethasone and bortezomib; OR
 - B. Carfilzomib (NCCN 2A); OR
 - C. Dexamethasone and lenalidomide (NCCN 2A).

Note:

Farydak (panobinostat) has black box warnings for fatal and serious cardiac and severe diarrhea toxicities. Severe and fatal cardiac ischemic events, severe arrhythmias, and ECG changes have occurred in individuals receiving Farydak. Arrhythmias may be exacerbated by electrolyte abnormalities. Obtain ECG and electrolytes at baseline and periodically during treatment as clinically indicated. Monitor for diarrhea symptoms, institute antidiarrheal treatment, interrupt and then reduce dose or discontinue Farydak if diarrhea occurs.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 19, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on June 19, 2020.
 - a. Multiple Myeloma. V4.2020. Revised May 8, 2020

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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