

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Farydak Prior Authorization Policy

- Farydak® (panobinostat capsules – Novartis)

**REVIEW DATE:** 06/12/2024

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### OVERVIEW

Farydak, a histone deacetylase inhibitor, was approved in combination with bortezomib injection and dexamethasone for the treatment of patients with **multiple myeloma** who have received at least two prior regimens, including bortezomib injection and an immunomodulatory drug (i.e., Thalomid® [thalidomide capsules], Revlimid® [lenalidomide capsules], Pomalyst® [pomalidomide capsules]).<sup>1</sup>

The FDA granted accelerated approval to Farydak in February 2015, based on progression free survival from a randomized, double-blind, placebo-controlled, multicenter, Phase III study. In December 2021, the manufacturer removed Farydak from the market because the required post-approval clinical studies were not feasible.

### Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for multiple myeloma (version 3.2023 – December 8, 2022) note that due to market withdrawal, regimens containing Farydak were removed from the guideline.<sup>2</sup>

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Farydak. All approvals are provided for the duration noted below.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Farydak is recommended in those who meet the following criteria:

#### FDA-Approved Indication

- 1. Multiple Myeloma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
  - A) Patient is currently receiving Farydak; AND
  - B) Patient has previously tried bortezomib injection; AND
  - C) Patient has tried one immunomodulatory drug (i.e., Thalomid [thalidomide capsules], lenalidomide capsules, or Pomalyst [pomalidomide capsules]); AND
  - D) The medication will be taken in combination with bortezomib injection and dexamethasone.

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### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Farydak is not recommended in the following situations:

1. **Pancreatic Cancer.** A Phase II study evaluating Farydak + bortezomib injection in patients with pancreatic cancer who were progressing on gemcitabine-based therapy was discontinued early due to toxicity and a lack of response.<sup>3</sup>
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

### REFERENCES

1. Farydak® capsules [prescribing information]. East Hanover, NJ: Novartis; June 2016.
2. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 3.2023 – December 8, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on May 23, 2023.
3. Wang H, Cao Q, Dudek AZ. Phase II study of panobinostat and bortezomib in patients with pancreatic cancer progressing on gemcitabine-based therapy. *Anticancer Res.* 2012;32(3):1027-1031.