PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Farydak Prior Authorization Policy
- Farydak® (panobinostat capsules – Novartis)

REVIEW DATE: 06/08/2022

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]).[1] 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 5.2022 – March 9, 2022) note that due to market withdrawal, regimens containing Farydak were removed from the guideline.[2]

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 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.

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.[3]

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 5.2022 – March 9, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 3, 2022.
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.