VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 05/12/2021; selected revision 12/08/2021

OVERVIEW

Farydak, a histone deacetylase inhibitor, is 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 Farykak in February 2015, based on progression free survival from a randomized, double-blind, placebo-controlled, multicenter phase 3 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, which address diagnosis, treatment, and follow-up for patients with multiple myeloma (version 7.2021 – April 26, 2021), note that Farydak/ bortezomib injection/dexamethasone (category 1) is an other regimen for patients who have tried at least two previous therapies, including bortezomib injection and an immunomodulatory drug.[2] Although not approved combinations, Farydak/Kyprolis® (carfilzomib injection) and Farydak/Revlimid/dexamethasone are also listed as useful in certain circumstances for previously treated multiple myeloma (both category 2A). While there are small studies evaluating these combinations in previously treated multiple myeloma, there are multiple other regimens that NCCN classifies as preferred regimens for previously treated multiple myeloma. These regimens have a more established place in therapy and a stronger recommendation by NCCN.

Safety

There is a Farydak Risk Evaluation and Mitigation Strategy (REMS) program which consists of a communication plan to inform healthcare professionals of risks of cardiotoxicity and diarrhea and how to minimize these events.[3]

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 Indications

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], Revlimid [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.[4]

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 7.2021 – April 26, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 9, 2021.
3. Food and Drug Administration. Farydak Risk Evaluation and Mitigation Strategy (REMS). Updated March 13, 2020. Available at: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=344. Accessed on May 9, 2021.
4. 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.