

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Farydak® (panobinostat capsules – Novartis Pharmaceuticals)

TAC APPROVAL DATE: 04/10/2019

OVERVIEW

Farydak is a histone deacetylase (HDAC) inhibitor, which, in combination with Velcade® (bortezomib injection) and dexamethasone, is indicated for the treatment of patients with multiple myeloma who have received at least two prior regimens, including Velcade and an immunomodulatory drug (IMiD) [i.e., Thalomid® {thalidomide capsules}, Revlimid® {lenalidomide capsules}, Pomalyst® {pomalidomide capsules}].¹ The recommended starting dose of Farydak is 20 mg, taken orally once every other day (QOD) for three doses per week in Weeks 1 and 2 of each 21-day cycle for up to eight cycles. Treatment may be continued for an additional eight cycles in patients with clinical benefit who do not experience unresolved severe or medically significant toxicity, up to a maximum of 16 cycles (48 weeks).

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines, which address diagnosis, treatment, and follow-up for patients with multiple myeloma (version 2.2019 – November 16, 2018), note that Farydak/Velcade/dexamethasone (category 1) is an Other Regimen for patients who have tried at least two previous therapies, including Velcade and an IMiD, for treatment of previously treated disease.² Although not approved combinations, Farydak/Kyprolis® (carfilzomib injection) and Farydak/Revlimid/dexamethasone are also listed as potential Other Regimens for previously treated multiple myeloma (both category 2A). While there are small studies evaluating these combinations in previously treated multiple myeloma, there are eight 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

FDA-Approved Indications

- Multiple Myeloma.** Approve for 1 year if the patient meets the following conditions (A and B):
 - Farydak will be taken in combination with Velcade® (bortezomib injection) and dexamethasone; AND
 - The patient has previously tried Velcade and one immunomodulatory drug (i.e., Thalomid [thalidomide capsules], Revlimid [lenalidomide capsules], or Pomalyst [pomalidomide capsules]).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Farydak has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

- Pancreatic Cancer.** A Phase II study evaluating Farydak + Velcade in patients with pancreatic cancer who were progressing on gemcitabine-based therapy was discontinued early due to toxicity and a lack of response.⁵
- Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

- Farydak® capsules [prescribing information]. East Hanover, NJ: Novartis; June 2016.
- The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (Version 2.2019 – November 16, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on April 2, 2019.
- Food and Drug Administration. Farydak Risk Evaluation and Mitigation Strategy (REMS). February 23, 2015. Available at: <https://www.accessdata.fda.gov/scripts/cder/remis/index.cfm?event=IndvRemsDetails.page&REMS=344>. Accessed on April 2, 2019.
- 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.

HISTORY

Type of Revision	Summary of Changes*	TAC Approval Date
Annual revision	No changes to the criteria.	03/29/2017
Annual revision	No changes to the criteria.	04/04/2018
Annual revision	No changes to the criteria.	04/10/2019

* For a further summary of criteria changes, refer to respective TAC minutes available at: <http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx>; TAC – Therapeutic Assessment Committee; NA – Not applicable.