Reference number(s)
2231-A

SPECIALTY GUIDELINE MANAGEMENT

FARYDAK (panobinostat)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Farydak, in combination with bortezomib and dexamethasone, is indicated for the treatment of patients with multiple myeloma who have received at least 2 prior regimens, including bortezomib and an immunomodulatory agent. This indication is approved under accelerated approval based on progression free survival. Continued approval of this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

B. Compendial Use
In combination with carfilzomib or in combination with dexamethasone and lenalidomide for the treatment of multiple myeloma in patients who have received at least 2 prior regimens, including bortezomib and an immunomodulatory agent

All other indications are considered experimental/investigational and are not covered benefits.

II. CRITERIA FOR INITIAL APPROVAL

Authorization of 12 months may be granted for the treatment of multiple myeloma when the member has received at least two prior regimens, including bortezomib and an immunomodulatory agent ("eg.," lenalidomide, thalidomide, pomalidomide).

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Farydak [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2015.
2. The NCCN Drugs & Biologics Compendium® © 2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 16, 2017.
3. The NCCN Clinical Practice Guidelines in Oncology® Multiple Myeloma (Version 2.2018) © 2017 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed October 16, 2017.