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 Uses
In combination with carfilzomib or in combination with dexamethasone and lenalidomide or in combination with dexamethasone and bortezomib for previously treated multiple myeloma for relapsed or progressive disease in patients who have received at least 2 prior regimens, including bortezomib and an immunomodulatory agent

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Multiple Myeloma
Authorization of 12 months may be granted for the treatment of relapsed or progressive multiple myeloma when the all of the following criteria are met:
A. The member has received at least two prior regimens, including bortezomib and an immunomodulatory agent
B. The requested medication will be used in any of the following regimens:
   1. In combination with bortezomib and dexamethasone
   2. In combination with lenalidomide and dexamethasone
   3. In combination with carfilzomib

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Farydak [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2016.
2. The NCCN Drugs & Biologics Compendium 2019 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 01, 2019.

3. The NCCN Clinical Practice Guidelines in Oncology Multiple Myeloma (Version 1.2020) 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed October 01, 2019.