Clinical Policy: Panobinostat (Farydak)

Reference Number: PA.CP.PHAR.382
Effective Date: 10.17.18
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Description
Panobinostat (Farydak®) is a histone deacetylase inhibitor.

FDA Approved Indication(s)
Farydak is indicated in combination with bortezomib and dexamethasone, for the treatment of patients with multiple myeloma (MM) who have received at least 2 prior regimens, including bortezomib and an immunomodulatory agent.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness® that Farydak is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Multiple Myeloma (must meet all)**:**

1. Diagnosis of MM;
2. Prescribed by or in consultation with a hematologist or oncologist;
3. Failure of at least 2 prior regimens for MM including bortezomib and an immunomodulatory agent (e.g., dexamethasone), unless contraindicated or clinically significant adverse effects are experienced;
4. Farydak is used in combination with one of the following (a, b, or c):
   a. Bortezomib and dexamethasone;
   b. Kyprolis®;
   c. Revlimid® and dexamethasone;
5. Request meets one of the following (a or b):
   a. Dose does not exceed 20 mg x 6 doses for each 21-day cycle;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. Multiple Myeloma (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If used in combination with bortezomib and dexamethasone, member has not received more than 16 cycles (48 weeks) of therapy;
4. If request is for a dose increase, request meets one of the following (a or b):
   5. New dose does not exceed 20 mg x 6 doses for each 21-day cycle;
   a. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currentlyreceiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
MM: multiple myeloma
REMS: risk evaluation and mitigation strategy

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name*	Dosing Regimen	Dose Limit/ Maximum Dose
Darzalex® (daratumumab)	16 mg/kg IV administered: *As monotherapy or in combination with lenalidomide/ dexamethasone*: weekly for weeks 1 to 8, then every 2 weeks for weeks 9 to 24, then every 4 weeks for week 25 onward until disease progression; *In combination with bortezomib/dexamethasone*: weekly for weeks 1 to 9, then every 3 weeks for weeks 10 to 24,	Varies

Drug Name*	Dosing Regimen	Dose Limit/ Maximum Dose
	then every 4 weeks for week 25 onward until disease progression.	
Doxil® (liposomal doxorubicin)	30 mg/m^2 IV over 1 hour on day 4 repeated every 4 weeks; used in combination with bortezomib.	Varies
Empliciti™ (elotuzumab)	10 mg/kg IV every week for the first two cycles, then every 2 weeks thereafter until disease progression; used in combination with lenalidomide and dexamethasone.	Varies
Kyprolis (carfilzomib)	20 mg/m^2 IV on two consecutive days each week for 3 weeks (Days 1, 2, 8, 9, 15 and 16) followed by a 12-day rest period (Days 17 to 28). Each 28-day period is considered one treatment cycle. If tolerated in cycle 1, the dose should be escalated to 27 mg/m^2 and in the subsequent cycles.	Varies
Ninlaro® (ixazomib)	4 mg PO on Days 1, 8, and 15 of a 28-day cycle; used in combination with lenalidomide and dexamethasone	4 mg/day
Pomalyst® (pomalidomide)	4 mg PO QD on days 1-21 of repeated 28-day cycles until disease progression; may be given in combination with dexamethasone.	4 mg/day
Revlimid® (lenalidomide)	25 mg PO QD on days 1-21 of repeated 28 day cycles; may be given in combination with dexamethasone.	25 mg/day
bortezomib (Velcade®)	1.3 mg/m^2 IV bolus or SC twice weekly, with at least 72 hours between doses (on days 1, 4, 8, 11, 22, 25, 29, and 32), for cycles 1 to 4; then once weekly for 6 weeks (on days 1, 8, 22, and 29) for cycles 5 through 9.	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Examples*

Appendix C: Contraindications
Not applicable

Appendix D: Black Box Warning
- Because of severe diarrhea and cardiac toxicities, Farydak has a risk evaluation and mitigation strategy (REMS) program that consists of a Medication Guide and a Dear Healthcare Professional Letter. Patient and physician enrollment in the manufacturer's REMS program is required.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
MM	20 mg PO every other week for 3 doses per week (on Days 1, 3, 5, 8, 10, and 12) of Weeks 1 and 2 for each 21-day cycle for 8 cycles. Consider continuing treatment for an additional 8 cycles for patients with clinical benefit who do not experience unresolved severe or medically significant toxicity (total treatment duration: up to 16 cycles [48 weeks]).	20 mg/dose

VI. Product Availability

Capsules: 10 mg, 15 mg, 20 mg

VII. References

1. Farydak Prescribing Information. East Hanover, MJ: Novartis Pharmaceuticals; June 2016. Available at: https://www.pharma.us.novartis.com/files/farydak.pdf . Accessed April 2018.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at http://www.nccn.org/professionals/drug_compendium. Accessed April 2018.
3. National Comprehensive Cancer Network. Multiple Myeloma Version 4.2018. Available at: http://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed April 2018.
4. Clinical Pharmacology [database online]. Tampa, FL. Available at: http://clinicalpharmacology-ip.com. Accessed April 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy Created	10/18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	