

Clinical Policy: Panobinostat (Farydak)

Reference Number: CP.PHAR.382

Effective Date: 11.16.16

Last Review Date: 08.19

Line of Business: Commercial, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

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 Centene Corporation[®] 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. Age \geq 18 years;
4. 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;
**Prior authorization may be required for the 2 prior regimens*
5. Farydak is used in combination with one of the following (a, b, or c):
 - a. Bortezomib and dexamethasone;
 - b. Kyprolis[®];
 - c. Revlimid[®] and dexamethasone;
**Prior authorization may be required for these agents*
6. Request meets one of the following (a or b):
 - a. Dose does not exceed six 20 mg doses per 21-day cycle for 16 cycles total;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration:

Medicaid – 6 months

Commercial – Length of Benefit

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Multiple Myeloma (must meet all):

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Farydak for a covered indication and has received this medication for at least 30 days;
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 six 20 mg doses per 21-day cycle for 16 cycles total;
 - 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:

Medicaid – 12 months

Commercial – Length of Benefit

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

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 – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage documents.

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: <i>As monotherapy or in combination with lenalidomide/ dexamethasone:</i> 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; <i>In combination with bortezomib/dexamethasone:</i> weekly for weeks 1 to 9, then every 3 weeks for weeks 10 to 24, then every 4 weeks for week 25 onward until disease progression.	Varies
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/Boxed Warnings

- Contraindication(s): None reported
- Boxed warning(s): 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, NJ: Novartis Pharmaceuticals; June 2016. Available at: <https://www.pharma.us.novartis.com/files/farydak.pdf>. Accessed May 16, 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at http://www.nccn.org/professionals/drug_compendium. Accessed May 16, 2019.
3. National Comprehensive Cancer Network. Multiple Myeloma Version 2.2019. Available at: http://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed May 16, 2019.
4. Clinical Pharmacology [database online]. Tampa, FL. Available at: <http://clinicalpharmacology-ip.com>. Accessed May 16, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template; minor changes to verbiage and grammar. References updated.	01.18.17	8.17
1Q18 annual review: Added age limit per PI. Added NCCN Compendium supported use in combination with dexamethasone and Revlimid. Added continuation of care language in Section II References reviewed and updated	11.10.17	02.18
3Q 2018 annual review: policies combined for Centene Medicaid (new) and Commercial lines of business; specialist requirement added; added hematologist; references reviewed and updated.	04.26.18	08.18
3Q 2019 annual review: limited number of cycles to 16 per PI; references reviewed and updated.	05.14.19	08.19

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note:

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