Farydak® (panobinostat)
(Oral)

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Last Review Date: 01/06/2020
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I. Length of Authorization

Coverage is provided for six months and may be renewed once up to a maximum of 16 cycles of therapy over 48 weeks.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Farydak 10 mg capsules: 6 capsules (1 blister pack) every 21 days (Days 1, 3, 5, 8, 10 and 12)
- Farydak 15 mg capsules: 6 capsules (1 blister pack) every 21 days (Days 1, 3, 5, 8, 10 and 12)
- Farydak 20 mg capsules: 6 capsules (1 blister pack) every 21 days (Days 1, 3, 5, 8, 10 and 12)

B. Max Units (per dose and over time) [HCPCS Unit]:

- 120 mg per 21 days

III. Initial Approval Criteria[1,2,3]

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**
- Baseline QTcF < 450msec prior to initiating therapy as measured by electrocardiogram (ECG); **AND**

Multiple Myeloma †

- Patient has relapsed or progressive disease and received at least two (2) prior therapies, including an immunomodulatory agent [i.e. lenalidomide, thalidomide or pomalidomide] and bortezomib; **AND**
    - Used in combination with bortezomib and dexamethasone; **OR**
    - Used in combination with carfilzomib‡; **OR**
    - Used in combination with lenalidomide and dexamethasone‡

† FDA-labeled indication(s) ‡ Compendia approved indication(s)

IV. Renewal Criteria[1,2,3]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III; **AND**
- Patient has not received more than 16 cycles of therapy; **AND**
- Disease response with treatment defined as stabilization of disease or decrease in size of tumor or tumor spread ; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hemorrhage, hepatotoxicity, severe diarrhea, cardiac toxicities (cardiac ischemic events, severe arrhythmias, ECG changes), myelosuppression, localized and systemic infections, etc.

V. Dosage/Administration[1,2,3]

Indication	Dose
Multiple Myeloma	20 mg orally once every other day for 3 doses per week (Days 1, 3, 5, 8, 10, and 12) during Weeks 1 and 2 of a 3 week cycle for 8 cycles. May be repeated once for an additional 8 cycles. The total duration of treatment may be up to 16 cycles (48 weeks)

VI. Billing Code/Availability Information

HCPCS Code:

- J8999 – Prescription drug, oral, chemotherapeutic, nos
- C9399 – Unclassified drugs or biologicals (Hospital Outpatient Use Only)

NDC:

- Farydak 10mg blister pack of 6 capsules: 0078-0650-xx
- Farydak 15mg blister pack of 6 capsules: 0078-0651-xx
- Farydak 20mg blister pack of 6 capsules: 0078-0652-xx

VII. References

1. Farydak [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corp; June 2016. Accessed December 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Panobinostat. National Comprehensive Cancer Network, 2019. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed December 2019.

3. San-Miguel JF, Hungria VT, Yoon SS, et al. Panobinostat plus bortezomib and dexamethasone versus placebo plus bortezomib and dexamethasone in patients with relapsed or relapsed and refractory multiple myeloma: a multicentre, randomised, double-blind phase 3 trial. Lancet Oncol. 2014 Oct;15(11):1195-206. doi: 10.1016/S1470-2045(14)70440-1. Epub 2014 Sep 18.

Appendix 1 – Covered Diagnosis Codes

ICD-10	Diagnosis
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse
C90.10	Plasma cell leukemia not having achieved remission
C90.12	Plasma cell leukemia in relapse
C90.20	Extramedullary plasmacytoma not having achieved remission
C90.22	Extramedullary plasmacytoma in relapse
C90.30	Solitary plasmacytoma not having achieved remission
C90.32	Solitary plasmacytoma in relapse
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Articles may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/Article): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC