POLICY NUMBER UM ONC_1271	**SUBJECT** Farydak™ (panobinostat)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 2**
DATES COMMITTEE REVIEWED 03/27/15, 05/24/16, 06/29/17, 07/26/17, 07/19/18, 06/12/19, 12/11/19, 06/10/20	**APPROVAL DATE** June 10, 2020	**EFFECTIVE DATE** June 26, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 03/27/15, 05/24/16, 06/29/17, 07/26/17, 07/19/18, 06/12/19, 12/11/19, 06/10/20	
PRIMARY BUSINESS OWNER: UM **APPROVED BY:** Dr. Andrew Hertler		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM 1		**NCQA STANDARDS** UM 2	**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** All	

I. PURPOSE

To define and describe the accepted indications for Farydak (panobinostat) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. **PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:**
    a. When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**
    b. When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**
    c. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies **AND**
    d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
    e. When available, generic alternatives are preferred over brand name drugs.
2. **Multiple Myeloma**
    a. **NOTE: PANOBINOSTAT containing regimens are NON-PREFERRED for use in relapsed/refractory multiple myeloma**.
    b. The member has relapsed/refractory multiple myeloma and Farydak (panobinostat) may be used as the following:
        i. In combination with bortezomib and dexamethasone **AND**
        ii. The member received at least 1-3 prior therapies including bortezomib and an immunodulatory agent (i.e. thalidomide, lenalidomide, or pomalidomide).

III. EXCLUSION CRITERIA

1. Disease progression while taking Farydak (panobinostat).
2. Dosing exceeds single dose limit of Farydak (panobinostat) 20 mg.
3. Treatment exceeds the maximum duration limit of 16 treatment cycles.
4. Treatment exceeds the maximum limit of 6 (20mg) capsules/month, 12 (10 mg) capsules/month, or 6 (15 mg) capsules/month.
5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Farydak prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, New Jersey. 2020.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.