POLICY NUMBER UM ONC_1239	SUBJECT Pomalyst™ (pomalidomide)		DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 04/10/13, 07/24/14, 12/18/15, 12/21/16, 11/08/17, 10/10/18, 09/11/19, 12/11/19, 03/11/20, 05/13/20, 07/08/20	APPROVAL DATE July 8, 2020	EFFECTIVE DATE July 31, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 04/10/13, 07/24/14, 12/18/15, 12/21/16, 11/08/17, 10/10/18, 09/11/19, 12/11/19, 03/11/20, 05/13/20, 07/08/20	
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 Pomalyst (pomalidomide) 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 dug alternatives are preferred over Brand name drugs.

2. Multiple Myeloma

a. NOTE: The preferred immunomodulatory agent, per NCH policy and pathway, is Revlimid (lenalidomide) over Pomalyst (pomalidomide) or Thalomid (thalidomide).

b. Pomalyst (pomalidomide) may be used as follows:

i. The member has relapsed or refractory multiple myeloma that has failed 2 prior therapies for myeloma including one proteasome inhibitor & one

immunomodulatory agent, and Pomalyst (pomalidomide) is being used as a single agent **OR** in combination with dexamethasone **OR** in **ANY** of the following regimens:

A. In combination with dexamethasone and Darzalex (daratumumab)

B. In combination with dexamethasone and Ninlaro (ixazomib)

C. In combination with dexamethasone and Cytoxan (cyclophosphamide)

D. In combination with dexamethasone and Velcade (bortezomib)

E. In combination with dexamethasone and Empliciti (elotuzumab)

F. In combination with dexamethasone and Kyprolis (carfilzomib).

3. AIDS related Kaposi sarcoma

a. The member has AIDS-related Kaposi sarcoma that has relapsed or is refractory to first line systemic therapy, including Doxil (liposomal doxorubicin) **AND**

b. Pomalyst (pomalidomide) will be used as subsequent therapy in combination with HAART-Highly Active Anti-Retroviral therapy.

III. EXCLUSION CRITERIA

1. Disease progression while receiving Pomalyst (pomalidomide) containing regimen.
2. Dosing exceeds single dose limit of Pomalyst (pomalidomide) 5 mg.
3. Treatment exceeds the maximum limit of 84 (1 mg), 42 (2 mg), or 21 (4 mg) capsules per month.
4. 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. Pomalyst prescribing information. Celgene Corporation. Summit, NJ. 2019.
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.