POLICY NUMBER UM ONC_1193	**SUBJECT** Revlimid™ (lenalidomide)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 01/04/12, 10/13/13, 12/03/14, 01/19/15, 07/25/16, 06/09/17, 06/13/18, 05/08/19, 12/11/19, 03/11/20	**APPROVAL DATE** March 11, 2020	**EFFECTIVE DATE** March 27, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 01/04/12, 10/13/13, 12/03/14, 01/19/15, 07/25/16, 06/09/17, 06/13/18, 05/08/19, 12/11/19, 03/11/20	
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 Revlimid (lenalidomide) 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: http://pathways.newcenturyhealth.com **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. The member has multiple myeloma and Revlimid (lenalidomide) is being used as **ONE** of the following:
        i. Initial therapy:
            A. Combination with dexamethasone +/- bortezomib. **NOTE: This is the preferred regimen for NCH Pathways.**

ii. Maintenance therapy as a single agent :

A. After completion of therapy for newly diagnosed or relapsed/refractory disease **OR**

B. After completion of autologous stem cell transplant.

iii. For relapsed or refractory disease as **ONE** of the following:

A. As a single agent or with dexamethasone

B. With daratumumab + dexamethasone **NOTE: This is a Preferred Regimen on NCH Pathway**

C. With bortezomib +/- dexamethasone

D. With ixazomib +/- dexamethasone

E. With carfilzomib +/- dexamethasone

F. With elotuzumab +/- dexamethasone

G. With panabinostat in members who have progressed on 2 prior regimens

H. In DT-PACE (dexamethasone, thalidomide, cisplatin, doxorubicin, cyclophosphamide, and etoposide) regimen

I. In VTD-PACE. (bortezomib, dexamethasone, thalidomide, cisplatin, doxorubicin, cyclophosphamide, and etoposide) regimen.

3. **Myelodysplastic Syndrome (MDS)**

a. The member has very low, low, or intermediate risk MDS associated with symptomatic anemia and Revlimid (lenalidomide) is being used as **ONE** of the following:

i. In members with del(5q) chromosomal abnormality with or without an ESA

ii. In members without del(5q) chromosomal abnormality with or without an ESA.

b. Revlimid (lenalidomide) is being used as a single agent or in combination with hypomethylating agent (i.e. decitabine or azacitidine).

4. **Non-Hodgkin Lymphoma**

a. The member has Non- Hodgkin's Lymphoma including Follicular Lymphoma Nodal Marginal Zone Lymphoma, Mantle Cell Lymphoma, and Splenic Marginal Zone Lymphoma **AND**

b. Revlimid (lenalidomide) is being used as second-line or subsequent therapy for recurrent or progressive disease, with or without Rituximab.

III. EXCLUSION CRITERIA

1. Off-label indications for Revlimid (lenalidomide) in other NHL subtypes, Hodgkin Lymphoma, and Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma shall be reviewed for appropriateness per National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or other compelling medical literature publications.
2. Dosing exceeds single dose limit of Revlimid (Lenalidomide) 10 mg (for MDS) or 25 mg (for MM).
3. Member has disease progression while taking Revlimid (lenalidomide).
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. Revlimid prescribing information. Celgene Corporation. Summit, New Jersey. 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.