POLICY NUMBER UM ONC_1297	SUBJECT Venclexta™ (venetoclax)		DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 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) 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 Venclexta (venetoclax) 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. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)

a. **NOTE #1: Please refer to the NCH Pathway document for the latest recommended regimens for CLL.**

b. **NOTE #2: Please note that per NCH Policy & NCH Pathway, the combination of Venclexta (venetoclax) and Gazyva (obinutuzumab) for first line therapy of CLL/SLL is a Non-Preferred Regimen.**

c. Venclexta (venetoclax) may be used as a single agent or in combination with rituximab for relapsed or refractory disease, with or without del(17p)/TP53 mutation.

3. **Acute Myeloid Leukemia (AML)**
    a. Venclexta (venetoclax) may be used in combination with decitabine or azacitidine for:
        i. Remission induction therapy & post-remission therapy for members with unfavorable-risk cytogenetics/members unsuitable for intensive remission induction therapy/members who decline intensive therapy.
4. **Mantle Cell Lymphoma**
    a. **NOTE: Please refer to the NCH Pathway document for the latest recommended treatment options for Mantle Cell Lymphoma.**
    b. Venetoclax may be used as a single agent for relapsed/refractory Mantle Cell Lymphoma, if the member is intolerant to/ has a contraindication to/has experienced disease progression on any of the NCH Pathway recommended therapies.

III. EXCLUSION CRITERIA

1. Disease progression while taking Venclexta (venetoclax).
2. Exclusions described above for specific diagnoses.
3. Dosing exceeds single dose limit of Venclexta (venetoclax) 400 mg.
4. Treatment exceeds the maximum limit of 120 (100 mg) or 240 (50 mg) tablets per 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. Venclexta prescribing information. Genentech USA, Inc. San Francisco, CA. 2019.
2. Clinical Pharmacology Elsevier Gold Standard. 2019.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2019.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2019.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2019.