Venclexta™ (venetoclax)
(Oral)

Document Number: IC-0276

Last Review Date: 12/04/2018
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Dates Reviewed: 05/2016, 04/2017, 04/2018, 12/2018

I. Length of Authorization

Coverage will be provided for six months and may be renewed.

- When used for CLL/SLL in combination with rituximab, coverage may be renewed up to a total 24 months of therapy (*from day 1 of cycle 1 of rituximab*).

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Venclexta Starting Pack 1 pack per 28 days
- Venclexta 10 mg tablet 2 per day
- Venclexta 50 mg tablet 1 per day
- Venclexta 100 mg tablet 1 per day

B. Max Units (per dose and over time) [Medical Benefit]:

- AML
  - 600 mg daily
- All other indications
  - 400 mg daily

III. Initial Approval Criteria

Coverage is provided for treatment of the following conditions:

- Patient is at least 18 years old (*unless otherwise specified*); **AND**
- Patient must not receive live attenuated vaccines prior to, during, or after venetoclax treatment (*until B-cell recovery*); **AND**
- Patient must not be on strong CYP3A-inhibitors during initiation and ramp-up phase; **AND**

Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) †

- Patient's disease is relapsed and/or refractory; **AND**

- Used as a single agent; **OR**
- Used in combination with Rituxan

Acute Myeloid Leukemia (AML) †

- Patient has newly-diagnosed disease; **AND**
- Used in combination with azacitidine, decitabine, or low-dose cytarabine; **AND**
- Patient is at least 75 years old or is unable to receive intensive induction therapy due to comorbidities (e.g., PS>2, moderate hepatic impairment, severe cardiac or pulmonary disease, CL_{CR} < 45 mL/min, etc)

NHL – Mantle Cell Lymphoma‡

- Must be second line therapy; **AND**
- Used as a single agent;

† FDA Approved Indication(s); ‡ Compendia Approved Indication(s)

IV. Renewal Criteria

Coverage can be renewed based on the following criteria:

- Patients continues to meet criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: tumor lysis syndrome; **AND**

Acute Myeloid Leukemia (AML)

- Disease stabilization or improvement as evidenced by a complete response [CR] (i.e. morphologic, cytogenetic or molecular complete response CR), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

All other indications

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- For CLL/SLL, when used in combination with rituximab, patient has not received more than 24 months of therapy

V. Dosage/Administration

Indication	Dose
CLL/SLL	Dose titration schedule: • Week 1: 20 mg daily • Week 2: 50 mg daily • Week 3: 100 mg daily • Week 4: 200 mg daily • Week 5 and thereafter: 400 mg daily

Indication	Dose
	Monotherapy: Continued until disease progression or unacceptable toxicity *Rituximab combination therapy: Continue for 24 months from Cycle 1 Day 1 of rituximab*
AML	Dose titration schedule: • Day 1: 100 mg daily • Day 2: 200 mg daily • Day 3: 400 mg daily • Day 4 and beyond: 400 mg daily (when used in combination with azacitidine or decitabine) or 600 mg daily (when used in combination with low-dose cytarabine) *Continued until disease progression or unacceptable toxicity*
All Other Indications	Dose titration schedule: • Week 1: 20 mg daily • Week 2: 50 mg daily • Week 3: 100 mg daily • Week 4: 200 mg daily • Week 5 and thereafter: 400 mg daily *Continued until disease progression or unacceptable toxicity*

VI. Billing Code/Availability Information

HCPCS code:

J8999 - Prescription drug, oral, chemotherapeutic, Not Otherwise Specified
C9399 – Unclassified drugs or biologicals (Hospital Outpatient Use ONLY)

NDC:

Venclexta Starting Pack: 0074-0579-xx
Venclexta 10mg tablet: 0074-0561-xx
Venclexta 50mg tablet: 0074-0566-xx
Venclexta 100mg tablet: 0074-0576-xx

VII. References

1. Venclexta [package insert]. North Chicago, IL; Abbvie, Inc. November 2018. Accessed November 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) venetoclax. National Comprehensive Cancer Network, 2018. 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 November 2018.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C83.00	Small cell B-cell lymphoma, unspecified site
C83.01	Small cell B-cell lymphoma, lymph nodes of head, face and neck
C83.02	Small cell B-cell lymphoma, intrathoracic lymph nodes
C83.03	Small cell B-cell lymphoma, intra-abdominal lymph nodes
C83.04	Small cell B-cell lymphoma, lymph nodes of axilla and upper limb
C83.05	Small cell B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.06	Small cell B-cell lymphoma, intrapelvic lymph nodes
C83.07	Small cell B-cell lymphoma, spleen
C83.08	Small cell B-cell lymphoma, lymph nodes of multiple sites
C83.09	Small cell B-cell lymphoma, extranodal and solid organ sites
C83.10	Mantle cell lymphoma, unspecified site
C83.11	Mantle cell lymphoma, lymph nodes of head, face, and neck
C83.12	Mantle cell lymphoma, intrathoracic lymph nodes
C83.13	Mantle cell lymphoma, intra-abdominal lymph nodes
C83.14	Mantle cell lymphoma, lymph nodes of axilla and upper limb
C83.15	Mantle cell lymphoma, lymph nodes of inguinal region and lower limb
C83.16	Mantle cell lymphoma, intrapelvic lymph nodes
C83.17	Mantle cell lymphoma, spleen
C83.18	Mantle cell lymphoma, lymph nodes of multiple sites
C83.19	Mantle cell lymphoma, extranodal and solid organ sites
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
C92.00	Acute myeloblastic leukemia not having achieved remission
C92.50	Acute myelomonocytic leukemia not having achieved remission
C92.60	Acute myeloid leukemia with 11q23-abnormality not having achieved remission
C92.A0	Acute myeloid leukemia with multilineage dysplasia not having achieved remission
C93.00	Acute monoblastic/monocytic leukemia not having achieved remission
C94.00	Acute erythroid leukemia not having achieved remission
C94.20	Acute megakaryoblastic leukemia not having achieved remission

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) and Local Coverage Determinations (LCDs) 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): 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
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