

SPECIALTY GUIDELINE MANAGEMENT

VENCLEXTA (venetoclax)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

Treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion, as detected by an FDA approved test, who have received at least one prior therapy.

B. Compendial Uses

Single-agent therapy for relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) with or without 17p deletion or *TP53* mutation

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Authorization of 12 months may be granted for treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) when the member has received at least one prior therapy.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Venclexta™ [package insert]. North Chicago, IL: AbbVie Inc.; April 2016.
2. The NCCN Drugs & Biologics Compendium® © 2016 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed October 20, 2016.
3. The NCCN Clinical Practice Guidelines in Oncology® Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (Version 1.2017) © 2016 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed October 20, 2016.