Venclexta

Description

Venclexta (venetoclax)

Background
Venclexta is used for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), with or without 17p deletion, who have received at least one prior therapy. Venclexta is FDA-approved treatment that targets the B-cell lymphoma 2 (BCL-2) protein, which supports cancer cell growth (1).

Regulatory Status
FDA-approved indication: Venclexta is a BCL-2 inhibitor indicated: (1)
1. For the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)
2. In combination with azacitidine or decitabine or low-dose cytarabine for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adults who are 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy

Off-Label Uses: (2-5)
1. Mantle cell lymphoma (MCL)
2. Acute myeloid leukemia (AML)

Venclexta can cause rapid reduction in tumor and thus poses a risk for Tumor Lysis Syndrome (TLS), which can occur within 6-8 hours after the first infusion. Patients with high tumor burden and/or high circulating lymphocyte count are at greater risk for TLS and should receive appropriate tumor lysis prophylaxis with anti-hyperuricemics (e.g., allopurinol) and hydration.
beginning 12-24 hours prior to the infusion of Venclexta. For treatment of TLS, correct electrolyte abnormalities, monitor renal function, and fluid balance, and administer supportive care, including dialysis as indicated (1).

Neutropenia may occur during Venclexta therapy. Complete blood counts (CBC) should be monitored throughout the treatment period. Dosing should be interrupted or reduced for severe neutropenia (1).

Venclexta may cause embryo-fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to avoid pregnancy during treatment. Pregnant patients should be advised of the potential hazard to the fetus (1).

The safety and efficacy of immunization with live or attenuated viral vaccines during or following Venclexta therapy has not been studied. Immunization with live virus vaccines is not recommended during treatment and until B-cell recovery (1).

The safety and effectiveness of Venclexta in pediatric patients have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Venclexta may be considered medically necessary in patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), mantle cell lymphoma (MCL), or relapsed or refractory acute myeloid leukemia (AML), or newly-diagnosed acute myeloid leukemia (AML) and if the conditions indicated below are met

Venclexta is considered investigational for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses
Patient must have **ONE** of the following:

1. Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

2. Mantle cell lymphoma (MCL)
   a. Patient has received at least **ONE** prior therapy

3. Relapsed or refractory acute myeloid leukemia (AML)

4. Newly-diagnosed acute myeloid leukemia (AML)

   **AND ALL** of the following:
   a. 75 years or older **OR** have comorbidities that preclude use of intensive induction chemotherapy
   b. Used in combination with azacitidine **OR** decitabine **OR** low-dose cytarabine

   **AND ALL** of the following for **ALL** diagnoses:
   a. Prescriber agrees to monitor complete blood count (CBC) for neutropenia
   b. Prescriber agrees to advise female patients of childbearing potential to avoid pregnancy during treatment

**Prior – Approval Renewal Requirements**

**Age**
18 years of age or older

**Diagnoses**

Patient must have the following:

1. Chronic lymphocytic leukemia (CLL)
2. Small lymphocytic lymphoma (SLL)
3. Mantle cell lymphoma (MCL)
4. Acute myeloid leukemia (AML)

**AND ALL** of the following for **ALL** diagnoses:
Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Duration 12 months

Prior – Approval Renewal Limits

Duration 24 months

Rationale

Summary
Venclexta is used for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). Venclexta is also approved for use in relapsed or refractory acute myeloid leukemia (AML) or newly-diagnosed AML. Venclexta can cause rapid reduction in tumor and thus poses a risk for Tumor Lysis Syndrome (TLS), which can occur within 12-24 hours after the first infusion. The safety and efficacy of immunization with live or attenuated viral vaccines during or following Venclexta therapy has not been studied. The safety and efficacy of Venclexta in pediatric patients has not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Venclexta while maintaining optimal therapeutic outcomes.

References


### Policy History

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<tr>
<td>April 2016</td>
<td>Addition to PA</td>
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<tr>
<td>June 2016</td>
<td>Annual review</td>
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<td>September 2016</td>
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<td>June 2017</td>
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<tr>
<td>June 2018</td>
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<td>Addition of “at least” to initiation criteria, patient must try and fail “at least” one prior CLL therapy per package insert</td>
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<td>Removal of the 17P deletion from the CLL diagnosis requirement</td>
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<td>March 2019</td>
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<td>May 2019</td>
<td>Removed requirement of trial of one prior therapy for CLL and SLL</td>
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### Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.