Reference number(s)
2374-A

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
1. Venclexta is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
2. Venclexta is indicated in combination with azacitidine, or decitabine, or low-dose cytarabine for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

B. Compendial Uses
1. Mantle cell lymphoma
2. In combination with decitabine, azacitidine or low-dose cytarabine for newly diagnosed acute myeloid leukemia (AML) in adults at least 60 years old
3. Relapsed or refractory acute myeloid leukemia (AML)
4. In combination with azacitidine, decitabine or low-dose cytarabine for blastic plasmacytoid dendritic cell neoplasm (BPDCN)
5. Relapsed or progressive multiple myeloma in combination with dexamethasone in patients with translocation t(11;14).

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Documentation of the presence of translocation t(11,14) (where applicable).

III. CRITERIA FOR INITIAL APPROVAL

A. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)
Authorization of 12 months may be granted for treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) when Venclexta will be used as monotherapy, in combination with rituximab (Rituxan), or in combination with obinutuzumab (Gazyva).

B. Newly-diagnosed Acute Myeloid Leukemia (AML)
Authorization of 12 months may be granted for treatment of newly-diagnosed acute myeloid leukemia (AML) when all of the following criteria is met:
1. Venclexta will be used in combination with decitabine, azacitidine, or low-dose cytarabine.
2. Member meets any of the following:
   a. The member is 75 years of age or older.
   b. The member has comorbidities that preclude treatment with intensive induction chemotherapy.

c. The member is 60 years of age or older (physiologic age) and is a candidate for intensive remission induction therapy with unfavorable-risk cytogenetics.
d. The member is 60 years of age or older (physiologic age) and is not a candidate for intensive remission induction therapy or declines intensive therapy.
e. The member is 60 years of age or older (physiologic age) and will use Venclexta as post induction therapy following response to a Venclexta-based regimen.

C. Relapsed or Refractory Acute Myeloid Leukemia (AML)
Authorization of 12 months may be granted for treatment of relapsed or refractory acute myeloid leukemia when Venclexta will be used in combination with azacitidine, decitabine or low-dose cytarabine.

D. Mantle Cell Lymphoma
Authorization of 12 months may be granted for subsequent treatment of mantle cell lymphoma as a single agent or in combination with rituximab.

E. Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)
Authorization of 12 months may be granted for BPDCN in combination with azacitidine, decitabine or low-dose cytarabine.

F. Multiple Myeloma
Authorization of 12 months may be granted for treatment of relapsed or progressive multiple myeloma in combination with dexamethasone in members with translocation t(11;14).

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. For members with CLL/SLL who will use Venclexta with Rituxan, Venclexta will not be used longer than 24 months from cycle 1 day 1 of Rituxan initiation. For members with CLL/SLL who will use Venclexta with Gazyva, Venclexta will not be used longer than 12 cycles.

V. REFERENCES

1. Venclexta® [package insert]. North Chicago, IL: AbbVie Inc.; November 2020.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed January 15, 2021.