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 adult 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 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

B. Compendial Uses
1. Mantle cell lymphoma (MCL)
2. Acute myeloid leukemia (AML)
3. Blastic plasmacytoid dendritic cell neoplasm (BPDCN)
4. Multiple myeloma (MM) with translocation t(11;14)
5. Systemic light chain amyloidosis (SLCA) with translocation t(11;14)
6. Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL)
7. Myelodysplastic syndrome (MDS)

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) and TP53-mutation (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 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 one of the following criteria is met:
1. Used in combination with decitabine, azacitidine, or low-dose cytarabine and 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 and is a candidate for intensive remission induction therapy with unfavorable-risk cytogenetics.
d. The member is 60 years of age or older and is not a candidate for intensive remission induction therapy or declines intensive therapy.
e. The member is 60 years of age or older and will use Venclexta in a post-induction therapy regimen following response to a Venclexta-based regimen.

2. Used in combination with azacitidine in a member less than 60 years of age for alternative induction treatment with unfavorable risk genetics and TP53-mutation.

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

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

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 (MM)
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).

G. Systemic light chain amyloidosis (SLCA)
Authorization of 12 months may be granted for treatment of relapsed or refractory systemic light chain amyloidosis with translocation t(11;14), as a single agent or in combination with dexamethasone.

H. Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL)
Authorization of 12 months may be granted for subsequent treatment of Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma, as a single agent.

I. Myelodysplastic syndrome (MDS)
Authorization of 12 months may be granted for treatment of MDS, in combination with azacitidine or decitabine.

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.; June 2022.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed January 3, 2023.

3. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at http://www.micromedexsolutions.com. Accessed January 3, 2023.