Reference number(s)
2374-A

Specialty Guideline Management
Venclexta

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Venclexta	venetoclax

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.

FDA-Approved Indications

- Venclexta is indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
- 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.

Compendial Uses

- Mantle cell lymphoma (MCL)
- Acute myeloid leukemia (AML)
- Blastic plasmacytoid dendritic cell neoplasm (BPDCN)
- Multiple myeloma (MM) with translocation t(11;14)
- Systemic light chain amyloidosis (SLCA) with translocation t(11;14)
- Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL)
- Myelodysplastic syndrome (MDS)
- Hairy cell leukemia
- Accelerated/blast phase myeloproliferative neoplasms

- B-cell Acute Lymphoblastic Leukemia/T-cell Acute Lymphoblastic Leukemia (B-ALL/T-ALL)
- Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL)

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

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).

Coverage Criteria

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 either of the following is met:

- The requested medication will be used as monotherapy, in combination with rituximab (Rituxan), or in combination with obinutuzumab (Gazyva), or
- The requested medication will be used as first line therapy in combination with ibrutinib (Imbruvica).

Newly-Diagnosed Acute Myeloid Leukemia (AML)

Authorization of 12 months may be granted for treatment of newly-diagnosed acute myeloid leukemia (AML) when used in combination with decitabine, azacitidine, or low-dose cytarabine and one of the following is met:

- The member is 75 years of age or older.
- The member has comorbidities that preclude treatment with intensive induction chemotherapy or is not a candidate for intensive induction therapy.
- The member has poor/adverse risk disease and is a candidate for intensive induction therapy.
- The member will use Venclexta in a post-induction therapy regimen following response to a Venclexta-based regimen.

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.

Mantle Cell Lymphoma (MCL)

Authorization of 12 months may be granted for subsequent treatment of mantle cell lymphoma when one of the following is met:

- The requested medication will be used as subsequent treatment and as a single agent or in combination with rituximab or ibrutinib, or
- The requested medication will be used as induction therapy for TP53 mutated disease and in combination with obinutuzumab (Gazyva) and zanubrutinib (Brukinsa).

Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)

Authorization of 12 months may be granted for BPDCN, in combination with azacitidine, decitabine or low-dose cytarabine.

Multiple Myeloma (MM)

Authorization of 12 months may be granted for treatment of relapsed or progressive multiple myeloma, in combination with dexamethasone and with or without daratumumab or daratumumab and hyaluronidase-fihj or a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib) in members with translocation t(11;14).

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.

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.

Myelodysplastic Syndrome (MDS)

Authorization of 12 months may be granted for treatment of MDS, in combination with azacitidine or decitabine.

Hairy Cell Leukemia

Authorization of 12 months may be granted for treatment of relapsed or refractory hairy cell leukemia, as a single agent or in combination with rituximab, when all of the following are met:

- Member has progressed on previous therapy for relapsed or refractory disease AND
- Member has disease resistant to BRAF inhibitor therapy

Myeloproliferative Neoplasms

Authorization of 12 months may be granted for the management of disease progression of accelerated/blast phase myeloproliferative neoplasms when used in combination with azacitidine or decitabine.

B-Cell Acute Lymphoblastic Leukemia/T-Cell Acute Lymphoblastic Leukemia (B-ALL/T-ALL)

Authorization of 12 months may be granted for the treatment of relapsed or refractory B-cell acute lymphoblastic leukemia/T-cell acute lymphoblastic leukemia (B-ALL/T-ALL) when used in combination with vincristine, pegaspargase or calaspargase, and prednisone or dexamethasone.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the Coverage Criteria section 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. For members with CLL/SLL who will use Venclexta with Imbruvica, Venclexta will not be used longer than 13 cycles.

References

1. Venclexta® [package insert]. North Chicago, IL: AbbVie Inc.; June 2022.
2. The The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed October 9, 2024.
3. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at http://www.micromedexsolutions.com. Accessed January 10, 2024.
4. The NCCN Clinical Practice Guidelines in Oncology Multiple Myeloma Version 2.2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed January 10, 2024.
5. The NCCN Clinical Practice Guidelines in Oncology Acute Myeloid Leukemia Version 1.2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed March 13, 2024.