Reference number(s)
2280-A

Specialty Guideline Management azacitidine-Vidaza

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
Vidaza	azacitidine

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[1,2]

- Myelodysplastic syndromes (MDS): azacitidine/Vidaza is indicated for treatment of adult patients with the following French-American-British (FAB) myelodysplastic syndrome subtypes: refractory anemia (RA) or refractory anemia with ringed sideroblasts (RARS) (if accompanied by neutropenia or thrombocytopenia or requiring transfusions), refractory anemia with excess blasts (RAEB), refractory anemia with excess blasts in transformation (RAEB-T), and chronic myelomonocytic leukemia (CMMoL).
- Juvenile myelomonocytic leukemia (JMML): azacitidine/Vidaza is indicated for treatment of pediatric patients aged 1 month and older with newly diagnosed juvenile myelomonocytic leukemia (JMML).

Compendial Uses[3-4]

- Acute myeloid leukemia (AML)
- Accelerated phase or blast phase myeloproliferative neoplasm

- Blastic plasmacytoid dendritic cell neoplasm (BPDCN)
- Myelodysplastic syndrome (MDS)/Myeloproliferative Neoplasms (MPN) Overlap Neoplasms
- Peripheral T-cell lymphoma

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

Coverage Criteria

Myelodysplastic Syndromes (MDS)[1,2,3]

Authorization of 12 months may be granted for the treatment of MDS.

Acute Myeloid Leukemia (AML)[3]

Authorization of 12 months may be granted for the treatment of AML.

Accelerated Phase or Blast Phase Myeloproliferative Neoplasm[3]

Authorization of 12 months may be granted for the treatment of accelerated phase or blast phase myeloproliferative neoplasm.

Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)[3]

Authorization of 12 months may be granted for the treatment of BPDCN when used in combination with venetoclax in either of the following settings:

- For the treatment of relapsed or refractory disease.
- For the treatment of systemic disease with palliative intent.

Myelodysplastic Syndrome (MDS)/Myeloproliferative Neoplasms (MPN) Overlap Neoplasms[3-4]

Authorization of 12 months may be granted for the treatment of MDS/MPN overlap neoplasms (i.e., chronic myelomonocytic leukemia (CMML), juvenile myelomonocytic leukemia (JMML), BCR-ABL negative atypical chronic myeloid leukemia (aCML), MDS/MPN with neutrophilia, unclassifiable MDS/MPN, MDS/MPN not otherwise specified (NOS), MDS/MPN with ring sideroblasts and thrombocytosis, or MDS/MPN with SF3B1 mutation).

Peripheral T-Cell Lymphoma (PTCL)[3]

Authorization of 12 months may be granted for the treatment of peripheral T-cell lymphoma (PTCL) [including the following subtypes: angioimmunoblastic T-cell lymphoma (AITL), nodal peripheral T-cell lymphoma with TFH phenotype (PTCL, TFH), follicular T-cell lymphoma (FTCL)] when all of the following criteria are met:

- The requested medication will be used as subsequent therapy for relapsed or refractory disease
- The requested medication will be used as a single agent

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.

References

1. Vidaza [package insert]. Princeton, NJ: Celgene Corporation; January 2024.
2. Azacitidine injection [package insert]. Princeton, NJ: Sandoz Inc.; September 2022.
3. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc.. Available at http://www.nccn.org. Accessed January 6, 2025.
4. Zoi K, Cross NC. Molecular pathogenesis of atypical CML, CMML and MDS/MPN unclassifiable. Int J Hematol 2015;101:229-242.