Reference number(s)
2288-A

Specialty Guideline Management decitabine

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
decitabine (brand unavailable)	decitabine

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]

Myelodysplastic syndromes (MDS): Decitabine is indicated for treatment of adult patients with myelodysplastic syndromes (MDS) including previously treated and untreated, de novo and secondary MDS of all French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.

Compendial Uses[2-3]

- Acute myeloid leukemia (AML)
- Accelerated phase or blast phase myeloproliferative neoplasms
- Lower risk myelodysplastic syndromes (MDS) associated with thrombocytopenia, neutropenia, symptomatic anemia, or increased marrow blasts
- Blastic plasmacytoid dendritic cell neoplasm (BPDCN)

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- Myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) Overlap Neoplasms
- Classic Hodgkin lymphoma

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

Coverage Criteria

Myelodysplastic syndromes (MDS)[1,2]

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

Acute myeloid leukemia (AML)[2]

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

Accelerated phase or blast phase myeloproliferative neoplasms[2]

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

Blastic plasmacytoid dendritic cell neoplasm (BPDCN)[2]

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/myeloproliferative neoplasm (MDS/MPN) overlap neoplasms[2-3]

Authorization of 12 months may be granted for the treatment of MDS/MPN overlap neoplasms (i.e., chronic myelomonocytic leukemia (CMML), 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).

Classic Hodgkin lymphoma[2]

Authorization of 12 months may be granted for the subsequent treatment of classic Hodgkin lymphoma in combination with pembrolizumab when the disease is refractory to at least 3 prior lines of therapy.

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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. Decitabine [package insert]. Princeton, NJ: Dr. Reddy's Laboratories Inc.; July 2020.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at http://www.nccn.org. Accessed January 8, 2025.
3. Zoi K, Cross NC. Molecular pathogenesis of atypical CML, CMML and MDS/MPN unclassifiable. Int J Hematol 2015;101:229-242.

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