Reference number(s)
4756-A

Standard Medicare Part B 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]

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[2-4]

- Acute lymphoblastic leukemia (ALL)
- Acute myeloid leukemia (AML)
- Accelerated/blast phase myeloproliferative neoplasm
- Blastic plasmacytoid dendritic cell neoplasm (BPDCN)
- Chronic myeloid leukemia (CML)
- Classic Hodgkin lymphoma

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- Lower risk myelodysplastic syndromes (MDS) associated with thrombocytopenia, neutropenia, symptomatic anemia, or increased marrow blasts
- Myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) Overlap Neoplasms

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Myelodysplastic syndromes (MDS)[1,2]

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

Acute Lymphoblastic Leukemia (ALL)[2,3]

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

Acute Myeloid Leukemia (AML)[2]

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

Accelerated/Blast Phase Myeloproliferative Neoplasm[2]

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

Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)[2]

Authorization of 12 months may be granted for the treatment of BPDCN in combination with venetoclax.

Chronic Myeloid Leukemia (CML)[3]

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

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 three prior lines of therapy.

Myelodysplastic Syndrome/Myeloproliferative Neoplasm (MDS/MPN) Overlap Neoplasms[2-4]

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],

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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).

Continuation Of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication listed in the coverage criteria section.
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen AND
    - No evidence of disease progression while on the current regimen.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for decitabine
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Acute Lymphoblastic Leukemia
- NCCN Guideline: Acute Myeloid Leukemia
- NCCN Guideline: Hodgkin Lymphoma
- NCCN Guideline: Myelodysplastic Syndromes
- NCCN Guideline: Myeloproliferative Neoplasms

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for decitabine are covered in addition to the following:

- Acute myeloid leukemia (AML)
- Accelerated/blast phase myeloproliferative neoplasm
- Blastic plasmacytoid dendritic cell neoplasm (BPDCN)
- Lower risk myelodysplastic syndromes (MDS) associated with thrombocytopenia, neutropenia, symptomatic anemia, or increased marrow blasts
- Myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) Overlap Neoplasms
- Classic Hodgkin lymphoma
- Acute lymphoblastic leukemia (ALL)
- Chronic myeloid leukemia (CML)

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Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using decitabine to treat acute myeloid leukemia, acute lymphoblastic leukemia, accelerated/blast phase myeloproliferative neoplasm, lower risk MDS, blastic plasmacytoid dendritic cell neoplasm, myelodysplastic syndrome/myeloproliferative neoplasm overlap neoplasms, and classic Hodgkin lymphoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support for using decitabine to treat acute lymphoblastic leukemia and chronic myeloid leukemia can be found in the Micromedex DrugDex database. Use of information in the DrugDex database for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Decitabine [package insert]. Princeton, NJ: Dr. Reddy's Laboratories Inc.; July 2020.
2. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at http://www.nccn.org. Accessed January 12, 2026.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at http://www.micromedexsolutions.com. Accessed January 12, 2026.
4. 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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