Reference number(s)
4756-A

STANDARD MEDICARE PART B MANAGEMENT

DACOGEN (decitabine)
decitabine (generic)

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

Myelodysplastic syndromes (MDS): Dacogen (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.

B. Compendial Uses

1. Acute myeloid leukemia (AML)
2. Accelerated phase or blast phase myeloproliferative neoplasms
3. Lower risk myelodysplastic syndromes (MDS) associated with thrombocytopenia, neutropenia, symptomatic anemia, or increased marrow blasts
4. Blastic plasmacytoid dendritic cell neoplasm (BPDCN)
5. Myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) Overlap Neoplasms
6. Acute Lymphoblastic Leukemia (ALL)
7. Chronic myeloid leukemia (CML)

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

II. CRITERIA FOR INITIAL APPROVAL

A. Myelodysplastic syndromes (MDS)
Authorization of 12 months may be granted for the treatment of MDS.

B. Acute myeloid leukemia (AML)
Authorization of 12 months may be granted for the treatment of AML.

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

D. **Blastic plasmacytoid dendritic cell neoplasm (BPDCN)**
Authorization of 12 months may be granted for the treatment of BPDCN when used in combination with venetoclax in either of the following settings:
1. For the treatment of relapsed or refractory disease.
2. For the treatment of systemic disease with palliative intent.

E. **Myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) overlap neoplasms**
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) or MDS/MPN with ring sideroblasts and thrombocytosis).

F. Acute lymphoblastic leukemia (ALL)
Authorization of 12 months may be granted for the treatment of ALL.

G. Chronic myeloid leukemia (CML)
Authorization of 12 months may be granted for the treatment of CML.

III. 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:
A. The member is currently receiving therapy with the requested medication.
B. The requested medication is being used to treat an indication enumerated in Section II.
C. The member is receiving benefit from therapy. Benefit is defined as:
   1. No evidence of unacceptable toxicity while on the current regimen and
   2. No evidence of disease progression while on the current regimen

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Dacogen and decitabine.
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology
3. NCCN Guideline: Myelodysplastic syndromes
4. NCCN Guideline: Acute myeloid leukemia
5. NCCN Guideline: Acute lymphoblastic leukemia

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Dacogen and decitabine are covered in addition to the following:
1. Acute myeloid leukemia (AML)
2. Accelerated phase or blast phase myeloproliferative neoplasm

3. Lower risk myelodysplastic syndromes (MDS) associated with thrombocytopenia, neutropenia, symptomatic anemia, or increased marrow blasts
4. Blastic plasmacytoid dendritic cell neoplasm (BPDCN)
5. Myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) Overlap Neoplasms
6. Acute Lymphoblastic Leukemia (ALL)
7. Chronic myeloid leukemia (CML)

V. 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 phase myeloproliferative neoplasm, blast phase myeloproliferative neoplasm, lower risk MDS, blastic plasmacytoid dendritic cell neoplasm, and myelodysplastic syndrome/myeloproliferative neoplasm overlap neoplasms 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).

VI. REFERENCES

1. Dacogen [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; November 2021.
2. Decitabine [package insert]. Princeton, NJ: Dr. Reddy's Laboratories Inc.; July 2020.
3. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at http://www.nccn.org. Accessed January 04, 2024.
4. IBM Micromedex System (electronic version). Truven Health Analytics, Ann Arbor, MI. Available at http://www.micromedexsolutions.com [available with subscription]. Accessed January 04, 2024.
5. Zoi K, Cross NC. Molecular pathogenesis of atypical CML, CMML and MDS/MPN unclassifiable. Int J Hematol 2015;101:229-242.