PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Decitabine Products Prior Authorization Policy
- Dacogen® (decitabine intravenous infusion – Otsuka, generic)

REVIEW DATE: 12/11/2024

OVERVIEW

Decitabine (Dacogen), a hypomethylating agent, is indicated for the treatment of **myelodysplastic syndromes** (MDS) in adults 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.[1]

Guidelines

Decitabine is addressed in National Comprehensive Cancer Network (NCCN) guidelines:

- **Acute Myeloid Leukemia:** Guidelines (version 3.2024 – May 17, 2024) recommend decitabine as a single agent, or in combination with Nexavar® (sorafenib tablet) or Venclexta® (venetoclax tablet) for lower intensity therapy, consolidation therapy, and for the treatment of relapsed/refractory disease.[2,4] Decitabine in combination with Venclexta is also recommended for intensive induction therapy. In addition, decitabine is recommended in combination with Venclexta for relapsed/refractory blastic plasmacytoid dendritic cell neoplasm or as palliative treatment.
- **Myelodysplastic Syndromes:** Guidelines (version 1.2025 – November 15, 2024) recommend decitabine for the treatment of lower risk and higher risk MDS, and for the treatment of myelodysplastic/myeloproliferative neoplasms.[2,3]
- **Myeloproliferative Neoplasms:** Guidelines (version 2.2024 – August 8, 2024) recommend decitabine for the treatment of myeloproliferative neoplasms (MPN)-accelerated phase or MPN-blast/acute myeloid leukemia phase.[2,5]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of decitabine. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with decitabine as well as the monitoring required for adverse events and long-term efficacy, approval requires decitabine to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of decitabine is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Myelodysplastic Syndromes.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   Note: Examples include refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia.
   A) Patient is ≥ 18 years of age; AND
   B) The medication is prescribed by or in consultation with an oncologist.

Other Uses with Supportive Evidence

2. **Acute Myeloid Leukemia**. Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) The medication is prescribed by or in consultation with an oncologist.

3. **Blastic Plasmacytoid Dendritic Cell Neoplasm**. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   A) Patient is ≥ 18 years of age; AND
   B) Patient meets ONE of the following (i or ii):
      i. Patient has relapsed or refractory disease; OR
      ii. Decitabine is used for palliative treatment; AND
   C) Decitabine is used in combination with Venclexta (venetoclax tablets); AND
   D) The medication is prescribed by or in consultation with an oncologist.

4. **Myeloproliferative Neoplasms.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient meets ONE of the following (i or ii):
      i. Patient has accelerated phase; OR
      ii. Patient has blast/acute myeloid leukemia phase; AND
   C) The medication is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of decitabine is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Dacogen® intravenous infusion [prescribing information]. Rockville, MD: Otsuka; June 2020.
2. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 4, 2024. Search term: decitabine.
3. The NCCN Myelodysplastic Syndromes Clinical Practice Guidelines in Oncology (version 1.2025 – November 15, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 4, 2024.
4. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 3.2024 – May 17, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 4, 2024.
5. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 2.2024 – August 8, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 4, 2024.