PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 11/30/2022

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 2.2022 – June 14, 2022) recommend decitabine as a single agent, or in combination with Nexavar® (sorafenib tablet) or Venclexta® (venetoclax tablet) in patients ≥ 60 years of age, and as a single agent, or in combination with Nexavar or Venclexta for the treatment of relapsed/refractory disease.[2,4] NCCN also recommends decitabine as a single agent for alternative induction therapy in patients < 60 years of age with unfavorable risk genetics and TP53 mutation. 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 1.2023 – September 12, 2022) 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 3.2022 – August 11, 2022) recommend decitabine for the treatment of myelofibrosis (MF)-accelerated phase or MF-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 Indications

1. **Myelodysplastic Syndromes.** Approve for 1 year if the patient meets the following criteria (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 the following criteria (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient meets one of the following criteria (i, ii, or iii):
      i. Patient is ≥ 60 years of age; OR
      ii. Patient has relapsed or refractory disease; OR
      iii. Patient has unfavorable risk cytogenetics and TP53 mutation; AND
   C) 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 the following criteria (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. Medication is used for palliative treatment; AND
   C) Decitabine is used in combination with Venclexta (venetoclax tablet); AND
   D) The medication is prescribed by or in consultation with an oncologist.

4. **Myelofibrosis.** Approve for 1 year if the patient meets the following criteria (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. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 16, 2022. Search term: decitabine.
3. The NCCN Myelodysplastic Syndromes Clinical Practice Guidelines in Oncology (version 1.2023 – September 12, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 16, 2022.
4. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 2.2022 – June 14, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 16, 2022.

5. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 3.2022 – August 11, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 16, 2022.