VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Decitabine Products Utilization Management Medical Policy
- Dacogen® (decitabine intravenous infusion – Otsuka, generic)

REVIEW DATE: 12/13/2023

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 6.2023 – October 24, 2023) recommend decitabine as a single agent, or in combination with Nexavar® (sorafenib tablet) or Venclexta® (venetoclax tablet) for lower intensity therapy, and for the treatment of relapsed/refractory disease.[2,4] Decitabine in combination with Venclexta is also recommended for intensive induction therapy. NCCN also recommends decitabine as a single agent for alternative induction therapy in patients < 60 years of age with unfavorable risk genetics with or without 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 3.2023 – November 10, 2023) 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 3.2023 – October 25, 2023) 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 medical benefit coverage of decitabine. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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

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1. **Myelodysplastic Syndromes.** Approve for 1 year if the patient meets 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.

   Dosing. Approve one of the following dosing regimens (A or B):
   A) Each individual dose must not exceed 15 mg/m^2 administered by intravenous infusion up to 3 times daily for up to 3 days in each 42-day cycle; OR
   B) Each individual dose must not exceed 20 mg/m^2 administered by intravenous infusion once daily for up to 5 days in each 28-day cycle.

Other Uses with Supportive Evidence

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2. **Acute Myeloid Leukemia**. Approve for 1 year if the patient meets 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.

   Dosing. Each individual dose must not exceed 20 mg/m^2 administered by intravenous infusion once daily for up to 10 days of each 28-day cycle.

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3. **Blastic Plasmacytoid Dendritic Cell Neoplasm**. Approve for 1 year if the patient meets 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 tablet); AND
   D) The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve one of the following dosing regimens (A or B):
   A) Each individual dose must not exceed 15 mg/m^2 administered by intravenous infusion up to 3 times daily for up to 3 days in each 42-day cycle; OR
   B) Each individual dose must not exceed 20 mg/m^2 administered by intravenous infusion once daily for up to 5 days in each 28-day cycle.

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4. **Myelofibrosis.** Approve for 1 year if the patient meets 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.

Dosing. Each individual dose must not exceed 20 mg/m^2 administered by intravenous infusion once daily for up to 5 days in each 28-day cycle.

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. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 8, 2023. Search term: decitabine.
3. The NCCN Myelodysplastic Syndromes Clinical Practice Guidelines in Oncology (Version 3.2023 – November 10, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 10, 2023.
4. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (Version 6.2023 – October 24, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 8, 2023.
5. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (Version 3.2023 – October 25, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 25, 2023.
6. Blum W, Garzon R, Klisovic RB, et al. Clinical response and *miR-29b* predictive significance in older AML patients treated with a 10-day schedule of decitabine. *Proc Natl Acad Sci USA*. 2010;107:7473-7478.
7. Kantarjian HM, Thomas XG, Dmoszynska A, et al. Multicenter, randomized, open-label, Phase III trial of decitabine versus patient choice, with physician advice, of either supportive care or low-dose cytarabine for the treatment of older patients with newly diagnosed acute myeloid leukemia. *J Clin Oncol*. 2012;30:2670-2677.
8. Welch JS, Petti AA, Miller CA, et al. *TP53* and decitabine in acute myeloid leukemia and myelodysplastic syndromes. *N Engl J Med*. 2016;375:2023-2036.
9. He PF, Zhou JD, Yao DM, et al. Efficacy and safety of decitabine in treatment of elderly patients with acute myeloid leukemia: A systematic review and meta-analysis. *Oncotarget*. 2017;8:41498-41507.
10. Badar T, Kantarjian HM, Ravandi F, et al. Therapeutic benefit of decitabine, a hypomethylating agent, in patients with high-risk primary myelofibrosis and myeloproliferative neoplasm in accelerated of blastic/acute myeloid leukemia phase. *Leuk Res*. 2015;39:950-956.
11. Rampal RK, Mascarenhas JO, Kosiorek HE, et al. Safety and efficacy of combined ruxolitinib and decitabine in accelerated and blast-phase myeloproliferative neoplasms. *Blood Res*. 2018;2:3572-3580.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Acute Myeloid Leukemia:** Unfavorable risk cytogenetics and TP53 mutation were added as another condition of approval. **Blastic Plasmacytoid Dendritic Cell Neoplasm:** Use for palliative treatment was added as another condition of approval.	11/30/2022
Annual Revision	**Acute Myeloid Leukemia:** Removed requirement that the patient is ≥ 60 years of age, has relapsed or refractory disease, OR has unfavorable cytogenetics and TP53 mutation.	12/13/2023