VENTURA COUNTY HEALTH CARE PLAN

Utilization Review Policy

POLICY: Oncology – Decitabine injection for intravenous use (Dacogen® – Otsuka America Pharmaceutical, generic)

APPROVAL DATE: 10/16/2019

OVERVIEW

Decitabine (Dacogen), a hypomethylating agent, is indicated for the treatment of adults 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.[1]

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for Myelodysplastic Syndromes (Version 1.2020 – August 27, 2019) recommend decitabine for the treatment of lower risk and higher risk MDS, and for the treatment of myelodysplastic/myeloproliferative neoplasms.[2,3]

The NCCN guidelines for Acute Myeloid Leukemia (Version 2.2020 – September 3, 2019) 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 Venclaxta for the treatment of relapsed/refractory disease.[2,4] NCCN also recommends decitabine in combination with Venclaxta for relapsed/refractory blastic plasmacytoid dendritic cell neoplasm.

The NCCN guidelines for Myeloproliferative Neoplasms (Version 3.2019 – September 4, 2019) 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 indication(s). 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.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Myelodysplastic Syndromes. (Note: Includes Refractory Anemia, Refractory Anemia with Ringed Sideroblasts, Refractory Anemia with Excess Blasts, Refractory Anemia with Excess Blasts in Transformation, Chronic Myelomonocytic Leukemia).** Approve for 1 year if the patient meets the following criteria (A and B):
   A) The patient is ≥ 18 years of age; AND
   B) Decitabine 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.[1]

Other Uses with Supportive Evidence

2. **Acute Myeloid Leukemia**. Approve for 1 year if the patient meets the following criteria (A and B):
   A) The patient meets one of the following criteria (i or ii):
      i. The patient is ≥ 60 years of age; OR
      ii. The patient has relapsed or refractory disease; AND
   B) Decitabine 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.[4,6-9]

3. **Blastic Plasmacytoid Dendritic Cell Neoplasm**. Approve for 1 year if the patient meets the following criteria (A, B, and C):
   A) The patient has relapsed or refractory disease; AND
   B) Decitabine is used in combination with Venclexta® (venetoclax tablet); AND
   C) Decitabine 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.[1]

4. **Myelofibrosis.** Approve for 1 year if the patient meets the following criteria (A and B):
   A) The patient has accelerate phase, or blast/acute myeloid leukemia phase; AND
   B) Decitabine 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.[10,11]

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Decitabine has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

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® injection for intravenous use [prescribing information]. Rockville, MD: Otsuka America Pharmaceutical; December 2018.
2. The NCCN Drugs and Biologics Compendium. © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on September 10, 2019. Search term: decitabine.
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4. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (Version 2.2020 – September 3, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on September 11, 2019.
5. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (Version 3.2019 – September 4, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on September 11, 2019.
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.
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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	Approval Date
New Policy	--	10/16/2019