Decitabine (Dacogen®)	Place of Service Office Administration Outpatient Facility Administration Infusion Center Administration Home Infusion HCPCS: **J0894** per 1 mg **J0893** per 1 mg (Sun Pharma only)

Condition(s) listed in policy (*see criteria for details*)

- Acute myeloid leukemia
- Blastic plasmacytoid dendritic cell neoplasm
- Myelodysplastic syndrome (MDS)/myeloproliferative overlap neoplasms (MPN) including: Chronic myelomonocytic leukemia (CMML)-1 and CMML-2
- Myelofibrosis in accelerated or blast phase

AHFS therapeutic class: Antineoplastic agent

Mechanism of action: Decitabine, an inhibitor of DNA methyltransferase causing hypomethylation of DNA, is an antineoplastic agent.

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Dacogen® (decitabine) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Acute myeloid leukemia (AML)

Covered Doses
Up to 20 mg/m^2 IV once daily for 5 days every 4 weeks or every 6 weeks
OR
Up to 20 mg/m^2 IV once daily for 10 days every 4 weeks
OR
Up to 15 mg/m^2 IV every 8 hours for 3 days and repeated every 6 weeks

Coverage Period
Indefinite

ICD-10:
C92.00-C92.02, C92.50-C92.52, C92.60-C92.62, C92.A0-C92.A2, C93.00-C93.02, C94.00-C94.02, C94.20-C94.22

Blastic plasmacytoid dendritic cell neoplasm (BPDCN)

Covered Doses
Up to 20 mg/m^2 IV once daily for 5 days every 4 weeks or every 6 weeks
OR
Up to 20 mg/m^2 IV once daily for 10 days every 4 weeks

OR
Up to 15 mg/m^2 IV every 8 hours for 3 days and repeated every 6 weeks

Coverage Period
Indefinite

ICD-10:
86.4

Myelodysplastic syndrome (MDS)/Myeloproliferative Overlap Neoplasms (MPN) including: Chronic Myelomonocytic Leukemia (CMML)-1 and CMML-2

Covered Doses
Up to 20 mg/m2 IV once daily for 5 days every 4 weeks
OR
Up to 15 mg/m2 IV every 8 hours for 3 days and repeated every 6 weeks

Coverage Period
Indefinite

ICD-10:
C92.2, C92.22, C93.10, C93.12, C94.6, D46.0, D46.1, D46.20, D46.21, D46.22, D46.4, D46.9, D46.A, D46.B, D46.C, D46.Z

Myelofibrosis in accelerated phase or blast phase

Covered Doses
Up to 20 mg/m2 IV once daily for 5 days every 4 weeks
OR
Up to 15 mg/m2 IV every 8 hours for 3 days and repeated every 6 weeks

Coverage Period
Indefinite

ICD-10:
C94.40-C94.42, C94.6, D47.1, D47.4, D75.81

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for Dacogen® (decitabine) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)
Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21): -

- Beta-Thalassemia
- Chronic Myelogenous Leukemia (CML)
- Solid Tumors

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

50 mg (single-use vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com.
- Dacogen® (decitabine) [Prescribing Information]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; 6/2020.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- National comprehensive cancer network. Acute myeloid leukemia (Version 3.2022). Available at http://www.nccn.org.
- National comprehensive cancer network. Myelodysplastic syndromes (Volume 3.2022). Available at http://www.nccn.org.
- National comprehensive cancer network. Myeloproliferative neoplasms (Volume 1.2022). Available at http://www.nccn.org.

(7) Policy Update

D ate of last revision: 4Q2022

Date of next review: 2Q2023

Changes from previous policy version:

- No clinical change to policy following revision.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee