Decitabine:

Dacogen®; Decitabine Ψ
(Intravenous)

Document Number: IC-0030

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- 50mg single-dose vial: 10 vials per 28 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- MDS: 900 billable units (900 mg) per 84 days
- AML: 500 billable units (500 mg) per 28 days
- MDS/MPN, BPDCN, & MPN-AP/BP: 250 billable units (250 mg) per 28 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Myelodysplastic Syndromes (MDS) † ‡ Φ [1,2,8]

Acute Myeloid Leukemia (AML) ‡ [2,6]

Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) ‡ [2,6]

Accelerated/Blast Phase Myeloproliferative Neoplasms (MPN-AP/BP) ‡ [2,11]

Myelodysplastic/Myeloproliferative (MDS/MPN) Overlap Neoplasms ‡ [2,8]

- Includes use for any of the following:
  - Chronic myelomonocytic leukemia type 1 or 2 (CMML-1 or 2)
  - MDS/MPN with neutrophilia

- MDS/MPN Not Otherwise Specified (NOS) ("overlap syndrome")
- MDS/MPN with SF3B1 mutation and thrombocytosis
- MDS/MPN with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) with wild-type SF3B1 mutation

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,2,9]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serious myelosuppression (e.g., anemia, neutropenia, and thrombocytopenia), etc.; **AND**
- Adequate documentation of disease stability and/or improvement as indicated by at least one of the following: decrease in bone marrow blasts percentage, increase in platelets, increase in hemoglobin, or increase in WBC/ANC over pretreatment values

V. Dosage/Administration [1,6,12-17]

Indication	Dose
MDS	Treat for a minimum of 4 cycles using one of the below regimens: ▪ Administer 15 mg/m² IV over 3 hours, repeated every 8 hours (45 mg/m²/day) for 3 days. Repeat cycle every 6 weeks. ▪ Administer 20 mg/m² IV over 1 hour, repeated daily for 5 days. Repeat cycle every 4 weeks.
MDS/MPN	▪ Administer 20 mg/m² IV over 1 hour on days 1 through 5 of every 28-day cycle until disease progression or unacceptable toxicity; **OR** ▪ Administer 20 mg/m² IV over 1 hour on days 8 through 12 of a 35-day cycle for 1 cycle, followed by 20 mg/m² IV on days 1 through 5 of every 28-day cycle (starting with cycle 2) until disease progression or unacceptable toxicity
AML	▪ Administer 20 mg/m² IV over 1 hour on days 1 through 5 of every 28-day cycle until disease progression or unacceptable toxicity; **OR** ▪ Administer 20 mg/m² IV over 1 hour on days 1 through 10 of every 28-day cycle until disease progression or unacceptable toxicity
BPDCN	▪ Administer 20 mg/m² IV over 1 hour on days 1 through 5 of every 28-day cycle until disease progression or unacceptable toxicity
MPN-AP/BP	▪ Administer 20 mg/m² IV over 1 hour on days 1 through 5 OR days 8 through 12 of every 28-day cycle until disease progression or unacceptable toxicity

VI. Billing Code/Availability Information

HCPCS Code(s):

- J0894 – Injection, decitabine, 1 mg; 1 billable unit = 1 mg
- J0893 – Injection, decitabine (sun pharma), not therapeutically equivalent to J0894, 1 mg; 1 billable unit = 1 mg
- J9999 – Not otherwise classified, antineoplastic **Ψ**

NDC:

- Dacogen***** 50 mg powder in a single-dose vial for injection: 59148-0046-xx

Multiple manufacturers produce ANDA generics
Ψ *Designated products approved by the FDA as a 505(b)(2) NDA of the innovator product. These products are not rated as therapeutically equivalent to their reference listed drug in the Food and Drug Administration's (FDA) Orange Book and are therefore considered single source products based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Act. For a complete list of all approved 505(b)(2) NDA products please reference the latest edition of the Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book | FDA*

VII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C86.4	Blastic NK-cell lymphoma
C92.00	Acute myeloblastic leukemia, not having achieved remission
C92.01	Acute myeloblastic leukemia, in remission
C92.02	Acute myeloblastic leukemia, in relapse
C92.20	Atypical chronic myeloid leukemia, BCR/ABL-negative, not having achieved remission
C92.22	Atypical chronic myeloid leukemia, BCR/ABL-negative, in relapse
C92.50	Acute myelomonocytic leukemia, not having achieved remission
C92.51	Acute myelomonocytic leukemia, in remission
C92.52	Acute myelomonocytic leukemia, in relapse
C92.60	Acute myeloid leukemia with 11q23-abnormality, not having achieved remission
C92.61	Acute myeloid leukemia with 11q23-abnormality, in remission
C92.62	Acute myeloid leukemia with 11q23-abnormality, in relapse
C92.A0	Acute myeloid leukemia with multilineage dysplasia, not having achieved remission
C92.A1	Acute myeloid leukemia with multilineage dysplasia, in remission
C92.A2	Acute myeloid leukemia with multilineage dysplasia, in relapse
C93.00	Acute monoblastic/monocytic leukemia, not having achieved remission
C93.01	Acute monoblastic/monocytic leukemia, in remission

ICD-10	ICD-10 Description
C93.02	Acute monoblastic/monocytic leukemia in relapse
C93.10	Chronic myelomonocytic leukemia, not having achieved remission
C93.11	Chronic myelomonocytic leukemia, in remission
C93.12	Chronic myelomonocytic leukemia, in relapse
C94.40	Acute panmyelosis with myelofibrosis, not having achieved remission
C94.41	Acute panmyelosis with myelofibrosis, in remission
C94.42	Acute panmyelosis with myelofibrosis, in relapse
C94.6	Myelodysplastic disease, not elsewhere classified
D46.0	Refractory anemia without ring sideroblasts, so stated
D46.1	Refractory anemia with ring sideroblasts
D46.20	Refractory anemia with excess of blasts, unspecified
D46.21	Refractory anemia with excess of blasts 1
D46.22	Refractory anemia with excess of blasts 2
D46.4	Refractory anemia, unspecified
D46.9	Myelodysplastic syndrome, unspecified
D46.A	Refractory cytopenia with multilineage dysplasia
D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts
D46.C	Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality
D46.Z	Other myelodysplastic syndromes
D47.1	Chronic myeloproliferative disease
D47.3	Essential (hemorrhagic) thrombocythemia
D47.4	Osteomyelofibrosis
D75.81	Myelofibrosis

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC