



Decitabine:

Dacogen®; Decitabine Ψ (Intravenous)

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Date of Origin: 01/01/2012

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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 and MDS/MPN: 450 billable units (450 mg) per 42 days
- AML: 500 billable units (500 mg) per 28 days
- BPDCN and MF: 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}

Myelofibrosis (MF) ‡ ²

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); Ⓢ 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 ^{1,4,6,8}

Indication	Dose
MDS & MDS/MPN	Treat for a minimum of 4 cycles using one of the below regimens: <ul style="list-style-type: none"> ▪ 15 mg/m² IV over 3 hours, repeated every 8 hours (45 mg/m²/day) for 3 days. Repeat cycle every 6 weeks. ▪ 20 mg/m² IV over 1 hour, repeated daily for 5 days. Repeat cycle every 4 weeks.
AML	<ul style="list-style-type: none"> ▪ 20 mg/m² IV over 1 hour, once daily, for 5 days every 28 days; OR ▪ 20 mg/m² IV over 1 hour, once daily, for 10 days every 28 days.
BPDCN & MF	<ul style="list-style-type: none"> ▪ 20 mg/m² IV over 1 hour, once daily, for 5 days every 28 days.

VI. Billing Code/Availability Information

HCPCS Code:

- 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 **Ⓢ**

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

1. Dacogen [package insert]. Rockville, MD; Otsuka America Pharmaceutical, Inc.; November 2021. Accessed June 2023.
2. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) for decitabine. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2023.
3. Swerdlow SH, Campo E, Harris NL, et al., editors. WHO Classification of Tumours of Hematopoietic and Lymphoid Tissues. Lyon, France: IARC; 2008.
4. 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 or blastic/acute myeloid leukemia phase. *Leuk Res.* 2015 Sep;39(9):950-6. doi: 10.1016/j.leukres.2015.06.001.
5. 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 Jul 20;30(21):2670-7. doi: 10.1200/JCO.2011.38.9429.
6. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Myeloid Leukemia Version 3.2023. National Comprehensive Cancer Network, 2023. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed June 2023.
7. Kantarjian H, Issa JP, Rosenfeld CS, et al. Decitabine improves patient outcomes in myelodysplastic syndromes: results of a phase III randomized study. *Cancer.* 2006 Apr 15;106(8):1794-803. doi: 10.1002/ncr.21792. PMID: 16532500.
8. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Myelodysplastic Syndromes Version 1.2023. National Comprehensive Cancer Network, 2023. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National

Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed June 2023.

9. Cheson BD, Greeberg PL, Bennet JM, et al. Clinical Application and Proposal for Modification of the International Working Group (IWG) Response Criteria in Myelodysplasia. *Blood*. 2006 Jul 15;108(2):419-25. doi: 10.1182/blood-2005-10-4149.
10. DiNardo CD, Rausch CR, Benton C, et al. Clinical experience with the BCL2-inhibitor venetoclax in combination therapy for relapsed and refractory acute myeloid leukemia and related myeloid malignancies. *Am J Hematol*. 2018 Mar;93(3):401-407. doi: 10.1002/ajh.25000.

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
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 classified

DECITABINE

(Dacogen®; Decitabine Ψ) Prior Auth Criteria

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ICD-10	ICD-10 Description
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
D47.4	Osteomyelofibrosis
D75.81	Myelofibrosis

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

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered 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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC