



Vidaza® (azacitidine) (Intravenous/Subcutaneous)

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed, unless otherwise specified.

- Coverage for Juvenile Myelomonocytic Leukemia (JMML) may not be renewed.

II. Dosing Limits

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

- Vidaza 100 mg single-dose vials: 21 vials per 28 day cycle

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

- All indications: 2,100 billable units every 28 days

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age, unless otherwise specified; **AND**

Universal Criteria ¹

- Patient does not have advanced malignant hepatic tumors; **AND**
- Patient does not have a hypersensitivity to mannitol; **AND**

Myelodysplastic Syndrome (MDS) † ⊕ ¹⁻³

Acute Myeloid Leukemia (AML) ‡ ^{2,4}

Myelofibrosis (MF) ‡ ²

MDS/MPN Overlap Neoplasms ‡ ^{2,3}

Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) ‡ ²

- Used in combination with venetoclax

Juvenile Myelomonocytic Leukemia (JMML) † ⊕ ¹

- Patient is 1 month to < 18 years of age; **AND**
- Used as single agent therapy for newly diagnosed disease

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

IV. Renewal Criteria ¹

Coverage may be renewed based on the following criteria:

- Patient continues to meet universal and other 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: severe cytopenias (anemia, neutropenia and thrombocytopenia), severe hepatic and renal toxicities, tumor lysis syndrome, etc.; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

Juvenile Myelomonocytic Leukemia (JMML)

- Coverage may not be renewed.

V. Dosage/Administration ^{1,2,4}

Indication	Dose
Myelodysplastic Syndromes (MDS)	75 mg/m ² daily for 7 days to be administered by subcutaneous (SC) injection or intravenous (IV) infusion. Repeat cycle every 4 weeks. <ul style="list-style-type: none"> • The dose may be increased to 100 mg/m² IV if no beneficial effect is seen after 2 treatment cycles. • A minimum of 4 to 6 cycles are recommended. Treatment may be continued as long as the patient continues to benefit.
Acute Myelogenous Leukemia (AML)/ Myelofibrosis/ MDS/MPN Overlap Neoplasms/ Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)	75 mg/m ² daily for 5 to 7 days to be administered by subcutaneous (SC) injection or intravenous (IV) infusion. Repeat cycle every 4 weeks.
Juvenile Myelomonocytic Leukemia (JMML)	<p><u>≥ 1 month of age to < 1 year of age OR weighing < 10 kg:</u> 2.5 mg/kg daily for 7 days to be administered by intravenous (IV) infusion. Repeat cycle every 4 weeks.</p> <p><u>≥ 1 year of age AND weighing ≥ 10 kg:</u> 75 mg/m² daily for 7 days to be administered by intravenous (IV) infusion. Repeat cycle every 4 weeks.</p> <ul style="list-style-type: none"> • Patients should be treated for a minimum of 3 cycles and a maximum of 6 cycles.

VI. Billing Code/Availability Information

HCP/PCS Code:

- J9025 – Injection, azacitidine, 1 mg: 1 billable unit = 1mg

NDC:

- Vidaza* 100mg single-dose vial powder injection: 59572-0102-xx

**Note: available generically through various manufacturers*

VII. References

1. Vidaza [package insert]. Summit, NJ; Celgene Corporation; May 2022. Accessed May 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for azacitidine. National Comprehensive Cancer Network, 2022. 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 May 2022.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Myelodysplastic Syndromes 3.2022. National Comprehensive Cancer Network, 2022. 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 May 2022.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Acute Myeloid Leukemia 1.2022. National Comprehensive Cancer Network, 2022. 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 May 2022.
5. Swerdlow SH, Campo E, Harris NL, et al., editors. WHO Classification of Tumours of Haematopoietic and Lymphoid Tissues. Lyon, France: IARC; 2008.
6. Niemeyer CM, Flotho C, Lipka DB, et al. Response to upfront azacitidine in juvenile myelomonocytic leukemia in the AZA-JMML-001 trial. Blood Adv. 2021 Jul 27;5(14):2901-2908. doi: 10.1182/bloodadvances.2020004144.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C86.4	Blastic NK-cell lymphoma

ICD-10	ICD-10 Description
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
C93.12	Chronic myelomonocytic leukemia, in relapse
C93.3	Juvenile myelomonocytic leukemia
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
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	Other and unspecified diseases of blood and blood-forming organs, myelofibrosis

VIDAZA® (azacitidine) Prior Auth Criteria

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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 Articles (LCAs) and Local Coverage Determinations (LCDs) 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.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC