



Vidaza® (azacitidine) (Intravenous/Subcutaneous)

Document Number: IC-0180

Last Review Date: 05/01/2020

Date of Origin: 11/07/2013

Dates Reviewed: 06/2014, 05/2015, 04/2016, 04/2017, 04/2018, 05/2019, 05/2020

I. Length of Authorization

Coverage will be for six months and be eligible for renewal.

II. Dosing Limits

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

- 100 mg 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 Criteria¹⁻⁴

Coverage is provided in the following conditions:

- Patient is 18 years or older; **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) †/Φ ¹⁻⁴

Acute myeloid leukemia ‡²⁻⁴

Myelofibrosis (MF) ‡²⁻⁴

Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) ‡

- Used for relapsed or refractory disease in combination with venetoclax

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

IV. Renewal Criteria ¹

Authorizations can 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 the following: 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

V. Dosage/Administration

| Indication | Dose |
|---|---|
| Myelodysplastic syndromes | 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/ Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) | 75 mg/m ² daily for 5 to 7 days to be administered by subcutaneous (SC) injection. Repeat cycle every 4 weeks. |

VI. Billing Code/Availability Information

HCPCS code:

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

NDC:

- Vidaza 100mg powder injection: 59572-0102-xx*

**(Note: available generically through various manufacturers)*

VII. References

1. Vidaza [package insert]. Summit, NJ; Celgene Corporation; March 2020. Accessed March 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium[®]) for azacitidine. National Comprehensive Cancer Network, 2020. 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 March 2020.

3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Myelodysplastic Syndromes 2.2020. National Comprehensive Cancer Network, 2020. 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 March 2020.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Acute Myeloid Leukemia 3.2020. National Comprehensive Cancer Network, 2020. 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 April 2020.
5. Swerdlow SH, Campo E, Harris NL, et al., editors. WHO Classification of Tumours of Haematopoietic and Lymphoid Tissues. Lyon, France: IARC; 2008.

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 |
| C92.50 | 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 |
| C94.00 | Acute erythroid leukemia not having achieved remission |
| C94.01 | Acute erythroid leukemia in remission |

VIDAZA® (azacitidine) Prior Auth Criteria

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| ICD-10 | ICD-10 Description |
|--------|---|
| C94.02 | Acute erythroid leukemia, in relapse |
| C94.20 | Acute megakaryoblastic leukemia not having achieved remission |
| C94.21 | Acute megakaryoblastic leukemia, in remission |
| C94.22 | Acute megakaryoblastic 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 |
| 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 |

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: <http://www.cms.gov/medicare-coverage-database/search/advanced-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) |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|--|---|---|
| Jurisdiction | Applicable State/US Territory | Contractor |
| 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 |