# Azacitidine (Vidaza®)

**NDC CODE(S)**

00143-9606-XX AZACITIDINE 100MG Suspension Reconstituted (HIKMA)
00781-3253-XX AZACITIDINE 100MG Suspension Reconstituted (SANDOZ)
16714-0927-XX AZACITIDINE 100MG Suspension Reconstituted (NORTHSTAR RX LLC)
16729-0306-XX AZACITIDINE 100MG Suspension Reconstituted (ACCORD HEALTHCARE)
43598-0305-XX AZACITIDINE 100MG Suspension Reconstituted (DR.REDDY'S LABORATORIES, INC.)
43598-0465-XX AZACITIDINE 100MG Suspension Reconstituted (DR.REDDY'S LABORATORIES, INC.)
43598-0678-XX AZACITIDINE 100MG Suspension Reconstituted (DR.REDDY'S LABORATORIES, INC.)
51991-0797-XX AZACITIDINE 100MG Suspension Reconstituted (BRECKENRIDGE)
59572-0102-XX VIDAZA 100MG Suspension Reconstituted (CELGENE CORP)
63323-0771-XX AZACITIDINE 100MG Suspension Reconstituted (FRESENIUS KABI USA)
64679-0096-XX AZACITIDINE 100MG Suspension Reconstituted (WOCKHARDT USA)
67457-0254-XX AZACITIDINE 100MG Suspension Reconstituted (MYLAN INSTITUTIONAL)
68001-0313-XX AZACITIDINE 100MG Suspension Reconstituted (BLUE POINT LABORATORIES)
69097-0805-XX AZACITIDINE 100MG Suspension Reconstituted (CIPLA USA)
72485-0201-XX AZACITIDINE 100MG Suspension Reconstituted (ARMAS PHARMACEUTICALS)

## DESCRIPTION

Azacitidine is a nucleoside metabolic inhibitor which is a pyrimidine nucleoside analog of cytidine. Its antineoplastic effects are thought to be from the hypomethylation of DNA. Azacitidine exerts direct cytotoxicity on hematopoietic cells in the bone marrow where it causes the death of rapidly dividing cells, including cancer cells which are no longer responsive to normal growth control mechanisms. Cells which are non-proliferative are relatively unaffected by azacitidine.

## POLICY

- Azacitidine for the treatment of the following is considered ***medically necessary*** if the medical appropriateness criteria are met: **(See Medical Appropriateness below.)**
  - Myelodysplastic syndrome
  - Myelodysplastic syndrome (MDS)/myeloproliferative neoplasm (MPN) Overlap Neoplasms
  - Acute myeloid leukemia
  - Myelofibrosis
- Azacitidine for the treatment of other conditions/diseases is considered ***investigational.***

## MEDICAL APPROPRIATENESS

### INITIAL APPROVAL CRITERIA

- Patient is 18 years or older; **AND**

### Universal Criteria

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

**Myelodysplastic syndrome (MDS)**

**Acute myeloid leukemia**

**Myelofibrosis (MF)**

**Myelodysplastic syndrome (MDS)/myeloproliferative neoplasm (MPN) Overlap Neoplasms**

**Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)**

- Used for relapsed or refractory disease in combination with venetoclax

**RENEWAL 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 the Initial Approval Criteria; **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

**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.<br>• The dose may be increased to 100 mg/m$^2$ IV if no beneficial effect is seen after 2 treatment cycles.<br>• 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. Repeat cycle every 4 weeks. |

**LENGTH OF AUTHORIZATION**

Coverage will be provided for 6 months and may be renewed

**DOSING LIMITS**

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

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

## APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

## IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

## ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

## SOURCES

1. Vidaza [package insert]. Summit, NJ; Celgene Corporation; March 2020. Accessed March 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for azacitidine. National Comprehensive Cancer Network, 2021. 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 2021
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Myelodysplastic Syndromes 3.2021. National Comprehensive Cancer Network, 2021. 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 2021.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Acute Myeloid Leukemia 3.2021. National Comprehensive Cancer Network, 2021. 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 2021.
5. Swerdlow SH, Campo E, Harris NL, et al., editors. WHO Classification of Tumours of Haematopoietic and Lymphoid Tissues. Lyon, France: IARC; 2008.

6. Lexi-Comp Online. (2021, February). AHFS DI. *Azacitidine*. Retrieved April 29, 2021 from Lexi-Comp Online with AHFS.
7. MICROMEDEX Healthcare Series. Drugdex Drug Evaluation. (2021, April) *Azacitidine*. Retrieved April 29, 2021 from MICROMEDEX Healthcare Series.

**EFFECTIVE DATE** 8/31/2021

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