| Azacitidine (Vidaza®) | Place of Service<br>Office Administration<br>Outpatient Facility Infusion<br>Administration Infusion Center<br>Administration<br><br>HCPCS: J9025 per 1 mg |
|---|---|

Conditions listed in policy (*see criteria for details*)

- Acute myeloid leukemia
- Blastic plasmacytoid dendritic cell neoplasm
- Juvenile myelomonocytic leukemia
- Myelodysplastic syndrome
- Myelofibrosis in accelerated or blast phase

**AHFS therapeutic class:** Antineoplastic agent

**Mechanism of action:** Azacitidine, a synthetic pyrimidine nucleoside analog of cytidine, is an antineoplastic agent.

## (1) Special Instructions and Pertinent Information

**Covered under the Medical Benefit**, please submit clinical information for prior authorization review via fax.

## (2) Prior Authorization/Medical Review is required for the following condition(s)

**All requests for Vidaza® (azacitadine) must be sent for clinical review and receive authorization prior to drug administration or claim payment.**

### Acute myeloid leukemia (AML)

**Covered Doses**
**Initial:** Up to 75 mg/m$^2$ SC or IV for 7 days, every 4 weeks for at least 2 treatment cycles
**Maintenance:** Up to 100 mg/m$^2$ SC or IV for 7 days every 4 weeks

**Coverage Period**
Indefinite

**ICD-10:**
C92.00-C92.02, C92.50-C92.52, C92.60-C92.62, C92.A0-C92.A2, C93.00-C93.02, C94.00-C94.02, C94.20-C94.22

### Blastic plasmacytoid dendritic cell neoplasm (BPDCN)

**Covered Doses**
Up to 75 mg/m$^2$ SC or IV for 7 days, every 4 weeks

**Coverage Period**
Indefinite

**ICD-10:**
C86.4

**Juvenile myelomonocytic leukemia (JMML)**

**Covered Doses**
Up to 75 mg/m$^2$ SC or IV for 7 days, every 4 weeks

**Coverage Period**
Indefinite

**ICD-10:**
C93.30, C93.31, C93.32

**Myelodysplastic syndrome (MDS)**

**Covered Doses**
**Initial:** Up to 75 mg/m$^2$ SC or IV for 7 days, every 4 weeks for at least 2 treatment cycles
**Maintenance:** Up to 100 mg/m$^2$ SC or IV for 7 days every 4 weeks

**Coverage Period**
Indefinite

**ICD-10:**
C92.2, C93.10, C93.12, C94.6, D46.0, D46.1, D46.20-D46.22, D46.4, D46.9, D46.A, D46.B, D46.C, D46.Z

**Myelofibrosis in accelerated phase or blast phase**

**Covered Doses**
**Initial:** Up to 75 mg/m$^2$ SC or IV for 7 days, every 4 weeks for at least 2 treatment cycles
**Maintenance:** Up to 100 mg/m$^2$ SC or IV for 7 days every 4 weeks

**Coverage Period**
Indefinite

**ICD-10:**
C94.40-C94.42, C94.6, D47.1, D47.4, D75.81

**(3) The following condition(s) DO NOT require Prior Authorization/Preservice**
**All requests for Vidaza® (azacitadine) must be sent for clinical review and receive authorization prior to drug administration or claim payment.**

**(4) This Medication is NOT medically necessary for the following condition(s)**
Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Beta-Thalassemia
- Chronic Myelogenous Leukemia(CML)
- Solid Tumors

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

## (5) Additional Information

How supplied:
100 mg lyophilized powder (single-use vial)

## (6) References


- AHFS®. Available by subscription athttp://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Available by subscription at: www.nccn.org.
- National Comprehensive Cancer Network. Acute Myeloid Leukemia (Version 3.2023). Available at http://www.nccn.org.
- National Comprehensive Cancer Network. Myelodysplastic Syndromes (Version 1.2023). Available at http://www.nccn.org.
- National Comprehensive Cancer Network. Myeloproliferative Neoplasms. (Version 1.2023). Available at http://www.nccn.org.
- Vidaza® (azacytidine) [Prescribing information]. Summit, NJ: Celgene Corporation; 9/2022.


## (7) Policy Update

Date of last review: 3Q2023
Date of next review: 3Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity Reviewed by P&T Committee*