Vidaza (azacitidine)

Override	Approval Duration
Prior Authorization	1 year

Medications
Vidaza (azacitidine)

APPROVAL CRITERIA

Requests for Vidaza (azacitidine) may be approved if the following criteria are met:

I. Individual has a diagnosis of myelodysplastic syndrome (MDS) (Label, NCCN 2A);

OR

II. Individual has a diagnosis of newly diagnosed juvenile myelomonocytic leukemia (JMML); **AND**
   A. Individual is at least one month and older;

OR

III. Individual has a diagnosis of acute myelogenous leukemia (AML), and one of the following are met (NCCN 2A):
   A. Azacitidine is used as a single agent for individuals 60 years of age and older or individuals who cannot tolerate more aggressive regimens; **OR**
   B. Azacitidine is used in combination with venetoclax for individuals 60 years of age and older or individuals who cannot tolerate more aggressive regimens (NCCN 2A, DiNardo 2019, DiNardo 2020); **OR**
   C. Azacitidine is used in combination with venetoclax for individuals with unfavorable risk genetics or TP53-mutated AML; **OR**
   D. Azacitidine is used in combination with sorafenib for relapsed or refractory AML with FLT3-ITD mutations; **OR**
   E. Azacitidine is used in combination with ivosidenib (Tibsovo) for newly diagnosed AML with a susceptible IDH1 (isocitrate dehydrogenase-1) mutation in adults 60 years of age or older, or who have comorbidities that preclude use of intensive induction chemotherapy (which includes at least one of the following: baseline Eastern Cooperative Oncology Group (ECOG) performance status of 2, severe cardiac or pulmonary disease, hepatic impairment with bilirubin > 1.5 times the upper limit of normal, creatinine clearance < 45 mL/min, or other comorbidity) (Tibsovo Label); **OR**
   F. Individual has AML arising from MDS.

OR

IV. Individual has a diagnosis of myelofibrosis (MF) and one of the following are met (NCCN 2A):
   A. Azacitidine is used with or without ruxolitinib, fedratinib, or pacritinib in MF-accelerated phase: **OR**
   B. Azacitidine is used with or without ruxolitinib, fedratinib, or pacritinib in MF- blast phase/acute myeloid leukemia.

Requests for Vidaza (azacitidine) may not be approved for the following:

I. Individual has advanced malignant hepatic tumors; **OR**
II. When the above criteria are not met or for all other indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 18, 2023.
3. DiNardo CD, Pratz K, Pullarkat V, et al. Venetoclax combined with decitabine or azacitidine in treatment-naïve, elderly patients with acute myeloid leukemia. Blood 2019;133:7-17
4. DiNardo CD, Jonas BA, Pullarkat V, et al. Azacitidine and venetoclax in previously untreated acute myeloid leukemia. N Engl. J Med 2020; 383:617-629.
5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 18, 2023.
    a. Acute Myeloid Leukemia. V1.2022. Revised December 2, 2021.
    b. Myelodysplastic Syndromes. V3.2022. Revised January 13, 2022.
    c. Myeloproliferative Neoplasms. V2.2021. Revised August 18, 2021.