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:
   A. Azacitidine is used as a single agent for individuals 18 years of age and older or individuals who cannot tolerate more aggressive regimens (NCCN 2A); **OR**
   B. Azacitidine is used in combination with venetoclax for individuals 18 years of age and older or individuals who cannot tolerate more aggressive regimens (NCCN 1, 2A, DiNardo 2019, DiNardo 2020); **OR**
   C. Azacitidine is used in combination with venetoclax for individuals who are candidates for intensive induction therapy with poor risk AML (NCCN 2A) ; **OR**
   D. Azacitidine is used in combination with venetoclax for Blastic Plasmacytoid Dendritic Neoplasm (BPDCN) in systemic disease treated with palliative intent or relapsed/refractory disease (NCCN 2A); **OR**
   E. Azacitidine is used in combination with sorafenib for relapsed or refractory AML with FLT3-ITD mutations; **OR**
   F. 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, NCCN 1); **OR**
   G. Individual has AML arising from MDS;

OR

IV. Individual has a diagnosis of Peripheral T-cell lymphomas (including angioimmunoblastic T-cell lymphoma (AITL), nodal peripheral T-cell lymphoma with TFH phenotype (PTCL, TFH), and follicular T-cell lymphoma (FTCL) (NCCN 2A); AND

A. Individual is using as second-line and subsequent therapy for relapsed/refractory disease; **AND**
B. Azacitidine is used as a single agent;

OR

V. Individual has a diagnosis of myelofibrosis (MF) and one of the following are met (NCCN 2A):
A. Azacitidine is used in combination with venetoclax for the management of disease progression of myeloproliferative neoplasms; **OR**
B. Azacitidine is used with or without ruxolitinib, fedratinib, momelotinib, or pacritinib in MF-accelerated/blast phase for palliation of splenomegaly or other disease related symptoms**.**

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.: 2024. 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. Updated periodically.
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. Dupuis J, Tsukasaki K, Bachy E, et al. Oral azacytidine in patients with relapsed/refractory angioimmunoblastic T-cell lymphoma: Final analysis of the Oracle phase III study [abstract]. Blood 2022;140(suppl 1):2310-2312.
6. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
8. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 18, 2024.
9. Acute Myeloid Leukemia. V6.2023. Revised October 24, 2023.
    a. Myelodysplastic Syndromes. V3.2023. Revised November 10, 2023.
    b. Myeloproliferative Neoplasms. V1.2024. Revised December 21, 2023.
    c. T-cell Lymphomas. V1.2024. Revised December 21, 2023.
10. Ruan J, Moskowitz AJ, Mehta-Shah N, et al. Multi-Center Phase II Study of Oral Azacitidine (CC-486) Plus CHOP As Initial Treatment for Peripheral T-Cell Lymphoma (PTCL) [abstract]. Blood 2020;136:33-34. Available at: https://doi.org/10.1182/blood-2020-136023.