

Generic Name: Azacitidine**Therapeutic Class or Brand Name:** Onureg[®],
Vidaza[®]**Applicable Drugs (if Therapeutic Class):** N/A**Preferred:** N/A**Non-preferred:** N/A**Date of Origin:** 12/16/2020**Date Last Reviewed / Revised:** 2/16/2023**PRIOR AUTHORIZATION CRITERIA***(May be considered medically necessary when criteria I – III are met)*

- I. Documented diagnosis of one of the following conditions A - C and must meet criteria listed under applicable diagnosis:
 - A. Acute Myeloid Leukemia (AML)- and criteria 1 – 4 are met:
 1. Request is for Onureg[®]
 2. Achieved complete remission (CR) or complete remission with incomplete blood count recovery (Cri) following intensive induction chemotherapy.
 3. Unable to complete intensive curative therapy.
 4. Age \geq 18 years
 - B. Myelodysplastic Syndrome (MDS) - and criteria 1 – 4 are met:
 1. Request is for Vidaza[®]
 2. Treatment of myelodysplastic syndromes (MDS) in patients with the following French American-British (FAB) classification subtypes:
 - (1) Refractory anemia (RA) or refractory anemia with ringed sideroblasts (if accompanied by neutropenia or thrombocytopenia or requiring transfusions).
 - (2) Refractory anemia with excess blasts (RAEB).
 - (3) Refractory anemia with excess blasts in transformation (RAEB-T), and
 - (4) Chronic myelomonocytic leukemia (CMML).
 3. Age \geq 18 years
 - C. Juvenile Myelomonocytic Leukemia (JMML) and criteria 1 – 3 are met:
 1. Request is for Vidaza[®]
 2. Treatment duration does not exceed 6 cycles.
 3. Age \geq 1 month
- II. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- III. Prescribed by or in consultation with an oncologist or hematologist

EXCLUSION CRITERIA

- Hypersensitivity to azacitidine or any component of the formulation; hypersensitivity to mannitol (injection only); advanced malignant hepatic tumors (injection only).

OTHER CRITERIA

- Bone marrow suppression: Neutropenia, thrombocytopenia, and anemia commonly occur; neutropenic fever has been reported. Monitor blood counts. Hematologic toxicity may require treatment interruption, dose reduction, and/or discontinuation.
- Hepatotoxicity: May cause hepatotoxicity in patients with preexisting hepatic impairment. Progressive hepatic coma leading to death has been reported in patients with extensive tumor burden due to metastatic disease, especially those with a baseline albumin <30 g/L.
- Hepatitis B virus reactivation: The American Society of Clinical Oncology hepatitis B screening and management provisional clinical opinion (ASCO [Hwang 2020]) recommends hepatitis B virus (HBV) screening with hepatitis B surface antigen (HBsAg), hepatitis B core antibody (anti-HBc), total Ig or IgG, and antibody to hepatitis B surface antigen (anti-HBs) prior to beginning (or at the beginning of) systemic anticancer therapy.
- GI toxicity: Azacitidine is associated with a moderate emetic potential (ASCO [Hesketh 2020]; MASCC/ESMO [Roila 2016]; POGO [Dupuis 2011]) antiemetics are recommended to prevent nausea and vomiting.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Onureg[®]: 200 mg, 300 mg tablets: Up to 14 tablets per 28 days.
- Vidaza[®]: 100 mg lyophilized powder in single-dose vial.
 - Treatment for adults with MDS:
 - Initial: dose does not exceed 75 mg/m² per day for 7 days.
 - Maintenance: dose does not exceed 100 mg/m² per day for 7 days in 28-day cycle.
 - Treatment for pediatric patients with JMML:
 - Age 1 month to less than 1 year OR weighing less than 10 kg: 2.5 mg/kg
 - Age 1 year and older AND weighing 10 kg or greater: 75 mg/ m²

APPROVAL LENGTH

- **Authorization:** 6 Months.
- **Re-Authorization:**
 - For the treatment of adults with MDS or AML: An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.
 - For the treatment of pediatric patients with JMML: none

APPENDIX

- N/A

REFERENCES

1. Onureg® (Azacitidine). Prescribing information. Princeton, NJ; Bristol-Meyer Squibb. October 2022. Accessed February 16, 2023. https://packageinserts.bms.com/pi/pi_onureg.pdf.
2. Vidaza® (Azacitidine). Prescribing information. Summit, NJ; Bristol-Meyer Squibb. September 2022. Accessed February 16, 2023. https://packageinserts.bms.com/pi/pi_vidaza.pdf.
3. National Comprehensive Cancer Network. Acute Myeloid Leukemia (Version 3.2022). https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed February 16, 2023.
4. National Comprehensive Cancer Network. Myelodysplastic Syndromes (Version 1.2023). https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed February 16, 2023.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.