Generic Name: Azacitidine

Therapeutic Class or Brand Name: Onureg®, Vidaza®, Azacitidine (generic)

Applicable Drugs (if Therapeutic Class): N/A

Preferred: Azacitidine (generic)

Non-preferred: Onureg, Vidaza

Date of Origin: 12/16/2020

Date Last Reviewed / Revised: 2/24/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met)

I. Documented diagnosis of one of the following conditions A through G AND must meet criteria listed under applicable diagnosis:

FDA-Approved Indication(s)

A. Acute Myeloid Leukemia (AML):
   i. Request is for Onureg.
   ii. Achieved complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy.
   iii. Unable to complete intensive curative therapy.
   iv. Onureg will be used as a single agent.

B. Myelodysplastic Syndrome (MDS):
   i. Request is for azacitidine IV/SC.
   ii. Treatment of patients with any of the following French-American-British (FAB) classification subtypes a through d:
      a. Refractory anemia or refractory anemia with ringed sideroblasts (if accompanied by neutropenia or thrombocytopenia or requiring transfusions.)
      b. Refractory anemia with excess blasts.
      c. Refractory anemia with excess blasts in transformation.
      d. Chronic myelomonocytic leukemia.

C. Newly diagnosed Juvenile Myelomonocytic Leukemia (JMML):
   i. Request is for azacitidine IV/SC.
   ii. Treatment duration does not exceed 6 cycles.
   iii. Age requirement: 1 month to 17 years old

Other Uses With Supportive Evidence

D. Acute Myeloid Leukemia (AML)
    i. Request is for azacitidine IV/SQ and one of the following criteria a through c are met:
        a. Used in combination treatment with one of the following for lower-intensity treatment induction, follow-up after induction therapy, or consolidation therapy:
            1. Venclexta (venetoclax)
            2. Tibsovo (ivosidenib) and documented IDH mutation
            3. Idhifa (enasidenib) and documented IDH-2 mutation
            4. Xospata (gilteritinib) and FLT3-ITD or TKD AML without IDH1 mutation
        b. Used as monotherapy for lower-intensity treatment induction, follow-up after induction therapy, consolidation therapy, or maintenance therapy.
        c. Used as monotherapy, in combination therapy with Venclexta (venetoclax), or in combination with sorafenib (if documented FLT3-ITD mutation) for relapsed/refractory disease.
    ii. Documentation of Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN).
        a. Request is for azacitidine IV/SQ.
            1. Combination therapy with Venclexta (venetoclax).
            2. Palliation of systemic disease OR relapsed/refractory disease.

E. Myeloproliferative Neoplasms (MPN)
    i. Request is for azacitidine IV/SQ and criteria a or b are met:
        a. Used as monotherapy OR in combination therapy with Jakafi (ruxolitinib), Inrebic (fedratinib), Ojjaara (momelotinib), or Vonjo (pacritinib) or palliation of splenomegaly or other disease-related symptoms.
        b. Used in combination with Venclexta (venetoclax).

F. Myelodysplastic Syndrome (MDS)/Myeloproliferative Neoplasms (MPN) Overlap
    i. Request is for azacitidine IV/SQ and one of the following criteria a through d are met:
        a. Used as monotherapy for one of the following:
            1. Chronic myelomonocytic leukemia (CMML)-1 or CMML-2
            2. MDS/MPN with neutrophilia
            3. MDS/MPN Not Otherwise Specified (NOS)
            4. MDS/MPN with documented SF3B1 mutation and thrombocytosis
        b. Used in combination with Venclexta (venetoclax) for CMML-2

c. Used in combination with Jakafi (ruxolitinib) for one of the following:
    1. CMML-2 symptom management or splenomegaly
    2. MDS/MPN with neutrophilia with documented CSF3R or JAK2 mutation.
d. Used in combination with lenalidomide with documented SF3B1 mutation and thrombocytosis.

G. Peripheral T-Cell Lymphoma
    i. If request is for Onureg, documented trial of and intolerance to intravenous azacitidine.
    ii. Documentation of relapsed or refractory disease.
    iii. Documentation of failure, contraindication, or intolerance to at least one prior systemic therapy.
    iv. Azacitidine or Onureg will be used as monotherapy.

II. Minimum age requirement: 18 years old unless otherwise specified in criteria.

III. Treatment must be prescribed by or in consultation with an oncologist, pediatric oncologist, or hematologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

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

OTHER CRITERIA

- Click or tap here to enter text.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Onureg: 200 mg, 300 mg tablets: Up to 14 tablets per 28 days.
- Vidaza: 100 mg lyophilized power in single-dose vial.
    - Treatment for adults:
        - Initial: dose does not exceed 75 mg/m^2 per day for 7 days per 28-day cycle.

- Maintenance: dose does not exceed 100 mg/m^2 per day for 7 days per 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 per day for 7 days per 28-day cycle.
  - Age 1 year and older AND weighing 10 kg or greater: 75 mg/m^2 per day per 28-day cycle.

APPROVAL LENGTH

- **Authorization:** 6 months.
  - Vidaza (JMML): treatment duration not to exceed 6 cycles.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.
  - Vidaza (JMML): treatment duration not to exceed 6 cycles.

APPENDIX

- N/A

REFERENCES

1. Onureg (Azacitidine). Prescribing Information. Bristol-Meyers Squibb; 2022. Accessed *February 7, 2025*.

   https://packageinserts.bms.com/pi/pi_onureg.pdf

2. Vidaza (Azacitidine). Prescribing Information. Bristol-Myers Squibb; 2024. Accessed *February 7, 2025*.

   https://packageinserts.bms.com/pi/pi_vidaza.pdf

3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Myelodysplastic Syndromes. Version 2.2025. Updated January 17, 2025. Accessed *February 7, 2025*.

   https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf

4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia. Version 2.2025. Updated January 27, 2025. Accessed *February 14, 2025*.

   https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf

5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Myeloproliferative Neoplasms. Version 2.2024. Updated August 8, 2024. Accessed *February 14, 2025*.

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6. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. T-Cell Lymphomas. Version 1.2025. Updated November 11, 2024. Accessed *February 14, 2025*.
   https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf