MEDICATION POLICY:

Azacitidine

Generic Name: Azacitidine

Therapeutic Class or Brand Name: Onureg®; Vidaza®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 213000030003 – Tablet
213000030019 -- Suspension

Preferred: N/A

Non-preferred: N/A

Date of Origin: 12/16/2020

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I - III are met)

I. Documented diagnosis of one of the following conditions A or B and must meet criteria listed under applicable diagnosis:

   A. Acute Myeloid Leukemia (AML)- and criteria 1 – 3 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.

   B. Myelodysplastic Syndrome (MDS) - and criteria 1 – 2 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 or refractory anemia with ringed sideroblasts (if accompanied by neutropenia or thrombocytopenia or requiring transfusions.

         (2) Refractory anemia with excess blasts.

         (3) Refractory anemia with excess blasts in transformation, and

         (4) Chronic myelomonocytic leukemia.

II. Age ≥ 18 years.

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 power in single-dose vial.
    - Initial: dose does not exceed 75 mg/m^2 per day for 7 days.
    - Maintenance: dose does not exceed 100 mg/m^2 per day for 7 days in 28-day cycle.

APPROVAL LENGTH

- **Authorization:** 6 Months.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

- N/A

REFERENCES

1. Onureg® (Azacitidine) [package insert]. Summit, NJ: Celgene Corporation.; September 2020. Available at: https://packageinserts.bms.com/pi/pi_onureg.pdf

2. Vidaza® (Azacitidine) [package insert]. Summit, NJ: Celgene Corporation.; March 2020. Available at: https://packageinserts.bms.com/pi/pi_vidaza.pdf
3. Medispan.
4. UPTODATE – Azacitidine (Vidaza®, Onureg® Tab)-
5. NCCN Guidelines Version 2.2021 Myelodysplastic Syndromes

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
12/16/2020	1. New Policy.