

Criteria for Use of Azacitidine (Vidaza™)

VA Pharmacy Benefits Management Strategic Healthcare Group and Medical Advisory Panel
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The following recommendations are based on current medical evidence and expert opinion from clinicians. The content of the document is dynamic and will be revised as new clinical data becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of individual patient situations.

Refer to the National PBM Drug Monograph Azacitidine (Vidaza™) at <http://vaww.pbm.va.gov/drugmonograph/9paerfAzacitidine.pdf> or <http://www.pbm.va.gov/monograph/9paerfAzacitidine.pdf> for recommendations on dosing, precautions, and monitoring.

Restricted to use by VA Hematologists and Oncologists

Diagnosis	#1
Initial therapy in the patients with the following myelodysplastic subtypes: <input type="checkbox"/> Refractory anemia (RA) or refractory anemia with ringed sideroblasts (RARS) (If accompanied by neutropenia OR thrombocytopenia OR clinical hemorrhage requiring platelet transfusions OR anemia requiring red blood cell transfusions) <input type="checkbox"/> Refractory anemia with excess blasts (RAEB) <input type="checkbox"/> Refractory anemia with excess blasts in transformation (RAEB-T) <input type="checkbox"/> Chronic myelomonocytic leukemia (CMML)	<input type="checkbox"/> Yes <input type="checkbox"/> No <i>If Yes to any subtype, go to #2. If No, patient is ineligible for azacitidine</i>
Exclusion Criteria	#2
Patient with any of the following conditions: <input type="checkbox"/> ECOG Performance Status >2 http://www.ecog.org/general/perf_stat.html <input type="checkbox"/> Serum Creatinine > 1.5 X ULN <input type="checkbox"/> Diagnosis of metabolic acidosis <input type="checkbox"/> Total bilirubin > 1.5 X ULN <input type="checkbox"/> AST/ALT > 2 X ULN <input type="checkbox"/> Patients with extensive hepatic tumor burden due to metastatic disease <input type="checkbox"/> Uncontrolled congestive heart failure <input type="checkbox"/> Hypersensitivity to mannitol <input type="checkbox"/> Life expectancy < 4 months <input type="checkbox"/> Pregnancy ² <input type="checkbox"/> Women actively breastfeeding	<input type="checkbox"/> Yes <input type="checkbox"/> No <i>If Yes to any condition in #2, patient is ineligible for azacitidine.</i>
Discontinuation	#3
<input type="checkbox"/> Progression of disease during initial 4 months of treatment (see Relapse criteria) <input type="checkbox"/> Stable disease after initial 4 months of treatment <input type="checkbox"/> Unacceptable toxicity <input type="checkbox"/> Relapse after initial response. Relapse criteria defined below: <ul style="list-style-type: none"> • Relapse from CR - >5% myeloblasts in bone marrow • Relapse from PR - ≥ 30% bone marrow blasts (in patients with RA or RARS, return to pretreatment peripheral blood values or return of transfusion requirements alone or in conjunction with bone marrow results) • Relapse from Improvement – Return of peripheral blood counts to pretreatment values or recurrence of transfusion requirements <input type="checkbox"/> Transformation to Acute Myelogenous Leukemia	<input type="checkbox"/> Yes <input type="checkbox"/> No <i>If Yes to any, discontinue azacitidine therapy</i>
Monitoring	
<input type="checkbox"/> Complete blood counts and assessment of renal function prior to each cycle and as needed (See Azacitidine drug monograph for dose reductions based on WBC and platelet counts) <input type="checkbox"/> Premedicate with oral prochlorperazine or oral ondansetron <input type="checkbox"/> If no beneficial bone marrow effect from initial dose by day 57 without significant toxicity, increase dose to 100mg/m ² /day for 7 days (optional) <input type="checkbox"/> Assess effect on bone marrow after fourth cycle (day 113) (optional) (see Discontinuation above) <input type="checkbox"/> Reduce dose by 50% on next course for unexplained reductions in serum bicarbonate to < 20 mEq/L; assess for renal tubular acidosis (alkaline urine, hypokalemia to <3 mEq/L along with drop in serum bicarbonate) <input type="checkbox"/> If unexplained increase in BUN or serum creatinine, delay dose until values return to normal or baseline, then resume at 50% dose reduction on next course	

¹ Neutropenia defined as ANC < 1.0 x 10⁹/L and thrombocytopenia defined as platelets ≤ 50 x 10⁹/L

² Women of child-bearing potential and men with the potential to father a child should use adequate contraception methods.

Approved by Physician: _____

Date/Time _____

Updated versions may be found at <http://vaww.pbm.va.gov> or www.pbm.va.gov

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