



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: azacitidine

Brand Name: Vidaza

Medication Class: DNA methyltransferase inhibitor (antineoplastic agent)

FDA Approved Uses: Treatment of myelodysplastic syndrome (MDS) subtypes:

- refractory anemia (RA)
- refractory anemia with ringed sideroblasts (RARS), if accompanied by neutropenia or thrombocytopenia or requiring transfusions,
- refractory anemia with excess blasts (RAEB),
- refractory anemia with excess blasts in transformation (RAEBT), and
- chronic myelomonocytic leukemia (CMML).

Available Dosage Forms: One single-use vial of 100mg lyophilized powder.

Usual Dose: 75mg/m² subcutaneously only daily for 7 days, q 4 weeks. May be increased to 100mg/m² if no beneficial effect is seen after 2 treatment cycles and if no toxicity other than nausea and vomiting occur.

Duration of Therapy: May be continued as long as patient continues to benefit.

Criteria for Use: *(bullet points below are all inclusive unless otherwise noted)*

- Clinically diagnosed MDS as defined under Indications:
refractory anemia (RA)
refractory anemia with ringed sideroblasts (RARS), if accompanied by neutropenia or thrombocytopenia or requiring transfusions,
refractory anemia with excess blasts (RAEB),
refractory anemia with excess blasts in transformation (RAEBT), and
chronic myelomonocytic leukemia (CMML).

Criteria for Continuation of Therapy:

- Patient continues to benefit from treatment

Cautions:

- Pre-existing hepatic impairment due to potential hepatotoxicity
- Decreased renal function due to substantial excretion by the kidneys and risk of toxic reactions.
- Pregnancy category D; if a patient is pregnant or becomes pregnant she should be apprised of the potential hazard to the fetus.
- Men should not father a child while received treatment with Vidaza



Monitoring:

- Complete blood counts performed prior to each dosing cycle.
- Renal and liver function obtained prior to the initiation of therapy.

Azacitidine Dosage Adjustments Based on Baseline and Nadir Blood Counts and Bone Marrow Cellularity			
<i>Patients with Baseline WBC $\geq 3 \times 10^9/L$, ANC $\geq 1.5 \times 10^9/L$, and Platelets $\geq 75 \times 10^9/L$</i>			
Nadir counts			% Dose in next course
ANC	Platelets		50
$< 0.5 \times 10^9/L$	$< 25 \times 10^9/L$		
$0.5 \text{ to } 1.5 \times 10^9/L$	$25 \text{ to } 50 \times 10^9/L$		
$> 1.5 \times 10^9/L$	$> 50 \times 10^9/L$		
<i>Patients with Baseline WBC $< 3 \times 10^9/L$, ANC $< 1.5 \times 10^9/L$, or Platelets $< 75 \times 10^9/L$</i>			
WBC or platelet nadir % decrease from baseline	Bone marrow biopsy cellularity at time of nadir (%)		
	30 to 60	15 to 30	< 15
	% Dose in next course		
50 to 75	100	50	33
> 75	75	50	

Vidaza (package insert). Boulder, CO: Pharmion Corporation; May 2004. Updated January 2007.

Contraindications:

- Advanced malignant hepatic tumors
- Hypersensitivity to mannitol or azacitidine

Not Approved if:

- Patient does not meet the above stated criteria
- Patient has any contraindications the use of azacitidine.

P&T Approval: _____ Date: _____