



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: Minimum of 4 cycles. May be continued as long as patient continues to benefit.

Approximate Monthly Cost (based on ASP current as of 1/1/08): \$4,500 per month

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

- Clinically diagnosed MDS as defined under Indications

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 to $1.5 \times 10^9/L$	25 to $50 \times 10^9/L$		
$> 1.5 \times 10^9/L$	$> 50 \times 10^9/L$		100
<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: _____