



## Prior Authorization Approval Criteria

### *Dacogen (decitabine)*

<b>Generic name:</b>	Decitabine
<b>Brand name:</b>	Dacogen
<b>Medication class:</b>	Antineoplastic agent; DNA demethylation agent
<b>FDA-approved use:</b>	Myelodysplastic syndromes (MDS)
<b>Available dosage form:</b>	Lyophilized powder for injection, 50 mg single-dose vials.
<b>Usual dose range:</b>	15 mg/m <sup>2</sup> by continuous intravenous (IV) infusion over 3 hours, Q 8 hours for 3 days. Patients may be pre-medicated with standard anti-emetic. Repeat cycle Q 6 weeks for a minimum of 4 cycles; complete or partial response may take longer than 4 cycles. Dose adjustments may be necessary for: <ul style="list-style-type: none"><li>• Elderly</li><li>• Toxicities: Hematological or Non-hematological</li></ul>
<b>Duration of therapy:</b>	Indefinite, while the patient demonstrates clinical benefit.
<b>Approximate cost:</b> (based on AWP 2006)	\$7,560 per cycle, minimum 4 cycles

**Criteria for use:** Documented, previously treated or untreated, de novo and secondary MDS of all French-American-British (FAB) subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System (IPSS) groups.

**Criteria for continuation of therapy:** Patient continues to show clinical benefit.

**Cautions:** Use with caution in elders, patients with hepatic/renal impairment. Men should not father a child during treatment and for two months post-treatment.

**Monitoring:** CBC and platelet count at each cycle or more frequently if needed: liver enzymes, serum creatinine.

**Contraindications:** Hypersensitivity to decitabine.

**Not approved if:**

- Does not meet the above stated criteria.
- Have any contraindications to the use of Dacogen.

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 12/13/06