| Reference number |
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| 2288-A |

# SPECIALTY GUIDELINE MANAGEMENT

## DACOGEN (decitabine)
## decitabine (generic)

**POLICY**

### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
Myelodysplastic syndromes (MDS): Dacogen is indicated for treatment of patients with myelodysplastic syndromes (MDS) including previously treated and untreated, *de novo* and secondary MDS of all French-American-British 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 groups.

B. Compendial Uses
1. Chronic myeloid leukemia (CML)
2. Acute myeloid leukemia (AML)
3. Accelerated phase or blast phase myelofibrosis

All other indications are considered experimental/investigational and are not a covered benefit.

### II. CRITERIA FOR INITIAL APPROVAL

**A. Myelodysplastic Syndromes (MDS)**
Authorization of 12 months may be granted for the treatment of MDS.

**B. Chronic myeloid leukemia (CML)**
Authorization of 12 months may be granted for the treatment of CML.

**C. Acute Myeloid Leukemia (AML)**
Authorization of 12 months may be granted for the treatment of AML.

**D. Accelerated Phase or Blast Phase Myelofibrosis**
Authorization of 12 months may be granted for the treatment of accelerated phase or blast phase myelofibrosis.

### III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

## IV. REFERENCES

1. Dacogen [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; October 2014.
2. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. http://www.nccn.org. Accessed August 23, 2017.