

## 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 Indication

1. Myelodysplastic syndromes (MDS)
  - i. 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 APPROVAL

##### 1. **Myelodysplastic syndromes (MDS)**

Authorization of 12 months may be granted for the treatment of MDS.

##### 2. **Chronic myeloid leukemia (CML)**

Authorization of 12 months may be granted for the treatment of CML.

##### 3. **Acute myeloid leukemia (AML)**

Authorization of 12 months may be granted for the treatment of AML

##### 4. **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]. Woodcliff Lake, NJ: Eisai Inc.; October 2014.
2. The NCCN Drugs & Biologics Compendium™ © 2016 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed September 27, 2016.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia. Version 2.2016. [http://www.nccn.org/professionals/physician\\_gls/pdf/aml.pdf](http://www.nccn.org/professionals/physician_gls/pdf/aml.pdf). Accessed August 15, 2016.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms. Version 1.2017. [https://www.nccn.org/professionals/physician\\_gls/PDF/mpn.pdf](https://www.nccn.org/professionals/physician_gls/PDF/mpn.pdf). Accessed September 27, 2016.