Reference number
2280-A

SPECIALTY GUIDELINE MANAGEMENT

VIDAZA (azacitidine)
azacitidine (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): Vidaza is indicated for treatment of patients with the following French-American-British (FAB) myelodysplastic syndrome subtypes: refractory anemia (RA) or refractory anemia with ringed sideroblasts (if accompanied by neutropenia or thrombocytopenia or requiring transfusions), refractory anemia with excess blasts (RAEB), refractory anemia with excess blasts in transformation (RAEB-T), and chronic myelomonocytic leukemia (CMMoL).

B. Compendial Uses
1. Acute myeloid leukemia (AML)
2. 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. Acute Myeloid Leukemia (AML)
Authorization of 12 months may be granted for the treatment of AML.

C. 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. Vidaza [package insert]. Summit, NJ: Celgene Corporation; July 2018.
2. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. http://www.nccn.org. Accessed August 07, 2018.