

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 Indication

1. Myelodysplastic syndromes (MDS)

- i. 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 (RARS) (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 (CMML).

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 APPROVAL

1. **Myelodysplastic syndromes (MDS)**

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

2. **Acute myeloid leukemia (AML)**

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

3. **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; March 2016.
2. The NCCN Drugs & Biologics Compendium™ © 2016 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed September 27, 2016.

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3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes. Version 1.2016. http://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed August 15, 2016.
4. 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. Accessed August 15, 2016.
5. 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. Accessed September 27.2016