Azacitidine

NDC CODE(S) 59572-0102-xx VIDAZA 100mg powder injection (CELGENE)

DESCRIPTION

Azacitidine is a nucleoside metabolic inhibitor which is a pyrimidine nucleoside analog of cytidine. Its antineoplastic effects are thought to be from the hypomethylation of DNA. Azacitidine exerts direct cytotoxicity on hematopoietic cells in the bone marrow where it causes the death of rapidly dividing cells, including cancer cells which are no longer responsive to normal growth control mechanisms. Cells which are non-proliferative are relatively unaffected by azacitidine.

POLICY

- Azacitidine for the treatment of the following is considered ***medically necessary*** if the medical appropriateness criteria are met: **(See Medical Appropriateness below.)**
  - Myelodysplastic syndrome
  - Acute myeloid leukemia
  - Myelofibrosis
- Azacitidine for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL

- Azacitidine is considered **medically appropriate** if **ALL** of the following:
  - Individual is 18 years of age or older
  - Diagnosis of **ANY ONE** of the following:
    - Myelodysplastic syndrome
    - Myelofibrosis (MF)
    - Acute myeloid leukemia

RENEWAL CRITERIA

- Azacitidine is considered **medically appropriate** for renewal if **ALL** of the following criteria are met:
  - Individual continues to meet the initial approval criteria
  - Absence of unacceptable toxicity from the agent such as severe neutropenia, severe thrombocytopenia, severe hepatic and renal toxicities, tumor lysis syndrome, etc.

INDICATION(S)	DOSAGE & ADMINISTRATION
Myelodysplastic syndromes	75 mg/m^{2}daily for 7 days to be administered by subcutaneous (SC) injection or intravenous (IV) infusion. Repeat cycle every 4 weeks. The dose may be increased to 100 mg/m^2 IV if no beneficial effect is seen after 2 treatment cycles. A minimum of 4 to 6 cycles are recommended.
Acute myelogenous leukemia (AML) / Myelofibrosis	75 mg/m^{2}daily for 5 to 7 days to be administered by subcutaneous (SC) injection. Repeat cycle every 4 weeks

LENGTH OF AUTHORIZATION

Coverage will be provided for 6 months and may be renewed

Click here to view **DOSAGE LIMITS**

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with **Tennessee** Code Annotated **Section 56-7-2352** regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

Leung, M., Highsmith, K., & Rexwinkle, A. (2017). Pharmacologic management of myelofibrosis. *Journal of Pharmacologic Practice,* 23 (8), 591-601. Abstract retrieved January 3, 2019 from PubMed database.

Lexi-Comp Online. (2018). AHFS DI. *Azacitidine*. Retrieved January 3, 2019 from Lexi-Comp Online with AHFS.

MICROMEDEX Healthcare Series. Drugdex Drug Evaluation. (2018, November) *Azacitidine*. Retrieved January 3, 2019 from MICROMEDEX Healthcare Series.

National Comprehensive Cancer Network. (2016). NCCN Drugs & Biologics Compendium™. *Azacitidine*. Retrieved January 3, 2019 from the National Comprehensive Cancer Network.

Ohba R., Usui, N., Ito, Y., Yanauchi, H., Machishima, T., Ishii, H., et al. (2017). Myelodysplastic syndrome with myelofibrosis in which azacitidine therapy was effective and cord blood transplantation was carried out. *Rinsho Ketsueki,* 58 (6), 601-606. Abstract retrieved January 3, 2019 from PubMed database.

U. S. Food and Drug Administration. (2018, July). Center for Drug Evaluation and Research. *Vidaza (azacitidine for injection)*. Retrieved January 3, 2019 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/050794s031lbl.pdf.

EFFECTIVE DATE 4/30/2019

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