Draft Revised Policy: Do Not Implement

Azacitidine (Vidaza®; Azacitidine)

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 or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

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
1. Myelodysplastic syndromes (MDS): azacitidine/Vidaza is indicated for treatment of adult 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 (CMMoL).
2. Juvenile myelomonocytic leukemia (JMML): azacitidine/ Vidaza is indicated for treatment of pediatric patients aged 1 month and older with newly diagnosed juvenile myelomonocytic leukemia (JMML).

B. Compendial Uses
1. Acute myeloid leukemia (AML)
2. Accelerated phase or blast phase ~~myelofibrosis~~ myeloproliferative neoplasm
3. Blastic plasmacytoid dendritic cell neoplasm (BPDCN)
4. Myelodysplastic syndrome (MDS)/Myeloproliferative Neoplasms (MPN) Overlap Neoplasms
5. Peripheral T-cell lymphoma

All other indications are considered experimental/investigational and not medically necessary.

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~~ myeloproliferative neoplasm

Authorization of 12 months may be granted for the treatment of accelerated phase or blast phase ~~myelofibrosis~~ myeloproliferative neoplasm.

D. Blastic plasmacytoid dendritic cell neoplasm (BPDCN)
Authorization of 12 months may be granted for the treatment of BPDCN when used in combination with venetoclax in either of the following settings:
1. For the treatment of relapsed or refractory disease.
2. For the treatment of systemic disease with palliative intent.

E. Myelodysplastic syndrome (MDS)/Myeloproliferative Neoplasms (MPN) Overlap Neoplasms
Authorization of 12 months may be granted for the treatment of MDS/MPN overlap neoplasms (i.e., chronic myelomonocytic leukemia (CMML), juvenile myelomonocytic leukemia (JMML), BCR-ABL negative atypical chronic myeloid leukemia (aCML), MDS/MPN with neutrophilia, unclassifiable MDS/MPN, ~~or~~ MDS/MPN not otherwise specified (NOS) or MDS/MPN with ring sideroblasts and thrombocytosis).

F. Peripheral T-Cell Lymphoma (PTCL)
Authorization of 12 months may be granted for the treatment of peripheral T-cell lymphoma (PTCL) [including the following subtypes: angioimmunoblastic T-cell lymphoma (AITL), nodal peripheral T-cell lymphoma with TFH phenotype (PTCL, TFH), follicular T-cell lymphoma (FTCL)] when all of the following criteria are met:
1. The requested medication will be used as subsequent therapy for relapsed or refractory disease
2. The requested medication will be used as a single agent

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

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.

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).

REFERENCES

1. Vidaza [package insert]. Summit, NJ: Celgene Corporation; September 2022.
2. Azacitidine injection [package insert]. ~~Parsippany~~ Princeton, NJ: ~~Actavis Pharma~~ Sandoz Inc.; September 2022.

3. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc.. Available at http://www.nccn.org. Accessed January 7, 2024.
4. Zoi K, Cross NC. Molecular pathogenesis of atypical CML, CMML and MDS/MPN unclassifiable. Int J Hematol 2015;101:229-242.

EFFECTIVE DATE

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