Clinical Policy: Azacitidine (Vidaza)

Reference Number: LA.PHAR.387
Effective Date:
Last Review Date: 3.21
Line of Business: Medicaid

Coding Implications Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Azacitidine (Vidaza®) is a pyrimidine nucleoside analog of cytidine.

FDA Approved Indication(s)

Vidaza is indicated for the treatment of patients with the following French-American-British (FAB) myelodysplastic syndrome (MDS) 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).

Policy/Criteria

Prior authorization is required. Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections that Vidaza is medically necessary when the following criteria are met:

I. Initial Approval Criteria

A. Myelodysplastic Syndromes (must meet all):

1. **Diagnosis of MDS;**
2. **Request is for Vidaza;**
3. **Prescribed by or in consultation with an oncologist or hematologist;**
4. **Age ≥ 18 years;**
5. **Request meets one of the following (a, b, or c):***
   a. **Initial: Dose does not exceed 75 mg/m^2 per day for 7 days;**
   b. **Maintenance: Dose does not exceed 100 mg/m^2 per day for 7 days per 4-week cycle;**
   c. **Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).**

Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration:
Medicaid – 6 months

B. Acute Myeloid Leukemia (Vidaza off-label) (must meet all):
1. **Diagnosis of AML;**
2. **Prescribed by or in consultation with an oncologist or hematologist;**
3. **Age ≥ 18 years;**
4. **Request meets one of the following (a or b):***
   a. **Vidaza: Dose does not exceed 100 mg/m^2 per day for 7 days per 4-week cycle;**
   b. **Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).**

Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration:
Medicaid – 6 months

C. Myelofibrosis (off-label) (must meet all):
1. **Diagnosis of advanced phase (i.e., accelerated- or blast-phase) myelofibrosis (MF);**
2. **Request is for Vidaza;**
3. **Prescribed by or in consultation with an oncologist or hematologist;**
4. **Age ≥ 18 years;**
5. **Request meets one of the following (a or b):***
   a. **Dose does not exceed 100 mg/m^2 per day for 7 days per 4-week cycle;**
   b. **Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).**

Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration:
Medicaid – 6 months

D. Other diagnoses/indications
1. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

II. Continued Therapy

A. All Indications in Section I (must meet all):
1. **Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Vidaza for a covered indication and has received this medication for at least 30 days;**
2. **Member is responding positively to therapy;**
3. **If request is for a dose increase, request meets one of the following (a or b):***
   a. **Vidaza: New dose does not exceed 100 mg/m^2 per day for 7 days per 4-week cycle;**
   b. **New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).**

Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration:

Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. **Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.**
   Approval duration: Duration of request or 6 months (whichever is less); or
2. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy –LA.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AML: acute myelogenous leukemia
ANC: absolute neutrophil count
CMMoL/CMML: chronic myelomonocytic leukemia
CR: complete remission
CRi: complete remission with incomplete blood count recovery
FAB: French-American-British
FDA: Food and Drug Administration
MDS: myelodysplastic syndrome
MF: myelofibrosis
NCCN: National Comprehensive Cancer Network
RA: refractory anemia
RAEB: refractory anemia with excess blasts
RAEB-T: refractory anemia with excess blasts in transformation
RARS: refractory anemia with ringed sideroblasts

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings:

- **Contraindication(s): advanced malignant hepatic tumors (Vidaza), hypersensitivity to azacitidine (or mannitol for Vidaza)**
- **Boxed warning(s): none reported**

Appendix D: General Information

The National Comprehensive Cancer Network (NCCN) AML treatment guidelines define morphologic CR in patients that are independent of transfusions as follows:

- **Absolute neutrophil count (ANC) > 1,000/mcL (blasts < 5%)**
- **Platelets ≥ 100,000/mcL (blasts < 5%)**
- **No residual evidence of extramedullary disease**

NCCN presents CRi (a variant of CR) as follows based on clinical trial information:

- **< 5% marrow blasts**

- **Either ANC < 1,000/mcL or platelets < 100,000/mcL**
- **Transfusion independence but with persistence of cytopenia (usually thrombocytopenia)**

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Azacitidine (Vidaza)	MDS	75 mg/m^2 SC or IV infusion QD for 7 days. Repeat cycle every 4 weeks. May increase to 100 mg/m^2 (after 2 treatment cycles). Patients should be treated for a minimum of 4 to 6 cycles. Doses may be adjusted or delayed based on hematology lab values, renal function, or serum electrolytes. Continue treatment as long as the patient continues to benefit	100 mg/m^2/day for 7 days/cycle

VI. Product Availability

Drug Name	Availability
Azacitidine (Vidaza)	Lyophilized powder in single dose vials: 100 mg

VII. References

1. Vidaza Prescribing Information. Summit, NJ: Celgene Corporation; March 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/050794s032lbl.pdf. Accessed August 7, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 10, 2020.
3. National Comprehensive Cancer Network. Myelodysplastic Syndromes Version 2.2020. Available at http://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed August 10, 2020.
4. National Comprehensive Cancer Network. Acute Myeloid Leukemia Version 4.2020. Available at http://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed September 28, 2020.
5. National Comprehensive Cancer Network. Myeloproliferative Neoplasms Version 1.2020. Available at https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf. Accessed August 10, 2020.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9025	Injection, azacitidine, 1 mg

Reviews, Revisions, and Approvals	Date
Converted corporate to local policy	03.2021

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are

solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.