Medical Policy:

Azacitidine (Vidaza®)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.14	April 2, 2024	October 2016

Definitions

Azacitidine is a pyrimidine nucleoside that interferes with DNA leading to cellular death. It is used to treat certain cancers.

Length of Authorization

Coverage will be provided for 6 months and may be renewed

Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:
All indications: 2,100 billable units every 28 days

Guideline

I. INITIAL CRITERIA

Subcutaneous or Intravenous azacitidine (Vidaza) may be considered medically necessary for any of the following:

1. **Myelodysplastic Syndromes (MDS)**
2. **Acute myeloid leukemia (AML) — off-label use**

II. RENEWAL CRITERIA

1. Patient continues to meet Initial Criteria; **AND**
2. Absence of unacceptable toxicity from the drug. *Examples of unacceptable toxicity include: severe cytopenias (anemia, neutropenia and thrombocytopenia), severe hepatic and renal toxicities, tumor lysis syndrome, etc.*; **AND**
3. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

Limitations/Exclusions

1. Azacitidine (Vidaza) is considered experimental or investigational for all other uses.
2. Contraindicated in patients with advanced malignant hepatic tumors
3. Patient must be 18 years of age or older.

Applicable Procedure Codes

Code	Description
J9025	Injection, azacitidine, 1 mg

Applicable NDCs

Code	Description
59572-0102-01	Vidaza single dose vial, 100 mg suspension reconstituted
68001-0313-56	Azacitidine single dose vial, 100 mg suspension reconstituted
68001-0504-54	Azacitidine single dose vial, 100 mg suspension reconstituted
71288-0115-30	Azacitidine single dose vial, 100 mg suspension reconstituted
71288-00153-95	Azacitidine single dose vial, 100 mg suspension reconstituted
43598-0305-62	Azacitidine single dose vial, 100 mg suspension reconstituted
00143-9606-01	Azacitidine single dose vial, 100 mg suspension reconstituted
72485-0201-01	Azacitidine single dose vial, 100 mg suspension reconstituted
16714-0927-01	Azacitidine single dose vial, 100 mg suspension reconstituted
69097-0805-40	Azacitidine single dose vial, 100 mg suspension reconstituted
16729-0306-10	Azacitidine single dose vial, 100 mg suspension reconstituted
43598-0678-11	Azacitidine single dose vial, 100 mg suspension reconstituted
51991-0797-98	Azacitidine single dose vial, 100 mg suspension reconstituted
63323-0771-39	Azacitidine single dose vial, 100 mg suspension reconstituted
43598-0465-62	Azacitidine single dose vial, 100 mg suspension reconstituted
64679-0096-01	Azacitidine single dose vial, 100 mg suspension reconstituted
64679-0096-02	Azacitidine single dose vial, 100 mg suspension reconstituted
67457-0254-30	Azacitidine single dose vial, 100 mg suspension reconstituted
00781-3253-94	Azacitidine single dose vial, 100 mg suspension reconstituted

ICD-10 Diagnoses

Code	Description

C92.00	Acute myeloblastic leukemia, not having achieved remission
C92.01	Acute myeloblastic leukemia, in remission
C92.02	Acute myeloblastic leukemia, in relapse
C92.40	Acute promyelocytic leukemia, not having achieved remission
C92.41	Acute promyelocytic leukemia, in remission
C92.42	Acute promyelocytic leukemia, in relapse
C92.50	Acute myelomonocytic leukemia, not having achieved remission
C92.51	Acute myelomonocytic leukemia, in remission
C92.52	Acute myelomonocytic leukemia, in relapse
C92.60	Acute myeloid leukemia with 11q23-abnormality not having achieved remission
C92.61	Acute myeloid leukemia with 11q23-abnormality in remission
C92.62	Acute myeloid leukemia with 11q23-abnormality in relapse
C92.A0	Acute myeloid leukemia with multilineage dysplasia, not having achieved remission
C92.A1	Acute myeloid leukemia with multilineage dysplasia, in remission
C92.A2	Acute myeloid leukemia with multilineage dysplasia, in relapse
C93.00	Acute monoblastic/monocytic leukemia, not achieve remission
C93.01	Acute monoblastic/monocytic leukemia, in remission
C93.02	Acute monoblastic/monocytic leukemia, in relapse
C93.90	Monocytic leukemia, unspecified, not having achieved remission
C94.00	Acute erythroid leukemia, not having achieved remission
C94.01	Acute erythroid leukemia, in remission
C94.02	Acute erythroid leukemia, in relapse
C94.20	Acute megakaryoblastic leukemia not having achieved remission
C94.21	Acute megakaryoblastic leukemia, in remission
C94.22	Acute megakaryoblastic leukemia, in relapse
D46.0	Refractory anemia without ring sideroblasts, so stated
D46.1	Refractory anemia with ring sideroblasts
D46.20	Refractory anemia with excess of blasts, unspecified
D46.21	Refractory anemia with excess of blasts 1
D46.22	Refractory anemia with excess of blasts 2
D46.4	Refractory anemia, unspecified
D46.9	Myelodysplastic syndrome, unspecified
D46.A	Refractory cytopenia with multilineage dysplasia
D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts
D46.C	Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality
D46.Z	Other myelodysplastic syndromes

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	4/2/2024	Annual Review: Updated length of authorization and dosing limits. Added renewal criteria
EmblemHealth & ConnectiCare	7/28/2023	Annual Review: Removed the following for Myelodysplastic Syndromes (MDS) Initial Criteria: a. "For high risk MDS in members who meet one of these criteria:

		i. Not a candidate for high-intensity therapy (e.g., allogenic hematopoietic stem cell transplant) ii. Candidate for high-intensity therapy who is awaiting improvement in status or a transplant iii. Member has no response or relapse after stem cell allogenic hematopoietic transplant b. For low-risk members who meet one of the following criteria: i. Use for initial treatment in members with significant increase in marrow blasts, thrombocytopenia, or neutropenia ii. Use for initial treatment in members with symptomatic anemia who have no deletion 5q abnormality, serum erythropoietin > 500 mU/mL and low likelihood of improvement with immunosuppressive therapy iii. Use for treatment in members who have symptomatic anemia with serum erythropoietin < 500 mU/mL, have failed erythropoietin therapy and failed immunosuppressive therapy iv. Use for treatment in members with deletion 5q abnormality who have serum erythropoietin > 500 mU/mL, have failed lenalidomide and have low likelihood of response to immunosuppressive therapy" And Removed the following for Acute myeloid leukemia (AML) — off-label use: Initial Criteria c. "For members ≥ 60 years of age who meet one of the following criteria: i. Use for induction therapy as a single agent or in combination with either Venclexta (venetoclax) or Nexavar (sorafenib) ii. Use for post-remission/maintenance therapy as a single agent iii. Use for post-induction therapy as a single agent or in combination with either Venclexta (venetoclax) or Nexavar (sorafenib); **OR** d. For members with relapsed/refractory disease as a single agent or in combination with Nexavar (sorafenib)"
EmblemHealth & ConnectiCare	3/30/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	10/05/2020	Removed: AML off-label use for: "Members > 60 years of age as a single agent for induction or post-remission therapy Either as a single agent or with nexavar (sorafenib) in members who cannot tolerate or have failed more intensive therapies" Clarified AML off-label use in accordance with NCCN guidelines
EmblemHealth & ConnectiCare	04/08/2020	Added under Limitations/Exclusions: Contraindicated in patients with advanced malignant hepatic tumors and Patient must be 18 years of age or older per FDA label
EmblemHealth & ConnectiCare	10/24/2016	Clarified prerequisite serum erythropoietin levels.

References

1. Estey, Elihu H, et al. Treatment of intermediate, low, or very low risk myelodysplastic syndromes. UpToDate, Waltham, MA. August 2017. http://www.uptodate.com/contents/treatment-of-intermediate-low-or-very-low-risk-myelodysplastic-syndromes. Accessed September 30, 2019.
2. Azacitidine (Vidaza) [package insert]. Summit, NJ: Celgene Corporation; 2004, revised September 2019.
3. National Comprehensive Cancer Network (NCCN). Azacitidine. NCCN Drug & Biologics Compendium®. 2016.
4. Specialty matched clinical peer review.