



Azacitidine (Vidaza®)

Revision: 2

Policy Number: M-0007

Last Update: 6/4/2014

Payment will not be made for any use of these drugs outside of the criteria without prior authorization. The member may not be billed unless the member explicitly agrees in writing to be responsible for the charges in accordance with the contract/provider manual. Prior authorization will only be given if the provider demonstrates the intended use meets Medicare coverage guidelines.

When appropriate compendia references the use of one of the chemotherapeutic agents listed in this Article as part of a 'combination therapy', the drug is only approved for use in such 'combinations', and the documentation should reflect, and be specific about, the use of the additional 'combination therapy' drugs.

Coverage Guidelines:

FDA:

1. Treatment of patients with the following FAB myelodysplastic syndrome (MDS) subtypes
 - a. Refractory anemia (RA) or refractory anemia with ringed sideroblasts (RARS) (if accompanied by neutropenia or thrombocytopenia or requiring transfusions)
 - b. Refractory anemia with excess blasts (RAEB), refractory anemia with excess blasts in transformation (RAEB-T)
 - c. Chronic myelomonocytic leukemia (CMML)

Off Label:

1. Acute myeloid leukemia

Coding Information:

HCPCS Code(s)

J9025	INJECTION, AZACITIDINE, 1 MG
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ICD-9 Code(s)

205.00-	ACUTE MYELOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION -
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205.02	ACUTE MYELOID LEUKEMIA, IN RELAPSE
205.10- 205.12	CHRONIC MYELOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - CHRONIC MYELOID LEUKEMIA, IN RELAPSE
238.71- 238.76	ESSENTIAL THROMBOCYTHEMIA - MYELOFIBROSIS WITH MYELOID METAPLASIA
238.79	OTHER LYMPHATIC AND HEMATOPOIETIC TISSUES
284.01	CONSTITUTIONAL RED BLOOD CELL APLASIA
284.09	OTHER CONSTITUTIONAL APLASTIC ANEMIA
284.11- 284.12	ANTINEOPLASTIC CHEMOTHERAPY INDUCED PANCYTOPENIA - OTHER DRUG INDUCED PANCYTOPENIA
284.19	OTHER PANCYTOPENIA
284.2	MYELOPHTHISIS
284.9	APLASTIC ANEMIA UNSPECIFIED
285.0	SIDEROBLASTIC ANEMIA

Background:

Vidaza is a pyrimidine nucleoside analog of cytidine. Vidaza is believed to exert its antineoplastic effects by causing hypomethylation of DNA and direct cytotoxicity on abnormal hematopoietic cells in the bone marrow.

Definitions:

CMMoL, chronic myelomonocytic leukemia—With CMMoL, you have between 5% and 20% blasts in the bone marrow and an increased number of monocytes, a type of WBC. About 10% of patients with MDS have CMMoL

FAB—French-American-British classification system of myelodysplastic syndromes

HCPCS Code—Healthcare Common Procedure Coding System - A system of letter and number codes assigned to procedures, medications, supplies and equipment used for pricing and billing.

ICD-9 Code—International Classification of Disease, 9th edition. A standardized classification of disease, injuries, and causes of death, by etiology and anatomic localization and codified into a 6-digit number, which allows clinicians, statisticians, politicians, health planners and others to speak a common language, both US and internationally.



RA, refractory anemia, or RARS, refractory anemia with ringed sideroblasts—With RA or RARS, you have less than 5% blasts or immature cells in the bone marrow and at least 1 cytopenia (abnormally low blood cell count [usually RBCs]). About 40% of patients with MDS have RA or RARS

RAEB, refractory anemia with excess blasts—With RAEB, you have 5% to 20% blasts in the bone marrow and at least 2 cytopenias (low counts of at least 2 types of blood cells [for example, RBCs and platelets]). About 30% of patients with MDS have RAEB

RAEB-T, refractory anemia with excess blasts in transformation—With RAEB-T, you have between 21% and 30% blasts in the bone marrow and at least 2 cytopenias. This form of MDS may turn into a type of cancer of the blood and bone marrow called acute myeloid leukemia (AML). About 20% of patients with MDS have RAEB-T

References:

1. Vidaza [package insert]. Summit, NJ: Celgene Corporation; January 2012. Available at: http://www.vidaza.com/pdf/PI_FINAL.pdf. Accessed May 23, 2012.
2. The NCCN Drugs & Biologics Compendium™ © 2010 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed May 23, 2012.
3. Local Coverage Article for Drugs and Biologics – Chemotherapeutic Agents (A48896) (R4). Available at http://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=48896&ver=92&ContrId=213&ContrVer=1&CtrctrSelected=213*1&Date=01%2f01%2f2014&DocId=A48896&bc=hAAAAAgAAAAAA%3d%3d&. Accessed June 4, 2014.
4. Micromedex® 2.0 – Vidaza. Available at: http://www.thomsonhc.com/micromedex2/librarian/ND_T/evidencexpert/ND_PR/evidencexpert/CS/FDF432/ND_AppProduct/evidencexpert/DUPLICATIONSHIELDSYNC/606D04/ND_PG/evidencexpert/ND_B/evidencexpert/ND_P/evidencexpert/PFActionId/evidencexpert.DisplayDrugpointDocument?docId=928135&contentSetId=100&title=Azacitidine&servicesTitle=Azacitidine&topicId=dosingAndIndicationsSection&subtopicId=nonfdaSection. Accessed May 23, 2012.
5. Vidaza. Available at: <http://www.vidaza.com/patient/default.aspx>. Accessed May 23, 2012.

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Internal Review: 6/9/2014

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For the Archived Policy, please go

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