

Commercial & HealthCare Exchange PA Criteria Effective: November 11, 2020

Prior Authorization: Onureg

Products Affected: Onureg (azacitidine) tablets

Medication Description: Azacitidine is a pyrimidine nucleoside analog of cytidine that inhibits DNA/RNA methyltransferases. Azacitidine is incorporated into DNA and RNA and inhibits DNA and RNA methyltransferases, reduces DNA and RNA methylation, alters DNA gene expression (including re-expression of genes that regulate tumor suppression and cell differentiation), and decreases RNA stability and decreases protein synthesis.

Covered Uses: Continued treatment of adult patients with acute myeloid leukemia who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy.

Exclusion Criteria:

1. Known hypersensitivity to azacitidine

Required Medical Information:

1. Diagnosis
2. Medical history
3. Previous therapies tried

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Prescribed by, or in consultation with, an oncologist or hematologist

Coverage Duration: 3 years

Other Criteria:

Acute Myeloid Leukemia

- A. Patient has a diagnosis of acute myeloid leukemia; **AND**
- B. Patient achieves one of the below following intensive induction chemotherapy (i or ii):
 - i. First complete remission; **OR**
 - ii. First complete remission with incomplete blood count recovery; **AND**
- C. Patient is not able to complete intensive curative therapy.

References:

1. Onureg [package insert]. Celgene Corporation. Summit, NJ 07901; September 2020
2. Azacitidine. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. October 2020.
3. Azacitidine. IBM Micromedex® DRUGDEX®. IBM Watson Health, Greenwood Village, Colorado, USA. September 2020.
4. "Onureg® (Azacitidine) Tablets For Healthcare Professionals". <http://onuregpro.com>. Accessed 19 Oct 2020.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	10/19/2020