

# Onureg (azacitidine)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

  

Medications	Quantity Limit
Onureg (azacitidine)	May be subject to quantity limit

## APPROVAL CRITERIA

Requests for Onureg (azacitidine) may be approved if the following criteria are met:

- I. Individual has a diagnosis of acute myeloid leukemia (AML), including de novo AML and AML secondary to prior myelodysplastic disease or chronic myelomonocytic leukemia (NCT01757535); **AND**
- II. Individual has achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy; **AND**
- III. Individual is unable to complete intensive curative therapy (e.g. allogeneic hematopoietic stem cell transplant); **AND**
- IV. Onureg is used as a single agent.

Requests for Onureg (azacitidine) may not be approved for the following:

- I. Individual has a current diagnosis of myelodysplastic syndrome.

## Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. Clinicaltrials.gov [Internet]. Bethesda, MD: National Library of Medicine (US) 2000 Feb 29- . Identifier NCT01757535. Efficacy of Oral Azacitidine Plus Best Supportive Care as Maintenance Therapy in Subjects With Acute Myeloid Leukemia in Complete Remission (QUAZAR AML-001): 2019 Oct 24 [cited 2020 Sept 10]. Available from: <https://clinicaltrials.gov/ct2/show/NCT01757535>. Accessed on December 29, 2020.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: December 29, 2020.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on December 29, 2020.
  - a. Myelodysplastic Syndromes. V2.2020. Revised February 28, 2020.
  - b. Acute Myeloid Leukemia. V2.2021. Revised November 12, 2020.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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