

Market Applicability						
Market	GA	KY	MD	NJ	NY	WA
Applicable	X	NA	X	X	X	X

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.

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.: 2020. 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 September 10, 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: September 9, 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.; 2020; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on September 9, 2020.
 - a. Myelodysplastic Syndromes. V2.2020. Revised February 28, 2020.
 - b. Acute Myeloid Leukemia. V3.2020. Revised December 23, 2019.

Market Applicability						
Market	GA	KY	MD	NJ	NY	WA
Applicable	X	NA	X	X	X	X

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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