

Clinical Pharmacy Program Guidelines for Onureg

Program	Prior Authorization- Onureg
Medication	Onureg [®] (azacitidine)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	12/2020
Pharmacy and Therapeutics Approval Date	12/2020
Effective Date	1/2021

1. Background:

Onureg (azacitidine) is a nucleoside metabolic inhibitor indicated for 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.

2. Coverage Criteria:

<p>A. <u>Acute Myeloid Leukemia</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Onureg will be approved based on <u>all</u> of the following criteria:</p> <ul style="list-style-type: none"> (1) Diagnosis of Acute Myeloid Leukemia <p style="text-align: center;">-AND-</p> <ul style="list-style-type: none"> (2) Achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy <p style="text-align: center;">-AND-</p> <ul style="list-style-type: none"> (3) Patient is not able to complete intensive curative therapy (e.g., transplant-ineligible) <p style="text-align: center;">Authorization will be issued for 12 months.</p>
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2. **Reauthorization**

a. **Onureg** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Onureg therapy

Authorization will be issued for 12 months.

B. NCCN Recommended Regimens

1. **Initial Authorization**

a. **Onureg** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Onureg** will be approved based on the following criterion:

- (1) Documentation of positive clinical response to Onureg therapy

Authorization will be issued for 12 months.

3. **Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. **References:**

1. Onureg [package insert]. Summit, NJ: Celgene Corporation; September 2020.

2. The NCCN Drugs and Biologics Compendium (NCCN Compendium[™]). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed on October 28, 2020

Program	Prior Authorization– Onureg [®] (azacitidine)
Change Control	
Date	Change
12/2020	New program