



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2021 P 1341-2
Program	Prior Authorization/Notification
Medication	Onureg <sup>®</sup> (azacitidine)
P&T Approval Date	12/2020, 12/2021
Effective Date	3/1/2022; Oxford only: 3/1/2022

**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.

**Coverage Information:**

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

**2. Coverage Criteria:**

**A. Patients less than 19 years of age**

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

- a. Patient is less than 19 years of age

**Authorization will be issued for 12 months.**

**B. Acute Myeloid Leukemia**

1. **Initial Authorization**

- a. Onureg will be approved based on **all** of the following criteria:

- (1) Diagnosis of Acute Myeloid Leukemia

**-AND-**

(2) Achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy

**-AND-**

(3) Patient is not able to complete intensive curative therapy (e.g., transplant-ineligible)

**Authorization will be issued for 12 months.**

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.**

C. **NCCN Recommended Regimens**

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

**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; May 2021.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at [http://www.nccn.org/professionals/drug\\_compendium/content/contents.asp](http://www.nccn.org/professionals/drug_compendium/content/contents.asp). Accessed on October 26, 2021

Program	Prior Authorization/Notification - Onureg® (azacitidine)
<b>Change Control</b>	
12/2020	New program.
12/2021	Annual review with no change to clinical criteria. Updated references.