UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1341-5
Program	Prior Authorization/Notification
Medication	Onureg® (azacitidine)
P&T Approval Date	12/2020, 12/2021, 12/2022, 12/2023, 12/2024
Effective Date	3/1/2025

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.

The National Comprehensive Cancer Network (NCCN) also recommends the use of Onureg for the treatment of certain peripheral T-cell lymphomas for initial palliative intent therapy or second-line and subsequent 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]:

A. <u>Patients less than 19 years of age</u>

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. <u>Acute Myeloid Leukemia</u>

1. **<u>Initial Authorization</u>**

   a. **Onureg** will be approved based on **<u>all</u>** 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. **Peripheral T-cell Lymphoma**

1. **Initial Authorization**

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

(1) Diagnosis of **one** of the following T-cell lymphomas:

a. Angioimmunoblastic T-cell lymphoma (AITL)
b. Nodal peripheral T-cell lymphoma with TFH phenotype (PTCL, TFH)
c. Follicular T-cell lymphoma (FTCL)

-AND-

(2) **One** of the following:

a. Used as initial palliative intent therapy
b. Used as second-line and subsequent therapy

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.

D. **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.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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; October 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed on October 24, 2024.

Program	Prior Authorization/Notification - Onureg® (azacitidine)
Change Control	
12/2020	New program.
12/2021	Annual review with no change to clinical criteria. Updated references.
12/2022	Annual review with no change to clinical criteria. Added state mandate and updated references.
12/2023	Annual review with no change to clinical criteria. Updated references.
12/2024	Annual review. Addition of T-cell lymphoma to criteria per NCCN.