PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Onureg Prior Authorization Policy
- Onureg® (azacitidine tablets – Celgene)

REVIEW DATE: 09/10/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Onureg, a nucleoside metabolic inhibitor, is indicated for the continued treatment of **acute myeloid leukemia** (AML) in adults who achieve first complete remission or complete remission with incomplete blood count recovery following intensive induction chemotherapy and are unable to complete intensive curative therapy.[1]

Guidelines

Onureg has been addressed by the National Comprehensive Cancer Network:

- **AML:** NCCN guidelines (version 2.2025 – January 27, 2025) recommend Onureg for the post-remission maintenance treatment of AML in patients who completed no consolidation, some consolidation, or are recommended to receive a course of consolidation; and with no allogeneic stem cell transplantation planned (category 1).[2,3]
- **T-cell lymphoma:** NCCN guidelines (version 2.2025 – May 28, 2025) recommended Onureg as a single agent for the initial palliative therapy

(category 2B) or for second-line and subsequent treatment (category 2A) of relapsed/refractory peripheral T-cell lymphoma including angioimmunoblastic T-cell lymphoma, nodal peripheral T-cell lymphoma with T-follicular helper (TFH) phenotype, and follicular T-cell lymphoma.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Onureg. All approvals are provided for the duration noted below.

- **Onureg® (azacitidine tablets – Celgene)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Acute Myeloid Leukemia.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) The medication is used for post-remission maintenance therapy; AND
   C) According to the prescriber, allogeneic hematopoietic stem cell transplant is not planned.

Other Uses with Supportive Evidence

2. **T-cell Lymphoma**. Approve for 1 year if the patient meets BOTH of the following (A and B):
   Note: Examples of peripheral T-cell lymphoma include Angioimmunoblastic T-cell lymphoma, Nodal peripheral T-cell lymphoma, Follicular helper T-cell lymphoma, and Follicular T-cell lymphoma.
   A) Patient is ≥ 18 years of age; AND
   B) Patient has peripheral disease.

CONDITIONS NOT COVERED

- **Onureg® (azacitidine tablets – Celgene)**

is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Onureg® tablets [prescribing information]. Summit, NJ: Celgene; October 2022.
2. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 2.2025 – January 27, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed September 2, 2025.

3. The NCCN T-cell Lymphomas Clinical Practice Guidelines in Oncology (version 2.2025 – May 28, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed September 2, 2025.
4. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed September 2, 2025. Search term: Onureg.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Acute Myeloid Leukemia:** According to the prescriber, patient has complete response to previous intensive induction chemotherapy was removed as an option for approval. The wording "according to the prescriber" was removed from the following requirement, "patient has intermediate- or poor-risk cytogenetics." Patient is not able to complete intensive consolidation chemotherapy was removed as a requirement. The requirement that according to the prescriber, the patient has declined or is not fit or eligible for allogeneic hematopoietic stem cell transplant was revised to "according to the prescriber, allogeneic hematopoietic stem cell transplant is not planned."	09/13/2023
Annual Revision	**Acute Myeloid Leukemia:** Removed requirement that the patient has intermediate- or poor-risk cytogenetics. **Peripheral T-Cell Lymphoma:** Added new condition of approval.	09/11/2024
Annual Revision	**T-Cell Lymphoma:** The condition of approval was changed to remove the descriptor of "Peripheral". The patient has peripheral disease was added as a requirement. Angioimmunoblastic T-cell lymphoma, nodal peripheral T-cell lymphoma, follicular helper T-cell lymphoma, and follicular T-cell lymphoma were moved from the criteria section to a Note listing examples of T-Cell Lymphoma. The requirements that the patient has relapsed or refractory disease and that the medication is used as a single agent were removed.	09/10/2025