PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 09/13/2023

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. 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

The National Comprehensive Cancer Network AML guidelines (version 4.2023 – July 11, 2023) recommend Onureg for the post-remission maintenance treatment of AML in patients with intermediate- or adverse-risk disease, 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]

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 the following (A, B, C, and D):
   A) Patient is ≥ 18 years of age; AND
   B) The medication is used for post-remission maintenance therapy; AND
   C) Patient has intermediate- or poor-risk cytogenetics; AND
   Note: Examples of intermediate- and poor-risk cytogenetics include the following genetic alterations: wild-type *NPM1* without *FLT3-ITD* or with *FLT3-ITD^{low}, MLLT3-KMT2A, DEK-NUP214,* and *KMT2A* rearranged.
   D) According to the prescriber, allogeneic hematopoietic stem cell transplant is not planned.

CONDITIONS NOT COVERED

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

is(are) considered experimental, investigational or unproven for ANY other use(s).

REFERENCES

1. Onureg® tablets [prescribing information]. Summit, NJ: Celgene; May 2021.
2. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 4.2023 – July 11, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed September 8, 2023.
3. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed September 8, 2023. Search term: Onureg.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/14/2022
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