PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 09/11/2024

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** guidelines (version 3.2024 – May 17, 2024) 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** guidelines (version 4.2024 – May 28, 2024) 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Onureg is recommended in those who meet one of the following criteria:

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. **Peripheral T-cell Lymphoma**. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

A) Patient is ≥ 18 years of age; AND
B) Patient has relapsed or refractory disease; AND
C) Patient has ONE of the following (i, ii, or iii):
  i. Angioimmunoblastic T-cell lymphoma; OR
  ii. Nodal peripheral T-cell lymphoma with T-follicular helper (TFH) phenotype; OR
  iii. Follicular T-cell lymphoma; AND
D) The medication is used as a single agent.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Onureg is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. 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 3.2024 – May 17, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed September 3, 2024.
3. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed September 3, 2024. Search term: Onureg.