PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 09/14/2022

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 2.2022 – June 14, 2022) 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 2A).[2,3] In addition, Onureg is recommended for patients ≥ 60 years of age following complete response to intensive therapy who are not able to receive conventional consolidation and decline or are not fit/eligible for allogeneic hematopoietic stem cell transplant (category 1).

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 the following criteria:

FDA-Approved Indication

1. **Acute Myeloid Leukemia.** Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication is used for post-remission maintenance therapy; AND
   - **C)** According to the prescriber, the patient meets one of the following (i or ii):
     - **i.** Patient has intermediate- or poor-risk cytogenetics; OR
       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.
     - **ii.** Patient has complete response to previous intensive induction chemotherapy; AND
       Note: Examples of intensive chemotherapy include Venclexta (venetoclax tablet) plus subcutaneous azacitidine or Venclexta plus intravenous decitabine.
   - **D)** Patient is not able to complete intensive consolidation chemotherapy; AND

E) According to the prescriber, the patient has declined or is not fit or eligible for allogeneic hematopoietic stem cell transplant.

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; May 2021.
2. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 2.2022 – June 14, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed September 6, 2022.
3. The NCCN Drugs & Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed September 6, 2022. Search term: Onureg.