PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 09/16/2020; selected revisions 11/18/2020

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 (NCCN) AML guidelines (version 1.2021 – October 22, 2021) recommend Onureg for the post-remission maintenance treatment of AML in patients < 60 years of age with intermediate- or poor-risk cytogenetics who decline or not fit or eligible for allogeneic hematopoietic stem cell transplantation or in patients ≥ 60 years of age following complete response to intensive therapy.[2,3]

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 Indications

1. **Acute Myeloid Leukemia.** Approve for 3 years if the patient meets the following criteria (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)** According to the prescriber, the patient meets one of the following (i or ii):
     - **i.** Patient has intermediate- or poor-risk cytogenetics who decline or are not fit or eligible for allogeneic hematopoietic stem cell transplant; 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 plus subcutaneous azacitidine or Venclexta plus intravenous decitabine.
   - **D)** Patient is not able to complete intensive consolidation chemotherapy.

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 Corporation; September 2020.
2. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 1.2021 – October 14, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed October 22, 2020.
3. The NCCN Drugs & Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed October 21, 2020.