

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Onureg Prior Authorization Policy

- Onureg® (azacitidine 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	09/16/2020
Selected revision	Acute Myeloid Leukemia. Removed criteria for use following intensive induction chemotherapy in patient who achieve first complete response or first complete response with incomplete blood count recovery. Added criteria for use as post-remission maintenance therapy; and for use in patients with intermediate- or poor-risk cytogenetics who decline or are not fit or eligible for allogeneic hematopoietic stem cell transplant or in patients with complete response to previous intensive chemotherapy.	11/18/2020