Reference number(s)
4194-A

Specialty Guideline Management Onureg

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Onureg	azacitidine

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indication[1]

Onureg is indicated for continued treatment of adult patients with acute myeloid leukemia (AML) who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy.

Compendial Uses[2]

- AML
- Peripheral T-Cell Lymphoma

All other indications are considered experimental/investigational and not medically necessary.

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Coverage Criteria

Acute Myeloid Leukemia (AML)[1]

Authorization of 12 months may be granted for treatment of non-core binding factor (non-CBF) AML when all of the following criteria are met:

- The requested medication will be used as a single agent.
- The member has achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy.
- The member is not able to complete intensive curative therapy.

Peripheral T-Cell Lymphoma (PTCL)[2]

Authorization of 12 months may be granted for the treatment of peripheral T-cell lymphoma (PTCL) [including the following subtypes: angioimmunoblastic T-cell lymphoma (AITL), nodal peripheral T-cell lymphoma with TFH phenotype (PTCL, TFH), follicular T-cell lymphoma (FTCL)] when all of the following criteria are met:

- The requested medication will be used as subsequent therapy for relapsed or refractory disease
- The requested medication will be used as a single agent

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Onureg [package insert]. Princeton, NJ: Celgene Corporation; October 2022.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed January 3, 2025.