

Reference number(s)
4194-A

SPECIALTY GUIDELINE MANAGEMENT

ONUREG (azacitidine)

POLICY

I. 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 Indications

Onureg is indicated for continued treatment of adult patients with acute myeloid leukemia 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.

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

II. CRITERIA FOR INITIAL APPROVAL

A. Acute Myeloid Leukemia (AML)

Authorization of 12 months may be granted for treatment of AML when all of the following criteria are met:

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

III. CONTINUATION OF THERAPY

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

IV. REFERENCES

1. Onureg [package insert]. Summit, NJ: Celgene Corporation; September 2020.