BlueCross BlueShield
Federal Employee Program

ONUREG
(azacitidine)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Onureg (azacitidine) is a pyrimidine nucleoside analog of cytidine that inhibits DNA/RNA methyltransferases. Onureg is incorporated into the DNA of cancer cells which inhibits DNA methyltransferases, reduces DNA methylation, and alters gene expression, including re-expression of genes regulating tumor suppression and cell differentiation. Incorporation of Onureg into the RNA of cancer cells inhibits RNA methyltransferases, reduces RNA methylation, decreases RNA stability, and decreases protein synthesis (1).

Regulatory Status

FDA-approved indication: Onureg is a nucleoside metabolic inhibitor 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 (1).

Onureg should not be substituted for intravenous or subcutaneous azacitidine. The indications and dosing regimen for Onureg differ from that of intravenous or subcutaneous azacitidine (1).

The recommended dosage of Onureg is 300 mg orally once daily with or without food on Days 1 through 14 of each 28-day cycle. If the absolute neutrophil count (ANC) is less than 0.5 Gi/L on Day 1 of a cycle, do not administer Onureg. Delay the start of the cycle until the ANC is 0.5 Gi/L or more (1).

Myelosuppression including neutropenia and thrombocytopenia may occur with Onureg therapy. Complete blood counts should be monitored every other week for the first 2 cycles and prior to the start of each cycle thereafter. Monitoring should be increased to every other week for the 2 cycles after any dose reduction for myelosuppression (1).

Onureg can cause fetal harm when administered to a pregnant woman. Pregnant women should be advised of the potential risk to a fetus. Females of reproductive potential should be advised to use effective contraception during treatment with Onureg and for at least 6 months after the last

dose. Males with female partners of reproductive potential should be advised to use effective contraception during treatment with Onureg and for at least 3 months after the last dose (1).

The safety and effectiveness of Onureg in pediatric patients have not been established (1).

Summary

Onureg (azacitidine) is a pyrimidine nucleoside analog of cytidine that inhibits DNA/RNA methyltransferases. Onureg is incorporated into the DNA of cancer cells which inhibits DNA methyltransferases, reduces DNA methylation, and alters gene expression, including re-expression of genes regulating tumor suppression and cell differentiation. Incorporation of Onureg into the RNA of cancer cells inhibits RNA methyltransferases, reduces RNA methylation, decreases RNA stability, and decreases protein synthesis (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Onureg while maintaining optimal therapeutic outcomes.

References

1. Onureg [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; October 2022.
2. NCCN Drugs & Biologics Compendium® Azacitidine 2025. National Comprehensive Cancer Network, Inc. Accessed on January 9, 2025