ONUREG™ (azacitidine) tablets 300 mg • 200 mg

Bristol Myers Squibb®
Access Support®

A REFERENCE GUIDE TO

Reimbursement and Coding for ONUREG® (azacitidine) tablets

To view authorized distributors/specialty pharmacies for ONUREG, please click here or visit www.BMSAccessSupport.com.

Please see Important Safety Information on page 8 and U.S. Full Prescribing Information.

Indication

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.

ONUREG® is available as 200 mg and 300 mg oral tablets.

Select Important Safety Information

ONUREG® is contraindicated in patients with known severe hypersensitivity to azacitidine or its components.

ONUREG® is associated with the following Warnings and Precautions: risks of substitution with other azacitidine products, myelosuppression, increased early mortality in patients with myelodysplastic syndromes, and embryo-fetal toxicity.

Please see Important Safety Information on page 8 and U.S. Full Prescribing Information.

For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday–Friday, or visit www.BMSAccessSupport.com.

Bristol Myers Squibb Is Committed to Helping Support Access

This brochure is designed to help appropriate patients get access to our medications by providing helpful reimbursement information for healthcare offices. Healthcare benefits vary significantly; therefore, it is important that healthcare provider offices verify each patient's insurance coverage prior to initiating therapy.

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Healthcare providers should code healthcare claims based upon the service that is rendered, the patient's medical record, the coding requirements of each health insurer, and the best coding practices. The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

Please see Important Safety Information on page 8 and U.S. Full Prescribing Information.

National Drug Code (NDC) Information for ONUREG® (azacitidine) tablets

The NDCs for ONUREG® are listed below.*

NDCs for ONUREG®[1]

200-mg tablets One blister card containing 7 tablets		300-mg tablets One blister card containing 7 tablets
59572-730-07		59572-740-07
59572-0730-07		59572-0740-07

ONUREG® may be dispensed as 1 or 2 blister cards.*

14-day supply = two 7-count blister cards
200-mg or 300-mg tablets

*ONUREG® bottle packaging is being phased out of production. Blister cards are available and provided in 7-count packages to provide flexibility in dispensing the recommended dosage and dosage modifications for adverse reactions.

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ICD-10-CM Codes

ICD-10-CM codes are used to identify a patient's diagnosis. On October 1, 2015, the newest version of these codes, ICD-10-CM, was implemented throughout the United States. This version replaces the previous version, ICD-9-CM.[2]

- The ICD-10-CM diagnosis codes contain **categories**, **subcategories**, and **codes**. Characters for categories, subcategories, and codes may be letters or numerals
- **All categories** are 3 characters
- **Subcategories** are either 4 or 5 characters
- **Codes** may be 3, 4, 5, 6, or 7 characters

The ICD-10-CM codes for the labeled indications for ONUREG® (azacitidine) tablets are provided on the following pages by Bristol Myers Squibb and should be verified with the payer. Some health plan and Medicare insurers may specify which codes are covered under their policies. Please code to the level of specificity documented in the medical record. For additional coding questions, call BMS Access Support® at **1-800-861-0048** or visit **www.BMSAccessSupport.com**.

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Acute Myeloid Leukemia (AML): ICD-10-CM Codes for ONUREG® (azacitidine) tablets

ICD-10-CM Codes for ONUREG®[8]	
C92 Myeloid leukemia*	
C92.0	Acute myeloblastic leukemia*
C92.00	Acute myeloblastic leukemia, not having achieved remission
C92.01	Acute myeloblastic leukemia, in remission
C92.5	Acute myelomonocytic leukemia*
C92.50	Acute myelomonocytic leukemia, not having achieved remission
C92.51	Acute myelomonocytic leukemia, in remission
C92.6	Acute myeloid leukemia with 11q23-abnormality*
C92.60	Acute myeloid leukemia with 11q23-abnormality, not having achieved remission
C92.61	Acute myeloid leukemia with 11q23-abnormality, in remission
C92.A	Acute myeloid leukemia with multilineage dysplasia*
C92.A0	Acute myeloid leukemia with multilineage dysplasia, not having achieved remission
C92.A1	Acute myeloid leukemia with multilineage dysplasia, in remission
C92.Z	Other myeloid leukemia*
C92.Z0	Other myeloid leukemia, not having achieved remission
C92.Z1	Other myeloid leukemia, in remission
C92.9	Myeloid leukemia, unspecified*
C92.90	Myeloid leukemia, unspecified, not having achieved remission
C92.91	Myeloid leukemia, unspecified, in remission
C93 Monocytic leukemia*	
C93.0	Acute monoblastic/monocytic leukemia*
C93.00	Acute monoblastic/monocytic leukemia, not having achieved remission
C93.01	Acute monoblastic/monocytic leukemia, in remission
C94 Other leukemias of specified cell type*	
C94.0	Acute erythroid leukemia*
C94.00	Acute erythroid leukemia, not having achieved remission
C94.01	Acute erythroid leukemia, in remission
C94.2	Acute megakaryoblastic leukemia*
C94.20	Acute megakaryoblastic leukemia, not having achieved remission
C94.21	Acute megakaryoblastic leukemia, in remission

*This is a category code and is invalid for stand-alone use. Please use the expanded code listed below.

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Recommended Dosing for ONUREG® (azacitidine) tablets

IMPORTANT ADMINISTRATION INFORMATION

Do not substitute ONUREG® for intravenous or subcutaneous azacitidine. The indications and dosing regimen for ONUREG® differ from that of intravenous or subcutaneous azacitidine

Recommended Dosage[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**
- Continue ONUREG® until disease progression or unacceptable toxicity

300 mg orally once daily for 2 weeks → 2 weeks off

- Administer an antiemetic 30 minutes prior to each dose of ONUREG® for the first 2 cycles. Antiemetic prophylaxis may be omitted after 2 cycles if there has been no nausea and vomiting
- 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

Instruct patients on the following:

- Swallow tablets whole. Do not cut, crush, or chew the tablets
- Take a dose at about the same time each day
- If a dose of ONUREG® is missed, or not taken at the usual time, take the dose as soon as possible on the same day, and resume the normal schedule the following day. Do not take 2 doses on the same day
- If a dose is vomited, do not take another dose on the same day. Resume the normal schedule the following day

ONUREG® is a hazardous drug. Follow applicable special handling and disposal procedures.

Please see Section 2.3, Monitoring and Dosage Modifications for Adverse Reactions information in the full Prescribing Information.

Please see Important Safety Information on page 8 and U.S. Full Prescribing Information.

Important Safety Information for ONUREG® (azacitidine) tablets

CONTRAINDICATIONS

ONUREG® is contraindicated in patients with known severe hypersensitivity to azacitidine or its components.

WARNINGS AND PRECAUTIONS

Risks of Substitution with Other Azacitidine Products

Due to substantial differences in the pharmacokinetic parameters, the recommended dose and schedule for ONUREG® are different from those for the intravenous or subcutaneous azacitidine products. Treatment of patients using intravenous or subcutaneous azacitidine at the recommended dosage of ONUREG® may result in a fatal adverse reaction. Treatment with ONUREG® at the doses recommended for intravenous or subcutaneous azacitidine may not be effective. Do not substitute ONUREG® for intravenous or subcutaneous azacitidine.

Myelosuppression

New or worsening Grade 3 or 4 neutropenia and thrombocytopenia occurred in 49% and 22% of patients who received ONUREG®. Febrile neutropenia occurred in 12%. A dose reduction was required for 7% and 2% of patients due to neutropenia and thrombocytopenia. Less than 1% of patients discontinued ONUREG® due to either neutropenia or thrombocytopenia. Monitor complete blood counts and modify the dosage as recommended. Provide standard supportive care, including hematopoietic growth factors, if myelosuppression occurs.

Increased Early Mortality in Patients with Myelodysplastic Syndromes (MDS)

In AZA-MDS-003, 216 patients with red blood cell transfusion-dependent anemia and thrombocytopenia due to MDS were randomized to ONUREG® or placebo. 107 received a median of 5 cycles of ONUREG® 300 mg daily for 21 days of a 28-day cycle. Enrollment was discontinued early due to a higher incidence of early fatal and/or serious adverse reactions in the ONUREG® arm compared with placebo. The most frequent fatal adverse reaction was sepsis. Safety and effectiveness of ONUREG® for MDS have not been established. Treatment of MDS with ONUREG® is not recommended outside of controlled trials.

Embryo-Fetal Toxicity

ONUREG® can cause fetal harm when administered to a pregnant woman. Azacitidine caused fetal death and anomalies in pregnant rats via a single intraperitoneal dose less than the recommended human daily dose of oral azacitidine on a mg/m^2 basis. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with ONUREG® and for at least 6 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with ONUREG® and for at least 3 months after the last dose.

ADVERSE REACTIONS

Serious adverse reactions occurred in 15% of patients who received ONUREG®. Serious adverse reactions in ≥2% included pneumonia (8%) and febrile neutropenia (7%). One fatal adverse reaction (sepsis) occurred in a patient who received ONUREG®.

Most common (≥10%) adverse reactions with ONUREG® vs placebo were nausea (65%, 24%), vomiting (60%, 10%), diarrhea (50%, 21%), fatigue/asthenia (44%, 25%), constipation (39%, 24%), pneumonia (27%, 17%), abdominal pain (22%, 13%), arthralgia (14%, 10%), decreased appetite (13%, 6%), febrile neutropenia (12%, 8%), dizziness (11%, 9%), pain in extremity (11%, 5%).

LACTATION

There are no data regarding the presence of azacitidine in human milk or the effects on the breastfed child or milk production. Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment with ONUREG® and for 1 week after the last dose.

Please see U.S. Full Prescribing Information.

References

1. ONUREG® (azacitidine). Prescribing Information. Celgene Corp.
2. eHealth University, Centers for Medicare & Medicaid Services. The ICD-10- transition: an introduction. Updated August 2014. Accessed July 14, 2021. https://www.cms.gov/Medicare/Coding/ICD10/Downloads/ICD10Introduction20140819.pdf
3. Centers for Medicare & Medicaid Services. ICD-10-CM tabular list of diseases and injuries. Accessed July 14, 2021. https://www.cms.gov/medicare/icd-10/2021-icd-10-cm

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Bristol Myers Squibb®

Access Support®

Looking for support? We're here for you.

Coverage assistance, educational resources, and financial support options may be available through **BMS Access Support®**

Call a Patient Access Specialist at **1-800-861-0048**, 8 AM to 8 PM ET, Monday–Friday

Visit **www.BMSAccessSupport.com**

Scheduling a meeting with a BMS Access and Reimbursement Manager on the BMS Access Support website

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2011-US-2400049 03/24