Authorized Distributors

The following distributors are authorized to sell ONUREG® and are able to service qualified accounts.

Authorized Distributor Network
Community Practices
Cardinal Health Specialty Pharmaceutical Distribution Phone: 1-877-453-3972 | https://specialtyonline.cardinalhealth.com/
McKesson Specialty Health Phone: 1-800-482-6700 | Fax: 1-800-289-9285 | https://mscs.mckesson.com
Oncology Supply Phone: 1-800-633-7555 | Fax: 1-800-248-8205 | https://oncologysupply.com
Specialty Pharmacies and Institutions/Hospital Outpatient Facilities
ASD Healthcare Phone: 1-800-746-6273 | Fax: 1-800-547-9413 | https://www.asdhealthcare.com
Cardinal Health Specialty Pharmaceutical Distribution Phone: 1-866-677-4844 | Fax: 1-614-553-6301 | https://orderexpress.cardinalhealth.com
McKesson Plasma and Biologics Phone: 1-877-625-2566 | Fax: 1-888-752-7626 | https://connect.mckesson.com
Puerto Rico Hospitals and Oncology Clinics
Cardinal Puerto Rico Phone: 787-625-4100 | Fax: 1-787-625-4398 | https://www.cardinalhealth.pr/
Cesar Castillo Inc Phone: 787-999-1616 | Fax: 787-999-1618 | https://www.facilfarmaciacci.com/

If you have any questions about procurement, coverage, or reimbursement of ONUREG®, please contact BMS Access Support®.

Billing and Coding

AML ICD-10-CM DIAGNOSIS CODES[a]

ICD-10-CM code	Descriptor
C92.00	Acute myeloblastic leukemia, not having achieved remission
C92.01	Acute myeloblastic leukemia, in remission
C92.50	Acute myelomonocytic leukemia, not having achieved remission
C92.51	Acute myelomonocytic leukemia, in remission
C92.60	Acute myeloid leukemia with 11q23-abnormality, not having achieved remission
C92.61	Acute myeloid leukemia with 11q23-abnormality, in remission
C92.A0	Acute myeloid leukemia with multilineage dysplasia, not having achieved remission
C92.A1	Acute myeloid leukemia with multilineage dysplasia, in remission
C92.Z0	Other myeloid leukemia, not having achieved remission
C92.Z1	Other myeloid leukemia, in remission
C92.90	Myeloid leukemia, unspecified, not having achieved remission
C92.91	Myeloid leukemia, unspecified, in remission
C93.00	Acute monoblastic/monocytic leukemia, not having achieved remission
C93.01	Acute monoblastic/monocytic leukemia, in remission
C94.00	Acute erythroid leukemia, not having achieved remission
C94.01	Acute erythroid leukemia, in remission
C94.20	Acute megakaryoblastic leukemia, not having achieved remission
C94.21	Acute megakaryoblastic leukemia, in remission

[a]This list may not be all-inclusive.

NATIONAL DRUG CODES (NDC) AND PACKAGING INFORMATION*

Tablet strength	Package configuration	10-digit NDC	11-digit NDC[a]
200 mg	One blister card containing 7 tablets	59572-730-07 **NEW**	59572-0730-07 **NEW**
300 mg	One blister card containing 7 tablets	59572-740-07 **NEW**	59572-0740-07 **NEW**
200 mg	Bottles of 14 with two desiccant canisters	59572-730-14	59572-0730-14
300 mg	Bottles of 14 with two desiccant canisters	59572-740-14	59572-0740-14

*Blister cards will be replacing bottles. Bottles will be phased out over the course of 2021. Blister cards are available as of March 8, 2021. There will be no supply disruptions during the transition from bottles to blister cards.
[a]Payer requirements regarding the use of NDCs may vary. Electronic data exchange generally requires use of the 11-digit NDC.

The information contained herein is not intended to provide specific coding and reimbursement advice for any specific patient or situation. You should check with your coding specialist to ensure appropriate submissions.

Abbreviations: AML, acute myeloid leukemia; ICD-10, *International Classification of Diseases*, Tenth Revision, Clinical Modification.

Please see Important Safety Information on page 5 and full Prescribing Information.

Product 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.

HOW SUPPLIED

- 200 mg: pink, oval, film-coated tablets with debossed "200" on one side and "ONU" on the other side
- 300 mg: brown, oval, film-coated tablets with debossed "300" on one side and "ONU" on the other side

STORAGE

Store blisters at 20°C to 25°C (68°F to 77°F)

- Excursions permitted between 15°C to 30°C (59°F to 86°F)
- Store in the original aluminum-aluminum blisters

Store bottles at 20°C to 25°C (68°F to 77°F)

- Excursions permitted between 15°C to 30°C (59°F to 86°F)
- Keep bottle tightly closed
- Store and dispense in the original bottle (with 2 desiccant canisters)
- Advise patients to keep the container tightly closed with both desiccant canisters inside and to not eat the desiccant canisters

CELGENE ONUREG® 200MG 7-TABLET RETURN PROGRAM

This program expires April 30, 2021. For more information, click here.

HANDLING AND DISPOSAL

ONUREG® is a hazardous drug. Follow applicable special handling and disposal procedures.* If powder comes in contact with skin, immediately and thoroughly wash with soap and water. If powder comes in contact with mucous membranes, immediately flush the area with water.

Selected Important Safety Information

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.

*Occupational Safety and Health Administration (OSHA). *OSHA Hazardous Drugs*. http://www.osha.gov/SLTC/hazardousdrugs/index.html.

Please see Important Safety Information on page 5 and full Prescribing Information.

Bristol Myers Squibb™

Access Support®

Three Simple Ways to Get Support

Contact your **Access & Reimbursement Manager** for general assistance and to schedule an office visit

Call Bristol Myers Squibb Access Support® at **1-800-861-0048**, 8 AM to 8 PM ET, Monday-Friday, to speak with a regionally assigned specialist

Visit **www.BMSAccessSupport.com** for information and resources, including the enrollment form, to help your patients with access to Bristol Myers Squibb products

Bristol Myers Squibb is committed to helping appropriate patients get access to our medications by providing access and reimbursement support services.

Indication

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Important Safety Information

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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 full Prescribing Information for ONUREG®.

Bristol Myers Squibb™

03/21 US-ONU-21-0066

ONUREG™ (azacitidine) tablets 300 mg • 200 mg