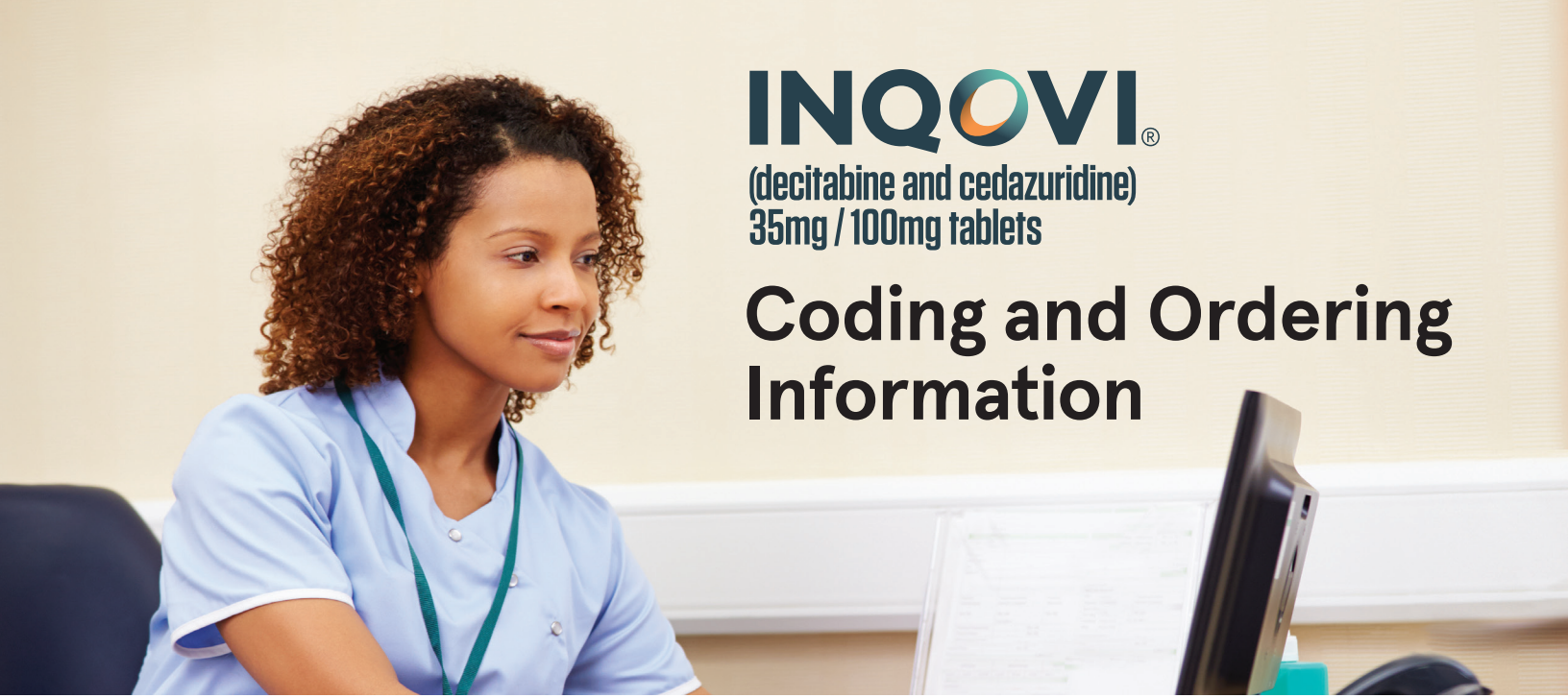

INQOVI®

(decitabine and cedazuridine)
35mg / 100mg tablets

Coding and Ordering Information

TaihoPatientSupport.com 1-844-TAIHO-4U (1-844-824-4648)

INDICATIONS

INQOVI is indicated for treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Myelosuppression

Fatal and serious myelosuppression can occur with INQOVI. Based on laboratory values, new or worsening thrombocytopenia occurred in 82% of patients, with Grade 3 or 4 occurring in 76%. Neutropenia occurred in 73% of patients, with Grade 3 or 4 occurring in 71%. Anemia occurred in 71% of patients, with Grade 3 or 4 occurring in 55%. Febrile neutropenia occurred in 33% of patients, with Grade 3 or 4 occurring in 32%.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION THROUGHOUT AND FULL PRESCRIBING INFORMATION.

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Diagnosis Codes for Myelodysplastic Syndromes

ICD-10-CM	Description
D46.0	Refractory anemia without ring sideroblasts, so stated Refractory anemia without sideroblasts, without excess of blasts
D46.1	Refractory anemia with ring sideroblasts (RARS)
D46.2	Refractory anemia with excess of blasts (RAEB)
D46.4	Refractory anemia, unspecified
D46.9	Myelodysplastic syndrome, unspecified Myelodysplasia NOS
D46.20	Refractory anemia with excess of blasts, unspecified (RAEB NOS)
D46.21	Refractory anemia with excess of blasts 1 (RAEB 1)
D46.22	Refractory anemia with excess of blasts 2 (RAEB 2)
D46.A	Refractory cytopenia with multilineage dysplasia
D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts (RCMD RS)
D46.C	Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality Myelodysplastic syndrome with 5q deletion 5q minus syndrome NOS
D46.Z	Other myelodysplastic syndromes (EXCLUDES chronic myelomonocytic leukemia [C93.1])

AAPC. ICD-10-CM Expert 2020 for Providers & Facilities. American Academy of Professional Coders; 2020:505.

This information is not intended as coverage or coding advice and does not guarantee reimbursement. You should verify the appropriate reimbursement information for services or items you provide. Each health care professional is responsible for ensuring all coding is accurate and appropriate.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Myelosuppression (thrombocytopenia, neutropenia, anemia, and febrile neutropenia) is the most frequent cause of INQOVI dose reduction or interruption, occurring in 36% of patients. Permanent discontinuation due to myelosuppression (febrile neutropenia) occurred in 1% of patients. Myelosuppression and worsening neutropenia may occur more frequently in the first or second treatment cycles and may not necessarily indicate progression of underlying MDS.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION THROUGHOUT AND FULL PRESCRIBING INFORMATION.

Diagnosis Codes for Chronic Myelomonocytic Leukemia

ICD-10-CM	Description
C93.1	Chronic myelomonocytic leukemia Chronic monocytic leukemia CMML-1 CMML-2 CMML with eosinophilia
C93.10	Chronic myelomonocytic leukemia not having achieved remission Chronic myelomonocytic leukemia with failed remission Chronic myelomonocytic leukemia NOS
C93.11	Chronic myelomonocytic leukemia, in remission
C93.12	Chronic myelomonocytic leukemia, in relapse

AAPC. *ICD-10-CM Expert 2020 for Providers & Facilities.* American Academy of Professional Coders; 2020:494.

This information is not intended as coverage or coding advice and does not guarantee reimbursement. You should verify the appropriate reimbursement information for services or items you provide. Each health care professional is responsible for ensuring all coding is accurate and appropriate.

Formulation	Packaging	NDC (11-digit format)[a]
35 mg decitabine and 100 mg cedazuridine	5-tablet blister pack	64842-0727-**0**9

[a]The **red zero** converts the 10-digit NDC to the 11-digit NDC. Payer requirements regarding the use of NDCs may vary. Electronic data exchange generally requires use of the 11-digit NDC.

Please contact an authorized distributor or one of the specialty pharmacies listed on next page for the average wholesale price (AWP) and wholesale acquisition cost (WAC) pricing.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Fatal and serious infectious complications can occur with INQOVI. Pneumonia occurred in 21% of patients, with Grade 3 or 4 occurring in 15%. Sepsis occurred in 14% of patients, with Grade 3 or 4 occurring in 11%. Fatal pneumonia occurred in 1% of patients, fatal sepsis in 1%, and fatal septic shock in 1%.

Obtain complete blood cell counts prior to initiation of INQOVI, prior to each cycle, and as clinically indicated to monitor response and toxicity. Administer growth factors and anti-infective therapies for treatment or prophylaxis as appropriate. Delay the next cycle and resume at the same or reduced dose as recommended.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION THROUGHOUT AND FULL PRESCRIBING INFORMATION.

Specialty Distributors Authorized to Supply INQOVI to Your On-Site Dispensing Practice

Specialty Distributor	Website	Telephone	Fax
AmerisourceBergen Oncology Supply	www.oncologysupply.com	(800) 633-7555	(800) 248-8205
AmerisourceBergen Specialty Distribution	www.asdhealthcare.com	(800) 746-6273	(800) 547-9413
Cardinal Health SPD Hospital	orderexpress.cardinalhealth.com	(855) 855-0708	(614) 553-6301
Cardinal Health SPD Physician Office and Clinic	specialtyonline.cardinalhealth.com	(877) 453-3972	(877) 274-9897
McKesson Plasma and Biologics	connect.mckesson.com	(877) 625-2566	(888) 752-7626
McKesson Specialty Health	mscs.mckesson.com	(800) 482-6700	(800) 289-9285
McKesson Specialty Health – Practices in The US Oncology Network	mscs.mckesson.com	(833) 726-8766	(800) 289-9285

Specialty Pharmacies Authorized to Dispense INQOVI to Your Patients

Specialty Pharmacy	Website	Telephone	Fax
Accredo	www.accredo.com	(877) 732-3431	(888) 302-1028
AllianceRx Walgreens Pharmacy	www.alliancerxwp.com	(888) 347-3416	(877) 231-8302
Biologics by McKesson	biologics.mckesson.com	(800) 850-4306	(800) 823-4506
CVS Specialty	www.cvsspecialty.com	(855) 539-4712	(888) 435-1256
Onco360	www.onco360.com	(877) 662-6633	(877) 662-6355
Optum Specialty Pharmacy	specialty.optumrx.com	(877) 445-6874	(877) 342-4596

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Embryo-Fetal Toxicity

INQOVI can cause fetal harm. Advise pregnant women of the potential risk to a fetus. Advise patients to use effective contraception during treatment and for 6 months (females) or 3 months (males) after last dose.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION THROUGHOUT AND FULL PRESCRIBING INFORMATION.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

Serious adverse reactions in > 5% of patients included febrile neutropenia (30%), pneumonia (14%), and sepsis (13%). Fatal adverse reactions included sepsis (1%), septic shock (1%), pneumonia (1%), respiratory failure (1%), and one case each of cerebral hemorrhage and sudden death.

The most common adverse reactions (≥ 20%) were fatigue (55%), constipation (44%), hemorrhage (43%), myalgia (42%), mucositis (41%), arthralgia (40%), nausea (40%), dyspnea (38%), diarrhea (37%), rash (33%), dizziness (33%), febrile neutropenia (33%), edema (30%), headache (30%), cough (28%), decreased appetite (24%), upper respiratory tract infection (23%), pneumonia (21%), and transaminase increased (21%). The most common Grade 3 or 4 laboratory abnormalities (≥ 50%) were leukocytes decreased (81%), platelet count decreased (76%), neutrophil count decreased (71%), and hemoglobin decreased (55%).

USE IN SPECIFIC POPULATIONS

Lactation
Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment with INQOVI and for 2 weeks after the last dose.

Renal Impairment
No dosage modification of INQOVI is recommended for patients with mild or moderate renal impairment (creatinine clearance [CLcr] of 30 to 89 mL/min based on Cockcroft-Gault). Due to the potential for increased adverse reactions, monitor patients with moderate renal impairment (CLcr 30 to 59 mL/min) frequently for adverse reactions. INQOVI has not been studied in patients with severe renal impairment (CLcr 15 to 29 mL/min) or end-stage renal disease (ESRD: CLcr <15 mL/min).

PLEASE SEE FULL PRESCRIBING INFORMATION.

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Visit Taiho Oncology Patient Support at
www.TaihoPatientSupport.com

For information regarding INQOVI access and reimbursement, please contact Taiho Oncology Patient Support™

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