



**TAIHO ONCOLOGY
PATIENT SUPPORT**

A partner in your cancer care.

NOW AVAILABLE

INQOVI®

(decitabine and cedazuridine) tablets

The first and only orally administered hypomethylating agent (HMA) for intermediate and high-risk myelodysplastic syndromes (MDS) and chronic myelomonocytic leukemia (CMML)

Please see below for Indications and Important Safety Information.

Dear State Society Member,

Taiho Oncology is excited to share that INQOVI, an orally administered hypomethylating agent (HMA), approved in July 2020, (<https://www.taihooncology.com/us/news/2020-07-ingovi-approval/>) is now available via the following distributors and specialty pharmacies:

SPECIALTY DISTRIBUTOR

ASD Healthcare
www.asdhealthcare.com
(800) 746-6273
(800) 547-9413

Cardinal Health SPD Hospital
orderexpress.cardinalhealth.com
(866) 677-4844
(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

Oncology Supply
www.oncologysupply.com
(800) 633-7555
(800) 248-8205

SPECIALTY PHARMACY

Accredo Specialty Pharmacy
www.accredo.com
(877) 732-3431
(888) 302-1028

Avella Specialty Pharmacy
www.avella.com
(877) 546-5779
(877) 546-5780

Biologics, Inc.
biologics.mckesson.com
(800) 850-4306
(800) 823-4506

CVS Specialty Pharmacy
www.cvsspecialty.com
(800) 237-2767
(800) 323-2445

Onco360 Oncology Pharmacy
www.onco360.com
(877) 662-6633
(877) 662-6355

Walgreens Specialty Pharmacy
www.walgreenshealth.com
(888) 347-3416
(877) 231-8302

Now, adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS of all French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups can take an oral HMA at home, reducing the need for frequent office visits to receive intravenous (IV) therapy.

INQOVI is a fixed-dose combination tablet containing 35 mg of decitabine and 100 mg of cedazuridine that patients take once a day, on days 1 through 5 of each 28-day cycle, for a minimum of 4 cycles.

INQOVI access and reimbursement support is available at:

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

► INSURANCE COVERAGE SUPPORT

Specialty Pharmacy Prescription Coordination | Personalized Nurse Support | Financial Support

► TAIHO ONCOLOGY CO-PAY ASSISTANCE PROGRAM

Eligible patients may pay \$0 per treatment cycle

► FULL PRESCRIBING INFORMATION

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%.

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.

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.

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, constipation, hemorrhage, myalgia, mucositis, arthralgia, nausea, dyspnea, diarrhea, rash, dizziness, febrile neutropenia, edema, headache, cough, decreased appetite, upper respiratory tract infection, pneumonia, and transaminase increased. The most common Grade 3 or 4 laboratory abnormalities (≥ 50%) were leukocytes decreased, platelet count decreased, neutrophil count decreased, and hemoglobin decreased.

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 at least 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).



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