INQOVI®
(decitabine and cedazuridine)
35mg / 100mg tablets

VETERANS ADMINISTRATION AND TRICARE STATUS

VA: Approved, Non-Formulary, Prescriptions Permitted With Criteria for Use[a]

TRICARE: Approved on the TRICARE Uniform Formulary With Prior Authorization Required[b]

INQOVI is the only oral hypomethylating agent (HMA) for the treatment of myelodysplastic syndromes (MDS) and CMML[1]

All other outcomes being similar, **77%** of patients with MDS said they would switch to an oral pill if available to them when offered alongside other options, according to an HMA treatment preference study.[2,c,d]

INQOVI contains 35 mg of decitabine and 100 mg of cedazuridine.[1]

28-day dosing cycle[1]

Week 1	Take 1 tablet once daily for 5 days	2 days rest
Week 2	Rest	
Week 3	Rest	
Week 4	Rest	

Do **NOT** substitute INQOVI for an IV decitabine product **within a cycle**.[1]

AML=acute myeloid leukemia; CFU=criteria for use; CMML=chronic myelomonocytic leukemia; IV=intravenous; VA=Veterans Affairs.

[a]VA CFU form available at va.gov/formularyadvisor.
[b]Prior Authorization form for INQOVI available at tricare.mil/formulary.
[c]When HMA treatments were assumed to be associated with the same risk of AML and level of fatigue but to differ in terms of mode and frequency administration.[2]
[d]A preference study was conducted using the discrete-choice experiment method in collaboration with patient organizations to understand HMA preferences for United States and Canadian patients with MDS. Eligibility included being an MDS patient or a caregiver of a patient with MDS and being 18 years of age or older. The study was comprised of two Phases. Phase 1 was qualitative and included a literature review, interviews with clinicians, patients, and caregivers, and input from patient organizations. Phase 2 was quantitative, during which survey participants indicated their preference between different hypothetical HMA profiles that varied in attributes. Sixteen participants completed Phase 1, and 184 (158 patients and 26 caregivers) completed Phase 2.[2]

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.

TAIHO ONCOLOGY

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS

Myelosuppression

Fatal and serious myelosuppression can occur with INQOVI. Based on laboratory values, new or worsening

Please see additional Important Safety Information on other side and full Prescribing Information at INQOVI.com/PI.

FEDERAL PRODUCT PORTFOLIO RESOURCES

Looking for more information?

Email FederalAccounts@taihooncology.com

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Myelosuppression (cont'd)

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%. 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.

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 (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 at INQOVI.com/PI.

References: 1. INQOVI. Prescribing Information. Taiho Oncology, Inc; 2022. **2.** Zeidan AM, Tsai JH, Karimi M, et al. Understanding what matters to myelodysplastic syndrome patients–a study of preferences for treatments with hypomethylating agents. Poster presented at: ASH (American Society of Hematology) Annual Meeting 2022; December 10-13, 2022; New Orleans, Louisiana.

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