Conversation handbook for nurses

Treatment at home with INQOVI

INQOVI® (decitabine and cedazuridine) tablets is the **only** oral hypomethylating agent (HMA) for the treatment of myelodysplastic syndromes (MDS) and CMML. Appropriate patients can take their therapy in the convenience and comfort of their own home.[1]

CMML=chronic myelomonocytic leukemia.

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.

SELECTED 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%. 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 Important Safety Information throughout and full Prescribing Information at INQOVI.com/PI.

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

Make the most of your conversations with patients with MDS

If you have patients who have been diagnosed with MDS, they may have questions about their disease and treatment. Patients with MDS are often treated with hypomethylating agents (HMAs). INQOVI® (decitabine and cedazuridine) tablets is the first and only combination oral HMA therapy approved by the FDA for the treatment of MDS and CMML.[1]

Whether you're already familiar with using HMAs or are about to prescribe INQOVI for the first time, here are some key points to get the conversation started with patients and their caregivers. It's important to help alleviate their concerns and to make them feel more informed and empowered.

Patients who may be appropriate for INQOVI[1]

- Have been diagnosed with de novo or secondary MDS and CMML
- Are classified as intermediate- or high-risk MDS
- Have not received prior treatment or have previously been treated

Additional patient considerations[1]:

- Wish to take their HMA therapy in the comfort of their own home
- Unable to have, or do not wish to have, infusion port placement
- Dos not have regular support to manage travel to the infusion center

Important topics to cover in your conversation with patients

SELECTED IMPORTANT SAFETY INFORMATION

Myelosuppression (continued)
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%.

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Common Patient Questions

Here are some questions patients and their caregivers might have about MDS and treating MDS with INQOVI. If these topics don't come up in conversation, feel free to address them to ensure that patients are well informed.

What is MDS?

MDS refers to a group of conditions, sometimes called bone marrow failure disorders, that can lead to abnormalities in the blood. MDS occurs when bone marrow produces fewer healthy blood cells that work properly.[2]

How is MDS treated?

Patients with MDS and CMML often receive blood transfusions. Some patients will also require treatment with HMAs.

HMAs are a type of chemotherapy that has been shown to improve blood counts in patients with MDS and CMML. This can lessen the need for blood transfusions.[3,4]

Treatment with HMAs often requires travel to and from chemotherapy infusion centers or hospitals for intravenous (IV) infusions or subcutaneous injections.[5,6]

Why should I consider taking an oral HMA?

Oral treatment can be taken in the comfort of your own home and does not require travel to and from chemotherapy infusion centers or hospitals for IV infusions or subcutaneous injections. Since these visits are often long and frequent, think about the time you'll save in your daily life.[5,6]

Oral treatment also does not require venous access and parenteral administration.[7,8]

SELECTED IMPORTANT SAFETY INFORMATION

Myelosuppression (continued)
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.

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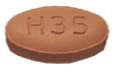
Common Patient Questions (continued)

What is INQOVI?

INQOVI® (decitabine and cedazuridine) tablets are a prescription medicine used to treat adults with certain types of MDS and CMML.[1]



INQOVI is an oral combination pill made of decitabine and cedazuridine. Decitabine has been used to treat MDS for many years, but was previously only available as an IV infusion. Cedazuridine is an ingredient that allows INQOVI to be taken by mouth.[1,9]

How effective is INQOVI?

In clinical trials, INQOVI was shown to be effective in some patients with MDS or CMML. In a trial of 133 people,

21% of patients achieved a **complete response**.[1]

Of the 57 people who needed blood infusions before starting the trial,

53% **no longer required blood transfusions** after treatment with INQOVI.[1]

Complete response=means there is no evidence of the signs and symptoms of MDS.[2]
In this trial, blood transfusions could mean either red blood cell or platelet transfusions.
Patients who did not need blood transfusions were able to go without a transfusion for 56 days.[1]

SELECTED IMPORTANT SAFETY INFORMATION

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.

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Common Patient Questions (continued)

What are some things I need to remember about taking INQOVI?

DO[1]

- Take INQOVI exactly as instructed
- Take it once a day at about the same time each day
- Take INQOVI on an empty stomach
- Swallow INQOVI tablets whole
- If you miss your dose, take it within 12 hours of your usual time
- If you miss a dose by more than 12 hours, take your next dose at the usual time the following day

DO NOT[1]

- Do not change your dose or stop taking INQOVI unless instructed to do so
- Do not eat for at least 2 hours before and 2 hours after taking INQOVI
- Do not cut, crush, or chew the tablet
- Do not take a dose missed by more than 12 hours
- Do not take an additional dose after vomiting a dose

How should I take INQOVI?

Take 1 tablet, by mouth, once a day, at approximately the same time for the first 5 days of each 28-day cycle, for a minimum of 4 cycles. This means that after days 1 through 5 of treatment, you do not need to take INQOVI for the next 23 days.[1]

28-day dosing cycle

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

SELECTED IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS (continued)

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%).

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Common Patient Questions (continued)

What are the common side effects of INQOVI?

You may experience side effects while taking INQOVI. Serious side effects, such as low blood cell counts, may occur. Low blood counts are common with INQOVI but can also be serious and can lead to infections that may be life-threatening. Blood tests will be taken before each cycle of INQOVI to monitor your blood counts and to check for side effects.[1]

The most common side effects of INQOVI include[1]:

- low white blood cell count (leukopenia)
- low platelets in your blood (thrombocytopenia)
- low white blood cell count (neutropenia)
- low red blood cell count (anemia)
- tiredness
- constipation
- bleeding
- muscle pain
- pain or sores in your mouth or throat
- joint pain
- nausea
- shortness of breath
- diarrhea
- rash
- dizziness
- fever with low white blood cell count (febrile neutropenia)
- swelling of arms or legs
- headache
- cough
- decreased appetite
- upper respiratory tract infection
- pneumonia
- changes in liver function tests

Always call the office to discuss any side effects you may experience.

INQOVI may cause serious side effects, including:

Low blood cell counts. Low blood counts (white blood cells, platelets, and red blood cells) are common with INQOVI but can also be serious and lead to infections that may be life-threatening. If your blood cell counts are too low, your healthcare provider may need to delay treatment with INQOVI, lower your dose of INQOVI, or in some cases give you a medicine to help treat low blood cell counts. Your healthcare provider may need to give you antibiotic medicines to prevent or treat infections or fever while your blood cell counts are low. Your healthcare provider will check your blood cell counts before you start treatment and regularly during treatment with INQOVI.

Call your healthcare provider right away if you get any of the following signs and symptoms of infection during treatment with INQOVI:

- fever
- chills
- body aches
- bruising more easily than usual

SELECTED IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS (continued)

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%).

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Taiho Oncology Patient Support™

Taiho Oncology Patient Support™ offers personalized services to help give patients, caregivers, and healthcare professionals access to Taiho Oncology products. This includes insurance coverage determination and help with medication affordability.

Getting patients access to their medicine is an important step. There is an easy enrollment form for the Co-Pay Assistance Program available online at TaihoPatientSupport.com.

TAIHO ONCOLOGY PATIENT SUPPORT
Supporting your treatment journey

Taiho Oncology Patient Support can assist with the following:

Insurance Coverage Support*
- Benefits investigation and prior authorization assistance
- Appeals assistance
- $0 Co-pay program enrollment for commercially insured patients

Specialty Pharmacy Prescription Coordination
- Prescriptions will be triaged to the in-network specialty pharmacy, self-dispensing practice, or hospital outpatient pharmacy

Personalized Nurse Support†
- Nurse support services are available to aid patient education and adherence

For more information on these services visit TaihoPatientSupport.com

*Visit TaihoPatientSupport.com to see full eligibility criteria.
†If selected on the Patient Enrollment Form, a Nurse Navigator will be assigned to provide telephone support and will address general inquiries about INQOVI treatment.

For questions about treatment with INQOVI, call **1-844-TAIHO-4U** (1-844-824-4648) or visit INQOVI.com.

SELECTED IMPORTANT SAFETY INFORMATION

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.

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Taiho Oncology provides useful tools to help patients in their treatment journey

Download these helpful INQOVI resources:

- Patient Brochure
- Caregiver Brochure

Review a comprehensive list of Advocacy Groups:

- Contact them for free resources and support
- Download the Advocacy Brochure for your easy reference

Get Cost Assistance:

- Learn about the Co-Pay Assistance Program
- Download the Enrollment Form in English and Spanish

To download these resources, visit INQOVI.com/PatientResources.

IMPORTANT SELECTED SAFETY INFORMATION

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).

References: 1. INQOVI [package insert]. Princeton, NJ: Taiho Oncology, Inc.; 2020. **2.** Kurtin S. Building blocks of hope. MDS Foundation website. https://www.mds-foundation.org/wp-content/uploads/2017/09/BBOH_Handbook_A4_Aus_16-9.21.17.pdf. Accessed December 2, 2022. **3.** General approach to treatment of myelodysplastic syndromes. American Cancer Society website. https://www.cancer.org/cancer/myelodysplastic-syndrome/treating/general-approach.html. Updated January 22, 2018. Accessed December 2, 2022. **4.** Frequently asked questions. MDS Foundation website. https://www.mds-foundation.org/faqs/. Accessed December 2, 2022. **5.** Savona MR, Odenike O, Amrein PC, et al. An oral fixed-dose combination of decitabine and cedazuridine in myelodysplastic syndromes: a multicentre, open-label, dose-escalation, phase 1 study. *Lancet Haematol*. 2019;6(4):e194-e203. doi:10.1016/S2352-3026(19)30030-4. **6.** Vidaza [package insert]. Summit, NJ: Celgene Corporation; 2020. **7.** Steensma DP, Komrokji RS, Stone RM, et al. Disparity in perceptions of disease characteristics, treatment effectiveness, and factors influencing treatment adherence between physicians and patients with myelodysplastic syndromes. *Cancer*. 2014;120(11):1670-1676. **8.** Leveque D. Subcutaneous administration of anticancer agents. *Anticancer Research*. 2014;34:1579-1586. **9.** Dacogen [package insert]. Dublin, CA: Astex Pharmaceuticals, Inc.; 2018.

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