

There's no place like home

INQOVI® (decitabine and cedazuridine) tablets—**THE ONLY** oral hypomethylating agent (HMA) for the treatment of myelodysplastic syndromes (MDS), including CMML. With INQOVI, patients can take their therapy in the convenience and comfort of their own home or wherever they are.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 on pages 18–19 and full Prescribing Information in pocket or at [INQOVI.com/PI](https://www.inqovi.com/PI).

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



INQOVI is a fixed-dose combination tablet containing decitabine (35 mg) and cedazuridine (100 mg), a cytidine deaminase inhibitor that limits breakdown in the gut and therefore enhances oral bioavailability of decitabine and increases its systemic exposure.¹

ASCERTAIN trial design

The phase 3 crossover trial was designed to assess systemic decitabine exposure, demethylation activity, and safety between IV decitabine and INQOVI® (decitabine and cedazuridine) tablets. The trial allowed for inpatient comparison in the first 2 randomized treatment cycles, and then assessment of the long-term efficacy and safety of INQOVI as a single arm.^{1,2}

Phase 3 ¹ N=133	
Primary endpoint	5-day area under the curve (AUC) between INQOVI and IV decitabine
Secondary endpoints	Complete response
	Rate of conversion from transfusion dependence to transfusion independence
Other results	Median duration of treatment: 8.2 months (range: 0.2-19.7)
	Median follow-up time: 12.6 months (range: 9.3-20.5)

AUC=area under the curve; IV=intravenous.

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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%.

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.

Phase 3 crossover design¹



Open-label, randomized, 2-cycle, 2-sequence, crossover clinical trial in treatment-experienced or -naïve patients with MDS, including CMML (International Prognostic Scoring System [IPSS] intermediate-1, -2, or high-risk).¹

- Patients were allowed to have 1 prior cycle of decitabine or azacitidine, and there was no limit for body weight or surface area
- Patients were randomized 1:1 to INQOVI (decitabine 35 mg/cedazuridine 100 mg) or IV decitabine 20 mg/m² daily from day 1 through day 5 of each 28-day cycle
- Patients received one agent in cycle 1 and then crossed over to receive the other agent in cycle 2
- All patients received INQOVI after cycle 2, and treatment continued until disease progression or unacceptable toxicity
- In the pooled safety population of phases 2 and 3, 61% of patients receiving INQOVI were exposed for ≥6 months and 24% were exposed for >1 year

The only oral HMA with equivalent systemic exposure to IV decitabine¹

Primary endpoint results

99% ratio of oral to IV 5-day decitabine AUC (90% CI: 93, 106)

- This ratio is the geometric mean of the 5-day cumulative decitabine AUC between INQOVI® (decitabine and cedazuridine) tablets and IV-administered decitabine when administered once daily for 5 consecutive days

Efficacy results in patients with MDS or CMML in phase 3 crossover trial (N=133)

21% of patients achieved a complete response (CR) (95% CI: 15, 29)

4.3 MONTHS

median time to CR
(range: 2.1-15.2)

7.5 MONTHS

median duration of CR*
(range: 1.6-17.5)

*From start of CR until relapse or death.
CI=confidence interval.

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.

Transfusion independence¹

53% of the patients treated with INQOVI who were initially transfusion dependent achieved posttreatment RBC and platelet transfusion independence (30/57)[†]

63% of patients who initially were both RBC and platelet transfusion independent remained transfusion independent (48/76)[†]

[†]During any consecutive 56-day postbaseline period.
RBC=red blood cell.

After taking INQOVI, 20% (27/133) of patients went on to receive stem cell transplantation.¹

SELECTED IMPORTANT SAFETY INFORMATION

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.

Baseline patient characteristics¹

Characteristic	Phase 3 overall All cycles (N=133)
Age (years)	
Median (min, max)	71 (44, 88)
Sex	
Male	65%
Female	35%
Race	
White	91%
Black or African-American	3%
Asian	2%
Other or not reported	4%
ECOG performance score	
0	41%
1	59%
2	0
Disease category/IPSS	
MDS intermediate-1 risk	44%
MDS intermediate-2 risk	20%
MDS high risk	16%
MDS low risk	8%
CMML	12%
Prior HMA therapy ^a	
Prior azacitidine	5%
Prior decitabine	3%
Transfusion dependence ^b	
RBC transfusion dependence	39%
Platelet transfusion dependence	8%

^aOne cycle only, per the exclusion criteria.
^bDefined as documentation of ≥2 units of transfusion within 56 days of the first day of study treatment.
ECOG=Eastern Cooperative Oncology Group.

Safety profile similar to IV decitabine¹

Adverse reactions reported in ≥10% of patients in the pooled phase 2 and phase 3 safety population

Adverse reactions ^a	INQOVI cycle 1 n=107		IV decitabine cycle 1 n=106		INQOVI all cycles n=208 ^c	
	All grades (%)	Grades 3-4 (%)	All grades (%)	Grades 3-4 (%)	All grades (%)	Grades 3-4 (%)
General disorders and administration site conditions						
Fatigue ^b	29	2	25	0	55	5
Hemorrhage ^b	24	2	17	0	43	3
Edema ^b	10	0	11	0	30	0.5
Pyrexia	7	0	7	0	19	1
Gastrointestinal disorders						
Constipation ^b	20	0	23	0	44	0
Mucositis ^b	18	1	24	2	41	4
Nausea	25	0	16	0	40	0.5
Diarrhea ^b	16	0	11	0	37	1
Transaminase increased ^b	12	1	3	0	21	3
Abdominal pain ^b	9	0	7	0	19	1
Vomiting	5	0	5	0	15	0
Musculoskeletal and connective tissue disorders						
Myalgia ^b	9	2	16	1	42	3
Arthralgia ^b	9	1	13	1	40	3
Respiratory, thoracic, and mediastinal disorders						
Dyspnea ^b	17	3	9	3	38	6
Cough ^b	7	0	8	0	28	0
Blood and lymphatic system disorders						
Febrile neutropenia	10	10	13	13	33	32
Skin and subcutaneous tissue disorders						
Rash ^b	12	1	11	1	33	0.5

^aPlease see full Prescribing Information for complete list of adverse events occurring during all cycles.
^bIncludes multiple adverse reaction terms.
^cIncludes adverse reactions that occurred during all cycles, including during treatment with 1 cycle of IV decitabine.

Safety profile similar to IV decitabine¹ (continued)

Adverse reactions reported in ≥10% of patients in the pooled phase 2 and phase 3 safety population (cont'd)

Adverse reactions ^a	INQOVI cycle 1 n=107		IV decitabine cycle 1 n=106		INQOVI all cycles n=208 ^c	
	All grades (%)	Grades 3-4 (%)	All grades (%)	Grades 3-4 (%)	All grades (%)	Grades 3-4 (%)
Nervous system disorders						
Dizziness ^b	16	1	11	0	33	2
Headache ^b	22	0	13	0	30	0
Neuropathy ^b	4	0	8	0	13	0
Metabolism and nutritional disorders						
Decreased appetite	10	1	6	0	24	2
Infections and infestations						
Upper respiratory tract infection ^b	6	0	3	0	23	1
Pneumonia ^b	7	7	7	5	21	15
Sepsis ^b	6	6	2	1	14	11
Cellulitis ^b	4	1	3	2	12	5
Investigations						
Renal impairment ^b	9	0	8	1	18	0
Weight decreased	5	0	3	0	10	1
Injury, poisoning, and procedural complications						
Fall	4	0	1	0	12	1

^aPlease see full Prescribing Information for complete list of adverse events occurring during all cycles.
^bIncludes multiple adverse reaction terms.
^cIncludes adverse reactions that occurred during all cycles, including during treatment with 1 cycle of IV decitabine.

Adverse reactions reported in ≥10% of patients in the pooled phase 2 and phase 3 safety population (cont'd)

Adverse reactions ^a	INQOVI cycle 1 n=107		IV decitabine cycle 1 n=106		INQOVI all cycles n=208 ^c	
	All grades (%)	Grades 3-4 (%)	All grades (%)	Grades 3-4 (%)	All grades (%)	Grades 3-4 (%)
Psychiatric disorders						
Insomnia	6	0	2	0	12	0.5
Vascular disorders						
Hypotension ^b	4	0	6	1	11	2
Cardiac disorders						
Arrhythmia ^b	3	0	2	0	11	1

^aPlease see full Prescribing Information for complete list of adverse events occurring during all cycles.
^bIncludes multiple adverse reaction terms.
^cIncludes adverse reactions that occurred during all cycles, including during treatment with 1 cycle of IV decitabine.

- No unexpected adverse reactions reported in the first 2 cycles
- Incidence of cytopenias was slightly higher in INQOVI[®] (decitabine and cedazuridine) tablets during cycle 1 compared to IV decitabine

Select hematologic lab abnormalities¹

>20% in the pooled safety population

Lab parameter ^a	INQOVI cycle 1 ^b		IV decitabine cycle 1 ^b		INQOVI all cycles ^b	
	All grades (%)	Grades 3-4 (%)	All grades (%)	Grades 3-4 (%)	All grades (%)	Grades 3-4 (%)
Hematology						
Leukocytes decreased	79	65	77	59	87	81
Platelet count decreased	79	65	77	67	82	76
Neutrophil count decreased	70	65	62	59	73	71
Hemoglobin decreased	58	41	59	36	71	55

^aIncludes any lab abnormalities that worsened by ≥1 grades. Grades 3 to 4 include any lab abnormalities that worsened to grade 3 or grade 4.
^bThe denominator used to calculate the rate varied from 103 to 107 for INQOVI® (decitabine and cedazuridine) tablets cycle 1, from 102 to 106 for the IV decitabine cycle, and from 203 to 208 for INQOVI (all cycles) based on the number of patients with a baseline value and ≥1 posttreatment value.

Please see full Prescribing Information for chemistry lab safety parameters.

Discontinuation rate

- **5% of patients discontinued** treatment with INQOVI due to an adverse reaction
- The most frequent adverse reactions resulting in permanent discontinuation were febrile neutropenia (1%) and pneumonia (1%)


Additional safety profile information

- **Clinically relevant adverse reactions** in <10% of patients who received INQOVI included: acute febrile neutrophilic dermatosis (Sweet’s syndrome) (1%) and tumor lysis syndrome (0.5%)
- **Serious adverse reactions** occurred in 68% of patients who received INQOVI. Serious adverse reactions in >5% of patients included febrile neutropenia (30%), pneumonia (14%), and sepsis (13%)
- **Fatal adverse reactions** occurred in 6% of patients, and included sepsis (1%), pneumonia (1%), respiratory failure (1%), septic shock (1%), and 1 case each of cerebral hemorrhage and sudden death
- **Dose interruptions** due to an adverse reaction occurred in 41% of patients who received INQOVI. Adverse reactions requiring dosage interruptions in >5% of patients who received INQOVI included neutropenia (18%), febrile neutropenia (8%), thrombocytopenia (6%), and anemia (5%)
- **Dose reductions** due to an adverse reaction occurred in 19% of patients who received INQOVI. Adverse reactions requiring dosage reductions in >2% of patients who received INQOVI included neutropenia (12%), anemia (3%), and thrombocytopenia (3%)

THE ONLY oral HMA for MDS, including CMML, that
Patients can take from the convenience of home¹

Oral dosing

- 1 tablet, once a day for 5 days per 28-day cycle
- Fixed-dose combination tablet containing decitabine (35 mg) and cedazuridine (100 mg)
- It is important to remind patients that response to INQOVI® (decitabine and cedazuridine) tablets may not be immediate. Premature discontinuation can limit therapeutic benefits that would otherwise have been reached³
- A complete or partial response may take longer than 4 cycles

 Tablet shown is not actual size. Actual tablet size is 7.94 mm x 14.29 mm.

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%). 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%).

Important dosing reminders

- Patients should avoid eating for 2 hours before and 2 hours after taking INQOVI
- Tablets must be swallowed whole—not cut, crushed, or chewed
- Consider administering antiemetics prior to each dose to minimize nausea and vomiting
- Do NOT substitute INQOVI for an IV decitabine product within a cycle
- Patients should take INQOVI at the same time each day

Storage and handling with INQOVI

- Store INQOVI tablets in original packaging at room temperature at 20°C to 25°C (68°F to 77°F); excursions permitted from 15°C to 30°C (59°F to 86°F)

DosePak is 7.35 in x 2.45 in.



Additional health resources

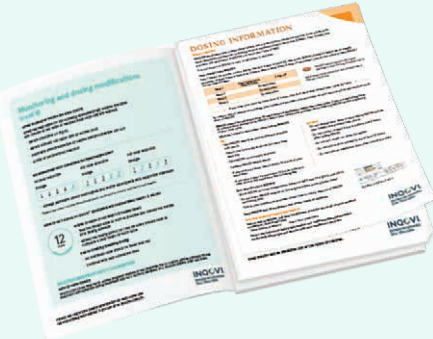
- Health Journal

A place for patients and caregivers to keep track of their dosing schedule, make note of any side effects, and jot down anything they want to discuss with their healthcare provider.



- Dosing Tear Pad

A tool to help ensure appropriate dosing and remind patients and caregivers how INQOVI should be taken.





Decitabine and cedazuridine (INQOVI®) is the only FDA-approved oral HMA option in MDS (IPSS Intermediate-1 and above) that the National Comprehensive Cancer Network® (NCCN®) recommends could be a substitution for IV decitabine^{1,4}

Oral decitabine and cedazuridine (DEC-C) (Category 2A) could be a substitution for intravenous decitabine in patients with IPSS intermediate-1 and above in the *NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Myelodysplastic Syndromes*.⁴

- Do not substitute decitabine and cedazuridine (INQOVI) for an IV decitabine product within a cycle¹

*Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.⁴

Referenced with permission from the *NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Myelodysplastic Syndromes V.1.2022*. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed October 19, 2021. To view the most recent and complete version of the guideline, go online to [NCCN.org](https://www.nccn.org).⁴

NCCN makes no warranties of any kind whatsoever regarding their content, use, or application, and disclaims any responsibility for their application or use in any way.

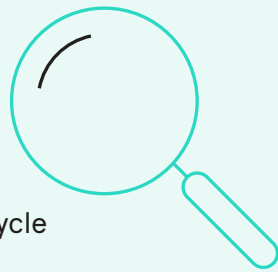
INDICATIONS

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.

Monitoring and dosing modifications¹

Dose interruptions due to an adverse reaction occurred in **41% of patients** who received INQOVI® (decitabine and cedazuridine) tablets. **Dose reductions** due to an adverse reaction occurred in **19% of patients** who received INQOVI.

- The most frequent cause of dose reduction or interruption was myelosuppression (thrombocytopenia, neutropenia, anemia, and febrile neutropenia)



Monitor response

- Obtain complete blood cell counts prior to initiating INQOVI and before each cycle
- Manage toxicity using dose delay, dose modification, growth factors, and anti-infective therapies for treatment or prophylaxis as needed



When to delay or reduce the dose

Delay the next cycle if absolute neutrophil count (ANC) is $<1000/\mu\text{L}$ and platelets are $<50,000/\mu\text{L}$ in the absence of active disease. Monitor complete blood cell counts until ANC is $\geq 1000/\mu\text{L}$ and platelets are $\geq 50,000/\mu\text{L}$.

If hematologic recovery does not occur within 2 weeks of achieving remission:

- Delay INQOVI for up to 2 additional weeks, AND
- Resume at a reduced dose by administering INQOVI on days 1 through 4
- Consider further dose reductions (listed on the next page) if myelosuppression persists after first dose reduction
- Maintain or increase dose in subsequent cycles as clinically indicated

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.

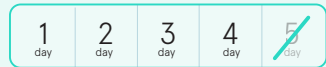
When to delay or reduce the dose (cont'd)

Delay the next cycle for the following nonhematologic adverse reactions and resume at the same or reduced dose once they are resolved:

- Serum creatinine ≥ 2 mg/dL
- Serum bilirubin ≥ 2 x upper limit of normal (ULN)
- Aspartate aminotransferase or alanine aminotransferase ≥ 2 x ULN
- Active or uncontrolled infection

Recommended dose reductions for myelosuppression*

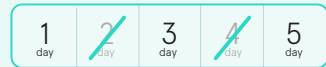
1st dose reduction
Dosage:



2nd dose reduction
Dosage:



3rd dose reduction
Dosage:



- Manage persistent severe neutropenia and febrile neutropenia with supportive treatment

*Myelosuppression includes thrombocytopenia, neutropenia, anemia, and febrile neutropenia.

If vomiting occurs following dosing:

- No additional dose should be taken that day
- Continue with next scheduled dose

What to do if a dose of INQOVI is missed



Within 12 hours of the time it is usually taken:

- Take the missed dose as soon as possible and resume the normal daily dosing schedule
- Extend the dosing period by 1 day for every missed dose to complete 5 daily doses for each cycle

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.

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 ($\geq 20\%$) 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 ($\geq 50\%$) 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).

Taiho Oncology Patient Support™ for you and your patients

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. For more information, please visit or refer patients to TaihoPatientSupport.com.



Meeting the access needs of your patients

Getting patients access to their medicine is an important step. Taiho Oncology Patient Support™ strives to make this process as simple as possible.

Taiho Oncology Patient Support™ can assist with:



Insurance Coverage Support*

- Benefits investigation and prior authorization assistance
- Appeals assistance
- \$0 Copay program enrollment for commercially insured patients



Specialty Pharmacy Prescription Coordination

Prescriptions will be triaged to the requested specialty pharmacy, self-dispensing practice, or hospital outpatient pharmacy.



Personalized Nurse Support†

Nurse support services are available to aid patient education and adherence.

Taiho Oncology Patient Support™ Co-pay Program

Eligible, privately insured patients can enroll in the Taiho Oncology Patient Support™ Co-pay program, which may help reduce out-of-pocket expenses to \$0 for their treatment with INQOVI® (decitabine and cedazuridine) tablets.

To determine patient eligibility, go to TaihoOncologyCopay.com or call **1-844-TAIHO-4U** (1-844-824-4648).

Support starts with an easy-to-complete Enrollment Form that can be downloaded at TaihoPatientSupport.com/how-to-enroll.

To register or learn more, visit or refer patients to TaihoPatientSupport.com or call **1-844-TAIHO-4U** (1-844-824-4648) Monday to Friday, 8 AM to 8 PM ET.

*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.

CO-PAY ASSISTANCE PROGRAM

\$0 CO-PAY*

If you are eligible, the Taiho Oncology Co-Pay Program may help reduce your co-pay responsibility to \$0



Additional patient resources

The INQOVI Treatment Kit

The INQOVI Treatment Kit is here to help patients and caregivers with INQOVI® (decitabine and cedazuridine) tablets treatment for MDS.

The kit includes:

- 1 A comprehensive patient brochure
- 2 Accompanying caregiver brochure
- 3 Blister pack opener with instruction card
- 4 Health journal
- 5 Advocacy support brochure



Treatment kit is approximately 10.125 in x 11.125 in x 1.625 in.

Patient advocacy organizations

These organizations offer patients information, support, and community. Feel free to share the following resources with your patients:



The Aplastic Anemia and MDS International Foundation (AAMDSIF)
Visit aamds.org or call 1-800-747-2820



The Leukemia & Lymphoma Society (LLS)
Visit lls.org or call 1-800-955-4572



The Myelodysplastic Syndromes (MDS) Foundation, Inc.
Visit mds-foundation.org or call 1-800-MDS-0839 (1-800-637-0839)

References: 1. INQOVI [package insert]. Princeton, NJ: Taiho Oncology, Inc.; 2022. 2. Garcia-Manero G, Griffiths EA, Steensma DP, et al. Oral cedazuridine/decitabine: a phase 2, pharmacokinetic/pharmacodynamic, randomized, crossover study in MDS and CMML. *Blood*. doi:10.1182/blood.2019004143. 3. Joshi N, Kale H, Corman S, Wert T. Direct medical costs associated with treatment nonpersistence in patients with higher-risk myelodysplastic syndromes receiving hypomethylating agents: a large retrospective cohort analysis. *Clin Lymphoma Myeloma Leuk*. 2021; 21(3):e248-e254. doi:10.1016/j.clml.2020.12.002. 4. Referenced with permission from the *NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Myelodysplastic Syndromes V.1.2022*. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed October 19, 2021. To view the most recent and complete version of the guideline, go online to NCCN.org.

Consider INQOVI, THE ONLY oral HMA for the treatment of MDS including CMML¹

For your patients who want to take their treatment in the comfort of home or wherever they are¹

- One pill, taken once daily for 5 days per 28-day cycle
- 99% geometric mean ratio of oral to IV 5-day decitabine AUC
- Complete response was achieved in 21% of patients (95% CI: 15, 29; N=133)
- 53% (30/57) of patients who were initially transfusion dependent achieved posttreatment RBC and platelet transfusion independence
- 20% (27/133) of patients went on to receive stem cell transplantation after taking INQOVI
- Demonstrated **equivalent** systemic exposure and a **similar safety profile to IV decitabine with no unexpected adverse reactions**
 - Incidence of cytopenias was slightly higher in INQOVI during cycle 1 compared to IV decitabine



For questions about treatment with INQOVI, call 1-844-878-2446 or go to [INQOVI.com](https://www.inqovi.com)

INQOVI® (decitabine and cedazuridine) tablets—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 and infectious complications can occur. Obtain complete blood cell counts prior to initiation of INQOVI, prior to each cycle, and as clinically indicated to monitor for response and toxicity.

Embryo-Fetal Toxicity: Can cause fetal harm.

Please see Important Safety Information, including information on myelosuppression and embryo-fetal toxicity, on pages 18-19 and full Prescribing Information in pocket or at [INQOVI.com/PI](https://www.inqovi.com/PI).

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