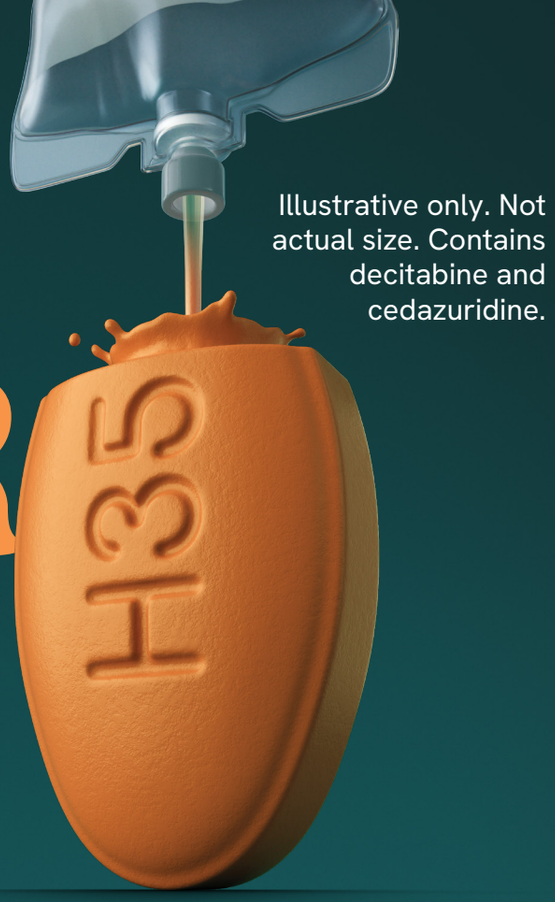
Nurse and Pharmacist Guide



Illustrative only. Not actual size. Contains decitabine and cedazuridine.

RESPONSES SHAPED BY A POWERFULL ORAL HMA TREATMENT

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

Help support patients living with AML or MDS, including CMML, with INQOVI—an oral HMA therapy with proven results regardless of treatment setting[1]

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.

INQOVI is indicated in combination with venetoclax for the treatment of patients with newly diagnosed acute myeloid leukemia (AML) who are 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Myelosuppression

INQOVI as Monotherapy for MDS or CMML

In patients with MDS or CMML, INQOVI can cause severe myelosuppression, including fatal adverse reactions. 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%. Thrombocytopenia, neutropenia, anemia, and febrile neutropenia are 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 in pocket or at INQOVI.com/PI.

An all-oral regimen of INQOVI with venetoclax for patients with AML or INQOVI alone for MDS and CMML[1,2]

About INQOVI

INQOVI is an oral hypomethylating agent (HMA) composed of decitabine and cedazuridine. The treatment has been approved for adults with[1]:

AML

INQOVI with venetoclax

- Newly diagnosed acute myeloid leukemia (AML) who are 75 years or older or who have comorbidities that preclude the use of intensive induction chemotherapy

MDS

INQOVI alone

- Previously treated or untreated, de novo or secondary myelodysplastic syndromes (MDS), including chronic myelomonocytic leukemia (CMML), classified as intermediate- or high-risk

Using this guide

This guide offers guidance on dosing, clinical trial data, adverse reaction management, patient support, and ordering and reimbursement to help you support the patients in your care taking INQOVI.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

Myelosuppression

INQOVI as Monotherapy for MDS and CMML

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.

Table of Contents

Please see Important Safety Information throughout and full Prescribing Information in pocket or at INQOVI.com/PI.

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

An all-oral regimen on a 28-day cycle[1]

Indicated dosage: 1 tablet once daily
Fixed-dose combination containing 35 mg of decitabine and 100 mg of cedazuridine

Tablet shown is not actual size. Actual tablet size is 7.94 mm x 14.29 mm.[2]

Dosing schedule

INQOVI is taken as 1 tablet orally once daily on Days 1 through 5 of each 28-day cycle. Venetoclax is taken daily using a ramp-up schedule in Cycle 1 and continuous dosing in subsequent cycles. Match Day 1 of INQOVI dosing with Day 1 of venetoclax dosing for each 28-day cycle.

When using INQOVI in combination with venetoclax for newly diagnosed AML, refer to the venetoclax Prescribing Information for additional dosing and administration information.

Scan this QR code to create a personalized INQOVI dosing calendar

CYCLE 1			
	INQOVI		Venetoclax
WEEK 1	Once daily for 5 days without food	2 days rest	**Day 1:** 100 mg **Day 2:** 200 mg **Day 3:** 400 mg **Days 4 to 7:** 400 mg once daily
WEEK 2	–	–	400 mg once daily
WEEK 3	–	–	400 mg once daily
WEEK 4	–	–	400 mg once daily
SUBSEQUENT CYCLES			
	INQOVI		Venetoclax
WEEK 1	Once daily for 5 days without food	2 days rest	400 mg once daily
WEEK 2	–	–	400 mg once daily
WEEK 3	–	–	400 mg once daily
WEEK 4	–	–	400 mg once daily

Monitoring

- Obtain complete blood cell counts before initiating INQOVI, before each cycle, and as clinically indicated to monitor for response and toxicity
- If patients develop cytopenias, frequently monitor blood cell counts through resolution
- If a bone marrow test is needed, order it as early as Day 22

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS (continued)
Myelosuppression
INQOVI in Combination with Venetoclax for AML
In patients with AML, INQOVI can cause severe myelosuppression, including fatal adverse reactions, when given in combination with venetoclax.

AML | Dosing and administration

Instruct patients to

- Take INQOVI at approximately the same time each day
- Swallow INQOVI whole. Do not cut, crush, or chew the tablets
- Take INQOVI on an empty stomach at least 2 hours before or 2 hours after eating
- Take INQOVI and venetoclax at least 2 hours apart. Do not take INQOVI and venetoclax at the same time
- If vomiting occurs after dosing, do not take an additional dose, and continue with the next scheduled dose
- Skip the dose if more than 12 hours late, take the next scheduled dose, and extend the dosing period by 1 day to ensure 5 daily doses each cycle

Dose delays or reductions

Hematologic ARs

If hematologic ARs occur, monitor complete blood cell counts until neutrophils and platelet counts have recovered to Grade 1 or 2 (an absolute neutrophil count [ANC] of ≥1000/µL and platelets of ≥50,000/µL).

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

- Delay INQOVI for up to 2 additional weeks
- Consider reducing the number of days of INQOVI per cycle according to the table below

Nonhematologic ARs

If nonhematologic ARs occur, reduce the INQOVI dose according to the table below.

Recommended INQOVI dose reductions for ARs

	Day 1	Day 2	Day 3	Day 4	Day 5
1st dose reduction	H35	H35	H35	~~H35~~	~~H35~~
2nd dose reduction	H35	~~H35~~	H35	~~H35~~	H35
3rd dose reduction	H35	H35	~~H35~~	~~H35~~	~~H35~~

Manage persistent severe neutropenia and febrile neutropenia with supportive treatment.

Please see Important Safety Information throughout and full Prescribing Information in pocket or at INQOVI.com/PI.

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

An oral regimen on a 28-day cycle[1]

Indicated dosage: 1 tablet once daily
Fixed-dose combination containing 35 mg of decitabine and 100 mg of cedazuridine

Tablet shown is not actual size. Actual tablet size is 7.94 mm x 14.29 mm.[2]

Dosing schedule

INQOVI is taken as 1 tablet orally once daily on Days 1 through 5 of each 28-day cycle, for a minimum of 4 cycles until disease progression or unacceptable toxicity.

A complete or partial response may take longer than 4 cycles.

Patients administered an IV treatment in an earlier cycle may be switched to INQOVI for subsequent cycles—*but not within a cycle.*

ALL CYCLES		
	INQOVI	
WEEK 1	Once daily for 5 days without food	2 days rest
WEEK 2	–	–
WEEK 3	–	–
WEEK 4	–	–

Monitoring

Obtain complete blood cell counts before initiating INQOVI, before each cycle, and as clinically indicated to monitor for response and toxicity.

Scan this QR code to create a personalized INQOVI dosing calendar

Instruct patients to

- Take INQOVI at approximately the same time each day
- Swallow INQOVI whole. Do not cut, crush, or chew the tablets
- Take INQOVI on an empty stomach at least 2 hours before or 2 hours after eating
- If vomiting occurs after dosing, do not take an additional dose, and continue with the next scheduled dose
- Skip the dose if more than 12 hours late, take the next scheduled dose, and extend the dosing period by 1 day to ensure 5 daily doses each cycle

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS (continued)
Myelosuppression
INQOVI in Combination with Venetoclax for AML
Based on laboratory values in Study ASTX727-07, Phase 2 new or worsening thrombocytopenia occurred in 70% of patients, with Grade 3 or 4 occurring in 69%.

MDS | Dosing and administration

Dose delays or reductions

Hematologic ARs

Delay the next cycle if absolute neutrophil count (ANC) is <1000/µL and platelets are <50,000/µL in the absence of active disease. Monitor complete blood cell counts until ANC is ≥1000/µL and platelets are ≥50,000/µL.

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 if myelosuppression persists after a dose reduction according to the table below
- Maintain or increase the dose in subsequent cycles as clinically indicated

Nonhematologic ARs

If the following nonhematologic ARs occur, delay the next cycle, and resume INQOVI at the same dose or at a reduced dose upon resolution:

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

Recommended INQOVI dose reductions for myelosuppression

	Day 1	Day 2	Day 3	Day 4	Day 5
1st dose reduction	H35	H35	H35	H35	~~H35~~
2nd dose reduction	H35	H35	H35	~~H35~~	~~H35~~
3rd dose reduction	H35	~~H35~~	H35	~~H35~~	H35

Manage persistent severe neutropenia and febrile neutropenia with supportive treatment.

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

INQOVI + venetoclax, an all-oral therapy, delivered meaningful response and consistent exposure for patients with AML[1,2]

Illustrative only. Not actual size.
Contains decitabine and cedazuridine.

INQOVI is an oral HMA therapy approved in combination with venetoclax for patients with newly diagnosed AML who are 75 years or older or who have comorbidities that preclude the use of intensive induction chemotherapy.[1]

ASCERTAIN-V (ASTX727-07; NCT04657081) was a single-arm, open-label, Phase 2 clinical trial that evaluated INQOVI + venetoclax in patients with newly diagnosed AML. Phase 2 Part A (N=58) assessed efficacy, pharmacokinetics, and safety. The pivotal portion, Phase 2 Part B (N=101), assessed efficacy as a primary objective, and efficacy, pharmacokinetics, and safety as secondary objectives.[1-3]

Primary endpoint outcome

INQOVI + venetoclax met the prespecified efficacy criterion for complete remission (CR) rate in Phase 2 Part B (N=101) of the clinical study.[1,2]

Meaningful clinical response[1]

41.6% **achieved CR**
(95% CI: 31.9%-51.8%)*

*The criterion required the lower limit of the 95% CI to exceed a clinically relevant critical value of 17.9%.[2]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

Myelosuppression

INQOVI in Combination with Venetoclax for AML

Neutropenia occurred in 48% of patients, with Grade 3 or 4 occurring in 48%. Anemia occurred in 54% of patients, with Grade 3 or 4 occurring in 50%. Febrile neutropenia occurred in 52% of patients, with Grade 3 or 4 occurring in 52%. Thrombocytopenia, neutropenia, anemia, and febrile neutropenia were a frequent cause of INQOVI and/or venetoclax dose reduction or interruption. Dose reductions of INQOVI due to neutropenia and thrombocytopenia occurred in 4% and 1% of patients, respectively. Dose interruptions of INQOVI due to neutropenia, febrile neutropenia, thrombocytopenia, and anemia occurred in 40%, 11%, 8%, and 2% of patients, respectively.

Secondary endpoint outcomes

Expanded clinical response[1]

CR IN PATIENTS WITH AML	
ENDPOINT	**PHASE 2 PART B** (N=101)
CR + CRh	52.5% (95% CI: 42.3%-62.5%)
Time to response	
Median time to CR (range)[a]	2.0 months (0.4-15.3)
Median time to CR + CRh (range)[b]	1.9 months (0.4-10.7)
DoCR	
CR at 9.0 months (range)	NR (0.5-16.3)
CR + CRh at 8.9 months (range)	NR (0.6-16.3)

The clinical cutoff date for the ongoing Phase 2 Part B of the clinical study was September 30, 2024.[2]
[a]Of the 42 patients who achieved CR.[1]
[b]Of the 53 patients who achieved CR + CRh.[1]
NR=not reached.

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INQOVI®
(decitabine and cedazuridine)
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Secondary endpoint outcomes (continued)

No pharmacokinetic drug-drug interactions between INQOVI and venetoclax[1]

The coadministration of INQOVI and venetoclax was consistent with the independent pharmacologic behavior of each drug in Phase 2 Part B of the clinical study.[1,2]

Transfusion independence in patients treated with INQOVI + venetoclax[1]*

- Among the 44 patients who were **dependent on red blood cell (RBC) or platelet transfusions** at baseline:
  - **16 (36.4%) became transfusion independent**
  - **28 (63.6%) remained transfusion dependent**

- Of the 57 patients who were **independent of both RBC and platelet transfusions** at baseline:
  - **25 (43.9%) remained transfusion independent**
  - **32 (56.1%) became transfusion dependent**

*Transfusion independence was defined as no RBC or platelet transfusions for ≥56 consecutive days during active treatment with INQOVI + venetoclax.[1]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

Myelosuppression

INQOVI in Combination with Venetoclax for AML

Fatal and serious infectious complications can occur during treatment with INQOVI and venetoclax. Pneumonia occurred in 25% of patients, with Grade 3 or 4 occurring in 20%. Sepsis occurred in 28% of patients, with Grade 3 or 4 occurring in 18%. Fatal pneumonia occurred in 2% of patients and fatal sepsis in 8%.

Obtain complete blood cell counts prior to initiation of INQOVI with venetoclax, 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.

A demonstrated safety profile[1,2]

The safety profile of INQOVI + venetoclax in patients with newly diagnosed AML was consistent with the known safety profiles of both agents.[2]

ADVERSE REACTIONS REPORTED IN ≥20% OF PATIENTS FOR ALL GRADES OR ≥5% FOR GRADES 3-4 IN THE COMBINED PHASE 2 SAFETY POPULATION[1]		
ADVERSE REACTIONS[a]	**PHASE 2** (N=159)	
	ALL GRADES (%)	**GRADES 3-4** (%)
GASTROINTESTINAL DISORDERS		
Diarrhea	38	4
Mucositis[b]	36	6
Constipation[b]	36	1
Nausea	31	0
Abdominal pain[b]	21	3
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		
Fatigue[b]	36	8
Edema[b]	31	2
METABOLISM AND NUTRITION DISORDERS		
Decreased appetite	31	3
BLOOD SYSTEM AND LYMPHATIC SYSTEM DISORDERS		
Neutropenia[b]	60	58
Febrile neutropenia	52	52
Thrombocytopenia[b]	52	50
Anemia	41	36
White blood cell count decreased	28	28
HEPATOBILIARY DISORDERS		
Transaminitis[b]	24	4
INFECTIONS AND INFESTATIONS		
Infection (excludes fungal)[b]	40	13
Sepsis[b]	28	18
Pneumonia[b]	25	20

Please see Important Safety Information throughout and full Prescribing Information in pocket or at INQOVI.com/PI.

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

A demonstrated safety profile (continued)[1,2]

ADVERSE REACTIONS REPORTED IN ≥20% OF PATIENTS FOR ALL GRADES OR ≥5% FOR GRADES 3-4 IN THE COMBINED PHASE 2 SAFETY POPULATION (CONTINUED)[1]		
ADVERSE REACTIONS (CONTINUED)[a]	**PHASE 2** (N=159)	
	ALL GRADES (%)	**GRADES 3-4** (%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		
Arthralgia[b]	35	6
Myalgia[b]	23	4
CARDIAC DISORDERS		
Arrhythmia[b]	21	4
RESPIRATORY, THORACIC, AND MEDIASTINAL DISORDERS		
Dyspnea[b]	30	12
RENAL AND URINARY DISORDERS		
Renal insufficiency[b]	18	5
VASCULAR DISORDERS		
Hemorrhage[b]	42	9
Hypotension	19	6
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		
Rash[b]	25	1

[a]Please see full Prescribing Information for complete list of adverse reactions (ARs) occurring during Phase 2.
[b]Includes multiple AR terms.

SELECT LABORATORY ABNORMALITIES OBSERVED IN >40% OF PATIENTS FOR ALL GRADES IN THE COMBINED PHASE 2 SAFETY POPULATION[1]		
LABORATORY ABNORMALITY	**PHASE 2** (N=159)	
	ALL GRADES (%)	**GRADES 3-4** (%)
HEMATOLOGY AND COAGULATION		
Lymphocytes (10^9/L) decreased	97	81
Leukocytes (10^9/L) decreased	91	91
Platelets (10^9/L) decreased	70	69
Hemoglobin (g/L) decreased	54	50
Neutrophils (10^9/L) decreased	48	48

Please see full Prescribing Information for chemistry lab safety parameters.

AML | Safety

Remind patients and their caregivers that INQOVI is a hazardous drug. Follow applicable special handling and disposal procedures. Store at 20°C to 25°C (68°F to 77°F); excursions permitted from 15°C to 30°C (59°F to 86°F).[1]

Fatal ARs occurred in 8% of patients[1]

- These included sepsis (5%), dyspnea (2%), myocardial infarction (1%), hemolytic anemia (1%), and tumor lysis syndrome (1%)

Permanent discontinuation due to an AR occurred in 9% of patients[1]

- The most frequent AR resulting in permanent discontinuation in >1 patient was hemorrhage (1%)

Dose interruptions due to an AR occurred in 55% of patients; dose reduction occurred in 6% of patients[1]

- ARs resulting in dose interruptions in ≥5% of patients included neutropenia (40%), febrile neutropenia (11%), infection (bacterial/viral) (8%), and thrombocytopenia (8%)
- The most common ARs requiring dose reductions were neutropenia (4%), thrombocytopenia (1%), and infection (1%)

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

Embryo-Fetal Toxicity

Advise patients of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with INQOVI and for 6 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with INQOVI and for 3 months after the last dose.

Please see Important Safety Information throughout and full Prescribing Information in pocket or at INQOVI.com/PI.

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

INQOVI, the only oral HMA, delivered equivalent systemic exposure to IV decitabine for patients with MDS and CMML[1,5,6]

ASCERTAIN was an open-label, randomized, Phase 3 crossover trial (N=133) that evaluated systemic decitabine exposure, demethylation activity, and safety between INQOVI and IV decitabine in a broad range of adult patients with intermediate-to high-risk MDS or CMML with cytogenetic risks.[1,5]

The trial assessed 5-day area under the curve (AUC) between oral decitabine–cedazuridine and IV decitabine for Cycles 1 and 2 as a primary objective. Key secondary objectives included clinical response and rates of conversion from transfusion dependence to independence.[1,5]

The trial allowed for intrapatient comparison in the first 2 randomized treatment cycles, then assessment of long-term efficacy and safety of INQOVI as a single arm. Median follow-up was approximately 2.6 years.[1,5]

Primary endpoint outcome

99% **ratio of oral to IV 5-day decitabine AUC** (indicating equivalent pharmacokinetic exposure) (90% CI: 93%-106%)[1,5*]

This ratio is the geometric mean of the 5-day cumulative decitabine AUC between INQOVI and IV-administered decitabine when administered once daily for 5 consecutive days.[1]

*Excludes data from some participants due to data confidence or quality issues.[5]

Illustrative only. Not actual size.
Contains decitabine and cedazuridine.

Secondary endpoint outcomes

Clinical response[5]

70% **of MDS patients experienced a clinical response, showing improvements like complete or partial response, complete marrow response, and hematological improvement**[†]

Evaluable participants: 82 of 117 (95% CI: 50%-69%)

[†]Based on International Working Group 2006 MDS response criteria.[5]

Secondary endpoint outcomes (continued)

COMPLETE RESPONSE (CR) IN PATIENTS WITH MDS OR CMML		
ENDPOINT	**PHASE 3** (N=133)[1,5]	**PHASE 3 LONG-TERM FOLLOW-UP** (N=133)[5]
Median follow-up time	12.6 months (range: 9.3-20.5)[1]	~32 months (IQR: ~30-35)[5]
Patients who achieved CR (CI)[a]	21% (95% CI: 15%-29%)[1]	25% (95% CI: 17%-34%)[5b]
Median duration of CR (range)[c]	7.5 months (1.6-17.5)[1]	14.1 months (11.7-18.7)[5]
Median time to CR (range)[a]	4.3 months (2.1-15.2)[1]	4.5 months (2.1-18.7)[2]

[a]Complete or partial response may take longer than 4 cycles.[1]
[b]Of the evaluable 117 participants, 25% (29/117) achieved a CR.[5]
[c]From the start of CR until relapse or death.[1]
IQR=interquartile range.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

INQOVI in Combination with Venetoclax for AML

Serious adverse reactions occurred in 82% of patients who received INQOVI+VEN. Serious adverse reactions in >5% of patients included febrile neutropenia (31%), sepsis (22%), pneumonia (15%), infection (bacterial/viral) (10%), hemorrhage (9%), and dyspnea (6%). Fatal adverse reactions occurred in 8% of patients who received INQOVI+VEN. These included sepsis (5%), dyspnea (2%), myocardial infarction (1%), hemolytic anemia (1%), and tumor lysis syndrome (1%).

MDS

Rates of transfusion independence were consistent at the long-term follow-up[5]

Phase 3 results (N=133)[1,5]

- Among the 57 patients who were **dependent on red blood cell (RBC) and/or platelet transfusions** at baseline, **30 (53%) became independent** of RBC and platelet transfusions during any 56-day post-baseline period
- Of the 76 patients who were **independent of both RBC and platelet transfusions** at baseline, **48 (63%) remained transfusion independent** during any 56-day post-baseline period

Phase 3 long-term follow-up results (N=133)[5]

- Among the 54 patients who were RBC transfusion dependent at baseline, **28 (52%) achieved RBC transfusion independence** during the study
- Of the 12 patients who required platelet transfusions at baseline, **6 (50%) achieved platelet transfusion independence** during the study
- **33% of patients in each category (RBC: 18/54; platelet: 4/12)** who were transfusion dependent at baseline **maintained transfusion independence** for at least 112 consecutive days

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

INQOVI in Combination with Venetoclax for AML

The most common adverse reactions (≥20%) were neutropenia (60%), febrile neutropenia (52%), thrombocytopenia (52%), hemorrhage (42%), anemia (41%), infection (bacterial/viral) (40%), diarrhea (38%), fatigue (36%), mucositis (36%), constipation (36%), arthralgia (35%), decreased appetite (31%), edema (31%), nausea (31%), dyspnea (30%), white blood cell count decreased (28%), sepsis (28%), pneumonia (25%), rash (25%), transaminitis (24%), myalgia (23%), arrhythmia (21%), and abdominal pain (21%). The most common Grade 3 or 4 laboratory abnormalities (≥20%) were decreased leukocytes (91%), decreased lymphocytes (81%), decreased platelets (69%), decreased hemoglobin (50%), and decreased neutrophils (48%).

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

Safety profile similar to IV decitabine[1,5]

- Incidence of cytopenias was slightly higher in patients receiving INQOVI during Cycle 1 compared with IV decitabine[1,7]
- 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[1]
- In the long-term follow-up, the adverse event (AE) profile was similar to what was observed in the pooled safety population[1,5]
  - The incidence of serious adverse reactions (ARs) in Cycles 1 and 2 was 31% (40/130) with oral decitabine-cedazuridine and 18% (24/132) with IV decitabine[1]

ADVERSE REACTIONS REPORTED IN ≥10% OF PATIENTS IN THE POOLED PHASE 2 AND PHASE 3 SAFETY POPULATION[1]

ADVERSE REACTIONS[a]	INQOVI CYCLE 1 (N=107)		IV DECITABINE CYCLE 1 (N=106)		INQOVI ALL CYCLES (N=208[c])	
	ALL GRADES (%)	GRADE 3 OR 4 (%)	ALL GRADES (%)	GRADE 3 OR 4 (%)	ALL GRADES (%)	GRADE 3 OR 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

ADVERSE REACTIONS (CONTINUED)[a]	INQOVI CYCLE 1 (N=107)		IV DECITABINE CYCLE 1 (N=106)		INQOVI ALL CYCLES (N=208[c])	
	ALL GRADES (%)	GRADE 3 OR 4 (%)	ALL GRADES (%)	GRADE 3 OR 4 (%)	ALL GRADES (%)	GRADE 3 OR 4 (%)
BLOOD AND LYMPHATIC SYSTEM DISORDERS						
Febrile neutropenia	10	10	13	13	33	32
SKIN AND SC TISSUE DISORDERS						
Rash[b]	12	1	11	1	33	0.5
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
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

[a]Please see full Prescribing Information for the complete list of ARs occurring during all cycles.
[b]Includes multiple AR terms.
[c]Includes ARs that occurred during all cycles, including during treatment with 1 cycle of IV decitabine.

Please see Important Safety Information throughout and full Prescribing Information in pocket or at INQOVI.com/PI.

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

Safety profile similar to IV decitabine (continued)[1,5]

SELECT HEMATOLOGIC LAB ABNORMALITIES (>20%) WORSENING FROM BASELINE IN THE POOLED SAFETY POPULATION[1]						
LAB PARAMETER[a]	INQOVI CYCLE 1[b]		IV DECITABINE CYCLE 1[b]		INQOVI ALL CYCLES[b]	
	ALL GRADES (%)	GRADE 3 OR 4 (%)	ALL GRADES (%)	GRADE 3 OR 4 (%)	ALL GRADES (%)	GRADE 3 OR 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

[a] Includes any lab abnormalities that worsened by ≥1 grade. Grades 3 to 4 include any lab abnormalities that worsened to Grade 3 or Grade 4.
[b] The denominator used to calculate the rate varied from 103 to 107 for INQOVI 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 post-treatment value.

Please see full Prescribing Information for chemistry lab safety parameters.

Remind patients and their caregivers that INQOVI is a hazardous drug. Follow applicable special handling and disposal procedures. Store at 20°C to 25°C (68°F to 77°F); excursions permitted from 15°C to 30°C (59°F to 86°F).[1]

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.

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).

MDS

Fatal ARs occurred in 6% of patients[1]

- These included sepsis (1%), pneumonia (1%), respiratory failure (1%), septic shock (1%), and 1 case each of cerebral hemorrhage and sudden death[1]
- Also in the long-term follow-up, 11 (8%) of 133 participants had fatal treatment-emergent serious ARs during the study. 5 of these deaths were deemed treatment related; 2 to oral therapy (sepsis and pneumonia) and 3 to IV treatment (septic shock [n=2] and pneumonia [n=1])[5]

Permanent discontinuation due to an AR occurred in 5% of patients[1]

- 1 participant in each group discontinued treatment during the first 2 cycles due to an AR[5]
- Overall treatment discontinuations due to an AR included 1 (out of 132) receiving IV decitabine and 2 (out of 130) receiving oral decitabine-cedazuridine[5]
- The most frequent ARs resulting in permanent discontinuation were febrile neutropenia (1%) and pneumonia (1%)[1]
- The most common reason for treatment discontinuation was undergoing allogeneic hematopoietic stem-cell transplantation (HSCT) (27 [20%])[5]

Dose interruptions due to an AR occurred in 41% of patients[1]

- ARs requiring dose interruptions in ≥5% of INQOVI patients included neutropenia (18%), febrile neutropenia (8%), thrombocytopenia (6%), and anemia (5%)

Dose reduction due to an AR occurred in 19% of patients[1]

- ARs requiring dose reductions in >2% of patients included neutropenia (12%), anemia (3%), and thrombocytopenia (3%)

Additional safety profile information[1]

- Clinically relevant ARs in <10% of patients who received INQOVI tablets included acute febrile neutrophilic dermatosis (Sweet's syndrome) (1%) and tumor lysis syndrome (0.5%)
- Serious ARs occurred in 68% of patients who received INQOVI. Serious ARs in >5% of patients included febrile neutropenia (30%), pneumonia (14%), and sepsis (13%)

Please see Important Safety Information throughout and full Prescribing Information in pocket or at INQOVI.com/PI.

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

Helping patients manage common adverse reactions

Encourage patients to maintain open communication with you or their healthcare team regarding any concerns or potential side effects while taking INQOVI with venetoclax for AML, or INQOVI alone for MDS, including CMML. The following information may help you assist patients in managing some of the common side effects of INQOVI.[1]

To start

Advise patients of the risk of myelosuppression and to report any symptoms of fever, infection, anemia, or bleeding as soon as possible. Blood-cell counts will be checked before the start of treatment with INQOVI and regularly throughout.[1]

For patients with AML starting venetoclax, instruct patients to adequately hydrate every day to reduce the risk of tumor lysis syndrome. The recommended volume is 6 to 8 glasses (approximately 56 ounces total) of water each day. Patients should drink this amount of water starting **2 days before and on the day of their first dose, and every time the dose is increased.**[4]

Fatigue[1]

Patients experiencing treatment-related fatigue may describe feeling weak, exhausted, worn-out, or unable to maintain their daily routine. Stress and anxiety can also increase these feelings.[8,9]

- If appropriate, encourage patients to stay active with short walks or other low-effort exercise[8,9]
- Advise patients to get 7-8 hours of sleep every night and create a bedtime routine[8,9]
- Share support groups or opportunities for counseling that patients may join[8,9]
  - See page 26 for a list of patient advocacy organizations
- Suggest they use assistive devices such as wheelchairs[9]
- Determine if an underlying condition is contributing to their fatigue and if additional intervention is necessary[8,9]
  - Review if other medications or other agents may be contributing to fatigue and advise accordingly

Neutropenia[1,4]

Neutropenia is a common adverse reaction for INQOVI, across both indications, and venetoclax. Patients with neutropenia often present with a fever, though may also be afebrile or hypothermic.[1,4,10]

- **Inform patients to contact you or their healthcare team if they have a fever or other signs of infection[1,4]**
- Determine if antibiotics are appropriate after a complete evaluation (history, physical, complete blood count, chest imaging, and more as appropriate)[1,10,11]
- Administer the first dose of empirical therapy in the clinic, emergency department, or hospital to verify if patient is stable[10,11]
- **Consider prophylaxis** like granulocyte-colony stimulating factor (G-CSF) for high-risk patients, if clinically appropriate[1,4]

Fever[1]

For patients with cancer, a fever is defined as a temperature of 100.4°F (38°C) or higher for at least 1 hour. In patients with neutropenia, fever may often be the first and only sign of an infection, so it is important to assume it may be an infection.[10-12]

- **Inform patients to contact you or their healthcare team right away if they develop a fever[1]**
- Prompt patients to drink water to prevent dehydration[13]
- Have patients rest and keep cool by using a cold compress[13]
- Determine if any over-the-counter medicines or other interventions may be appropriate[11,12]

Decreased appetite[1]

Some patients may lose their appetite for a short time, while others may lose their appetite for days or weeks during treatment. Decreased appetite in patients can lead to muscle and overall weight loss as well as weakness and fatigue.[14,15]

- Advise patients to eat 5 to 6 small meals or snacks each day rather than 3 large meals[14,15]
- Recommend that patients drink liquid foods, such as soup or smoothies[14,15]
- When eating, have patients choose foods that are high in nutrition and/or protein[15,16]
- If appropriate, determine how patients can perform light exercise during treatment[14,15]
- Determine if treatments or interventions may be appropriate[16]

Please see Important Safety Information throughout and full Prescribing Information in pocket or at INQOVI.com/PI.

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Helping patients manage common adverse reactions (continued)

Constipation[1]

Constipation can be caused by more than one factor. Patients may describe having small, hard bowel movements, no bowel movements at all, or difficulty and discomfort.[15,17]

- **Inform patients to contact you or their healthcare team if they have not had a bowel movement in 3 days[17]**
- Suggest they keep a diary of their baseline bowel movements to help identify changes[15]
- Recommend patients eat high-fiber foods, such as whole grain breads and cereals, dried fruits, and cooked dried beans or peas[15]
- Counsel patients to stay hydrated[15]
  - Warm fluids like tea may help
- Suggest patients use a footrest to raise their feet 8 to 12 inches above the ground while trying to have a bowel movement[17]

Diarrhea[1]

Diarrhea, like constipation, can be caused by more than one factor. Patients may experience an increase in frequent, loose watery stool and stomach pain or cramps.[15,16,18]

- **Inform patients to contact you or their healthcare team if[15,18]:**
  - **Their diarrhea lasts for more than 24 hours**
  - **They experience intense stomach pain**
  - **Their rectal area is sore or bleeds**
  - **They notice any blood in their stool**
- Suggest they keep a diary of their baseline bowel movements to help identify changes[18]
- Recommend a low-fiber diet with foods such as bananas, white rice, white toast, and plain or vanilla yogurt[14,15]
- Counsel patients to stay hydrated by[14,15]:
  - Drinking 8 to 12 cups of clear liquids, such as water or clear broth, may help
  - Sipping liquids slowly and at room temperature
- Recommend patients use dampened toilet paper or baby wipes to help soothe sore areas[15,18]
- Determine if treatments or interventions to help alleviate diarrhea are appropriate[16,18]

Cough or dyspnea[1]

Patients can develop a cough, a productive cough, or dyspnea (shortness of breath) due to treatment or from other underlying causes, conditions, or concurrent therapies.[1,16]

- **Inform patients to contact you or their healthcare team if they cough up blood or colored mucus, or other symptoms with their cough[19]**
- Advise patients to avoid irritants or allergens, such as secondhand smoke or dust[19]
- Recommend that patients try using fans to keep cool, stress management, and/or relaxation therapy to help relieve symptoms[16]
- Determine if treatments that may help alleviate cough or dyspnea are appropriate[16,19]

Nausea or vomiting[1]

Patients may feel nauseous on days where they take INQOVI or shortly after. Patients may describe feeling queasy, and have other symptoms, such as pain or bloating in the abdomen and headaches.[1,15,20]

- **If patients vomit after a dose, advise them to not take an additional dose that day and continue with their next scheduled dose[1]**
- Recommend anti-nausea and vomiting treatments or interventions[16]
  - Consider administering antiemetics prior to each dose[1]
- Have patients eat bland and easy-to-digest foods, such as crackers or toast[15,20]
- Tell patients to avoid strong smells, if possible[20]
- Advise patients to eat 5 to 6 small meals or snacks each day rather than 3 large meals[15]

Advocate for patients to lean on their caregiver or support network for help, whether it is for their day-to-day needs or their appointments to take notes.

Taiho Oncology Patient Support™ for you and your patients

TAIHO ONCOLOGY PATIENT SUPPORT
Supporting your treatment journey

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

Taiho Oncology Patient Support can assist with

Insurance coverage support

- Benefits investigation
- Prior authorization (PA) assistance
- Appeals assistance
- Coordination of prescriptions with pharmacies

Patient affordability assistance*

- $0 Co-Pay Program enrollment for eligible commercially insured patients
- Patient assistance program designed to provide free medication to eligible patients who are uninsured or underinsured
- Referrals to third-party foundations for co-pay or other assistance based on eligibility and additional criteria
- Referrals to Medicare Part D Low-Income Subsidy (LIS)/ Extra Help Program

Personalized nurse support†

- One-on-one nurse educational support for patients, available via opt-in

*Visit TaihoPatientSupport.com to see full eligibility criteria.
†If this option is selected on the Patient Enrollment Form, a Nurse Navigator will be assigned to provide telephone support and will address general inquiries about INQOVI, your patient's Taiho Oncology medicine treatment.

Eligible, commercially 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. To determine patient eligibility, visit taihooncologycopay.com or call **1-844-TAIHO-4U (1-844-824-4648)**.

‡**Restrictions and eligibility:** Offer valid in the US, Puerto Rico, and US territories only. Only valid for patients with private insurance. Offer not valid for prescriptions reimbursed under Medicaid, a Medicare drug benefits plan, Tricare, or other federal or state programs (such as medical assistance programs). If the patient is eligible for drug benefits under any such program, this offer is not valid and the patient cannot use this offer. By presenting or accepting this benefit, patient and pharmacist agree not to submit claim for reimbursement under the above programs. Patient further agrees to comply with any and all terms of his or her health insurance contract requiring notification to his or her payer for the existence and/or value of this offer. It is illegal to or offer to sell, purchase, or trade this benefit. Maximum reimbursement limits apply; patient out-of-pocket expense may vary. Taiho Oncology, Inc. reserves the right to rescind, revoke or amend this offer at any time without notice.

Enroll in Taiho Oncology Patient Support

By fax

- Visit **TaihoPatientSupport.com/how-to-enroll**
- Download the **Enrollment Form**, and print it out to complete
- Fax the completed form to **1-844-287-2559**

OR

By phone

- Call **1-844-TAIHO-4U** (1-844-824-4648) for help with enrollment

Expedited review of PA for AML

Request an expedited or 24-hour review of PA for INQOVI for the treatment of AML. Support the request for expedited review by documenting the reason for the risk of serious harm to life, health, or ability to regain maximum function.

Scan this QR code to visit **TaihoPatientSupport.com** to learn more or **to enroll.**

Resources to support your practice and your patients

These materials and resources are designed to help manage treatment, billing, and support needs with INQOVI. Visit **INQOVI.com/hcp/resources** to view and download these resources and more for your practice and for your patients.

For your practice

Co-Pay Brochure
Eligibility criteria and enrollment details for the Taiho Oncology Co-Pay Assistance Program

Patient Access Brochure
Enrollment instructions and support information for Taiho Oncology Patient Support

Patient and Caregiver Brochure
Dosing guidance, side effect management, and financial support

For your patients

INQOVI Patient Welcome Kit

To help your patients start and stay on INQOVI, the kit includes content such as:

Patient and Caregiver Brochure
Important information on INQOVI for patients and caregivers, including dosing guidance, side effect management, and financial support

Health Journal
A journal of treatment and symptom trackers that help patients record their doses for adherence and side effects for management

Blister Pack Opener
A tool designed to help patients safely and easily open INQOVI blister packs

Scan this **QR code** to request a Taiho representative for more information and instructions on ordering the **Patient Welcome Kit**.

Patient advocacy organizations

American Cancer Society (ACS)
24/7 support line, disease education, transportation to treatment, and lodging assistance

1-800-227-2345 | cancer.org

Aplastic Anemia and MDS International Foundation (AAMDSIF)
Educational materials, one-on-one support, clinical trial listings, and local events for patients with MDS

1-800-747-2820 | aamds.org

Blood Cancer United
Personalized support, financial aid, clinical trial navigation, and disease-specific information

1-800-955-4572 | bloodcancerunited.org

Cancer*Care*
Free counseling, support groups, financial assistance, and educational resources for patients with AML or MDS and their caregivers

1-800-813-4673 | cancercare.org

HealthTree Foundation
Education, clinical trial matching, expert directories, and community support for patients with AML or MDS and their caregivers

1-800-709-1113 | healthtree.org

Know AML
Global awareness initiative offering educational tools and support for patients with AML and their caregivers

know-aml.com

Leukemia Research Foundation (LRF)
Patient education, financial support, and research funding focused on advancing leukemia care

1-847-424-0600 | leukemiarf.org

The Max Foundation
Access to treatment, emotional support, and care navigation for patients with AML in underserved regions

1-425-778-8660 | themaxfoundation.org

Myelodysplastic Syndromes (MDS) Foundation
Trusted information, insurance navigation, treatment center referrals, and events for patients with MDS and their caregivers

1-800-637-0839 | mds-foundation.org

Additional resources
youandmds.org
youandaml.org

These organizations are independent and not affiliated with Taiho. This list is provided for informational purposes only.

Please see Important Safety Information throughout and full Prescribing Information in pocket or at INQOVI.com/PI.

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

Diagnostic codes for INQOVI

The diagnostic ICD-10-CM codes contained in this section are designed to provide important reimbursement information for your pharmacy when ordering INQOVI. ICD codes continually change, so it is recommended that you consult your ICD-10 code book or contact the payer for coding and billing guidance.

DIAGNOSTIC CODES FOR AML	
C92.00	Acute myeloblastic leukemia, not having achieved remission
C92.60	Acute myeloid leukemia with 11q23-abnormality not having achieved remission
C92.61	Acute myeloid leukemia with 11q23-abnormality in remission
C92.62	Acute myeloid leukemia with 11q23-abnormality in relapse
C92.A0	Acute myeloid leukemia with multilineage dysplasia
C92.A1	Acute myeloid leukemia with multilineage dysplasia, not having achieved remission
C92.A2	Acute myeloid leukemia with multilineage dysplasia, in remission
C92.Z0	Other myeloid leukemia, not having achieved remission (for other specific subtypes)

AAPC. ICD-10-CM Expert 2025 for Providers & Facilities. American Academy of Professional Coders; 2025.
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 healthcare professional is responsible for ensuring all coding is accurate and appropriate.

DIAGNOSTIC CODES FOR CMML	
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 2025 for Providers & Facilities. American Academy of Professional Coders; 2025.

DIAGNOSTIC CODES FOR MDS	
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)
D46.20	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
D46.4	Refractory anemia, unspecified
D46.Z	Other myelodysplastic syndromes (EXCLUDES chronic myelomonocytic leukemia [C93.1])
D46.9	Myelodysplastic syndrome, unspecified Myelodysplasia NOS

AAPC. ICD-10-CM Expert 2025 for Providers & Facilities. American Academy of Professional Coders; 2025.
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 healthcare professional is responsible for ensuring all coding is accurate and appropriate.

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Formulation codes for INQOVI

FORMULATION	PACKAGING	NDC (11-DIGIT FORMAT)*
35 mg decitabine and 100 mg cedazuridine	5-tablet blister pack	64842-0727-**0**9

For formulation codes for venetoclax, refer to the venetoclax Prescribing Information.

*The National Drug Code (NDC) has been "zero-filled" to convert the 10-digit NDC to an 11-digit NDC that meets Centers for Medicare & Medicaid Services standards. The zero-fill location is indicated in bold. Check payer requirements for appropriate reporting of the NDC.

Specialty distribution and availability

The following lists include specialty distributors and pharmacies where INQOVI is available for your on-site dispensing practice or your patients.

SPECIALTY DISTRIBUTORS AUTHORIZED TO SUPPLY INQOVI TO YOUR ON-SITE DISPENSING PRACTICE			
SPECIALTY PHARMACY	**WEBSITE**	**TELEPHONE**	**FAX**
Cardinal Health SPD Hospitals	pdlogin.cardinalhealth.com	(866) 677-0708	(614) 553-6301
Cardinal Health SPD Physician Office and Clinic	pdlogin.cardinalhealth.com	(877) 453-3972	(877) 274-9897
Cencora ASD Healthcare	www.asdhealthcare.com	(800) 746-6273	(800) 547-9413
Cencora Oncology Supply	www.oncologysupply.com	(800) 633-7555	(800) 248-8205
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

SPECIALTY PHARMACIES AUTHORIZED TO DISPENSE INQOVI TO YOUR PATIENTS			
SPECIALTY PHARMACY	**WEBSITE**	**TELEPHONE**	**FAX**
Accredo Specialty Pharmacy	www.accredo.com	(877) 732-3431	(888) 302-1028
Biologics by McKesson	biologics.mckesson.com	(800) 850-4306	(800) 823-4506
CVS Specialty Pharmacy	www.cvsspecialty.com	(855) 539-4712	(888) 435-1256
Onco360 Oncology Pharmacy	www.onco360.com	(877) 662-6633	(877) 662-6355
Optum	www.specialty.optumrx.com	(877)-445-6874	(877) 342-4596
McKesson Specialty Health	www.walgreensspecialtyrx.com	(888) 347-3416	(877) 231-8302

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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.

INQOVI is indicated in combination with venetoclax for the treatment of patients with newly diagnosed acute myeloid leukemia (AML) who are 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Myelosuppression

INQOVI as Monotherapy for MDS or CMML

In patients with MDS or CMML, INQOVI can cause severe myelosuppression, including fatal adverse reactions. 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%. Thrombocytopenia, neutropenia, anemia, and febrile neutropenia are 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.

INQOVI in Combination with Venetoclax for AML

In patients with AML, INQOVI can cause severe myelosuppression, including fatal adverse reactions, when given in combination with venetoclax. Based on laboratory values in Study ASTX727-07, Phase 2 new or worsening thrombocytopenia occurred in 70% of patients, with Grade 3 or 4 occurring in 69%. Neutropenia occurred in 48% of patients, with Grade 3 or 4 occurring in 48%. Anemia occurred in 54% of patients, with Grade 3 or 4 occurring in 50%. Febrile neutropenia occurred in 52% of patients, with Grade 3 or 4 occurring in 52%. Thrombocytopenia, neutropenia, anemia, and febrile neutropenia were a frequent cause of INQOVI and/or venetoclax dose reduction or interruption. Dose reductions of INQOVI due to neutropenia and thrombocytopenia occurred in 4% and 1% of patients, respectively. Dose interruptions of INQOVI due to neutropenia, febrile neutropenia, thrombocytopenia, and anemia occurred in 40%, 11%, 8%, and 2% of patients, respectively.

Fatal and serious infectious complications can occur during treatment with INQOVI and venetoclax. Pneumonia occurred in 25% of patients, with Grade 3 or 4 occurring in 20%. Sepsis occurred in 28% of patients, with Grade 3 or 4 occurring in 18%. Fatal pneumonia occurred in 2% of patients and fatal sepsis in 8%.

Obtain complete blood cell counts prior to initiation of INQOVI with venetoclax, 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

Advise patients of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with INQOVI and for 6 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with INQOVI and for 3 months after the last dose.

ADVERSE REACTIONS

INQOVI as Monotherapy for MDS or CMML

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. These 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%).

INQOVI in Combination with Venetoclax for AML

Serious adverse reactions occurred in 82% of patients who received INQOVI+VEN. Serious adverse reactions in >5% of patients included febrile neutropenia (31%), sepsis (22%), pneumonia (15%), infection (bacterial/viral) (10%), hemorrhage (9%), and dyspnea (6%). Fatal adverse reactions occurred in 8% of patients who received INQOVI+VEN. These included sepsis (5%), dyspnea (2%), myocardial infarction (1%), hemolytic anemia (1%), and tumor lysis syndrome (1%).

The most common adverse reactions (≥20%) were neutropenia (60%), febrile neutropenia (52%), thrombocytopenia (52%), hemorrhage (42%), anemia (41%), infection (bacterial/viral) (40%), diarrhea (38%), fatigue (36%), mucositis (36%), constipation (36%), arthralgia (35%), decreased appetite (31%), edema (31%), nausea (31%), dyspnea (30%), white blood cell count decreased (28%), sepsis (28%), pneumonia (25%), rash (25%), transaminitis (24%), myalgia (23%), arrhythmia (21%), and abdominal pain (21%). The most common Grade 3 or 4 laboratory abnormalities (≥20%) were decreased leukocytes (91%), decreased lymphocytes (81%), decreased platelets (69%), decreased hemoglobin (50%), and decreased neutrophils (48%).

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 in pocket or at INQOVI.com/PI.

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

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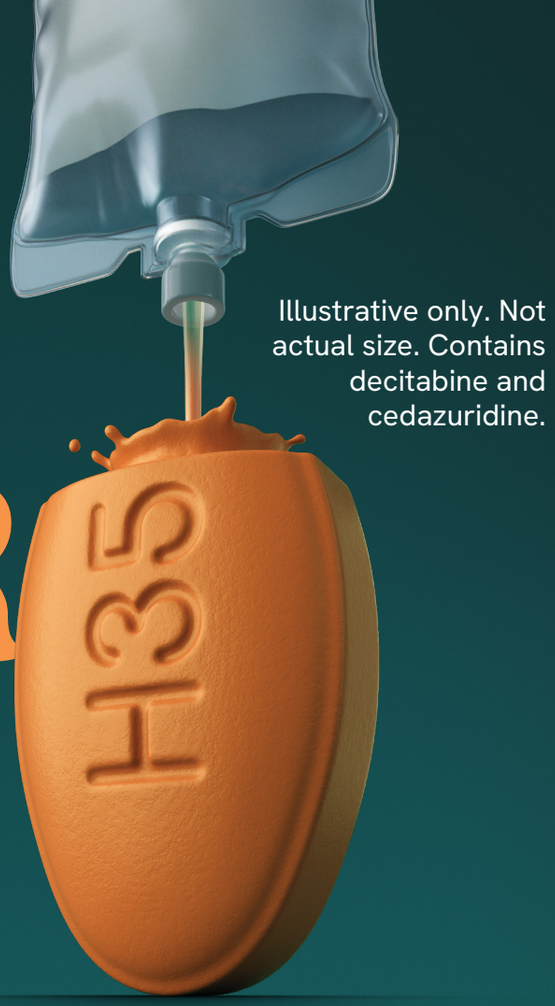
Nurse and Pharmacist Guide



Illustrative only. Not actual size. Contains decitabine and cedazuridine.

RESPONSES SHAPED BY A

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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Myelosuppression

INQOVI as Monotherapy for MDS or CMML

In patients with MDS or CMML, INQOVI can cause severe myelosuppression, including fatal adverse reactions. 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%. Thrombocytopenia, neutropenia, anemia, and febrile neutropenia are 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 in pocket or at INQOVI.com/PI.

TAIHO ONCOLOGY