

# Minimize your patients' out-of-pocket expenses for INQOVI

INQOVI is the only oral hypomethylating agent (HMA) for the treatment of myelodysplastic syndromes (MDS) and chronic myelomonocytic leukemia<sup>1</sup>

All other outcomes being similar,

77%

of patients with MDS said they would switch to an oral pill if available to them, according to an HMA treatment preference study<sup>2,a,b</sup>

### **INDICATIONS**

INQOVI is indicated for treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.

## IMPORTANT SAFETY INFORMATION WARNINGS AND PRECAUTIONS

### Myelosuppression

Fatal and serious myelosuppression can occur with INQOVI. Based on laboratory values, new or worsening thrombocytopenia occurred in 82% of patients, with Grade 3 or 4 occurring in 76%. Neutropenia occurred in 73% of patients, with Grade 3 or 4 occurring in 71%. Anemia occurred in 71% of patients, with Grade 3 or 4 occurring in 55%. Febrile neutropenia occurred in 33% of patients, with Grade 3 or 4 occurring in 32%.

Please see additional Important Safety Information on the last page and full <u>Prescribing Information</u>.



<sup>&</sup>lt;sup>a</sup>When HMA treatments were assumed to be associated with the same risk of acute myeloid leukemia and level of fatigue but to differ in terms of mode and frequency administration.<sup>2</sup>

<sup>&</sup>lt;sup>b</sup>A preference study was conducted using the discrete-choice experiment method in collaboration with patient organizations to understand HMA preferences for United States and Canadian patients with MDS. Eligibility included being an MDS patient or a caregiver of a patient with MDS and being 18 years of age or older. The study was comprised of two phases. Phase 1 was qualitative and included a literature review, interviews with clinicians, patients, and caregivers, and input from patient organizations. Phase 2 was quantitative, during which survey participants indicated their preference between different hypothetical HMA profiles that varied in attributes. Sixteen participants completed Phase 1, and 184 (158 patients and 26 caregivers) completed Phase 2.<sup>2</sup>

# The Taiho Oncology Patient Support Program



### **CO-PAY ASSISTANCE PROGRAM**

**Potential** 

\$0 CO-PAY

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





To determine patient eligibility for the Co-Pay Program, visit **TaihoOncologyCopay.com.** 

Taiho Oncology Patient Support™ offers personalized services to help patients, caregivers, and healthcare professionals (HCPs) access Taiho Oncology medications. This includes insurance verification, help with medication costs, and treatment plan support. For patients with commercial insurance coverage, the Taiho Oncology Co-Pay Assistance Program may help reduce out-of-pocket (OOP) costs to \$0.ª

The Taiho Oncology Patient Assistance Program provides free medication for eligible patients who are underinsured or uninsured and may arrange for patients to receive prescribed Taiho Oncology medications at no cost based on financial criteria.

**HOW TO ENROLL** We offer 3 convenient ways to enroll in Taiho Oncology Patient Support services:



### Via the HCP Portal

**Enroll online** directly through our HCP portal at **TaihoPatientSupport.com**. Patients may also download and complete the **Enrollment Form** and take it to the HCP's office.



### **By Phone**

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



### **Download, Print, and Fax**

Download and fill in the **Enrollment Form** from **TaihoPatientSupport.com**.
Print it out and fax the completed form to **1-844-287-2559**.



### **Patient Support Website**

Scan the QR code to visit **TaihoPatientSupport.com**.

### FOUNDATION FINANCIAL ASSISTANCE<sup>b</sup>



### FundFinder (fundfinder.panfoundation.org)

FundFinder is a free resource that provides information, in one place, about various available patient assistance programs and notifies you when a disease fund opens at any of the charitable patient assistance foundations.

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 benefit 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 of 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.

<sup>b</sup>Taiho Oncology does not influence or control the decisions of independent co-pay assistance foundations; each co-pay assistance foundation has its own criteria for patient eligibility. We cannot guarantee financial assistance.

# Your patients may be eligible for financial assistance through the Medicare Extra Help program<sup>3</sup>

### Extra Help can help patients with limited income pay for medications and other related costs<sup>3</sup>

To qualify for Extra Help, annual income must be  $\leq$ 150% of the federal poverty level (FPL) and total resources must be at or below the amounts shown below.<sup>3,4</sup>

	ANNUAL INCOME <sup>3,a,b</sup>	OTHER RESOURCES <sup>5,c</sup>
Individual	Limited to <b>\$22,590</b> per year	Limited to <b>\$15,720</b> per year
Married Couple	Limited to \$30,660 per year	Limited to <b>\$31,360</b> per year

Patients who meet any of the following conditions automatically qualify for Extra Help<sup>6</sup>:

- Enrolled in both Medicare and Medicaid (dual-eligible)
- Qualify for a Medicare Savings Program
- Receive Supplemental Security Income benefits

Everyone who qualifies for Extra Help will pay6:

- No monthly premium
- No annual deductible
- No Part D late enrollment penalty
- A reduced amount for both generic and brand-name drugs (see table below)

EXTRA HELP CATEGORY⁵	GENERIC	BRAND
Non-Dual-Eligible Beneficiaries	\$4.90	\$12.15
Dual-Eligible Beneficiaries With Income ≤100% FPL	\$1.60	\$4.80
Dual-Eligible Beneficiaries With Income >100% but ≤150% FPL	\$4.90	\$12.15

### How can you identify dual-eligible patients?

These patients carry cards for Medicare and Medicaid, as well as their prescription drug card.



 $<sup>^{\</sup>mathrm{a}}$ FPL is as of 2024 and may increase in 2025. Annual income limits are higher in Alaska and Hawaii.  $^{\mathrm{4.7}}$ 

References: 1. INQOVI. Prescribing Information. Taiho Oncology. Inc; 2022. 2. Zeidan AM, Tsai JH, Karimi M, et al. Understanding what matters to myelodysplastic syndrome patients-a study of preferences for treatments with hypomethylating agents. Poster presented at: ASH (American Society of Hematology) Annual Meeting 2022; December 10-13, 2022; New Orleans, Louisiana. 3. Centers for Medicare & Medicaid Services. Help with drug costs. Accessed July 8, 2024. https://www.medicare.gov/basics/costs/help/drug-costs 4. National Council on Aging. Part D low income subsidy/extra help eligibility and coverage chart. January 25, 2024. Accessed July 8, 2024. https://www.ncoa.org/article/part-d-low-income-subsidy-extra-help-eligibility-and-coverage-chart 5. Centers for Medicare & Medicaid Services. Announcement of Calendar Year (CY) 2025 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. April 1, 2024. Accessed July 8, 2024. https://www.cms.gov/files/document/2025-announcement.pdf 6. National Council on Aging. Medicare Part D: how to get "extra help" paying for prescriptions. October 31, 2023. Accessed July 8, 2024. https://www.ncoa.org/article/medicare-part-d-how-to-get-extra-help-paying-for-prescriptions 7. 2024
Federal Poverty Level Guidelines (FPL): 2024/2025 LIS Qualifications and Benefits. QiMedicare. January 13, 2024. Accessed July 8, 2024. https://dimedicare.com/news/virticle.php?article.id=10348category.id=18 8. Social Security Administration | Indeptatoning

2024. https://qlmedicare.com/news/Article.php?article\_id=1034&category\_id=8 8. Social Security Administration. Understanding the Extra Help With Your Medicare Prescription Drug Plan. Accessed July 8, 2024. https://www.ssa.gov/pubs/EN-05-10508.pdf
9. Kaiser Family Foundation. Changes to Medicare Part D in 2024 and 2025 under the Inflation Reduction Act and how enrollees will benefit. Issue brief. April 20, 2023. Accessed July 8, 2024. https://www.kff.org/medicare/issue-brief/changes-to-medicare-part-d-in-2024-and-2025-under-the-inflation-reduction-act-and-how-enrollees-will-benefit/

(decitabine and cedazuridine) 35mg / 100mg tablets

blncome and resource limits vary according to the number of dependents living with the Medicare beneficiary and whether the beneficiary has income from work.8

<sup>&</sup>lt;sup>c</sup>Resource limits are as of 2024 and may change in 2025. Resources include money in a checking or savings account, stocks, bonds, mutual funds, and Individual Retirement Accounts (IRAs). Resources do not include a primary residence, vehicles, household items, burial plots, up to \$1500 for burial expenses (per person), or life insurance policies.<sup>5,8</sup>

### Medicare beneficiaries taking INQOVI or a similarly priced medication will pay approximately 39% less in 2025 than they did in 2024, due to the change in the annual OOP cap<sup>9,a</sup>

### TOTAL OOP COSTS BY YEAR

	2023	2024	2025
DEDUCTIBLE	100% of drug costs up to \$505	100% of drug costs up to \$545	100% of drug costs up to \$540
INITIAL COVERAGE	25% of drug costs up to \$4660 in total drug costs (≤\$1038 OOP)	25% of drug costs up to \$5029 in total drug costs (\$1121 OOP)	25% of drug costs up to \$2000 OOP
COVERAGE GAP	25% of drug costs up to \$3100 OOP	25% of drug costs up to ~\$3300 OOP	None
CATASTROPHIC PHASE	5% of drug costs with no maximum OOP	None	None

<sup>&</sup>lt;sup>a</sup>Assuming INQOVI or a similarly priced medication is taken the full calendar year.

### IMPORTANT SAFETY INFORMATION (cont'd) WARNINGS AND PRECAUTIONS (cont'd)

Myelosuppression (cont'd)

Myelosuppression (thrombocytopenia, neutropenia, anemia, and febrile neutropenia) is the most frequent cause of INQOVI dose reduction or interruption, occurring in 36% of patients. Permanent discontinuation due to myelosuppression (febrile neutropenia) occurred in 1% of patients. Myelosuppression and worsening neutropenia may occur more frequently in the first or second treatment cycles and may not necessarily indicate progression of underlying MDS.

Fatal and serious infectious complications can occur with INQOVI. Pneumonia occurred in 21% of patients, with Grade 3 or 4 occurring in 15%. Sepsis occurred in 14% of patients, with Grade 3 or 4 occurring in 11%. Fatal pneumonia occurred in 1% of patients, fatal sepsis in 1%, and fatal septic shock in 1%.

Obtain complete blood cell counts prior to initiation of INQOVI, prior to each cycle, and as clinically indicated to monitor response and toxicity. Administer growth factors and anti-infective therapies for treatment or prophylaxis as appropriate. Delay the next cycle and resume at the same or reduced dose as recommended.

### **Embryo-Fetal Toxicity**

INQOVI can cause fetal harm. Advise pregnant women of the potential risk to a fetus. Advise patients to use effective contraception during treatment and for 6 months (females) or 3 months (males) after last dose.

#### ADVERSE REACTIONS

Serious adverse reactions in > 5% of patients included febrile neutropenia (30%), pneumonia (14%), and sepsis

(13%). Fatal adverse reactions included sepsis (1%), septic shock (1%), pneumonia (1%), respiratory failure (1%), and one case each of cerebral hemorrhage and sudden death.

The most common adverse reactions (≥ 20%) were fatigue (55%), constipation (44%), hemorrhage (43%), myalgia (42%), mucositis (41%), arthralgia (40%), nausea (40%), dyspnea (38%), diarrhea (37%), rash (33%), dizziness (33%), febrile neutropenia (33%), edema (30%), headache (30%), cough (28%), decreased appetite (24%), upper respiratory tract infection (23%), pneumonia (21%), and transaminase increased (21%). The most common Grade 3 or 4 laboratory abnormalities (≥ 50%) were leukocytes decreased (81%), platelet count decreased (76%), neutrophil count decreased (71%), and hemoglobin decreased (55%).

### **USE IN SPECIFIC POPULATIONS**

### Lactation

Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment with INQOVI and for 2 weeks after the last dose.

### **Renal Impairment**

No dosage modification of INQOVI is recommended for patients with mild or moderate renal impairment (creatinine clearance [CLcr] of 30 to 89 mL/min based on Cockcroft-Gault). Due to the potential for increased adverse reactions, monitor patients with moderate renal impairment (CLcr 30 to 59 mL/min) frequently for adverse reactions. INQOVI has not been studied in patients with severe renal impairment (CLcr 15 to 29 mL/min) or endstage renal disease (ESRD: CLcr <15 mL/min).

Please see full Prescribing Information.



