# AQVESME™ (mitapivat) Start Form

This form acts as a prescription for AQVESME and also enrolls your patient into myAgios® Patient Support Services

## 1 PATIENT INFORMATION

**Please provide the following information about your patient. All fields are required unless otherwise noted.**

Patient first name _____ Patient middle initial _____ Patient last name _____

Date of birth (MM/DD/YYYY) _____ Age _____ ◯ Male ◯ Female Last four digits of Social Security number _____

**Patient preferred language:**

◯ Arabic ◯ Hindi ◯ Vietnamese
◯ Chinese (Simplified) ◯ Spanish ◯ Other language: _____
◯ English ◯ Urdu

**Mailing address** (for medication delivery)

Street address _____ City _____ State _____ ZIP _____

Mobile phone number (preferred) _____ Home phone number (optional) _____

Email address _____

Name of caregiver (optional) _____ Relation of caregiver _____

Primary mobile phone number of caregiver _____ Email address of caregiver _____

## 2 PATIENT DIAGNOSIS AND AQVESME™ (MITAPIVAT) TABLETS PRESCRIPTION

**Thalassemia:**

◯ D56.0: Alpha-thalassemia ◯ D56.1: Beta-thalassemia*
◯ D56.9: Thalassemia, unspecified ◯ Other: _____

**Hemoglobin E (HbE) beta-thalassemia is included under D56.1.*

***If your patient does not have a diagnosis code, please contact your Patient Support Manager (PSM). Your PSM will contact you to convey additional information.***

**Please be sure to fill in all the information below, including the number of refills. All fields are required unless otherwise noted.**

Patient name _____ Date of birth (MM/DD/YYYY) _____

**AQVESME 100 mg Tablets**

SIG: ◯ Take 1 tablet by mouth twice daily for 28 days QTY: 56

***Dispense no more than a 28-day supply per fill per REMS requirements*

Refills: ◯ 6 ◯ Other (please specify): _____

Prescriber Signature _____ Date _____

Name of supervising physician _____
*(If required).*

*No stamps. NY providers must submit a valid NY prescription or eScribe to the exclusive Specialty Pharmacy for AQVESME, Biologics.*

To complete the enrollment process, please be sure to complete all pages (1-4), and then fax it to myAgios Patient Support Services at 1-800-951-7814
For questions, call **1-877-77-AGIOS (1-877-772-4467)**, Mon-Fri, 8 AM to 8 PM ET

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For more information about AQVESME, please visit **AQVESME.com/hcp** and for additional information regarding AQVESME REMS, visit **AQVESMEREMS.com**.

## 3 INSURANCE INFORMATION

**Please check and provide information about your patient's insurance(s). All fields are required unless otherwise noted.** ***Be sure to include a copy of both sides of your patient's insurance card(s).***

**Patient insurance (check all that apply):** ◯ **No insurance** ◯ **Medicare** ◯ **Medicaid** ◯ **Commercial/private** ◯ **Other**

### Primary health insurance

Plan name _____ Phone # _____

Policy ID # _____ Group # _____

**Policy holder** **(if other than patient)**

Name _____ Date of birth (MM/DD/YYYY) _____

### Prescription drug insurance

Plan name _____ Phone # _____

Policy ID # _____ Group # _____

RX BIN # _____ PCN # _____

## 4 PRESCRIBER & PRACTICE CONTACT INFORMATION AND DECLARATION

**Please provide the following information about you and your practice. All fields are required unless otherwise noted.**

Practice staff contact name _____

Practice staff contact email address _____

Practice staff contact phone number _____

Prescriber name _____

Prescriber specialty
◯ Hematologist/Oncologist ◯ Hematologist
◯ Primary care provider

Practice name _____

Street address _____ City _____ State _____ ZIP _____

NPI number _____ Fax number _____

If your patient has participated in a clinical trial, please include the trial identification code:

Trial ID _____

I certify that the patient and physician information contained in this Start Form is complete and accurate to the best of my knowledge. I have prescribed AQVESME based on my judgment of medical necessity, and in accordance with its labeled indication I will be supervising my patient's treatment. I authorize, if appropriate, the forwarding of this prescription to an authorized specialty pharmacy on behalf of myself and my patient. I understand that neither I nor my patient may seek reimbursement from any government program or third-party insurer for any free product received under the program. I certify that I have obtained my patient's authorization to release the above information and such other information as may be required by Agios or its agents to assist my patient in obtaining coverage for AQVESME, to assist my patient in initiating or continuing AQVESME therapy, and to provide financial assistance to my patient.

Prescriber Signature _____ Date _____

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## 5 PATIENT AUTHORIZATION TO USE/DISCLOSE HEALTH INFORMATION (REQUIRED)

**Please have your patient agree to the terms below. All fields are required unless otherwise noted.**

I understand that myAgios Patient Support Services is a service offered by Agios Pharmaceuticals, Inc. to help eligible patients who have been prescribed AQVESME™ (mitapivat) tablets obtain insurance coverage and financial assistance for AQVESME, including through its Coverage Interruption and Patient Assistance Programs (the "Programs"). I give permission for my physician and their staff to disclose my health and other personal information, including, but not limited to the information on this form, to Agios Pharmaceuticals, Inc. and its agents and representatives (collectively "Agios") so that Agios may use and further disclose my information to healthcare providers, pharmacies, insurance companies, prescription drug plans, and other third-party payers and patient assistance groups (collectively, "Third Parties") in order to: (1) enroll me in the Programs; (2) facilitate the filling of my prescription for and the delivery and administration of AQVESME; (3) assist me in obtaining insurance coverage for AQVESME; (4) contact me about AQVESME and the Programs (this may include supplemental educational materials, information, offers, and services related to my therapy or my medical condition, or opportunities to participate in focus groups, surveys, or interviews); and (5) manage the Programs. I further authorize the Third Parties to disclose health and other personal information about me in their possession to Agios in order to assist Agios in accomplishing the purposes described above. I understand that once my information is disclosed pursuant to this authorization, it may no longer be protected by federal privacy laws (the Health Insurance Portability and Accountability Act) or state privacy laws and may be further disclosed to others. However, I understand that Agios will not release my information to any party, except as provided in this authorization or as permitted by applicable law, without first obtaining my (or my authorized representative's) separate written consent. I understand that I may refuse to sign this authorization and such refusal will not affect my ability to receive AQVESME that is paid for by my insurer, my treatment, payment for treatment, eligibility for or enrollment in health benefits, but it will limit my ability to receive support services for AQVESME, including participation in free medication programs. I understand that this authorization will remain in effect for 3 years, or a shorter period as may be required by state law, from the date of my signature, unless I revoke it earlier by contacting Agios in writing at ConnectMed360 c/o myAgios Patient Support Services, 13410 Eastpoint Centre Dr., Louisville, KY 40223. If I revoke this authorization, Agios and any Third Parties who are notified of my revocation will stop using and disclosing my information as soon as possible, but the revocation will not affect prior use or disclosure of my information in reliance on this authorization. I understand that the services described in this authorization may be reduced at any time, without prior notification. However, if any services are added, Agios will obtain my authorization to receive any such additional services. I understand that certain Third Parties may receive compensation in exchange for their disclosure of my information to Agios. I also understand that I have the right to receive a copy of this authorization. I verify the information provided is true and correct. If I am the caregiver/representative for the patient, I confirm I am authorized to sign on behalf of the patient.

Patient name _____ Caregiver/Guardian name _____

Patient Signature _____ Date _____

Caregiver/Guardian Signature _____ Date _____

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## 6 CONSENT TO RECEIVE SMS TEXT FROM AGIOS (OPTIONAL)*

**By enrolling in myAgios Patient Support Services, you may receive SMS text messages with appointment reminders and other healthcare-related communications.**

◯ By checking this box, I consent to receive text messages from Agios Pharmaceuticals. Reply STOP to opt out. Reply HELP for assistance. Message and data rates may apply. Message frequency may vary. I understand that this consent is not required or a condition of purchasing or obtaining goods or services from Agios. Review Privacy Policy for additional information: https://www.agios.com/privacy-notice/.

Please see **Important Safety Information** below and accompanying **full Prescribing Information**.

*Patient's consent to Section 6 is not required or a condition of purchasing or obtaining products or services from Agios.

## 7 CONSENT TO RECEIVE MATERIAL FROM AGIOS (OPTIONAL)*

**By enrolling in myAgios Patient Support Services, you may receive support and educational materials on thalassemia and AQVESME™ (mitapivat) tablets.**

By clicking I Agree, I consent that the information I am providing may be used by Agios and its agents and service providers to keep me informed about Agios products, patient support services, or other opportunities that may be of interest to me via mail and/or email. Agios may also combine the information I provide with information about me from third parties to better match information with my interests. You may receive mail or emails that contain information to support and educate on thalassemia as well as those that market or advertise Agios products or services. Agios understands protecting your personally identifiable information is very important. I understand from time to time, Agios' Online Privacy Policy may change and for the most recent version of the Online Privacy Policy, I should visit myAgios.com/privacy policy.

Please see **Important Safety Information** below and accompanying **full Prescribing Information**.

◯ I agree.

**Please present the following checkbox and statement to your patients as an option for patients to agree to when signing the Patient Authorization form:**

◯ I understand that I will receive educational information and updates about thalassemia, research opportunities, and other information that may be of interest to me from Agios.

◯ I consent to receive mail or email from or on behalf of Agios [and its affiliates] that contain information on research opportunities, as well as those that market or advertise Agios products or services at the mailing address or email I provide on this form. I understand that this consent is not required or a condition of purchasing or obtaining goods or services from Agios.

*Patient is under no obligation to complete Section 7 to receive their prescription or to enroll in the Patient Support Program.

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## 8 SUBMIT FORM

**Just one more step to go. To complete the enrollment process, please be sure to download your completed form, print it, and then fax it to myAgios Patient Support Services at 1-800-951-7814.**

## INDICATION

AQVESME is indicated for the treatment of anemia in adults with alpha- or beta-thalassemia.

## IMPORTANT SAFETY INFORMATION

**BOXED WARNING: HEPATOCELLULAR INJURY**

**AQVESME can cause serious hepatocellular injury. Measure liver laboratory tests (ALT, AST, alkaline phosphatase and total bilirubin with fractionation) at baseline and every 4 weeks for 24 weeks and then as clinically indicated. Avoid use of AQVESME in patients with cirrhosis. Discontinue AQVESME if hepatic injury is suspected.**
**Because of the risk of hepatocellular injury, AQVESME is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the AQVESME REMS.**

**WARNINGS AND PRECAUTIONS**

**Hepatocellular Injury**
AQVESME can cause hepatocellular injury. Avoid use of AQVESME in patients with cirrhosis. In patients with thalassemia treated with AQVESME, liver injury with and without jaundice has been observed within the first 6 months of exposure. Obtain liver tests (including ALT, AST, alkaline phosphatase, total bilirubin with fractionation) prior to the initiation of AQVESME, then every 4 weeks for the first 24 weeks, and as clinically indicated thereafter. Interrupt AQVESME if clinically significant increases in liver tests are observed or alanine aminotransferase is >5 times the upper limit of normal (ULN). Complete a comprehensive evaluation to rule out other causes of liver injury when drug-induced liver injury is suspected. Discontinue AQVESME if hepatocellular injury due to AQVESME is suspected.

Symptoms and signs of early liver injury may mimic those of thalassemia. Advise patients to report new or worsening symptoms of loss of appetite, nausea, right-upper-quadrant abdominal pain, vomiting, scleral icterus, jaundice, or dark urine while on AQVESME treatment.

During the double-blind period, 2 of 301 patients (0.66%) with thalassemia treated with AQVESME experienced adverse reactions suggestive of hepatocellular injury. Three additional patients experienced adverse reactions suggestive of hepatocellular injury during the open-label extension periods after switching from placebo to AQVESME. Of these 5 patients, 2 had serious liver injury requiring hospitalization, including 1 patient who developed jaundice (peak bilirubin 32 mg/dL). Another patient developed jaundice (peak bilirubin 4 mg/dL) without requiring hospitalization. These reactions were characterized by a time to onset within the first 6 months of treatment with peak elevations of alanine aminotransferase of >5×ULN with or without jaundice. All patients discontinued treatment with AQVESME, and these reactions improved upon treatment discontinuation.

**AQVESME REMS**
AQVESME is available only through a restricted program under a REMS called the AQVESME REMS because of the risk of hepatocellular injury.

**ADVERSE REACTIONS**
The most common adverse reactions (≥5%) among patients taking AQVESME were headache and insomnia.

**DRUG INTERACTIONS**
- Strong CYP3A Inhibitors and Inducers: Avoid concomitant use.
- Moderate CYP3A Inhibitors: Avoid concomitant use.
- Moderate CYP3A Inducers: Consider alternatives that are not moderate inducers. If there are no alternatives, see full Prescribing Information for recommended dosage for drug interactions with moderate CYP3A inducers.
- Sensitive CYP3A Substrates, including hormonal contraceptives: Avoid concomitant use with substrates that have narrow therapeutic index.
- CYP2B6, CYP2C, and UGT1A1 Substrates: Monitor patients for efficacy of the substrates with narrow therapeutic index.
- P-gp Substrates: Monitor patients for adverse reactions of the substrates with narrow therapeutic index.

**HEPATIC IMPAIRMENT**
Avoid use of AQVESME in patients with cirrhosis (Child-Pugh Class A, B, or C).

**Please see full Prescribing Information for AQVESME, including Boxed Warning.**

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