myagios™

TIBSOVO® (ivosidenib) 250 mg tablets

Enrollment Form

Complete this form for myAgios™ Patient Support Services and for TIBSOVO® (ivosidenib) prescriptions.

This form is not required for patients to apply for the Commercial $25 Co-Pay Program for TIBSOVO. This program is for eligible patients with commercial insurance. To apply, please visit myAgios-copay.com*

*Please see myAgios.com for full Terms and Conditions.

Service selection

With this single form you can connect your TIBSOVO patient to a variety of services. *Please fill out entire form except where noted below.*

What services do you need?

Prescription fulfillment	Benefits investigation and/or free product programs (insurance delay, uninsured/underinsured patients)	Neither of these options or you are not sure
Complete all sections on pages 2 and 3	Complete the entire form, except Section 5	Please call myAgios™ Patient Support Services at 1-844-409-1141 for assistance
Be sure provider has signed where indicated. Fax completed pages of the form and a copy of both sides of the patient's insurance card(s) to one of the following specialty pharmacies. **Biologics** **Fax:** 1-800-823-4506 **Ph:** 1-800-850-4306 **Diplomat** **Fax:** 1-800-550-6272 **Ph:** 1-877-977-9118	Be sure provider and patient have signed where indicated. Send the completed sections of form and a copy of both sides of the patient's insurance card(s), if applicable, to myAgios™ Patient Support Services via fax (1-844-409-1143). ***NOTE:*** *Physician signature is required in section 3 and 6. Patient signature is required for sections 7 and 8. Without patient signature on section 7, ability to receive support services for TIBSOVO, including participation in free medication programs, may be limited.*	

BEFORE FAXING:

- ☐ Be sure provider and patient have signed where indicated
- ☐ Be sure to include completed form and a copy of both sides of the patient's insurance card(s)

If you have questions or would like more information, please call myAgios™ Patient Support Services at 1-844-409-1141 Monday to Friday, 8 AM to 6 PM ET

Please see additional Important Safety Information on pages 6-7 and accompanying full Prescribing Information, including Boxed WARNING, and Medication Guide for additional Important Safety Information.

Reset Form

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1 PATIENT INFORMATION

Patient name (first and last) _____

Date of birth *(MM/DD/YYYY)* ____/____/____ ◯ Male ◯ Female Social Security number ____-____-____
(to be used for verifying identity and eligibility for some programs)

Mailing address *(to be used for medication delivery)*:

Street address _____ City _____ State ____ ZIP____

Primary phone (best contact number) ____-____-____ Alternate phone ____-____-____

2 INSURANCE INFORMATION

Please copy both sides of patient's insurance card(s)

Patient insurance *(check all that apply)*:

☐ No insurance ☐ Medicare ☐ Medicaid ☐ Commercial/private ☐ Other

Primary health insurance	Prescription drug insurance	Secondary insurance
Plan name _____	Plan name _____	Plan name _____
Phone # ____-____-____	Phone # ____-____-____	Phone # ____-____-____
Policy ID # _____	Policy ID # _____	Policy ID # _____
Group # _____	Group # _____	Group # _____
Policy holder (if other than patient)	Rx BIN # _____	
Name _____	PCN # _____	
Date of birth ____/____/____ *(MM/DD/YYYY)*		

Completed Prior Authorization form/information was submitted on: ____/____/____
(leave blank if prior authorization has not been completed)

3 FREE-PRODUCT PRESCRIPTIONS *(select only one - each subject to eligibility requirements)*

◯ 14-day QuickStart in the event of coverage delay of 5 or more days (available only for a **new patient** with a confirmed diagnosis of relapsed or refractory AML and a positive test for *IDH1* mutation)

◯ 30-day Patient Assistance Program prescription for a **new or existing patient**

◯ 30-day Coverage Interruption prescription for an **existing privately-insured patient**

Rx start date ____/____/____

TIBSOVO 250 mg tablets Quantity *(select one box matching quantity above)* ◯ 14-day supply ◯ 30-day supply Refills ____
(QuickStart only)

Instructions _____

The recommended dose for TIBSOVO is 500 mg (two 250-mg tablets) orally once daily until disease progression or unacceptable toxicity.

> Physician Signature _____ Date ____/____/____

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PATIENT NAME _____ DOB ____/____/_____

4 PATIENT DIAGNOSIS

- ◯ C92 — Myeloid leukemia
- ◯ ICD-10-CM C92.0 — Acute myeloblastic leukemia
- ◯ ICD-10-CM C92.00 — Acute myeloblastic leukemia, not having achieved remission
- ◯ ICD-10-CM C92.01 — Acute myeloblastic leukemia, in remission
- ◯ ICD-10-CM C92.02 — Acute myeloblastic leukemia, in relapse
- ◯ Other ICD-10 *(fill in below)*

_____

Current medications _____

Allergies _____

5 TIBSOVO PRESCRIPTION *(for specialty pharmacy fulfillment only)*

Rx start date _____/_____/_____

TIBSOVO dosage _____ Quantity *(days)* _____ Refills _____

Instructions _____

The recommended dose for TIBSOVO is 500 mg (two 250-mg tablets) orally once daily until disease progression or unacceptable toxicity.

> Physician Signature _____ Date ____/____/_____

6 PRESCRIBER INFORMATION AND DECLARATION

Prescriber name _____ Prescriber specialty _____

Practice name _____ Practice contact _____

Phone _____-_____-_____ Fax _____-_____-_____

Email _____

Street address _____ City _____ State _____ ZIP _____

NPI # _____ Tax ID # _____ State license # _____

DEA # _____ Medicare/Medicaid provider # _____

Provider Transaction Access Number (PTAN) _____

Practice prefers to dispense TIBSOVO from an associated office or hospital-based pharmacy: ◯ **No** ◯ **Yes:**

> Pharmacy name _____ Pharmacy phone ____-____-_____ Pharmacy fax ____-____-_____

I certify that the patient and physician information contained in this enrollment form is complete and accurate to the best of my knowledge. I have prescribed TIBSOVO based on my judgment of medical necessity and I will be supervising the patient's treatment. I authorize the forwarding of this prescription to an authorized specialty pharmacy on behalf of myself and the patient. I understand that neither I nor the 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 the patient's authorization to release the above information and such other information as may be required by Agios or its agents to assist the patient in obtaining coverage for TIBSOVO, to assist the patient in initiating or continuing TIBSOVO therapy and to provide financial assistance to the patient.

If I have requested QuickStart, I certify that this prescription is for a new patient with a diagnosis of relapsed or refractory AML and a positive test for an *IDH1* mutation.

> Physician Signature _____ Date ____/____/_____

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PATIENT NAME _____ DOB ____/____/_____

7 PATIENT AUTHORIZATION TO USE/DISCLOSE HEALTH INFORMATION

I understand that myAgios™ Patient Support Services is a service offered by Agios Pharmaceuticals, Inc. to help eligible patients who have been prescribed TIBSOVO obtain insurance coverage and financial assistance for TIBSOVO, including through its co-pay assistance, Quick Start, Coverage Interruption and Patient Assistance Program (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 TIBSOVO; (3) assist me in obtaining insurance coverage for TIBSOVO; (4) contact me about TIBSOVO 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 TIBSOVO 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 TIBSOVO, 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 Sonexus c/o Agios™ Patient Support Services 1330 Enclave Parkway, Suite 125, Houston TX, 77077. 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 *(print)* _____ Representative name *(print, if applicable)* _____

Patient/Representative Signature _____ Date ____ /____ /_____

Please see additional Important Safety Information on pages 6-7 and accompanying full Prescribing Information, including Boxed WARNING, and Medication Guide for additional Important Safety Information.

PATIENT NAME _____ DOB ____/____/_____

8 INTEREST IN PATIENT ASSISTANCE PROGRAM (PAP) FOR UNINSURED/UNDERINSURED PATIENTS

- ○ Yes, please assess my eligibility for Patient Assistance Program (PAP)
- ○ Yes, I am a US resident

Number of family members in household _____
(people who contribute to or are dependent on the household income)

Annual gross pretax household income *(prior 12 months)* _____

- ○ Yes, I understand that in order to qualify for the Patient Assistance Program I must meet program requirements. I certify that the information I have provided about my household income and size is accurate. I know that myAgios may ask me for a copy of my recent tax returns or other proof of income for the purpose of an audit and I agree to provide such documentation in a timely manner, if requested. I certify that the information provided above is truthful and accurate to the best of my knowledge and that any other information I provide at Agios' request will be truthful and accurate.

I understand that my eligibility for the program is based on requirements determined by Agios in its discretion (that Agios may change at any time) and that, if approved, I must reapply and continue to meet eligibility requirements on an ongoing basis. I certify that I will notify the Patient Assistance Program at 1-844-409-1141 if my income or health insurance status changes. I agree not to seek reimbursement from any government program or third-party insurer for any free product received under the program.

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 *(print)* _____ Representative name *(print, if applicable)* _____

Patient/Representative Signature _____ Date ____ /____ /_____

INDICATION

TIBSOVO (ivosidenib) is indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.

IMPORTANT SAFETY INFORMATION

WARNING: DIFFERENTIATION SYNDROME

Patients treated with TIBSOVO have experienced symptoms of differentiation syndrome, which can be fatal if not treated. Symptoms may include fever, dyspnea, hypoxia, pulmonary infiltrates, pleural or pericardial effusions, rapid weight gain or peripheral edema, hypotension, and hepatic, renal, or multi-organ dysfunction. If differentiation syndrome is suspected, initiate corticosteroid therapy and hemodynamic monitoring until symptom resolution.

WARNINGS AND PRECAUTIONS

Differentiation Syndrome: See Boxed WARNING. In the clinical trial, 19% (34/179) of patients with relapsed or refractory AML treated with TIBSOVO experienced differentiation syndrome. Differentiation syndrome is associated with rapid proliferation and differentiation of myeloid cells and may be life-threatening or fatal if not treated. Symptoms of differentiation syndrome in patients treated with TIBSOVO included noninfectious leukocytosis, peripheral edema, pyrexia, dyspnea, pleural effusion, hypotension, hypoxia, pulmonary edema, pneumonitis, pericardial effusion, rash, fluid overload, tumor lysis syndrome, and creatinine increased. Of the 34 patients who experienced differentiation syndrome, 27 (79%) recovered after treatment or after dose interruption of TIBSOVO. Differentiation syndrome occurred as early as 1 day and up to 3 months after TIBSOVO initiation and has been observed with or without concomitant leukocytosis.

If differentiation syndrome is suspected, initiate dexamethasone 10 mg IV every 12 hours (or an equivalent dose of an alternative oral or IV corticosteroid) and hemodynamic monitoring until improvement. If concomitant noninfectious leukocytosis is observed, initiate treatment with hydroxyurea or leukapheresis, as clinically indicated. Taper corticosteroids and hydroxyurea after resolution of symptoms and administer corticosteroids for a minimum of 3 days. Symptoms of differentiation syndrome may recur with premature discontinuation of corticosteroid and/or hydroxyurea treatment. If severe signs and/or symptoms persist for more than 48 hours after initiation of corticosteroids, interrupt TIBSOVO until signs and symptoms are no longer severe.

QTc Interval Prolongation: Patients treated with TIBSOVO can develop QT (QTc) prolongation and ventricular arrhythmias. One patient developed ventricular fibrillation attributed to TIBSOVO. Concomitant use of TIBSOVO with drugs known to prolong the QTc interval (e.g., anti-arrhythmic medicines, fluoroquinolones, triazole anti-fungals, 5-HT_3 receptor antagonists) and CYP3A4 inhibitors may increase the risk of QTc interval prolongation. Conduct monitoring of electrocardiograms (ECGs) and electrolytes. In patients with congenital long QTc syndrome, congestive heart failure, electrolyte abnormalities, or in those who are taking medications known to prolong the QTc interval, more frequent monitoring may be necessary.

Interrupt TIBSOVO if QTc increases to greater than 480 msec and less than 500 msec. Interrupt and reduce TIBSOVO if QTc increases to greater than 500 msec. Permanently discontinue TIBSOVO in patients who develop QTc interval prolongation with signs or symptoms of life-threatening arrhythmia.

Guillain-Barré Syndrome: Guillain-Barré syndrome occurred in <1% (2/258) of patients treated with TIBSOVO in the clinical study. Monitor patients taking TIBSOVO for onset of new signs or symptoms of motor and/or sensory neuropathy such as unilateral or bilateral weakness, sensory alterations, paresthesias, or difficulty breathing. Permanently discontinue TIBSOVO in patients who are diagnosed with Guillain-Barré syndrome.

Please see accompanying full Prescribing Information, including Boxed WARNING, and Medication Guide for additional Important Safety Information.

ADVERSE REACTIONS

- The most common adverse reactions (≥20%) of any grade were fatigue (39%), leukocytosis (38%), arthralgia (36%), diarrhea (34%), dyspnea (33%), edema (32%), nausea (31%), mucositis (28%), electrocardiogram QT prolonged (26%), rash (26%), pyrexia (23%), cough (22%), and constipation (20%).
- The most frequently reported ≥Grade 3 adverse reactions (≥5%) were electrocardiogram QT prolonged (10%), dyspnea (9%), leukocytosis (8%), tumor lysis syndrome (6%), and differentiation syndrome (5%).
- Serious adverse reactions (≥5%) were differentiation syndrome (10%), leukocytosis (10%), and electrocardiogram QT prolonged (7%). There was one case of progressive multifocal leukoencephalopathy (PML).

DRUG INTERACTIONS

Strong or Moderate CYP3A4 Inhibitors: Reduce TIBSOVO dose with strong CYP3A4 inhibitors. Monitor patients for increased risk of QTc interval prolongation.

Strong CYP3A4 Inducers: Avoid concomitant use with TIBSOVO.

Sensitive CYP3A4 Substrates: Avoid concomitant use with TIBSOVO.

QTc Prolonging Drugs: Avoid concomitant use with TIBSOVO. If co-administration is unavoidable, monitor patients for increased risk of QTc interval prolongation.

LACTATION

Many drugs are excreted in human milk and because of the potential for adverse reactions in breastfed children, advise women not to breastfeed during treatment with TIBSOVO and for at least 1 month after the last dose.

Please see accompanying full Prescribing Information, including Boxed WARNING, and Medication Guide for additional Important Safety Information.