ITF ARC
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DUVYZAT® (givinostat) In-Home Lab Monitoring Program Form Instructions

ITF ARC helps to facilitate access to DUVYZAT for patients.

1) Complete the In-Home Lab Monitoring Program Form

- **Complete Section 1**
  - The patient, their guardian/legally authorized representative, or the healthcare provider may complete this section
- **Complete Sections 2 and 3** (Prescriber Information and In-home Nursing Services to Conduct Lab Draws)
  - These sections must be completed by the healthcare provider
- Be sure the authorization for lab draws in Section 3 is signed and dated, and the checkbox is selected
- This form is intended solely to enroll patients who have an existing prescription for DUVYZAT into the DUVYZAT In-Home Lab Monitoring Program
- If the patient has not yet been prescribed DUVYZAT, please use the ITF ARC Start Form to initiate therapy and baseline laboratory testing
- **Please note:** While our field nurses have access to near-infrared vein visualization devices, patients who require ultrasound-guided venous access may not be good candidates for the In-Home Lab Monitoring Program

2) Sign the Patient Authorization

- **The patient or their guardian/legally authorized representative must sign and date the Patient Authorization**
  - This step is **mandatory** and authorizes ITF ARC to provide program services and to communicate with the prescriber and patient
  - If the patient is **NOT** in the office, ITF ARC will obtain patient consent before services can be provided

3) Fax or mail the completed and signed form to ITF ARC

FAX: 855-748-3272 | **MAIL:** 121 Bayer Road, Building 5, Pittsburgh, PA 15205

Please contact ITF ARC with questions at 855-448-3272, 8 AM-8 PM ET, Monday-Friday

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Patient Name_____ Date of Birth__/__/____

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Section 1: Patient Information

Please check primary contact ❑ Patient ❑ Parent/Caregiver

Patient Information

First Name_____ Last Name_____

Date of Birth ___/___/_____ Gender: ❑ Male ❑ Female ❑ Other_____

Address_____ City_____ State_____ ZIP_____ Email_____

Phone_____ Best time to call: ❑ Morning ❑ Afternoon ❑ Evening

Cell Phone_____ Best time to call: ❑ Morning ❑ Afternoon ❑ Evening

❑ Okay to leave voicemail Preferred Language: ❑ English ❑ Spanish ❑ Other_____

Parent/Guardian/Caregiver Information

First Name_____ Last Name_____ Relationship to Patient_____

Address_____ City_____ State_____ ZIP_____ Email_____

Phone_____ ❑ Home ❑ Cell ❑ Other Best time to call: ❑ Morning ❑ Afternoon ❑ Evening

❑ Okay to leave voicemail Preferred Language: ❑ English ❑ Spanish ❑ Other_____

Section 2: Prescriber Information

First Name_____ Last Name_____

Specialty_____ NPI #_____ State License #_____

Facility Name_____ Facility Address_____ City_____ State_____ ZIP_____

Facility Contact Name_____ Role_____

Phone_____ Fax_____ Email_____

Please select your preferred method of communication: ❑ Phone ❑ Fax ❑ Email

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Section 3: In-home Nursing Services to Conduct Lab Draws

☐ **I authorize all of the following lab draws for my patient:** CBC + differential: At baseline, every 2 weeks for the first 2 months of treatment, at month 3, and then every 3 months thereafter; Fasting triglycerides: At baseline, month 1, month 3, month 6, and then every 6 months thereafter; In the event of a dosing change, start lab draws over at the beginning of the sequence; If fasting triglycerides are >300 mg/dL or platelets are <150 x 10^9/L, redraw labs 1 week later.

Order valid for 12 months from the Date of Prescriber signature in Section 3 of this form. Laboratory draws must follow the testing schedule above. Minor rescheduling is permitted up to 3 calendar days before or after the scheduled date during the first 8 weeks from therapy initiation or dosage change, and up to 7 calendar days before or after the scheduled date during subsequent periods of therapy. Tests performed outside this window require additional prescriber authorization and are not covered by the DUVYZAT In-Home Lab Monitoring Program.

Notes:_____

If different from the phone number listed in Section 2, **provide a phone number to reach the on-call physician in case Critical (Panic) Lab Values need to be reported** (please visit Labcorp.com for a list of critical lab values).

Phone Number:_____

Testing Requests and Specifications

Current DUVYZAT patient ❑ Yes ❑ No Have baseline lab tests been performed? ❑ Yes ❑ No

Does this patient have a port/central line? ❑ Yes ❑ No **If yes,** should the central line be used for these blood draws? ❑ Yes ❑ No

☐ **By checking yes, I prescribe the following selected items to be dispensed by the Specialty Pharmacy (or local pharmacy if required):**

For venipuncture/port access:

❑ Lidocaine/prilocaine 2.5%/2.5% anesthetic cream. Substitution permissible.
Directions: Apply topically 30 minutes prior to venipuncture or port access as needed for numbing.
Dispense: #4 – 30 gram tubes

Additional items for port access:

❑ Heparin 100 units/mL 5 mL flush. Substitution permissible.
Directions: For use by home health nurse for DUVYZAT blood draw via port – post access of port.
Qty: #1 box of 60 flushes

❑ Sodium chloride 0.9% flush 10 mL. Substitution permissible.
Directions: For use by home health nurse for DUVYZAT blood draw via port – (10-20 mL before and after port access).
Qty: #4 boxes of 30 flushes

I also authorize Naven Health Nursing to access the implanted port and draw labs from the central line if available and possible.

❑ Supplies: 2 sterile dressing change kits, 2 Huber needles, 2 10 mL sterile syringes, 2 clave connectors.
Required needle size/type (if left blank, standard venipuncture will be attempted):_____ gauge _____ inch

❑ Skilled Nursing to perform central line care: Cleanse site with alcohol 3 times, betadine 3 times, or ChloraPrep™ swab.
Apply transparent semipermeable membrane (TSM) dressing with port access for ordered lab draws and PRN for loss of integrity

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Section 3: In-home Nursing Services to Conduct Lab Draws (cont'd)

Please indicate the **date the last testing was performed** and whether it was **baseline or subsequent testing**:

Platelets: ___/___/_____ ❑ Baseline ❑ Subsequent ❑ No testing performed **Triglycerides:** ___/___/_____ ❑ Baseline ❑ Subsequent ❑ No testing performed

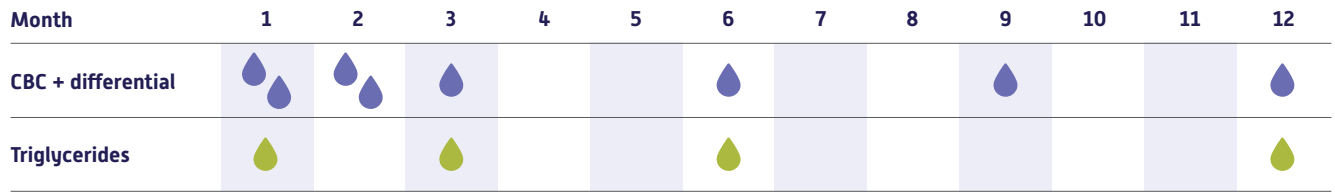
Indicate the date the patient should have their **next** blood draw: ___/___/_____ and select which lab tests should occur: ❑ Platelets ❑ Triglycerides

Indicate where this **next** blood draw date falls within the monitoring schedule. Select the week or month when the testing schedule should begin.

❑ Baseline
❑ Month 1 week 2 (CBC w/diff)
❑ Month 1 week 4 (CBC w/diff, TG)
❑ Month 2 week 6 (CBC w/diff)
❑ Month 2 week 8 (CBC w/diff)
❑ Month 3 (CBC w/diff, TG)
❑ Month 6 (CBC w/diff, TG)
❑ Month 9+ (ongoing monitoring: every 3 months CBC w/diff, every 6 months TG)

Does this coincide with a dose adjustment/restart? ❑ Yes ❑ No

Refer to the image below for the standard monitoring schedule during the first year of DUVYZAT treatment:



CBC + differential: Monitor blood counts every 2 weeks for the first 2 months of treatment, at month 3, and then every 3 months thereafter

Triglycerides: Monitor at 1 month, 3 months, 6 months, and then every 6 months thereafter

Please note: If after the next (or baseline) lab draw you are requesting subsequent testing be performed on a schedule different from the schedule depicted in the above image, please clearly indicate that below. Minor adjustments to the schedule may be able to be accommodated. Alternatively, you can contact ITF ARC to discuss this request.

_____

_____

PRESCRIBER AUTHORIZATION (no stamps)

By signing below, I confirm that I comply with all applicable HIPAA and privacy laws in sharing patient health information for this in-home lab monitoring program. I acknowledge that the above testing schedule is the standard supported by the program. I understand that minor rescheduling (within 3 calendar days of a planned draw) is allowed for logistical reasons, but tests outside these windows or at different frequencies are not covered and may require separate orders.

I authorize Naven Health Nursing to perform laboratory blood draws (CBC + differential and fasting triglycerides) according to the testing schedule above.

IF I HAVE AUTHORIZED CENTRAL LINE ACCESS ABOVE (by checking "Yes" on page 3): I also authorize Naven Health Nursing to access the implanted port/central line for laboratory blood draws and prescribe the medications and supplies specified in the central line protocol above (including heparin, sodium chloride flushes, lidocaine/prilocaine cream, and associated supplies) to be dispensed by the Specialty Pharmacy (or local pharmacy if required) to support safe blood draw procedures.

Prescriber Signature for Services to Conduct Lab Draws_____ Date___/___/_____

Prescriber Name (Print):_____

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Part A: Required Patient Authorization for Program Participation and Personal Information Disclosure

In order for ITF Therapeutics LLC ("ITF") to provide me with the services and/or programs described below, ITF needs to collect and use my personal information, including my Protected Health Information, as defined under the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA") as set forth below. I understand that my personal information, including my Protected Health Information (collectively, "My Personal Information") may include any information, in electronic or physical form, in the possession of or derived from a health care provider, health care plan, pharmacy, pharmaceutical company, laboratory, and/or their contractor (each, a "Health Care Provider"). By signing this form, I understand and authorize my Health Care Providers to share My Personal Information with ITF for the purposes explained below. My Personal Information will not be used or disclosed for any purpose other than those stated herein.

1) Use and Disclosure of My Personal Information for Program Services

(a) Health Care Provider Disclosures: I authorize my Health Care Providers to provide My Personal Information by and between themselves and ITF and its business partners, agents, vendors, and contractors (including but not limited to PANTHERx, Naven Health, and other qualified service providers selected by ITF) for the purposes set forth in this Authorization. This may include, but is not limited to, information from or about my medical history and general health, my health care plan benefits, payment limits or restrictions covered by my health care plan policy, demographic information, current medications, laboratory results, and/or my adherence to my treatment. I understand that certain of my Health Care Providers (such as pharmacies and specialty pharmacies) may receive remuneration from ITF in exchange for disclosing My Personal Information, and/or for using My Personal Information to contact me with communications about ITF products which have been prescribed to me (for example, medication reminder programs and other patient support services). I understand that once My Personal Information has been released to ITF, it may no longer be covered by HIPAA. **(b) ITF Use and Disclosure of My Personal Information:** I authorize ITF, its business partners, agents, vendors, and contractors (including specialty pharmacies, nursing service providers, and patient support vendors) to use and disclose My Personal Information to improve, develop, and evaluate ITF's products, services, materials, and programs related to my condition or treatment and to facilitate my access to ITF patient support services, which may include: • Therapy access and reimbursement support services • Laboratory monitoring and coordination programs (such as the DUVYZAT In-Home Lab Monitoring Program) • Patient education and support services • Treatment adherence and medication management support • Program administration and quality improvement assessments • Program enrollment verification and eligibility determination. **(c) Laboratory Billing Authorization (For NY, NJ, and RI Residents Only):** I acknowledge that state law requires Labcorp to bill my insurance company directly for laboratory testing services provided under the DUVYZAT In-Home Lab Monitoring Program. I understand that I may be responsible for co-pays, deductibles, or co-insurance as determined by my insurance plan. I authorize Labcorp to bill my insurance and authorize ITF ARC to provide my insurance information to Labcorp for this purpose. **(d) Treatment and Disease-Related Communications:** ITF, its business partners, agents, vendors, and contractors to provide treatment and disease-related healthcare communications via email, mail, phone calls, texts, and other communication methods understanding that ITF may use automated/autodialed and pre-recorded/artificial voice calls and messages to contact me at the telephone number I have provided and that my mobile provider may charge me to receive these calls and messages to support my DUVYZAT treatment, including: • Welcome and orientation communications about ITF ARC support services and resources available to me • Clinical educational information about DUVYZAT therapy, including adherence tips and side effects management • Medical milestone communications and check-ins related to my treatment progress • Patient experience stories and caregiver resources to support me, my family, and/or caregivers during treatment • Laboratory monitoring reminders and medication administration guidance • Other program-related notifications, surveys, and/or requests.

I understand I may unsubscribe from communications at any time by clicking the unsubscribe link in any email or by contacting ITF ARC at 855-448-3272. I may opt out of text messages at any time by replying "STOP" to any text message or by calling 855-448-3272. Unsubscribing from communications will not affect my participation in ITF programs or access to DUVYZAT.

2) Authorization Terms and Patient Rights

- **Optional Authorization, Right to Obtain a Copy, and Revocation Right:** I understand this Authorization is entirely optional. I also understand that I have the right to obtain a copy of this Authorization or revoke this authorization at any time by contacting ITF ARC at 855-448-3272 or in writing. Revocation will not affect actions already taken based on this authorization.
- **Program Participation Requirement:** This authorization is required to participate in the DUVYZAT In-Home Lab Monitoring Program. If I do not sign or revoke this authorization at any point, I understand that ITF ARC will not be able to provide program support services, though my prescriber may continue DUVYZAT treatment outside of this program if medically appropriate.
- **Expiration:** I understand that I am authorizing those who rely on this Authorization to disclose My Personal Information as set forth in this Authorization for ten (10) years, unless earlier revoked or unless a shorter time period is required by applicable law.

Part B: Optional Marketing Authorization

The following authorization is completely optional and separate from your program participation in Part A. Declining or later canceling this authorization will NOT affect your participation in ITF programs, your access to DUVYZAT (or any ITF products), or the quality of care you receive.

☐ I authorize ITF Therapeutics ("ITF") and companies working with ITF to use, disclose, and/or transfer the personal information I supply (1) to contact me for marketing purposes, including targeted online marketing, or otherwise provide me with information and marketing materials and clinical trial opportunities related to my condition or treatment by any method of communication (text, email, phone, mail, etc.) understanding that ITF may use automated/autodialed and pre-recorded/artificial voice calls and messages to contact me at the telephone number I have provided and that my mobile provider may charge me to receive these calls and messages, (2) to help ITF improve future products, services, and offerings, (3) to offer me information about additional ITF products, programs, and services, and (4) to conduct or contact me about market research. This authorization will remain in effect until I cancel it, which I may do at any time by using the link provided in the communications I receive from ITF, contacting ITF ARC at 855-448-3272 or by sending written notice to ITF ARC, 121 Bayer Rd, Building 5, Pittsburgh, PA 15205. Revocation will be effective upon receipt and will not affect any disclosures already made in reliance on this authorization.

Patient/Guardian/Legally Authorized Representative Signature and Acknowledgment

By signing below, I acknowledge and confirm that: I have read and fully understand the Patient Authorization in Parts A and B of this DUVYZAT In-Home Lab Monitoring Program Form. I understand my privacy rights and how my health information will be used and disclosed under this authorization. I understand and accept the terms of this authorization.

PATIENT/GUARDIAN/LEGALLY AUTHORIZED REPRESENTATIVE SIGNATURE

Patient/Guardian/Legally Authorized Representative Signature_____ Date___/___/_____

Printed Name_____

Relationship to Patient (if not patient)_____

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