TEXAS Health and Human Services

Texas Department of State Health Services

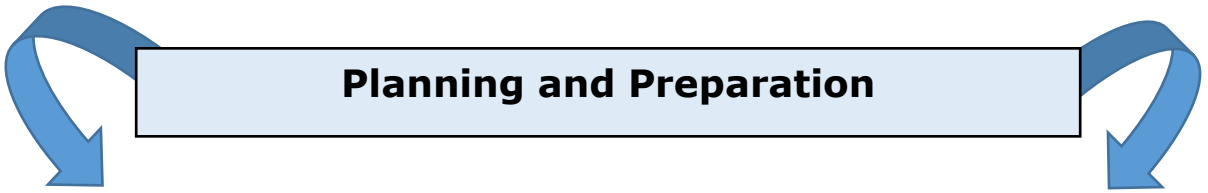
# Bedaquiline (Sirturo) Ordering Process

## Process Overview

Bedaquiline (BDQ), a medication used to treat some types of drug-resistant tuberculosis (DR-TB), is a non-first-line oral anti-TB medication. This medication is typically prescribed for at least six months of therapy but may be required longer. Consultation from a DSHS-Recognized Tuberculosis Medical Consultant is required for use.

The outpatient ordering process is different from other medications that are available through the DSHS Pharmacy ordering system, and additional planning and preparation are required. This medication is very costly, therefore the DSHS Tuberculosis and Hansen's Disease Unit (TB Unit) will work with local and regional health departments (L/RHDs) to obtain the medication through no-cost assistance programs. Ordering BDQ from DSHS will be allowed only as a last resort.

There are several steps needed to obtain BDQ which are outlined in this document.




| Medical Consultation | Discharge Planning | TB Unit Notification | Insurance Verification |
|---|---|---|---|
| • A consult from a DSHS Recognized Medical TB Consultant is required for patients with drug-resistant TB:<br><br>dshs.texas.govdisease/tb/consultants.shtm | • If the patient was started on BDQ while at the Texas Center for Infectious Disease (TCID), they will be provided **two weeks'** of BDQ at discharge.<br>• Medication will be mailed to the health department prior to patient's discharge. | • Notify the TB Unit's Drug-Resistant TB Monitoring Program Nurse Consultant (DR TB Nurse Consultant) when BDQ is prescribed.<br>• See *Texas TB Work Plan* for information on requesting second-line medications:<br><br>dshs.texas.gov/IDCU/disease/tb/policies/TBWorkPlan.pdf | • L/RHDs must determine if the patient is privately insured or uninsured.<br>• Private insurance may include Medicare/ Medicaid. |

TEXAS Health and Human Services

Texas Department of State Health Services

# Bedaquiline (Sirturo) Ordering Process

## STEPS

### Step 1: Notify the TB Unit when BDQ is Prescribed

Email the DR-TB Nurse Consultant a request for BDQ with the answers to the following questions **(for Binational TB Program patients, skip to page 7):**

1. Name of prescribing physician: *(must be a DSHS physician or physician working directly with the health department)*
2. Name of consulting physician: *(must be a DSHS-Recognized TB Medical Consultant unless recent TCID discharge)*
3. Name of program requesting the medication/program contact (with best contact phone numbers):
4. Describe plan of care for patient access to routine follow up, including but not limited to, ECGs:
5. Is the patient insured or uninsured? Specify:

**After emailing the answers above, send securely a copy of the consult or discharge summary (if applicable) to the DR-TB Nurse Consultant.**

**Once approved, an email will be sent to the requestor (the person listed in #3 above) instructing the L/RHD to order BDQ from DSHS pharmacy, if needed.**

### Step 2: Order BDQ from the DSHS Pharmacy for Short-Term Use

BDQ may be obtained from DSHS for short-term use while the L/RHD TB program is pursuing other patient coverage options; see step 3.

1. Fill out the Metro Medical Solutions (MMS) *Sirturo Prescription Order Form* (see sample form, page 8) and fax it to the DSHS Pharmacy at: **Fax 512-776-7489, Phone: 512-776-7500.** (Note: This form will be emailed to the requestor once approved by the DR-TB Nurse Consultant. It only needs to be sent to pharmacy once).

2. For patients discharged from TCID, order in one-week increments while pursuing patient assistance programs. For patients starting treatment as an outpatient, BDQ may be ordered in two-week increments while pursuing patient assistance programs. Verify the physician orders and request the number of doses needed per week. (Note: Ensure the patient ID# and details regarding how the patient should take the medication are written in the pharmacy ordering system notes/comments section).

TEXAS Health and Human Services

Texas Department of State Health Services

# Bedaquiline (Sirturo) Ordering Process

## Step 3: Pursue Patient Assistance Options

Knowing whether the patient is insured or uninsured will guide which patient assistance program L/RHDs may pursue.

**Patient is Insured**

**Pursue BDQ from Metro Medical Solutions (MMS)**

***Follow Step 3a***

**Patient is Uninsured**

**Pursue BDQ from the Johnson and Johnson Patient Assistance Foundation (JJPAF)**

***Follow Step 3b***

**Patient is Binational**

**Regardless of insurance status, binational patients have a separate process**

***Follow Step 3d***

**Manage Co-Pays**

**Pursue co-pay costs via the Janssen CarePath program, if applicable**

***Follow Step 3c***

**JJPAF will provide the medication with no co-pay cost**

TEXAS Health and Human Services

Texas Department of State Health Services

# Bedaquiline (Sirturo) Ordering Process

## Step 3a: Request BDQ from Metro Medical Solutions (MMS)

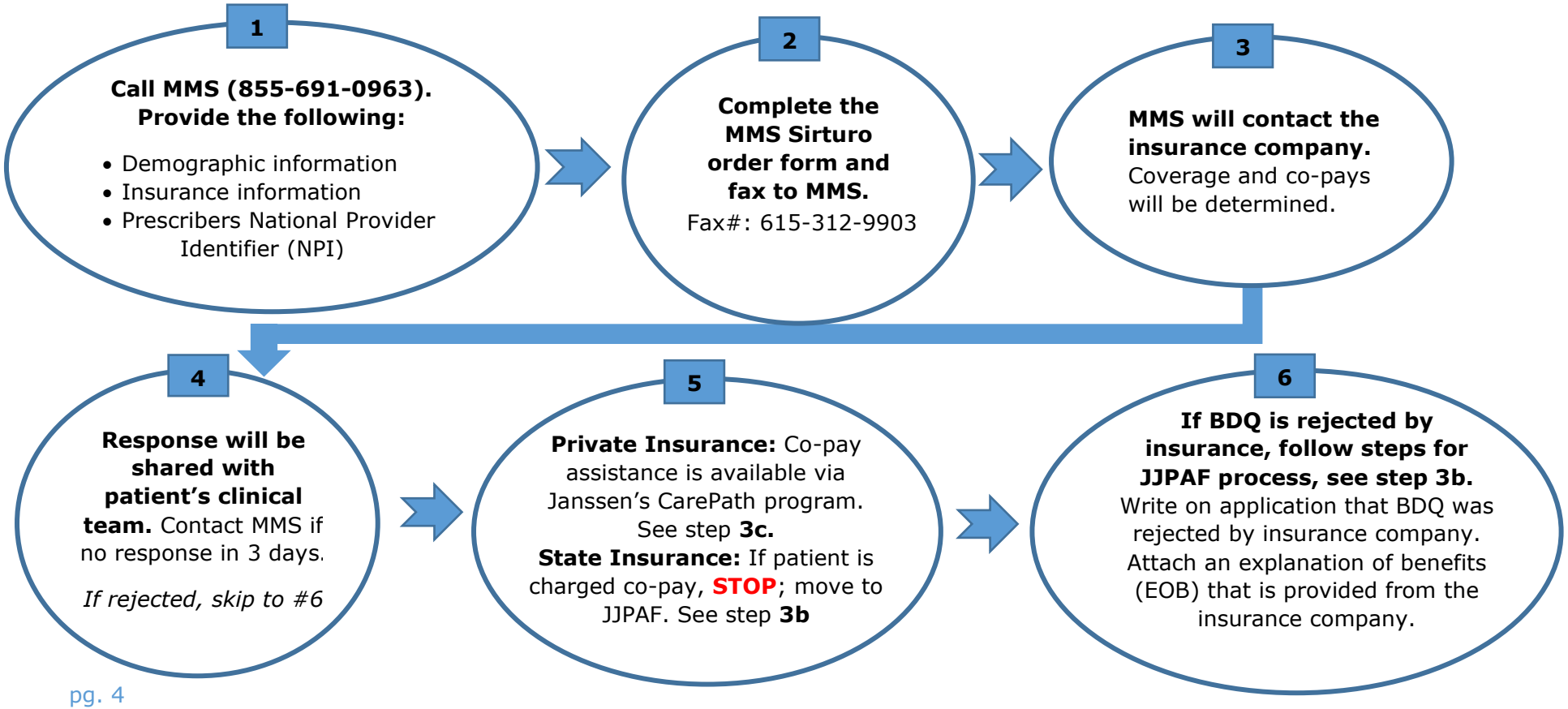
MMS is a specialty pharmacy licensed to dispense medication. Verify the patient's medical insurance coverage (either through a private company or state insurance [i.e., Medicare/Medicaid]) and document coverage prior to initiating this process. After verification, the steps for requesting from MMS are the same regardless of insurance type.

### Privately Insured Patients

Programs may be asked to provide justification that drug resistance is a public health issue, describe why the patient is being treated by the public health program, and must be prepared to justify why bedaquiline is the drug of choice.

### Medicare/Medicaid Insured Patients

Medicare may require the patient meets a deductible, and some plans may require pre-authorization. If needed, request an expedited review based on DR-TB status. NOTE: If patient **is** charged a deductible/co-pay, do not continue with MMS (see #5, below).



TEXAS Health and Human Services

Texas Department of State Health Services

# Bedaquiline (Sirturo) Ordering Process

## Step 3b: Request BDQ from the Johnson and Johnson Patient Assistance Foundation (JJPAF)

BDQ is provided at no cost to uninsured patients via JJPAF. It may also be available to insured patients who meet certain financial criteria and whose insurance does not cover the cost of BDQ.

1. **Download and complete the Patient Assistance Program Application located at:** https://www.jjpaf.org/resources/jjpaf-application.pdf. Ensure the following:
   a. The patient signs the *Patient Declaration* (section 4, page 2 of application) and the prescribing physician signs the *Prescription* (section 3, page 3 of application).
   b. Submit completed pages 2 and 3 and fax to Johnson and Johnson at: 1-740-966-1797.
   c. Include supporting documentation showing rejection of insurance and/or out-of-pocket costs for the current year with the application to facilitate process, where applicable. See page 1 of the application for details.

   *Note: A social security number or a copy of a federal tax form are **not** necessary for Bedaquiline (Sirturo) requests*

2. **Await response.**
   a. Contact JJPAF if no response is received **within 2-3 days** of submitting application. This step is imperative as JJPAF is not responsible for contacting the submitter if the request is denied.

3. **Once approved, requestor will be notified. JJPAF will provide the following information:**
   a. Retail card number (this number is also on the card that will be given to the patient)
   b. Group number
   c. BIN number

4. **Notify the DR-TB Nurse Consultant once approved.**

5. **Complete a new *MMS Sirturo Prescription Order Form***. This new form should be separate from the one sent to DSHS pharmacy while awaiting this approval, as the funding source will change to JJPAF. See pg. 8 for example Fax to MMS at: 615-312-9903.

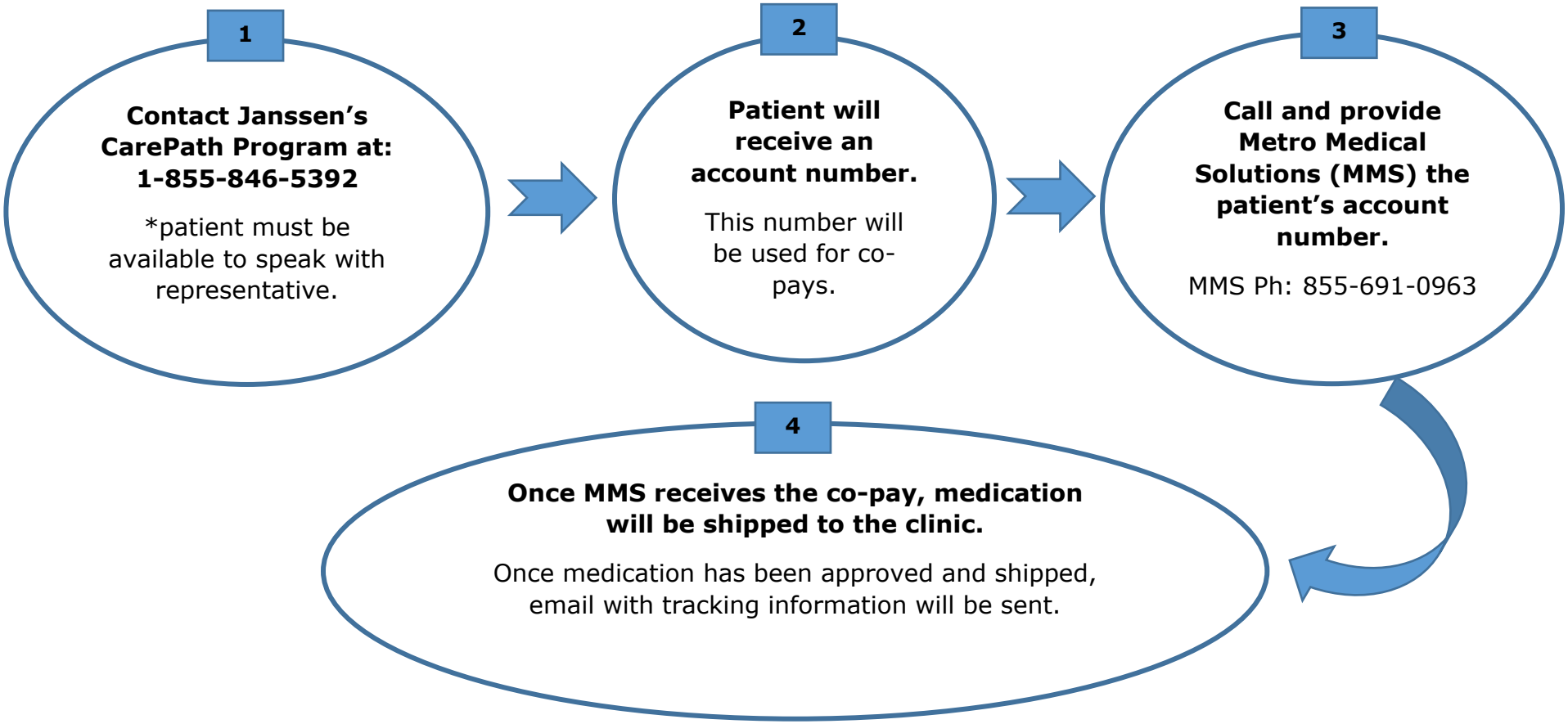
6. **MMS will ship out supply via the two-day UPS service.** The medication will be mailed to the health department, not the patient.

7. **Once BDQ is shipped, requestor will receive an email with tracking information.**

# Bedaquiline (Sirturo) Ordering Process

## Step 3c: Request co-pay coverage with Janssen's CarePath Program

This program has been identified as a resource for patients with private insurance who incur costs associated with co-pays. It will not apply to patients who have state insurance (i.e., Medicare/Medicaid). Up to $7,500 will be available for assisting TB patients through a co-pay card.



TEXAS Health and Human Services

Texas Department of State Health Services

# Bedaquiline (Sirturo) Ordering Process

## Step 3d: Request BDQ for Binational Tuberculosis (BNTB) Patients

BNTB programs should attempt to secure BDQ from Mexico. In the interim, BDQ may be available to BN patients managed by a DSHS Binational TB Program. (For BNTB patients with a Texas address, follow steps 3a, 3b, and/or 3c above).

***Note**: Patients are not allowed to be given BDQ without approval from the COEFAR* or GANAFAR** (refer to #7, below). Do not submit answers until this approval has been obtained. Once approval has been obtained follow the steps below.*

**1. Submit answers to the DR-TB Nurse Consultant with the following responses:**

1. Explain what qualifies this patient for care under the Binational TB Program *(check all that apply):*
   - ☐ The patient lives in Mexico but has relatives in the U.S.;
   - ☐ The patient has dual residency in the U.S. and Mexico;
   - ☐ The patient has contacts on both sides of the border, in the U.S. and Mexico
   - ☐ The patient started treatment in the U.S. but returns to live in Mexico; or
   - ☐ The patient is referred from the U.S. for treatment or follow-up in Mexico
2. Name of Texas Consulting Physician: *(must be a DSHS physician or physician working directly with L/RHD)*
3. Name of Mexico's Binational Treating Physician:
4. Name of DSHS-Recognized Medical TB Consultant physician:
5. Name of BNTB program requesting BDQ and BN Coordinator (with best contact phone numbers):
6. Describe the plan of care for the patient's access to routine follow-up, including but not limited to ECGs:
7. Has the approval letter for BDQ use been verified by the Binational TB Program Coordinator? (*If not contact the DR-TB Nurse Consultant)*

**2. Once the approval letter is verified, the binational TB coordinator will notify the consulting physician, the treating physician, and the DR-TB Nurse Consultant.**

- Send securely a copy of the Heartland consult and approval letter to the DR-TB Nurse Consultant.

**3. Once all the above have been met, the DR-TB Nurse Consultant will send an email with approval to proceed with ordering BDQ from the pharmacy's ordering system:**

1. Fill out the Metro Medical Solutions (MMS) *Sirturo Prescription Order Form* (Note: form will be emailed to requestor when approved).
2. Fax the form to the DSHS Pharmacy: **Fax: 512-776-7489 Phone: 512-776-7500**
3. Order **1 month supply** at a time.

*Drug-resistant TB committee in Mexico, by state
**Mexico's national advisory committee on drug resistant TB

# Bedaquiline (Sirturo) Ordering Process

## *Metro Medical Solutions (MMS) Sirturo Prescription Order Form*
## INSTRUCTIONS
Contact DSHS for form

MMS SOLUTIONS METRO

202 Cumberland Bend
Nashville, TN 37228
www.mmspharmacy.com

Sirturo bedaquiline 100mg tablets

**Prescription Order**

**FAX TO: 615-312-9903**
**MMS Phone: 855-691-0963 (toll free); 615-312-9888 (local)**

| | | | |
|---|---|---|---|
| **Date:** | | **Facility Name:** | |
| **PO#:** | Leave Blank | **Metro Account #:** | Leave Blank |
| **Patient Last Name:** | | **Facility Phone:** | Health department information here; include email address |
| **Patient First Name:** | | **Facility Fax:** | |
| **Patient Date of Birth:** | | **Facility Address:** | |
| **Patient Phone:** | | **Facility City, ST, Zip:** | |
| **Patient Address:** | | Pharmacy Benefit Coverage provide the following; ID#, Rx BIN#, Rx PCN#, Rx GRP# | |
| **Patient City, ST, Zip:** | | | |

***Orders cannot be shipped directly to Patient

**All orders must be shipped to the Prescriber address or Facility/Site of Care Address

**Drug Allergies:** Include client diagnosis here

| ITEM # | MEDICATION | QTY | DIRECTIONS FOR USE |
|---|---|---|---|
| | Sirturo 100mg tabs (NDC:59676-0701-01) | 68 | Example: Take 4 tabs po daily for 2 weeks then 2 tabs po 3 times a week |
| Other | | | |
| Other | | | |
| Other | Example: | | |
| Other | Sirturo 100 mg tabs(NDC:59676-0701-01) | 24w/4 refills | Take 2 tabs po 3 times a week |
| Other | | | |
| Other | Write *"Sirturo"* not *"Bedaquiline"* | | Examples: Write entire Sirturo regimen, even if intial phase was completed at TCID |
| Other | | | |
| Other | | | |

| | | | |
|---|---|---|---|
| Prescriber Name: | | Prescriber Phone: | Fill out this section as indicated |
| Prescriber NPI: | | Prescriber Signature: | |

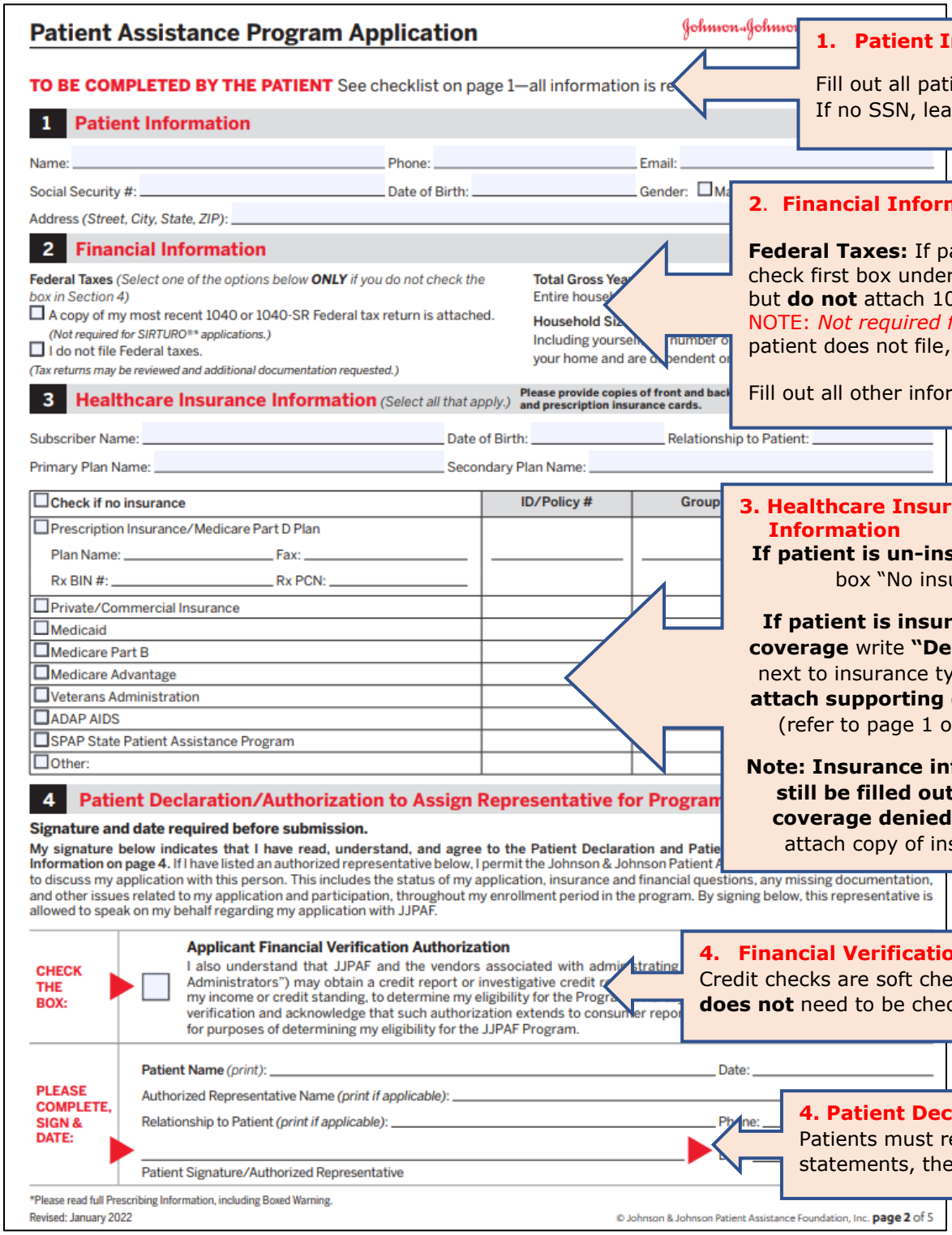
**SHIPPING METHOD**

2nd Day Air
☒ (Standard Method) ☐ Overnight

# Bedaquiline (Sirturo) Ordering Process

***Johnson & Johnson Patient Assistance Foundation (JJPAF) Program Application***
**INSTRUCTIONS**
Download form from https://www.jjpaf.org/resources/jjpaf-application.pdf

## JJPAF application page 2



Patient Assistance Program Application

**TO BE COMPLETED BY THE PATIENT** See checklist on page 1—all information is re

**1 Patient Information**

Name: _____ Phone: _____ Email: _____

Social Security #: _____ Date of Birth: _____ Gender: ☐ Ma

Address (*Street, City, State, ZIP*): _____

**2 Financial Information**

**Federal Taxes** (*Select one of the options below* ***ONLY*** *if you do not check the box in Section 4*)

☐ A copy of my most recent 1040 or 1040-SR Federal tax return is attached.
(*Not required for SIRTURO®* applications.*)

☐ I do not file Federal taxes.

(*Tax returns may be reviewed and additional documentation requested.*)

Total Gross Yea
Entire housel

Household Siz
Including yoursel number o
your home and are d pendent o

**3 Healthcare Insurance Information** (*Select all that apply.*) **Please provide copies of front and back and prescription insurance cards.**

Subscriber Name: _____ Date of Birth: _____ Relationship to Patient: _____

Primary Plan Name: _____ Secondary Plan Name: _____

| ☐ Check if no insurance | ID/Policy # | Group |
|---|---|---|
| ☐ Prescription Insurance/Medicare Part D Plan<br>Plan Name: _____ Fax: _____<br>Rx BIN #: _____ Rx PCN: _____ | | |
| ☐ Private/Commercial Insurance | | |
| ☐ Medicaid | | |
| ☐ Medicare Part B | | |
| ☐ Medicare Advantage | | |
| ☐ Veterans Administration | | |
| ☐ ADAP AIDS | | |
| ☐ SPAP State Patient Assistance Program | | |
| ☐ Other: | | |

**4 Patient Declaration/Authorization to Assign Representative for Program**

**Signature and date required before submission.**

**My signature below indicates that I have read, understand, and agree to the Patient Declaration and Patie Information on page 4.** If I have listed an authorized representative below, I permit the Johnson & Johnson Patient A to discuss my application with this person. This includes the status of my application, insurance and financial questions, any missing documentation, and other issues related to my application and participation, throughout my enrollment period in the program. By signing below, this representative is allowed to speak on my behalf regarding my application with JJPAF.

CHECK THE BOX: ☐

**Applicant Financial Verification Authorization**
I also understand that JJPAF and the vendors associated with admi strating Administrators") may obtain a credit report or investigative credit r my income or credit standing, to determine my eligibility for the Progra verification and acknowledge that such authorization extends to consumer repo for purposes of determining my eligibility for the JJPAF Program.

PLEASE COMPLETE, SIGN & DATE:

**Patient Name** (*print*): _____ Date: _____

Authorized Representative Name (*print if applicable*): _____

Relationship to Patient (*print if applicable*): _____ Ph ne: _____

_____

Patient Signature/Authorized Representative

*Please read full Prescribing Information, including Boxed Warning.

Revised: January 2022

© Johnson & Johnson Patient Assistance Foundation, Inc. **page 2** of 5

**1. Patient Information**

Fill out all patient information. If no SSN, leave blank.

**2. Financial Information**

**Federal Taxes:** If patient files taxes, check first box under "Federal Taxes" but **do not** attach 1040/1040 EZ. NOTE: *Not required for Sirturo.* If patient does not file, check that box.

Fill out all other information.

**3. Healthcare Insurance Information**

**If patient is un-insured,** check the box "No insurance".

**If patient is insured but denied coverage** write **"Denied coverage"** next to insurance type checked and **attach supporting documentation** (refer to page 1 of application).

**Note: Insurance information must still be filled out if insurance coverage denied.** Make sure to attach copy of insurance card.

**4. Financial Verification Authorization**

Credit checks are soft checks. This box **does not** need to be checked for Sirturo.

**4. Patient Declaration**

Patients must read all statements, then sign and date.

# Bedaquiline (Sirturo) Ordering Process

## JJPAF application page 3, continued from previous page

### Patient Assistance Program Application

Johnson & Johnson PATIENT ASSISTANCE FOUNDATION, INC.

**TO BE COMPLETED BY THE HEALTHCARE PROFESSIONAL (HCP)**—all informat

**1 Prescription** *(If requesting more than 1 product, attach additional prescription information.)*

Patient Name: _____

ICD Code *(HCP-administered products only)*: _____

Name of Product: _____

Strength: _____ Sig

Quantity: _____ Days' Supply: _____

**BALVERSA®, ERLEADA®, IMBRUVICA®, or ZYTIGA®:**

- If you are a prescriber in New York, South Carolina, or Washington and are requesting BALVERSA®, ERLEADA®, IMBRUVICA®, or ZYTIGA®, you must attach prescription on your state official prescription form with this application.

**BALVERSA®, ERLEADA®, IMBRUVICA®, or ZYTIGA®:**

- List any patient allergies:

_____ or ☐ NKDA

**BALVERSA®, ERLEADA®, IMBRUVICA®, or ZYTIGA®:**

- List patient's current medications:

_____ or ☐ none

**BALVERSA®:**

- Has the patient tested positive for FGFR? ☐Yes ☐No

**HIV Medication:**

- Check if patient is currently ☐INTELENCE® ☐EDURA

**PROCRIT®*:**

- Hemoglobin level based on
- Required: Is the patient bein

**RYBREVANT®:**

- Has the patient tested positive for EGFR exon 20 insertion mutation? ☐Yes ☐No

**Select STELARA® Distribution Option (must select one):**

☐ Ship to HCP's office
☐ Retail or specialty pharmacy. HCP must provide a prescription.

**Select TREMFYA® Distribution Option (must select one):**

☐ Ship to HCP's office
☐ Retail or specialty pharmacy. HCP must provide a prescription.

**2 HCP Information**

Name: _____ Site Name: _____

Site Contact: _____ Business Hours: _____

Address *(Street, City, State, ZIP)*: _____

Phone: _____ Fax: _____ Email: _____

Tax ID #: _____ NPI # *(required)*: _____

State License # *(required)*: _____ Expiration *(mm/yyyy)*: _____ DEA # *(required)*: _____

Collaborating MD *(for mid-level providers)*: _____ Collaborating MD NPI # *(required)*: _____

Provider Transaction Access Number (PTAN) *(required if the patient has Medicare)*: _____

**HCP Distribution Shipping Address or SPRAVATO® REMS-Certified Treatment Center Address (if different from above):**

Site Name: _____ Contact Name for Shipment: _____

Business Hours: _____ Phone: _____ Fax: _____

Address *(Street, City, State, ZIP)*: _____

*Please note, Florida HCPs may be required to provide Florida Pedigree information at time of first shipment.*

**3 HCP Authorization**

**My signature below indicates that I have read, understand, and agree to the Johnson & Johnson Patient Assistance Foundation, Inc. p and the terms of Program participation on page 5.**

**HCP SIGN & DATE:** _____ Date: _____

Healthcare Professional Signature

*Please read full Prescribing Information, including Boxed Warning.
†Contact Amgen Inc. 1-800-772-6436.
Revised: January 2022

 page 3 of 5

Clear Form Print Form

**1. Prescription**

**ICD Code**: leave blank if UNK
**Name of Product:** "Sirturo/bedaquiline"

**Note:** If ordering daily supply, quantity and days' supply should be reflected
*ex: quantity=68 pills*
*days' supply= 14 days*

Submit a separate page 3 anytime a change in prescription is made. For example, daily prescription and 3x week prescription need to be submitted separately. Do not send in together.

**2. HCP Information**
Health Department Physician information here. Include health department address so bedaquiline is shipped directly to the health department.

**DO NOT** fill out this section, medication must be mailed to contact in above section.

**3. HCP Authorization**
Prescribing health department physician signs and dates here.

# Contacts and Resources

Patient Assistance Programs for BDQ

- **Metro Medical Central Contact,** Phone: 855-691-0963
  https://www.metromedical.com
- **Johnson & Johnson Patient Assistance Foundation (JJPAF),** Phone: 800-652-6227
  http://jjpaf.org
- **Janssen CarePath,** Phone: 855-846-5392
  https://www.janssencarepath.com/hcp

Additional Resources

- **Sirturo Product Guide**
  https://www.sirturo.com/sites/default/files/pdf/SIRTURO-product-guide.pdf
- **TB Controllers Bedaquiline Access Guide**
  http://www.tbcontrollers.org/docs/bedaquiline/Bedaquiline_Access_Guide_v2.0_04June2019.pdf
- **CDC Bedaquiline Factsheet**
  https://www.cdc.gov/tb/publications/factsheets/treatment/bedaquiline.htm
- **CDC Guidelines for the Use and Safety Monitoring of Bedaquiline Furmarate (Sirturo) for the Treatment of Multidrug-Resistant Tuberculosis**
  https://www.cdc.gov/mmwr/PDF/rr/rr6209.pdf
- **Sirturo Label Insert**
  https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/204384s000lbl.pdf
- **Medicare.gov**
  https://www.medicare.gov/claims-appeals/how-do-i-file-an-appeal
- **Medicare Drug Finder**
  https://q1medicare.com/PartD-SearchPDPMedicarePartDDrugFinder.php
- **Texas Statues, Health and Safety Code-** ***if requested for assistance program justification***
  https://statutes.capitol.texas.gov/Docs/HS/htm/HS.81.htm