

# TUBERCULOSIS AND HANSENS'S DISEASE UNIT

# **BEDAQUILINE ORDERING GUIDE**



**TEXAS**  
Health and Human  
Services

Texas Department of State  
Health Services

Tuberculosis and Hansen’s Disease Unit  
**Bedaquiline Ordering Guide**

# Contents

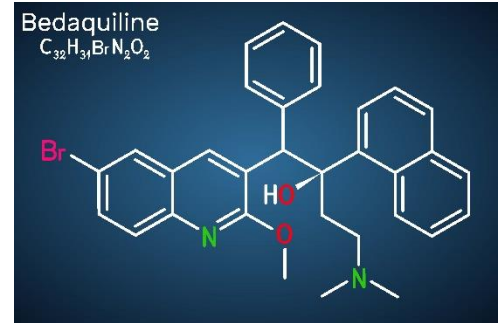
<b>Bedaquiline Overview .....</b>	<b>2</b>
Considerations Prior to Using BDQ.....	2
<b>BDQ Ordering Steps .....</b>	<b>3</b>
Step 1: Seek Medical Consultation and Obtain a Medical Order .....	3
Step 2: Initiate Request to the Appropriate Patient Assistance Program (PAP).....	3
Step 3: Notify the DSHS TB Unit. ....	4
Step 4: Follow Up with PAP .....	4
Step 5: Obtain and Administer BDQ.....	5
Appendix A: Metro Medical Solutions (MMS) Process .....	6
Appendix B: Janssen’s CarePath Program .....	8
Appendix C: Johnson and Johnson Patient Assistance Foundation Program (JJPAF) ...	9
Appendix D: Binational Process.....	13
Appendix E: Contacts and Resources .....	15

# Tuberculosis and Hansen's Disease Unit

## Bedaquiline Ordering Guide

### Bedaquiline Overview

Bedaquiline (BDQ), brand name Sirturo, is an oral medication primarily used to treat drug-resistant tuberculosis (DR-TB). In 2012, it was the first TB medication approved by the U.S. Food and Drug Administration (FDA) in over 40 years. BDQ supports an all-oral short course treatment plan when rifampin cannot be used in a TB regimen.



Metro Medical Solutions (MMS) is a specialty pharmacy and is the distributor of BDQ. Due to the extremely high cost of the drug, the Department of State Health Services (DSHS) Tuberculosis and Hansen's Disease Unit (TB Unit) requires health departments to engage patient assistance programs (PAPs) to offset costs. These programs are available to insured and uninsured patients and include:

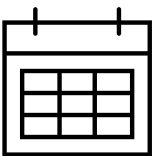
- 1) The Johnson and Johnson Patient Assistance Foundation (JJPAF), a non-profit organization which covers the cost of designated medications to eligible patients **without insurance or those with inadequate prescription coverage.**
- 2) Janssen's Care Path Program, which provides up to \$7,500 assistance for patients with private insurance who incur costs associated with copays.

This document outlines steps local and regional health departments (L/RHDs) must follow to obtain BDQ at no cost to the patient or the L/RHD.

### Considerations Prior to Using BDQ

Before including BDQ in a TB regimen, L/RHDs must consider the following:

- ✓ BDQ must be recommended in consultation with a **DSHS-Recognized TB Medical Consultant.**
- ✓ L/RHDs must have a plan for monitoring medication toxicity before BDQ can be safely administered. This includes electrocardiogram (ECG) monitoring and laboratory testing. Refer to the DSHS **Standing Delegation Orders (SDOs)** and **Nursing Guide for Second-Line Tuberculosis Medications.**
- ✓ L/RHDs will order BDQ through the MMS specialty pharmacy and will also assist patients in applying to PAPs to cover costs.
- ✓ BDQ may be ordered from the DSHS Pharmacy Unit upon TB Unit approval while the L/RHD is awaiting a response from the PAP application and MMS.



It could take up to **two-weeks** before BDQ is approved by the patient assistance program. Missing information may delay the application process. L/RHDs should apply for BDQ *as soon as possible* and communicate with the TB Unit's Drug-Resistant TB Monitoring Program (DR-TB Program) for assistance when needed.

# Tuberculosis and Hansen's Disease Unit

## Bedaquiline Ordering Guide

### BDQ Ordering Steps

#### Step 1: Seek Medical Consultation and Obtain a Medical Order

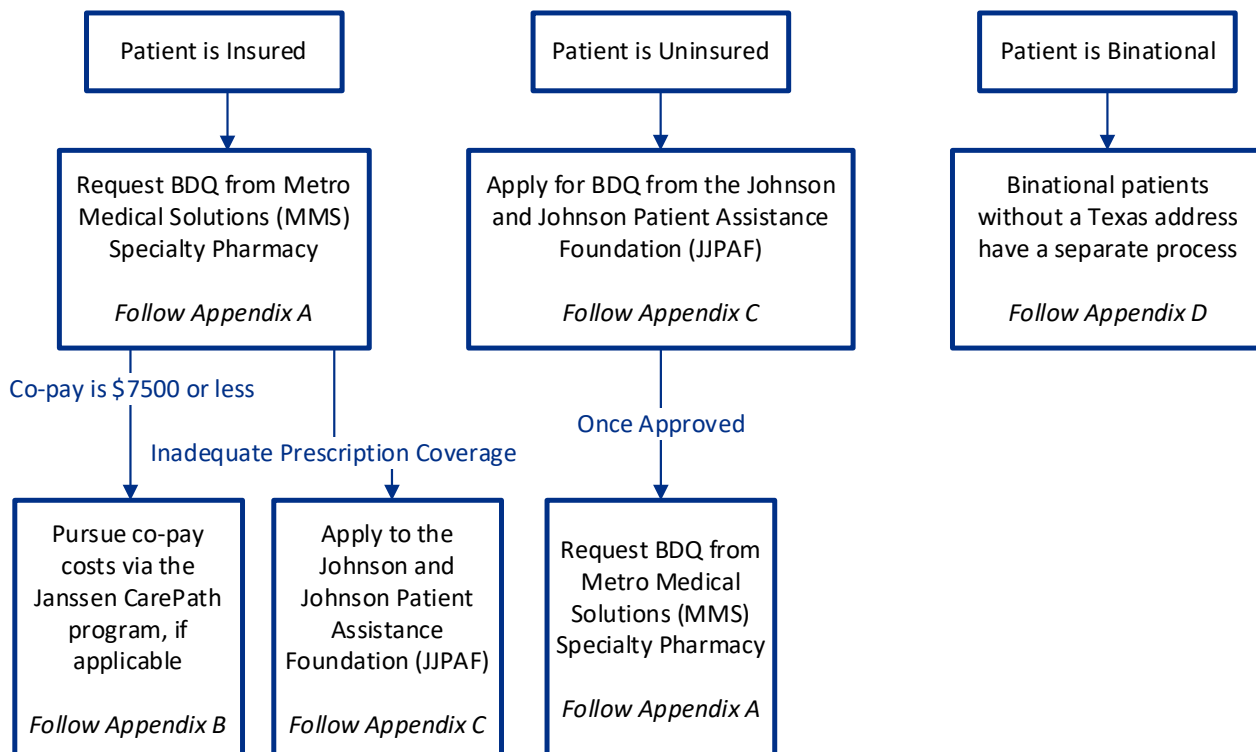
- BDQ is only available after a consult with a **DSHS-Recognized TB Medical Consultant**.
- Once recommended, obtain a medical order for BDQ from the patient's licensed healthcare provider. *Note: Consultant recommendations and/or discharge summaries from the Texas Center for Infectious Disease (TCID) do not serve as medical orders.*

#### Step 2: Initiate Request to the Appropriate Patient Assistance Program (PAP)

Verify a patient's insurance status and pursue applicable patient assistance programs, see Figure 1.

- For patients who are insured either privately (i.e., Blue Cross/Blue Shield), or by state or federal programs (i.e., Medicare or Medicaid), the L/RHD will request BDQ directly from MMS (refer to **Appendix A**). Some health insurance plans may require a preauthorization and/or justification for BDQ use. Reference **Texas statutes** regarding communicable disease control if necessary.
  - For health insurance plans with co-pays, L/RHDs will request additional assistance from Janssen CarePath (**Appendix B**).
- For patients who are uninsured or have inadequate prescription coverage, request BDQ from JJPAF before ordering from MMS (refer to **Appendix C**).
- For patients enrolled in the binational TB program *with* residency in Texas, follow the above bullets. For binational TB patients residing in Mexico, skip to **Appendix D**.

Figure 1: Determination of Patient Assistance



## Tuberculosis and Hansen's Disease Unit

### Bedaquiline Ordering Guide

#### Step 3: Notify the DSHS TB Unit.

Notification to the TB Unit includes outlining the plan of care and, when necessary, requesting BDQ be ordered via the DSHS Pharmacy Unit in one-week increments while awaiting PAP approval. Submit answers to the following questions via email to the **TB Unit Clinical Care Team** (do not include protected health information [PHI]):

1. Name of prescribing physician (*must be a DSHS-affiliated physician, i.e., L/RHD TB clinician*):  
\_\_\_\_\_
2. Name of consulting physician (must be a **DSHS-Recognized TB Medical Consultant** or TCID physician): \_\_\_\_\_
3. L/RHD program contact (this is typically the nurse case manager; include email address and phone number): \_\_\_\_\_
4. Have baseline toxicity assessments and labs (to include ECG, cardiac monitoring, CBC, CMP, TSH, and Mg) been performed?  Yes  No
  - a. If no, specify the date to be completed: \_\_\_\_/\_\_\_\_/\_\_\_\_\_
5. Briefly describe the plan of care for medication toxicity monitoring and clinical assessments, including but not limited to, obtaining ECGs: \_\_\_\_\_
6. Insurance status:  
 Insured (including Medicaid or Medicare)  
 Uninsured
7. Date of patient assistance program (PAP) application:  
 MMS Date submitted: \_\_\_\_/\_\_\_\_/\_\_\_\_\_  
 JJPAF Date submitted: \_\_\_\_/\_\_\_\_/\_\_\_\_\_
8. Are you requesting a 7-day (1-week) supply of BDQ from DSHS Pharmacy Unit, or will you be awaiting BDQ from MMS?  
 Yes, I am requesting a 7-day supply from DSHS while awaiting PAP  
 No, I am waiting for MMS to provide BDQ, patient is stable.

Once the above is reviewed, the DR-TB Program will respond as necessary. If DSHS-purchased medications are requested, the email will contain instructions for how to order BDQ from the DSHS Pharmacy Unit. NOTE: BDQ may only be ordered as a one-week supply while awaiting PAP.

- When ordering BDQ from the DSHS Pharmacy Unit, include in the comments section the patient surveillance ID# and prescription details (i.e., "Surveillance ID #; BDQ 400mg PO daily x 7 days").

#### Step 4: Follow Up with PAP

After applying for BDQ from either MMS or any PAP, contact the selected entity if there is no response **within 3 business days**.

- Continue to communicate with the entity as necessary to process the order.

## Tuberculosis and Hansen's Disease Unit

### Bedaquiline Ordering Guide

If BDQ cannot be obtained **within a week** of the initial PAP application, contact the **TB Unit Clinical Care Team** for approval to continue placing orders from the DSHS Pharmacy Unit.

- Medications provided by the DSHS Pharmacy Unit are available in **one-week increments**. On each request, include the reason for needing continued DSHS-purchased medication (e.g., explain reason for delay in patient assistance).

#### Step 5: Obtain and Administer BDQ

When approval is received from PAP and BDQ has been shipped to the health department by MMS (or provided temporarily by the DSHS pharmacy), patient can begin BDQ.

- Email the **TB Unit Clinical Care Team** the outcome of how BDQ will be obtained (i.e., approval date from MMS or PAP).
- Ensure a baseline ECG, cardiac monitoring, and laboratory results are reviewed by the licensed healthcare provider.
- Monitor the patient as per consultation recommendations, medical orders, and as outlined in the **DSHS Standing Delegation Orders (SDOs)**.
- Document assessments on the **TB 702** or equivalent.
- Obtain updated medical orders as applicable. Note: after the initial daily dosing for two weeks/14 days, BDQ must be administered in thrice-weekly dosing. ***If the patient misses any of these doses, treatment may need to be adjusted depending on the phase of therapy and duration of the interruption. Seek consultation for patient-specific guidance.***
- Enter BDQ start and stop dates in the DSHS TB surveillance and reporting database. Remember to enter a start and stop date when dosage or frequency changes.
- Update the DR-TB Program regarding patient status, as outlined in the **Texas Tuberculosis Work Plan, Chapter VI**.

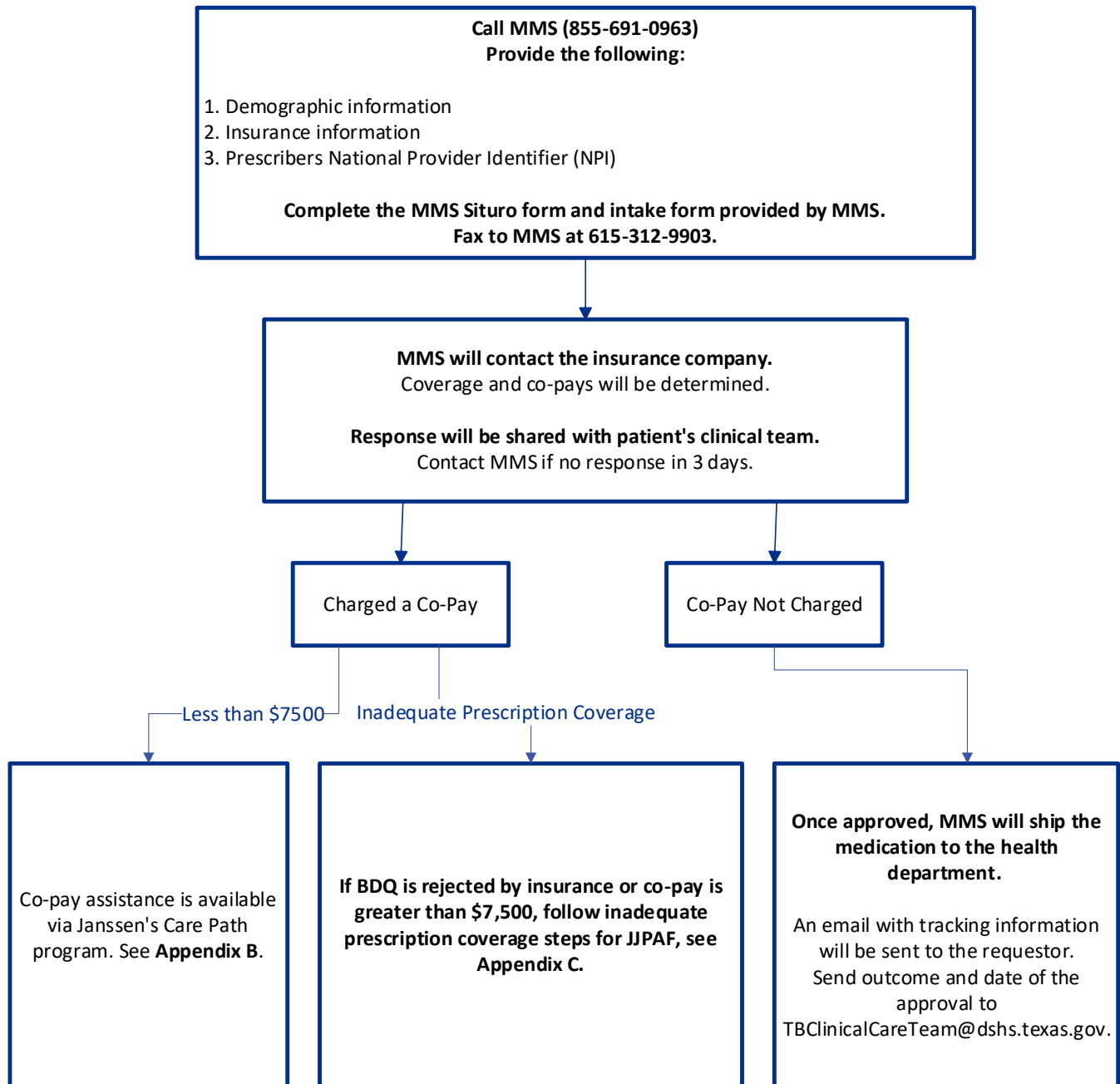
# Tuberculosis and Hansen's Disease Unit

## Bedaquiline Ordering Guide

### Appendix A: Metro Medical Solutions (MMS) Process

Contact MMS directly when ordering BDQ. Refer to Figure 2, below, for contact information and ordering details. Specify the exact BDQ prescription on the MMS order form shown in Figure 3, below. Contact MMS for the order form as needed.

Figure 2: Process for ordering BDQ through MMS specialty pharmacy



# Tuberculosis and Hansen's Disease Unit

## Bedaquiline Ordering Guide

Figure 3: Metro Medical Solutions Prescription Instructions

**MMS SOLUTIONS™**  
METRO  
 202 Cumberland Bend  
 Nashville, TN 37228  
[www.mmspharmacy.com](http://www.mmspharmacy.com)



### Prescription Order

<b>FAX TO: 615-312-9903</b>			
<b>MMS Phone: 855-691-0963 (toll free); 615-312-9888 (local)</b>			
Date: _____ PO#: <u>Leave Blank</u> Patient Last Name: _____ Patient First Name: _____ Patient Date of Birth: _____ Patient Phone: _____ Patient Address: _____ Patient City, ST, Zip: _____	Facility Name: _____ Metro Account #: <u>Leave Blank</u> Facility Phone: _____ Facility Fax: _____ Facility Address: _____ Facility City, ST, Zip: _____	<div style="border: 1px solid red; padding: 5px; color: red;">                     Health department information here; include email address                 </div>	
***Orders cannot be shipped directly to Patient **All orders must be shipped to the Prescriber address or Facility/Site of Care Address			
Drug Allergies: <span style="border: 1px solid blue; padding: 2px;">Include client diagnosis here</span>			
<b>ITEM #</b>	<b>MEDICATION</b>	<b>QTY</b>	<b>DIRECTIONS FOR USE</b>
	Sirturo 100mg tabs (NDC:59676-0701-01)	<u>68</u>	Example: Take 4 tabs po daily for 2 weeks then 2 tabs po 3 times a week
Other	_____	_____	_____
Other	_____	_____	_____
Other	Example: Sirturo 100 mg tabs(NDC:59676-0701-01)	<u>24w/4 refills</u>	Take 2 tabs po 3 times a week
Other	_____	_____	_____
Other	<span style="border: 1px solid blue; padding: 2px;">Write "Sirturo" not "Bedaquiline"</span>	_____	<div style="border: 1px solid blue; padding: 5px; color: blue;">                     Examples: Write entire Sirturo regimen, even if initial phase was completed at TCID                 </div>
Other	_____	_____	_____
Other	_____	_____	_____
Other	_____	_____	_____
Prescriber Name: _____		Prescriber Phone: _____	
Prescriber NPI: _____		Prescriber Signature: _____	
<b>SHIPPING METHOD</b>			
<input checked="" type="checkbox"/> <b>2nd Day Air (Standard Method)</b> <input type="checkbox"/> <b>Overnight</b>			

CONFIDENTIALITY NOTICE: This communication and any attachments are intended solely for the use of the addressee named above and contain confidential health information that is legally privileged. The authorized recipient of this information is prohibited from disclosing this information to any other party unless permitted by law or appropriate customer/patient authorization is obtained. Unauthorized disclosure or failure to maintain confidentiality could subject you to penalties described in federal and state laws.

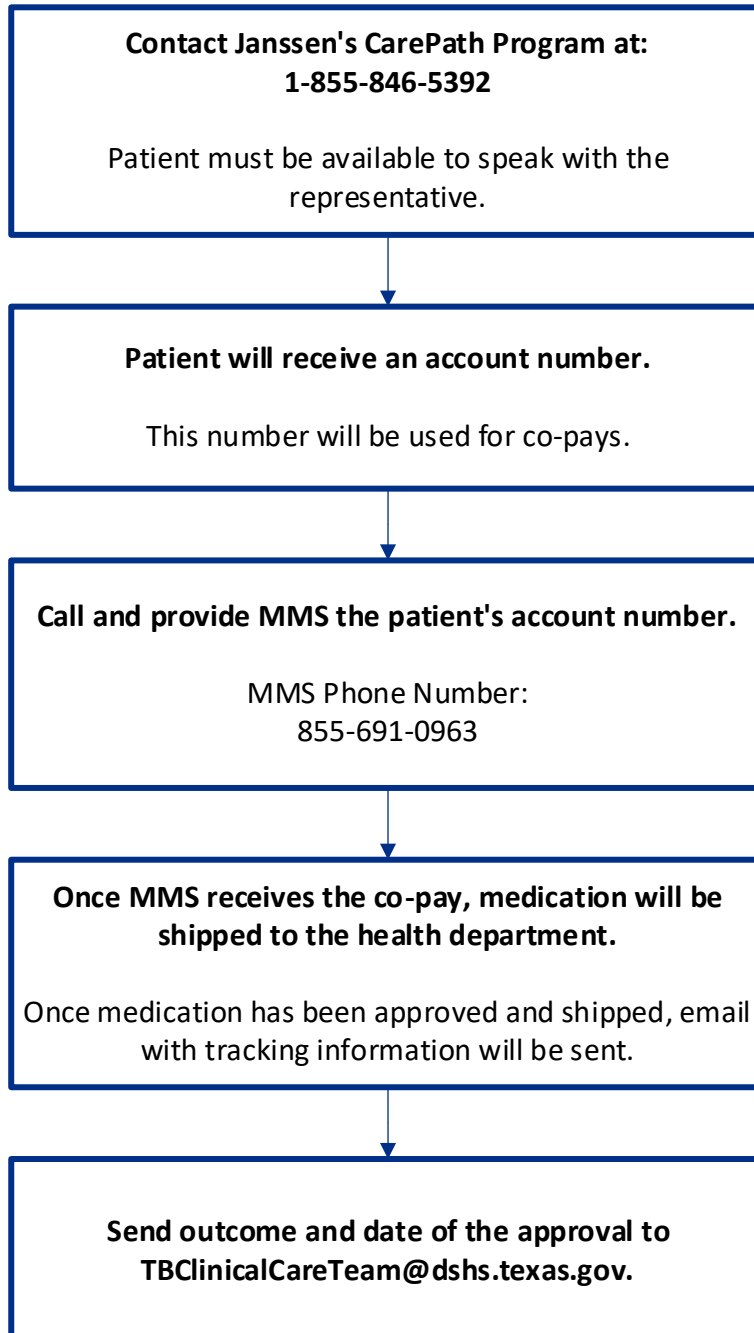


Tuberculosis and Hansen's Disease Unit  
**Bedaquiline Ordering Guide**

**Appendix B: Janssen's CarePath Program**

Janssen's CarePath Program is a resource for patients with private insurance who are charged co-pays. It does not apply to patients who have state insurance (i.e., Medicare/Medicaid). Refer to Figure 4 for program details. Note: Janssen will cover up to \$7,500 through a co-pay card. If the patient has been given a co-pay of greater than \$7,500, **STOP** and apply to JJPAF, see **Appendix C**.

**Figure 4: Process for applying through Janssen's CarePath Program**

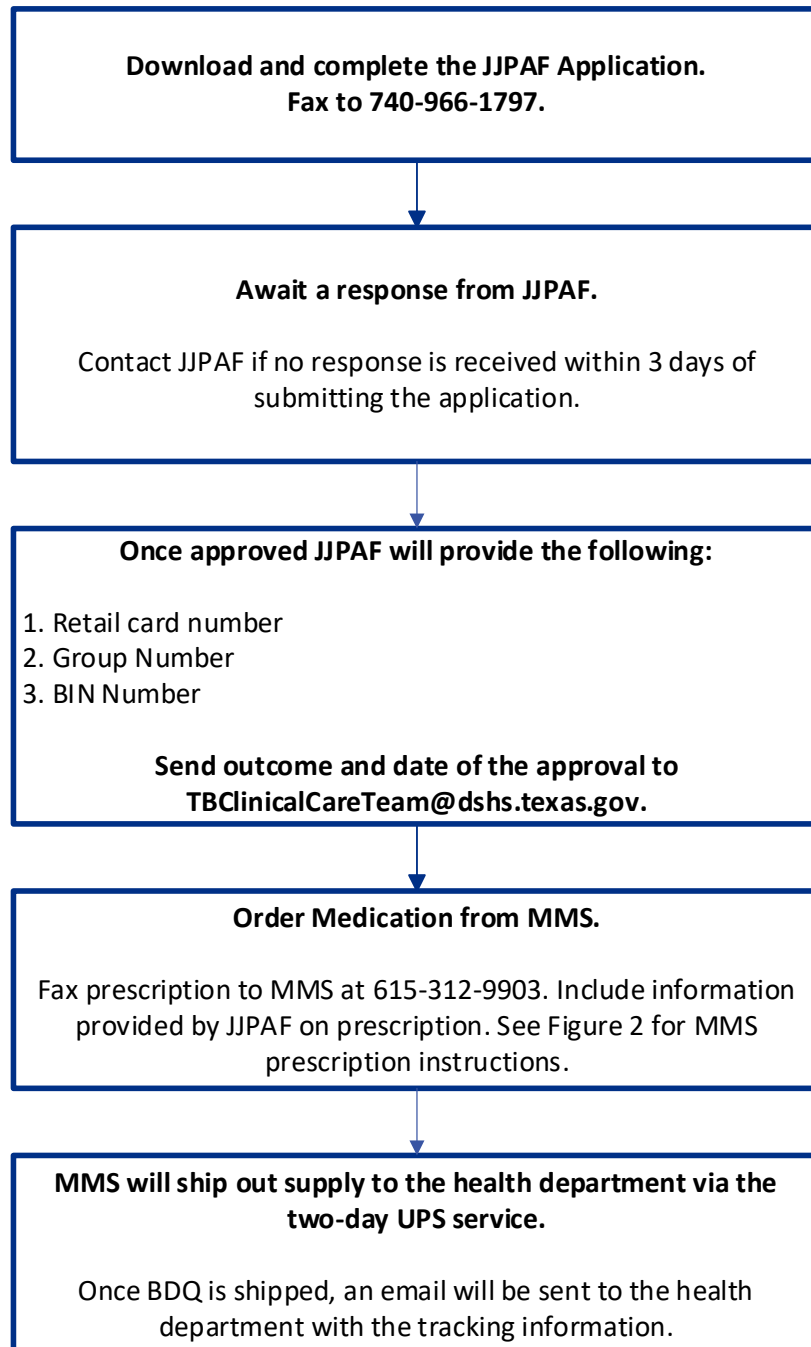


Tuberculosis and Hansen's Disease Unit  
**Bedaquiline Ordering Guide**

**Appendix C: Johnson and Johnson Patient Assistance Foundation Program (JJPAF)**

JJPAF will cover the cost of BDQ for uninsured or patients with inadequate prescription coverage. After approval from JJPAF, the medication can be ordered from MMS. Download the application at [https://www.jjpaf.org/resources/JJPAF\\_Application\\_INS.pdf](https://www.jjpaf.org/resources/JJPAF_Application_INS.pdf). Refer to Figure 5 and 6 for application details.

**Figure 5: Process for applying for assistance through JJPAF**



# Tuberculosis and Hansen's Disease Unit

## Bedaquiline Ordering Guide

Figure 6: Johnson and Johnson Application Instructions/Example

Download the application at [https://www.jjpaf.org/resources/JJPAF\\_Application\\_INS.pdf](https://www.jjpaf.org/resources/JJPAF_Application_INS.pdf)

**SUBMIT THIS PAGE**

---

### Patient Assistance Program (PAP) Application

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

#### 1 Patient Information

Name: John Doe Phone: (555) 444-7777 Email: John.Doe@gmail.com  
Social Security #: If no SS#, leave blank Date of Birth: 01/01/1959 Gender:  Male  Female  
Address (Street, City, State, ZIP): 1313 Mockingbird Lane, Austin, Texas 77777

#### 2 Financial Information

**Federal Taxes** (Indicate your federal tax filing status below **ONLY** if you do not check the box in Section 5 authorizing JJPAF to obtain a credit report or investigative credit report.)

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 Yearly Income** (required)  
Entire household: \$ 20

**Household Size** (required)  
Including yourself, the number of people who live in your home and are dependent on your household income: 4

Read section carefully, fill out yearly income, and check the appropriate box

#### 3 Healthcare Insurance Coverage

The Program only provides medicine at no cost to patients who do not have access to insurance coverage for the medicine or to Medicare Part D patients who have coverage but cannot afford copayments and deductibles for their medicines. Before you can be eligible for free medicine from the Program, you must be able to show that you cannot get assistance from other sources, including other insurance such as Medicaid that is available at no or minimal cost or assistance from other charities. If you are not sure what other sources might exist, please call JJPAF and a JJPAF representative will help you.

Please check **all** the boxes that describe your current healthcare insurance coverage and your access to other sources of patient assistance. JJPAF may ask for documentation confirming your current healthcare coverage before a determination can be made about your eligibility for the Program.

**FOR ALL INSURED PATIENTS (GOVERNMENT OR COMMERCIAL INSURANCE)**

I have insurance but my insurance denied coverage for my medicine and the decision is final.

**FOR GOVERNMENT-INSURED PATIENTS**

I have Medicare, and Medicare covers my medicine, but I cannot afford the copayments and deductibles. I have applied for financial assistance from known third party charities with funding available for patients with my condition, but I was denied financial assistance. If I require assistance or have questions about a third party charity with funding available, I will call the JJPAF.

I have Medicare, and Medicare covers my medicine, but I cannot afford the copayments and deductibles. I could not apply for assistance from known third party charities during the past 30 days because there have been no foundations with funding available for patients with my condition accepting applications. If I require assistance or have questions about a third party charity with funding available, I will call the JJPAF.

I have Medicare and applied for Medicare Part D low-income subsidy (known as Extra Help) to help with my Medicare Part D prescription drug coverage premium, but I was denied this assistance.

**FOR PATIENTS WITH NO INSURANCE**

I have no insurance at all and have checked eligibility requirements or applied to all available options for free or minimal cost insurance or other assistance. If I require assistance or have questions about other sources of assistance, I will call the JJPAF.

Revised: April 2023 © Johnson & Johnson Patient Assistance Foundation, Inc. page 2 of 7

# Tuberculosis and Hansen's Disease Unit

## Bedaquiline Ordering Guide

**SUBMIT THIS PAGE**

### Patient Assistance Program (PAP) Application

*Johnson & Johnson* **PATIENT ASSISTANCE**  
FOUNDATION, INC.

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

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

Subscriber Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_ Relationship to Patient: \_\_\_\_\_  
 Primary Plan Name: \_\_\_\_\_ Secondary Plan Name: \_\_\_\_\_

<input type="checkbox"/> Check if no insurance	ID/Policy #	Group #	Phone
<input type="checkbox"/> Prescription Insurance/Medicare Part D Plan Plan Name: _____ Fax: _____ Rx BIN #: _____ Rx PCN: _____			
<input type="checkbox"/> Private/Commercial Insurance			
<input type="checkbox"/> Medicaid			
<input type="checkbox"/> Medicare Part B			
<input type="checkbox"/> Medicare Advantage			
<input type="checkbox"/> Veterans Administration			
<input type="checkbox"/> ADAP AIDS			
<input type="checkbox"/> SPAP State Patient Assistance Program			
<input type="checkbox"/> Other:			

If applicable, fill this section with patient insurance information. If insurance is denied, attach the insurance refusal letter with the application

**5 Patient Declaration/Authorization to Assign Representative for Program Enrollment**

**Patient signature and date required before submission.**

My signature below indicates that I have read, understand, and agree to the Patient Declaration and Patient Authorization to Share Health Information on pages 5 and 6. If I have listed an authorized representative below, I permit the Johnson & Johnson Patient Assistance Foundation, Inc. (JJPAF) 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. I acknowledge and agree that JJPAF may request documentation confirming that the representative has the appropriate authority to speak on my behalf. I further understand that I remain responsible for the information submitted on my behalf by any authorized representative, including any misrepresentations or other false information.

<b>CHECK THE BOX:</b>	▶ <input checked="" type="checkbox"/>	<p><b>Applicant Financial Verification Authorization</b></p> <p>I understand that JJPAF and the vendors associated with administrating the Program (collectively the "Program Administrators") may obtain a credit report or investigative credit report about me, which may contain information as to my income or credit standing, to determine my eligibility for the Program. I hereby authorize such credit report and income verification and acknowledge that such authorization extends to consumer reporting agencies and to subsequent reports for purposes of determining my eligibility for the JJPAF Program.</p>
<b>PLEASE COMPLETE, SIGN &amp; DATE:</b>	▶	<p>Patient Name (print): <u>John Doe</u> Date: _____</p> <p>Authorized Representative Name (print if applicable): <u>Jane Doe</u></p> <p>Relationship to Patient (print if applicable): <u>Wife</u> Phone: _____</p> <p>_____ Patient Signature/Authorized Representative</p> <p style="text-align: right;">▶ Date: _____</p>

If an authorized representative is listed, both the patient and the representative must sign and date

# Tuberculosis and Hansen's Disease Unit

## Bedaquiline Ordering Guide

**SUBMIT THIS PAGE**

### Patient Assistance Program (PAP) Application

Johnson & Johnson PATIENT ASSISTANCE  
FOUNDATION, INC.

**TO BE COMPLETED BY THE HEALTHCARE PROFESSIONAL (HCP)—all information is required.**

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

Patient Name: John Doe Date of Birth: 01/01/1959

ICD Code: \_\_\_\_\_ Name of Product: Sirturo

Strength: 100mg Sig: 400mg daily X14 days, then 200mg trice weekly X24 weeks

Quantity: 200 Days' Supply: 86 Number of Refills (maximum II): 11

List any patient allergies: \_\_\_\_\_ or  NKDA

List all allergies here.  
\_\_\_\_\_  
\_\_\_\_\_

List patient's current medications: \_\_\_\_\_ or  none

List all current medications here.  
\_\_\_\_\_  
\_\_\_\_\_

**If you are a prescriber in New York, South Carolina, or Washington, you must attach prescription on your state official prescription form with this application.**

**The prescriber is responsible for ensuring the prescription complies with their state-specific prescription requirements, such as e-prescribing, state-specific prescription form, or fax language. Noncompliance with state-specific requirements could result in outreach to the prescriber.**

#### 2 HCP Information

Fill this section out completely

Name: LICENSED HEALTHCARE PROVIDER NAME HERE Site Name: NAME OF HEALTH DEPARTMENT HERE

Site Contact: LIST NAME HERE Business Hours: LIST HOURS

Address (Street, City, State, ZIP): THIS IS WHERE MEDICATION WILL BE MAILED

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): \_\_\_\_\_

#### 3 HCP Authorization

My signature below indicates that I have read, understand, and agree to the Johnson & Johnson Patient Assistance Foundation, Inc. policy and the terms of Program participation on page 7.

HCP SIGN & DATE:  Licensed healthcare provider signs and dates  Date: \_\_\_\_\_  
Healthcare Professional Signature

Revised: April 2023

© Johnson & Johnson Patient Assistance Foundation, Inc. page 4 of 7

Clear Form

Print Form

# Tuberculosis and Hansen’s Disease Unit

## Bedaquiline Ordering Guide

### Appendix D: Binational Process

If patient is followed by the DSHS Binational TB (BNTB) Program and does **not** have a Texas address of residency, follow these steps to obtain BDQ:

1. **Obtain a TB consult.** BDQ is available to DSHS BNTB programs after consultation with a **DSHS-Recognized TB Medical Consultant** and no other alternative regimen is available.
  
2. **Notify the Regional Mycobacteriology TB Program.**
  - 1) Inform the BNTB treating physician of the consultation recommendations for BDQ use according to local BNTB program procedures.
  - 2) Coordinate information sharing with the Regional Mycobacteriology Program, who in turn should inform the State Mycobacteriology Department and the National TB Program(s) in Mexico.

Note: this applies to any patient with drug-resistant TB but is especially important when requesting BDQ.

    - a) Include the DSHS-Recognized TB Medical Consultant’s recommendations and pertinent patient medical record information.
    - b) If approved, follow local processes to elevate request to the COEFAR\* and the GANAFAR\*\*; include a formal request that medications be provided by Mexico.
  - 3) Notify the **TB Unit Clinical Care Team** via email that the application to the COEFAR and GANAFAR has been submitted. Note: If Mexico agrees to procure BDQ, a “dictamen” letter will be provided from the GANAFAR; see step #4, below.

*\*Drug-resistant TB committee in Mexico, by state*

*\*\*Mexico’s national advisory committee on drug resistant TB*

3. **Notify the DSHS TB Unit regarding the order.**
  - 1) Name of the requesting BNTB program and coordinator (include contact number):  
\_\_\_\_\_
  - 2) Name of Mexico’s BNTB program treating physician: \_\_\_\_\_
  - 3) Name of Texas consulting physician (must be a DSHS physician or physician working directly with L/RHD): \_\_\_\_\_
  - 4) Name of DSHS Recognized TB Medical Consultant: \_\_\_\_\_
  - 5) Have baseline toxicity assessments and labs (to include ECG, cardiac monitoring, CBC, CMP, TSH, and Mg) been performed?  Yes  No
    - a) If no, specify date to be completed: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_
  - 6) Describe the plan of care for the patient’s access to routine follow-up, including but not limited to obtaining ECGs: \_\_\_\_\_.

## Tuberculosis and Hansen's Disease Unit

### Bedaquiline Ordering Guide

4. **Await TB Unit approval and order initial BDQ supply.** Once the above has been reviewed by the DR-TB Program, an approval email will be sent to the requesting BNTB program and BDQ may be ordered from the DSHS pharmacy.
  - 1) Order initial 14-day supply through DSHS pharmacy. If patient tolerates medication, BDQ may be ordered in 1-month increments following the first order request.
  - 2) When ordering BDQ from the DSHS pharmacy, include in the comments section the patient surveillance ID# and prescription details (i.e., "Surveillance ID #; BDQ 400mg PO daily x 14 days").
  
5. **Secure and administer BDQ for the remainder of therapy.**
  - 1) Email the DR-TB Program the outcome of how BDQ will be obtained for duration of therapy.
    - a) While awaiting the "dictamen" approval letter from the COEFAR/GANAFAR to obtain BDQ from Mexico, continue ordering BDQ through DSHS pharmacy.
    - b) Prior to ordering refills, send an updated email to the DR-TB Program indicating the progress made with the COEFAR/GANAFAR.
    - c) Once received and reviewed, the DR-TB Program will authorize another month of BDQ to be ordered (and will copy the DSHS pharmacy of the approval to order).
    - d) If a "dictamen" is received, upload to Globalscape and notify by email the DR-TB Program indicating the receipt of the letter and Mexico's anticipated date of medication arrival to the BNTB program.
      - If a "dictamen" is never obtained, continue to order BDQ from the DSHS pharmacy in monthly increments, as per #1) b).
  - 2) Ensure written orders are received from the licensed healthcare provider prior to administering medication. *Note: DSHS-Recognized TB Medical Consultant recommendations and/or TCID discharge summaries are not medical orders; L/RHDs must work with their licensed healthcare provider to obtain orders.*
  - 3) Ensure a baseline ECG, cardiac monitoring, and laboratory results are reviewed by the licensed healthcare provider.
  - 4) Track patient status and document assessments on the **TB 702a** or equivalent.
  - 5) Obtain updated medical orders as applicable. Note: after an initial daily dosing for two weeks/14 days, BDQ is administered in thrice-weekly dosing. ***If the patient misses any of these doses, treatment may need to be adjusted depending on phase of therapy and duration of interruption. Seek consultation when needed.***
  - 6) Enter BDQ start and stop dates in the DSHS surveillance system. Remember to enter a start and stop date when dosages change (i.e., include a stop date of daily dosing when the regimen changes to thrice weekly dosing).
  - 7) Update the TB Unit at least quarterly on patient status and report closures to the TB Unit.

Tuberculosis and Hansen’s Disease Unit  
**Bedaquiline Ordering Guide**

**Appendix E: Contacts and Resources**

<b>DSHS TB Unit</b>	
<b>Main phone:</b> 737-255-4300 <b>Email Address:</b> TBClinicalCareTeam@dshs.texas.gov	
<b>DSHS Pharmacy Unit</b>	
<b>Main phone:</b> 512-776-7500 <b>Website:</b> <a href="https://www.dshs.texas.gov/pharmacy">https://www.dshs.texas.gov/pharmacy</a>	
<b>Specialty Pharmacy and Patient Assistance Contacts</b>	
<b>Metro Medical Solutions (MMS)</b>	Phone: 855-691-0963 <a href="https://www.metromedical.com">https://www.metromedical.com</a>
<b>Johnson &amp; Johnson Patient Assistance Foundation (JJPAF)</b>	Phone: 800-652-6227 <a href="http://jjpaf.org">http://jjpaf.org</a>
<b>Janssen’s CarePath Program</b>	Phone: 855-846-5392 <a href="https://www.janssencarepath.com/hcp">https://www.janssencarepath.com/hcp</a>
<b>Additional Resources</b>	
<b>Sirturo Product Guide</b>	<a href="https://www.sirturo.com/sites/default/files/pdf/SIRTURO-product-guide.pdf">https://www.sirturo.com/sites/default/files/pdf/SIRTURO-product-guide.pdf</a>
<b>National TB Controllers Association (NTCA) Bedaquiline Access Guide</b>	<a href="http://www.tbcontrollers.org/docs/bedaquiline/Bedaquiline_Access_Guide_v2.0_04June2019.pdf">http://www.tbcontrollers.org/docs/bedaquiline/Bedaquiline_Access_Guide_v2.0_04June2019.pdf</a>
<b>Centers for Disease Control and Prevention (CDC) Bedaquiline Fact Sheet</b>	<a href="https://www.cdc.gov/tb/publications/factsheets/treatment/bedaquiline.htm">https://www.cdc.gov/tb/publications/factsheets/treatment/bedaquiline.htm</a>
<b>CDC Guidelines for the Use and Safety Monitoring of Bedaquiline Fumarate (Sirturo) for the Treatment of Multidrug-Resistant Tuberculosis</b>	<a href="https://www.cdc.gov/mmwr/PDF/rr/rr6209.pdf">https://www.cdc.gov/mmwr/PDF/rr/rr6209.pdf</a>
<b>Sirturo Label Insert</b>	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/204384s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/204384s000lbl.pdf</a>



Tuberculosis and Hansen's Disease Unit  
[dshs.texas.gov/tuberculosis-tb](https://dshs.texas.gov/tuberculosis-tb)