TUBERCULOSIS AND HANSENS'S DISEASE SECTION

SIRTURO (BEDAQUILINE) ORDERING GUIDE

TEXAS Health and Human Services | Texas Department of State Health Services

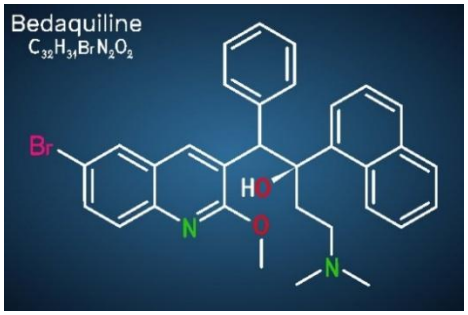
Texas Department of State Health Services
Tuberculosis and Hansen's Disease Section

Sirturo (Bedaquiline) Ordering Guide

Figures

Sirturo (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 a rifamycin cannot be used in a TB regimen.

Cardinal Health ™ Metro Medical Solutions ™ (MMS) is a specialty pharmacy and sole distributor of BDQ. The Department of State Health Services (DSHS) Tuberculosis and Hansen's Disease Section (TB Section) provides anti-TB medications to patients without charge; however, due to the extremely high cost of procuring BDQ, the TB Section requires health departments to utilize patient assistance programs (PAPs) to offset the price of BDQ.

This document outlines steps public health regions (PHRs) and local health departments (LHDs) must follow to obtain BDQ at no cost to the patient or the health department.

Considerations for BDQ Use

Review the following before using BDQ:

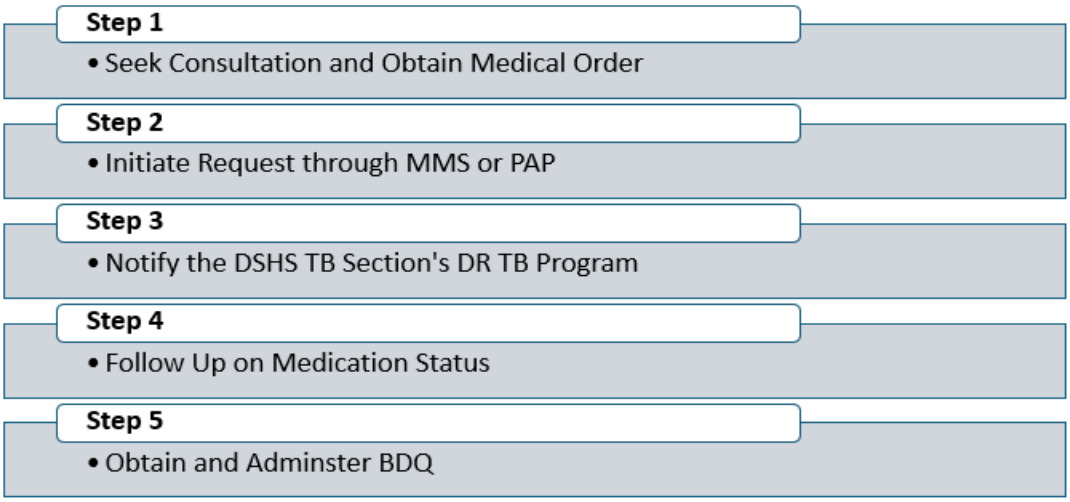
- ✓ Obtain BDQ after consulting with a **DSHS-Recognized TB Medical Consultant** or DSHS regional medical director (RMD).
- ✓ Develop a plan for monitoring medication toxicity so that BDQ can be safely administered. This includes electrocardiogram (ECG) monitoring and laboratory testing. Refer to the DSHS **Standing Delegation Orders (SDOs)** and **Nursing Guide for Second-Line Tuberculosis Medications.**
- ✓ BDQ is available through the MMS specialty pharmacy. PHRs and LHDs will need to assist patients in applying to a PAP to cover costs.
- ✓ PHRs and LHDs may order BDQ from the DSHS Pharmacy upon TB Section approval while awaiting a response from the PAP application and MMS.

It can take up to <u>two-weeks</u> before BDQ is approved by the PAP. Missing information may delay the application process. PHRs and LHDs should apply for BDQ *as soon as possible* and, when needed, communicate with the TB Section's Drug-Resistant TB Monitoring Program (DR-TB Program) for assistance**.**

BDQ Ordering Steps

PHRs and LHDs managing patients prescribed BDQ will need to coordinate medication procurement following the steps below. Refer to **Figure 1**: BDQ Ordering Steps and the details in the following pages. Use the applicable appendices to support procurement requirements.

Figure 1: BDQ Ordering Steps



Step 1: Seek Medical Consultation and Obtain a Medical Order

- BDQ may be used upon consultation with a **DSHS-Recognized TB Medical Consultant** or RMD.
- Once recommended, obtain a medical order for BDQ from the licensed healthcare provider.

Note: Consultant recommendations and discharge summaries from the Texas Center for Infectious Disease (TCID) do not serve as medical orders.

Step 2: Initiate BDQ Procurement through MMS or a PAP

Verify patient's insurance status and request BDQ from the applicable entity. See **Figure 2**.

Insured Patients:

- For patients who are insured privately (e.g., Blue Cross Blue Shield) or by state or federal programs (e.g., Medicare or Medicaid), request BDQ directly from MMS. See **Appendix A.**
  - ► Some insurance plans require a preauthorization or justification for BDQ.
  - ► If the patient is charged a copay, patients may qualify for copay assistance through Johnson and Johnson withMe (J&J withMe) savings program. See **Appendix B** for details.
  - ► If the patient is denied coverage, apply to the Johnson and Johnson Patient Assistance Program (J&JPAP). See **Appendix C**.

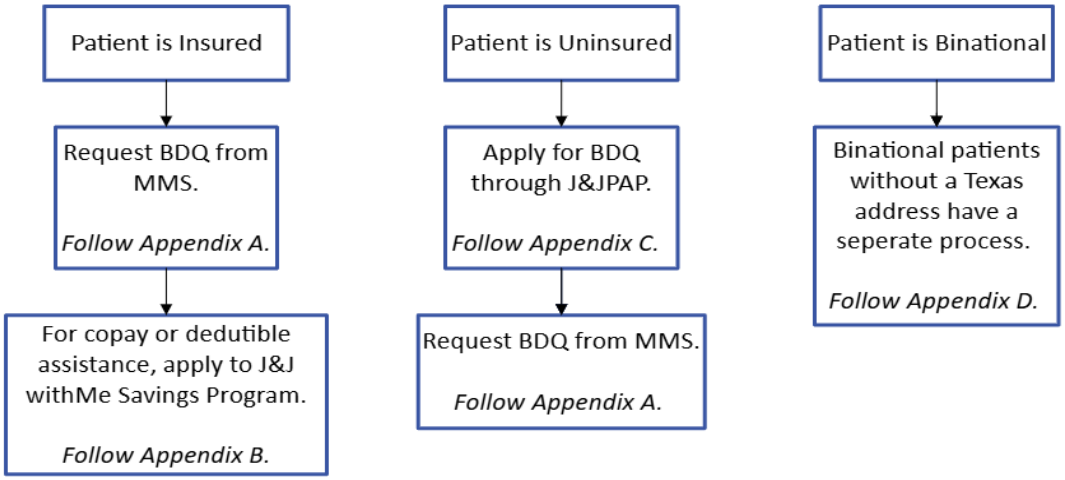
Uninsured Patients:

- For patients who are uninsured, first request BDQ from J&JPAP; once approved, J&JPAP will provide coverage information to MMS and submitters will be instructed to order BDQ directly from MMS. Refer to **Appendix C** for J&JPAP application process.

Binational TB Program Patients:

- For eligible patients enrolled in the DSHS Binational TB program *with* residency in Texas, follow the above bullets. For binational TB patients without Texas residency, refer to **Appendix D**.

Figure 2: Determination of Patient Assistance



Step 3: Notify the DSHS TB Section's DR-TB Program

Notify the DSHS TB Section that BDQ has been prescribed and email complete responses to the questions below to **TB Feedback**. *Note: Do not include protected health information (PHI).*

1. Name of prescribing physician:
2. Name of consulting physician (**DSHS-Recognized TB Medical Consultant,** RMD, or TCID physician):
3. PHR or LHD program contact (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, specify: ☐ Private or Commercial Insurance ☐ Medicaid ☐ Medicare
   ☐ Uninsured
7. Date of patient assistance program (PAP) application:
   ☐ MMS (*if insured*). Date submitted: ____/____/_____
   ☐ J&J withMe *(for copays)*. Date submitted: ____/____/_____
   ☐ J&JPAP (*if uninsured or inadequate insurance*). Date submitted: ____/____/_____
8. Do you need a 7-day supply of BDQ from DSHS pharmacy while awaiting BDQ from MMS?
   ☐ Yes, I am requesting a 7-day supply from DSHS while awaiting J&JPAP.
   ☐ No, patient is stable. We can wait to start BDQ when provided by MMS.

Once the above is received and reviewed, the DR-TB Program will respond with next steps via email.

Requesting BDQ from DSHS pharmacy:

Follow this guidance when requesting BDQ from the DSHS pharmacy, once approved (see **Step 3**):

- BDQ can be provided **in one-week increments** by the DSHS pharmacy while awaiting PAP.
- Include in the comment section the patient's NEDSS ID# and prescription details (i.e., "NEDSS Investigation ID #; BDQ 400mg PO daily x 7 days" or "BDQ 200mg TIW x 1 week").
- For refill requests, include the reason for needing continued DSHS-purchased medication (e.g., delay in patient assistance due to PAP requesting additional information).

***Note**: Patients may be recommended a "bridging regimen" while awaiting BDQ. A "bridging regimen" consists of multiple second-line TB drugs that are administered until drugs in the preferred regimen (e.g., BDQ, Pretomanid, Linezolid [BPaL]) can be obtained.* ***Patients should not remain on a "bridging regimen" without BDQ for longer than seven doses (one week) if managed outpatient unless otherwise stated by consultation**.*

Step 4: Follow Up on Medication Status

After applying for BDQ via MMS or J&JPAP, if there is no response **within 2 business days,** contact them again.

- Continue to communicate with the organization as often as necessary to process the order.
- Email **TB Feedback** once the order is approved or if there are delays in medication approvals, e.g., preauthorization needed.
- A hardship letter may be requested by J&JPAP for patients unable to cover the cost of

Step 5: Obtain and Administer BDQ

BDQ will be shipped to the health department by MMS (or provided temporarily by the DSHS pharmacy). Once the required laboratory and toxicity assessments have been performed and reviewed by the licensed healthcare provider, the patient can begin BDQ as prescribed.

- Ensure baseline ECG, cardiac monitoring, and laboratory results are reviewed by the licensed healthcare provider prior to starting medication.
- Monitor the patient as per medical orders, consultation recommendations, and as outlined in the **DSHS Standing Delegation Orders (SDOs)**.
- Document assessments on the **TB-702** or equivalent.
  - ► Obtain updated medical orders from the licensed healthcare provider as applicable.
  - ► After the initial daily dosing of BDQ for two weeks (14 days), BDQ must be administered in thrice-weekly dosing – refer to the SDOs.
- Enter BDQ start and stop dates, including when dosages are adjusted in the patient's NEDSS case investigation.
- Update the DR-TB Program regarding patient status throughout the course of care, as outlined in the **Texas Tuberculosis Manual, Chapter VI**.

Appendix A: Metro Medical Solutions (MMS) Process

Contact MMS directly at 855-691-0963 when ordering BDQ for insured patients or after first seeking approval from the Johnson and Johnson Patient Assistance Program (PAP) for other eligible patients. MMS will provide an order form as needed and an application form. Refer to **Figure 3** for ordering details and **Figure 4** for prescription details.

Figure 3: Process for Ordering BDQ from MMS Specialty Pharmacy

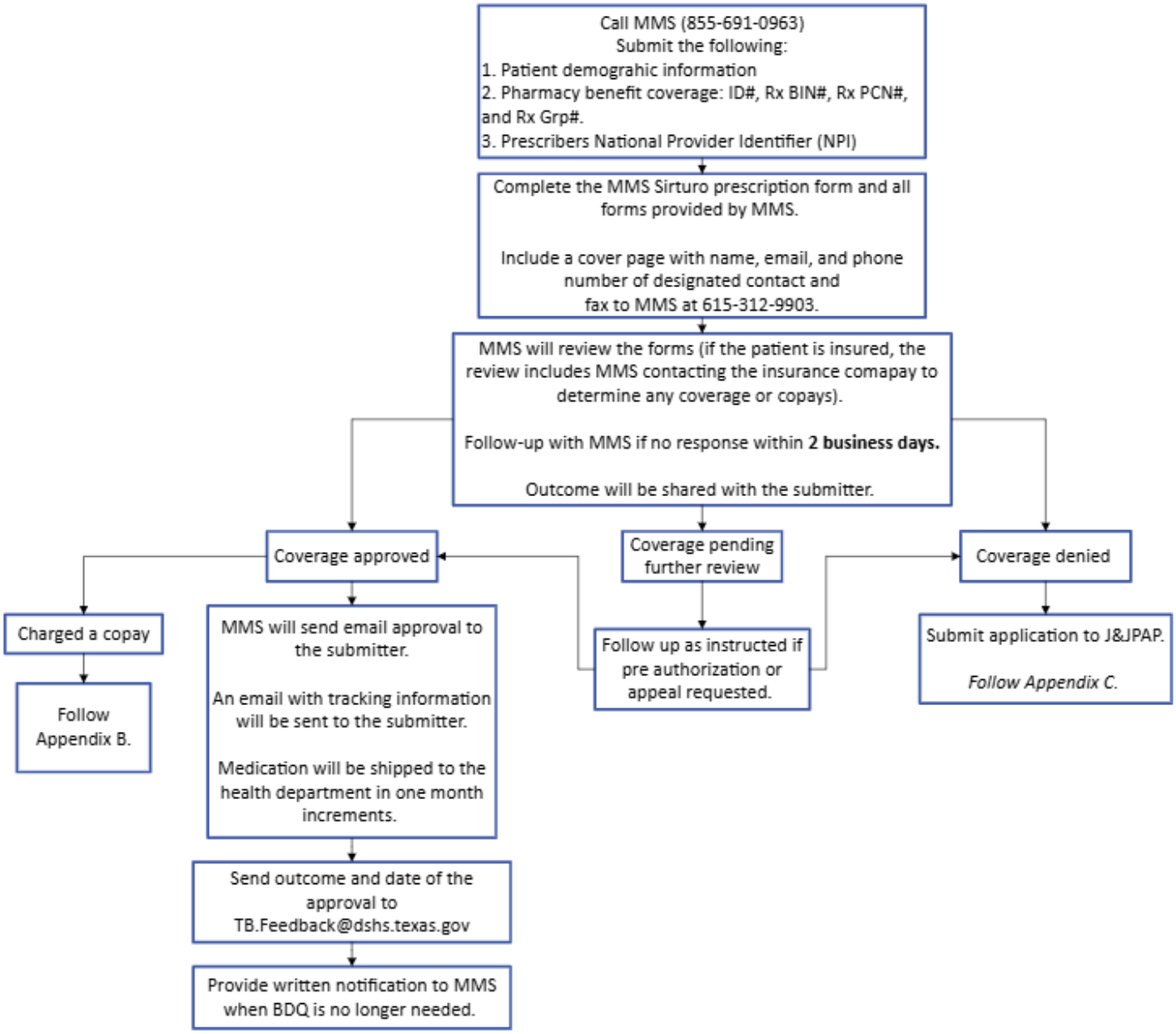


Figure 4: Metro Medical Solutions Prescription Form Example

MMS SOLUTIONS METRO

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

For patients with insurance, ensure to fax a legible copy of the insurance card (front and back) to MMS.

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:**	Enter health department (HD) information
PO#:	Leave blank	**Metro Account #:**	Leave blank
Patient Last Name:		**Facility Phone:**	
Patient First Name:		**Facility Fax:**	Also include HD email address
Patient Date of Birth:		**Facility Address:**	
Patient Phone:		**Facility City, ST, Zip:**	
Patient Address:			
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: List allergies and add client diagnosis

ITEM #	MEDICATION	QTY	DIRECTIONS FOR USE
	Sirturo 100mg tabs (NDC:59676-0701-01)	68 tabs	**First month supply:**
Other			Take 4 tabs po daily for 2 weeks, then
Other			2 tabs po 3 times a week for 2 weeks
Other			
Other		**Remaining prescription for 26-week regimen:**	
Other	Sirturo 100 mg tabs(NDC:59676-0701-01)	24 tabs w/5 refills	Take 2 tabs po 3 times a week
Other		12 tabs	Take 2 tabs po 3 times a week
Other	Write *"Sirturo"* not *"Bedaquiline"*	**Remaining prescription for 39-week regimen:**	
Other		24 tabs w/8 refills	Take 2 tabs po 3 times a week
		18 tabs	Take 2 tabs po 3 times a week

Prescriber Name: _____ Prescriber Phone: _____

Prescriber NPI: _____ Prescriber Signature: _____

Write entire prescription even if started at TCID.

SHIPPING METHOD

☒ **2nd Day Air (Standard Method)** ☐ **Overnight**

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.

Appendix B: Johnson and Johnson withMe (J&J withMe) Savings Program

J&J withMe is a cost savings program for eligible patients who may have an out-of-pocket cost for BDQ. Eligible patients with commercial or private insurance coverage may qualify for a maximum of $7,500 per calendar year to be applied toward co-pays, co-insurance, or deductibles. For more information on eligibility, visit: https://asset.jnjwithme.com/document/id-savings-program-overview.pdf.

There are two options to apply:

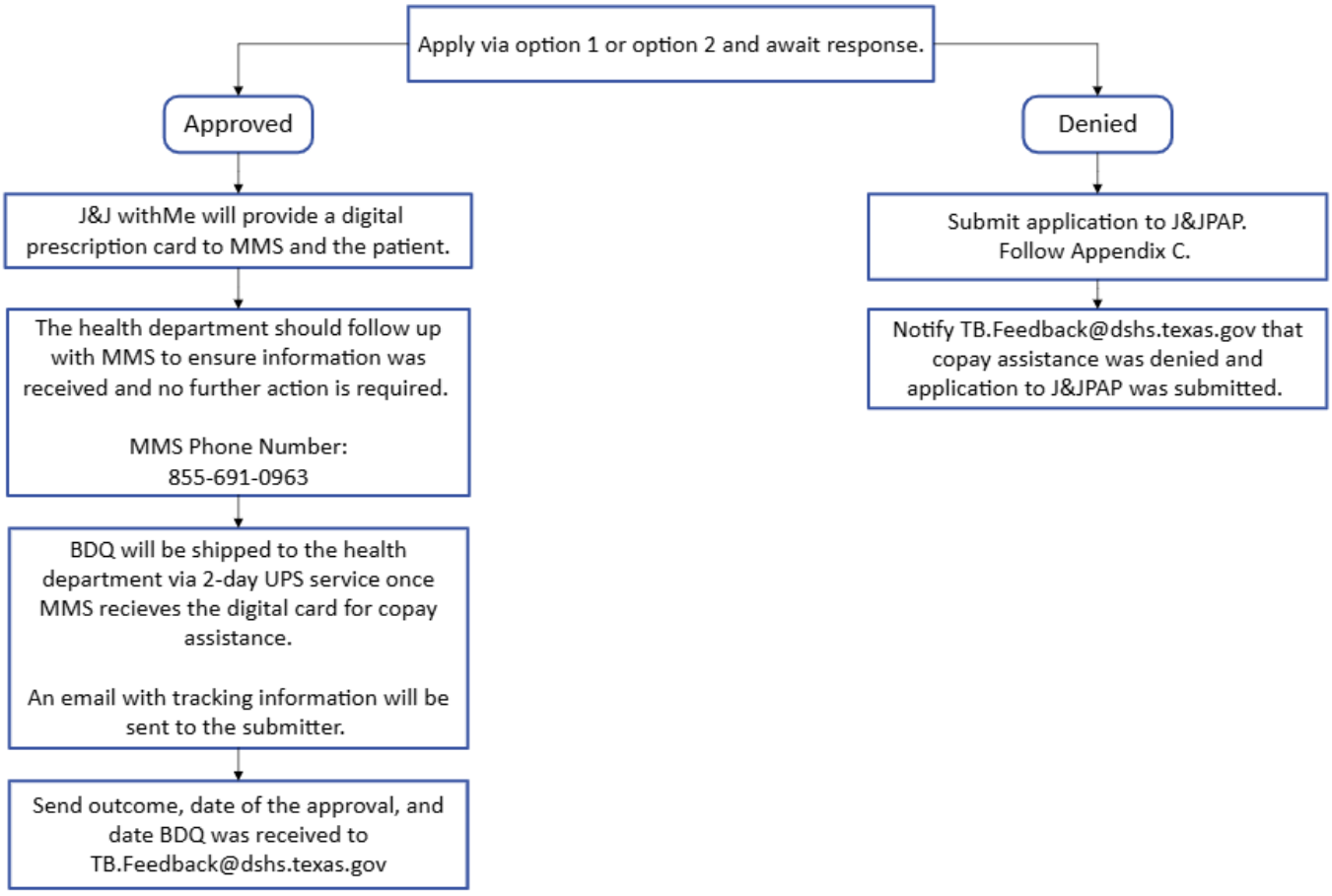
Option 1: Apply via electronic portal. (*Patient may apply independently or programs may assist patient when applying).*

- Follow the instructions at **myjanssencarepath.com**.
- Select 'Guide Me -Customize My Experience'.
- Select 'Patient' option then select 'Symtuza' from the drop-down menu and continue to follow the prompts.
- For questions, call 866-863-0114.

Option 2: Providers may enroll patients on their behalf.

- Call 1-855-846-5391 for guidance.

Figure 5: Process for Applying through J&J withMe



Appendix C: Johnson and Johnson Patient Assistance Program (J&JPAP)

The Johnson and Johnson Patient Assistance Program (J&JPAP) is an independent, non-profit organization that covers the cost of designated medications for eligible patients who are uninsured, or who have insurance but who may not be able to cover the out-of-pocket (OOP) expenses. For eligibility, visit: **https://asset.jnjwithme.com/document/JnJ_Patient_Assistance_Quick_Reference_Guide_Other_Medications.pdf**.

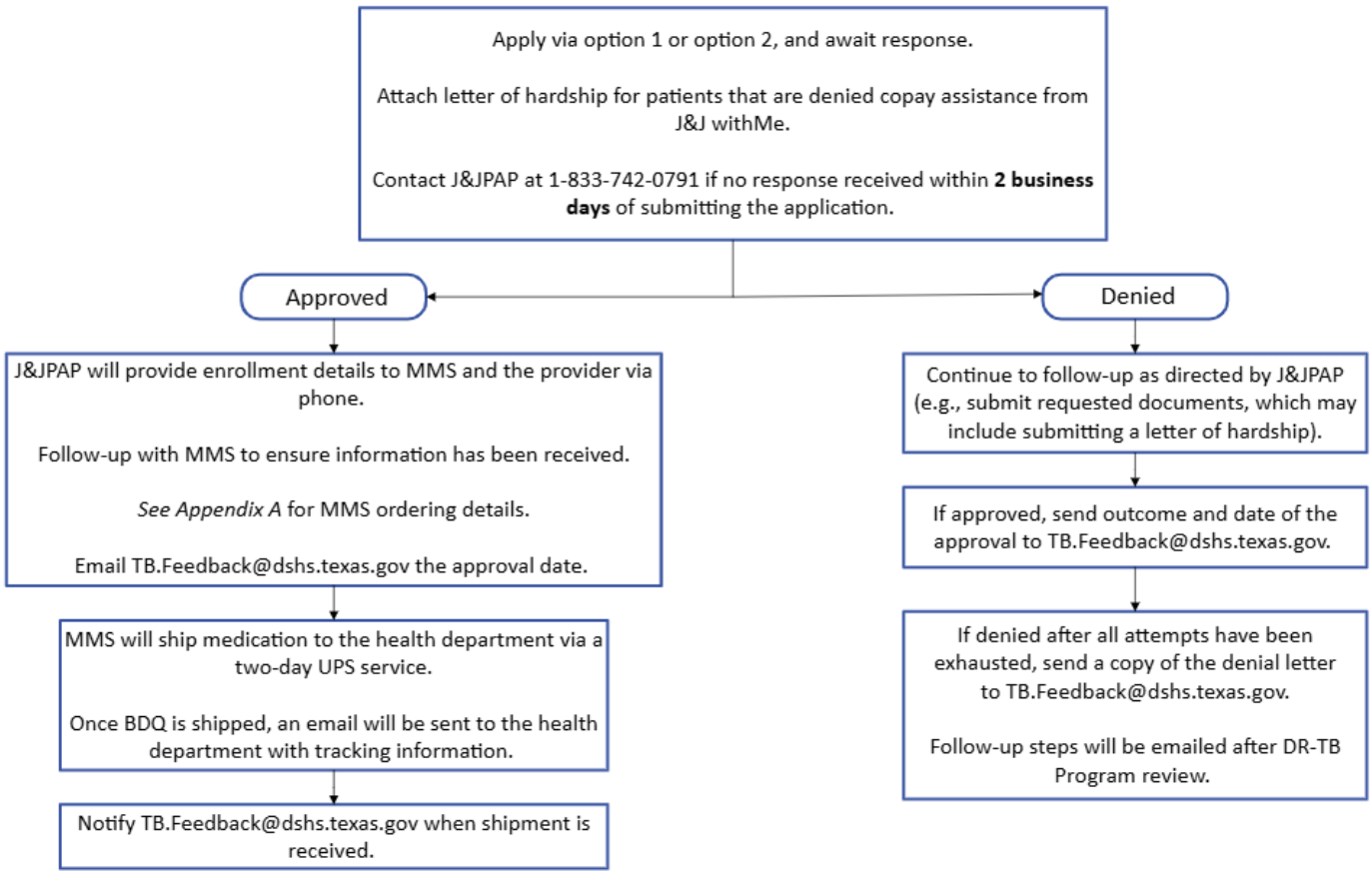
There are two options to apply:

Option 1: Apply via paper application.
https://asset.jnjwithme.com/document/JnJ_Patient_Assistance_Enrollment_Form_English.pdf.
- Download application.
- Fax completed application to: 833-512-0497.

Option 2: Apply via the online portal.
https://www.portal.jnjwithme.com/patient-assistance.
- Select 'Apply Now', then 'Sirturo' from drop-down.
- Select 'Continue' and follow prompts.

When submitting the application, include supporting documents listed on page 1; also, include a **hardship letter**[1] if necessary. Refer to **Figures 6** and **7** when applying for J&JPAP.

Figure 6: Process for Applying through J&JPAP



[1] Hardship letters explain factors that make it difficult for the patient to pay for OOP expenses despite their income eligibility. Include current health status, the medication copay OOP cost, and additional income factors. The letter should be written by the health department and ideally signed by the treating physician.

Figure 7: Johnson and Johnson Patient Assistance Application Example

Fill out and submit page 2 and 3.

Patient Assistance Enrollment Form. See page 1 for enrollment checklist and supporting documents needed.

The information you provide will be used by Johnson & Johnson Health Care Systems Inc., our affiliates, and our service providers to determine your eligibility for and enroll you in the Johnson & Johnson Patient Assistance Program. You may withdraw your request for these services by calling 833-742-0791. Our **Privacy Policy** further governs the use of the information you provide.

To Be Completed by Patient Fields marked with an (*) are required

1. PATIENT INFORMATION

*First Name: _____ *Last Name: _____ *Primary Phone: _____
Email: _____ *Date of Birth (mm/dd/yyyy): _____ *Sex: _____
*Address Line 1: _____ Address Line 2: _____
*City: _____ *State: _____ *ZIP Code: _____
*Product Name: _____
This is the address that all self-administered medicine will be shipped to. For a change of address, please contact 833-742-0791 and share the information with your Healthcare Provider.

2. INSURANCE INFORMATION *(Complete for all available insurance and submit copies of front and back of all insurance cards.)*

☐ I have no insurance and have checked eligibility requirements or applied to all available options for free or minimal cost insurance or other assistance.
If you were previously enrolled in a patient assistance program, please provide your patient ID #: Enter ID # for existing patients only. _____
Primary Prescription Insurance (PPI): Fill out if applicable _____ PPI Prescription Card BIN #: _____ PPI Phone: _____
PPI Cardholder Name (First, MI, Last): _____ PPI Cardholder Date of Birth: _____
PPI Relationship to Cardholder: _____
PPI Policy #: _____ PPI Group #: _____
Primary Medical Insurance (PMI): _____ PMI Phone: _____
PMI Cardholder Name (First, MI, Last): _____ PMI Cardholder Date of Birth: _____
PMI Relationship to Cardholder: _____
PMI Policy #: _____ PMI Group #: _____
Secondary Medical Insurance (SMI): _____ SMI Phone: _____
SMI Cardholder First Name (First, MI, Last): _____
SMI Relationship to Cardholder: _____
SMI Policy #: _____ SMI Group #: _____
*Cardholder Employer Name: _____ *Cardholder Employer Phone: _____
*Cardholder Employer Address: _____
*Cardholder Employer City: _____ *Cardholder Employer State: _____ *Cardholder Employer ZIP Code: _____

3. FINANCIAL INFORMATION

***Total Gross Annual Income**
Entire household: $ _____

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

(A credit check is required to confirm you meet the income eligibility. This will not impact your credit score.)

4. PATIENT CONSENT FORM *(Please review Patient Consent Form on pages 4-6.)*

My signature below certifies that I have provided accurate and complete information and that I have read, understood, and agree to the Patient Consent Form on pages 4-5. Your signature also allows Johnson & Johnson to perform a credit check. This will not impact your credit score.

*Print Patient Name: _____
*Patient or legally authorized representative† sign here: _____ *Date: _____
†A Legally Authorized Representative is a person authorized, under state or other applicable law, to act on behalf of the individual in making healthcare-related decisions, such as a parent, guardian, or (court-appointed) representative.

5. PATIENT AUTHORIZATION FORM CONSENT *(Please review Patient Authorization Form on pages 6-7.)*

By signing below, I certify that I have read, understand, and agree to the Johnson & Johnson Patient support program patient authorization form on pages 6-7.

*Print Patient Name: _____
*Patient or legally authorized representative† sign here: _____ *Date: _____
†A Legally Authorized Representative is a person authorized, under state or other applicable law, to act on behalf of the individual in making healthcare-related decisions, such as a parent, guardian, or (court-appointed) representative.
*Describe relationship to patient and authority to make medical decisions for patient: _____

6. OPTIONAL COMMUNICATIONS

Permission for communications outside of Johnson & Johnson's patient support programs:
☐ Yes, I would like to receive communications relating to my medicine from J&J.
☐ Yes, I would like to receive communications relating to other products and services from J&J.

For privacy rights and choices specific to California, Colorado, Connecticut, Utah, Virginia, and Washington residents, please see J&J's US Supplemental Privacy Notice available at InnovativeMedicine.JNJ.com/us/privacy-policy#supplemental

Permission for text communications:
☐ Yes, I would like to receive text messages. By selecting this option, I agree to receive text messages as allowed by this Form to the cell phone number provided below. Message and data rates may apply. Message frequency varies. I understand I am not required to provide my permission to receive text messages to participate in J&J's patient support programs or to receive any other communications I have selected. Cell Phone Number: _____

FOR ADMINISTRATIVE PURPOSES ONLY page 2 of 7 Clear Form Print Form

Patient Assistance Enrollment Form

The information you provide will be used by Johnson & Johnson Health Care Systems Inc., our affiliates, and our service providers to determine your patient's eligibility and enroll your patient in the program. You may withdraw your request for these services by calling 833-742-0791. Our **Privacy Policy** further governs the use of the information you provide.

To Be Completed by Provider

Fields marked with an (*) are required

1. PRESCRIPTION *(Please complete a copy of this page for each medicine and dosage strength you are requesting.)*

*Patient First Name: _____ *Patient Last Name: _____ *Patient Primary Phone: _____

*Patient Address Line 1: _____ Patient Address Line 2: _____

*Patient City: _____ *Patient State: _____ *Patient ZIP Code: _____

*Patient Date of Birth (*mm/dd/yyyy*): _____ Patient Weight: _____ Patient Height: _____ *Patient Sex: _____

*ICD Code: _____ *Name of Product: Sirturo _____ *Strength: 100 mg _____

*Sig: 400 mg daily x 14 days, then 200 mg trice weekly x 24 weeks _____ *Quantity: ** _____ *Day Supply: 86 _____

First Time Fill: ☐ Yes ☐ No *Number of Refills (*maximum 11*): 11 _____ *Need by Date: XX/XX/XX

Additional Notes: **Filling out this form electronically will only allow for a two-digit number. Enter 200 here if downloading and faxing the application; if using electronic submission, enter a 2-digit number, e.g., 99, and confirm with MMS the correct quantity. The above is for a 26-week prescription.

***Ship to Location:**

☐ Patient Home (same as above) ☒ Prescriber Office (same as section 2. HCP Information) ☐ Treatment Center (if different from Prescriber Office)

Site Name: Enter health department information here _____ Site Contact Name for Shipment: _____

Site Business Hours: _____ Site Phone: _____ Site Fax: _____

Site Address Line 1: _____ Site Address Line 2: _____

Site City: _____ Site State: _____ Site ZIP Code: _____

*Patient Allergies: _____ or ☐ none

*List of Patient's Current Medicines: _____ or ☐ none

For SPRAVATO® (esketamine): Due to the product being a controlled substance, an Rx cannot be captured in the Patient Enrollment Form. An electronic prescription must be sent to "*Wegmans Specialty Pharmacy #198*" directly from the HCP.

2. HCP INFORMATION *(The address you provide here will be used to ship HCP-administered medicines. Self-administered medicines will be shipped directly to the Patient.)*

*HCP First Name: _____ *HCP Last Name: _____ *HCP Site Name: _____

HCP Site Contact: _____ HCP Business Hours: _____

*HCP Address Line 1: _____ HCP Address Line 2: _____

*HCP City: _____ *HCP State: _____ *HCP ZIP Code: _____

*HCP Phone: _____ *HCP Fax: _____ HCP Email: _____

*HCP Tax ID #: _____ *HCP NPI #: _____

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

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

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

If you are aware of an Assistance Diversion Program (ADP) being part of the patient's plan design, please provide the details below:

ADP Name: _____ ADP Address: _____

ADP City: _____ ADP State: _____ ADP ZIP Code: _____

ADP Phone: _____ ADP Fax: _____

3. HCP AUTHORIZATION

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.

My signature below indicates that I have read, understand, and agree to the Johnson & Johnson Health Care Systems Inc. policy and the terms of Program participation.

HCP SIGN & DATE: *Healthcare Provider Signature _____ *HCP Authorization Date (*mm/dd/yyyy*): _____

FOR ADMINISTRATIVE PURPOSES ONLY page 3 of 7 Clear Form Print Form

Appendix D: Binational TB Program Process

If the patient is enrolled in 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 consultation.** BDQ is available after consulting with a **DSHS-Recognized TB Medical Consultant** or DSHS RMD, and when an alternative regimen is unavailable.

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 in Mexico, which 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 it is especially important when requesting BDQ.*
        a) Include the consultant's recommendations and applicable medical record details.
        b) Follow local processes to elevate request to the COEFAR* and the GANAFAR**; include a formal petition requesting medications from Mexico.
    3) Email **TB Feedback** when the application to the COEFAR and GANAFAR has been submitted. *Note: If Mexico agrees to provide BDQ, a "dictamen" letter will be provided from the GANAFAR*; see **#5**, below.

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

3. **Notify the DSHS TB Section.** Send a notification to the DR-TB Program that includes outlining the plan of care prior to ordering BDQ via the DSHS pharmacy.

    Submit via **TB Feedback** email answers to the following questions. Do not include protected health information (PHI):
    1) Does the patient have a Texas address? ☐ Yes ☐ No
    2) Indicate eligibility criteria (check all that apply):
        ☐ Confirmed or suspected TB.
        ☐ Referred from the U.S. for follow-up or treatment continuation.
        ☐ Has dual residency in the U.S. and Mexico with proof of residency card
        ☐ Resides in Mexico or *Texas and* reports frequent cross-border activity or maintains contact with people in both Mexico and Texas during the infectious period.
    3) Name of the requesting BNTB program and coordinator (include contact number):
    4) Name of Mexico's BNTB program treating physician and nurse case manager in Mexico:
    5) Name of Texas consulting physician (must be a DSHS physician or physician working directly with the PHR or LHD):
    6) Name of **DSHS-Recognized TB Medical Consultant** or RMD:
    7) Date COEFAR/GANAFAR notified by the Mexico BNTB program and the TB Nacional program for medication procurement:

8) 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: _____/_____/_____
9) Describe the plan of care for the patient's access to routine follow-up, including but not limited to obtaining ECGs:

4. **Await TB Section 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 to proceed with ordering BDQ 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's NEDSS ID# and prescription details (i.e., "NEDSS Investigation ID #; BDQ 400mg PO daily x 14 days or BDQ 200 mg PO x 30 days").

5. **Secure and administer BDQ for the remainder of therapy**.
   1) Email the DR-TB Program monthly prior to ordering BDQ refills from DSHS pharmacy, indicating the progress made with the COEFAR or GANAFAR.
      a) Once the email is received and reviewed, the DR-TB Program will authorize another month of BDQ and will copy the DSHS pharmacy of the approval to order.
      b) While awaiting the "dictamen" approval letter from the COEFAR or GANAFAR to obtain BDQ from Mexico, continue ordering BDQ through DSHS pharmacy.
      c) If a "dictamen" is received, upload it to the patient's NEDSS case identification and email **TB Feedback** 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 directed by the DR-TB Program.
   2) Ensure written orders are received from the licensed healthcare provider prior to administering medication. *Note: DSHS-Recognized TB Medical Consultant recommendations and TCID discharge summaries are not medical orders; BNTB programs 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 prior to starting treatment.
   4) Track patient status and document assessments on the **TB 702a** or equivalent.
   5) Obtain updated medical orders as applicable.
      a. After an initial daily dosing for two weeks (14 days), BDQ is administered in thrice-weekly dosing.
   6) Enter BDQ start and stop dates and treatment adjustment in NEDSS (e.g., include a stop date for daily dosing when the regimen changes to thrice-weekly dosing).
   7) Update the DR-TB Program on patient status at least quarterly and upon closure.

Appendix E: Contacts and Resources

DSHS TB Section's DR-TB Monitoring Program	
Main phone: 737-255-4300 **Email Address:** TB.Feedback@dshs.texas.gov	
DSHS Pharmacy Unit	
Main phone: 512-776-7500 **Website:** dshs.texas.gov/pharmacy-unit	
Specialty Pharmacy and Patient Assistance Contacts	
Metro Medical Solutions (MMS)	Phone: 855-691-0963 metromedical.com
Johnson & Johnson Patient Assistance Program (J&JPAP)	Phone: 800-652-6227 janssencarepathportal.com/patient-assistance
Johnson & Johnson withMe (J&J withMe)	Phone: 866-836-0114 www.jnjwithme.com
Additional Resources	
Sirturo Product Guide	janssenlabels.com/package-insert/product-patient-information/SIRTURO-medication-guide.pdf
National TB Controllers Association (NTCA) Bedaquiline Access Guide	tbcontrollers.org/docs/bedaquiline/Bedaquiline_Access_Guide_v1.1_23July2019.pdf
CDC Guidelines for the Use and Safety Monitoring of Bedaquiline Furmarate (Sirturo) for the Treatment of Multidrug-Resistant Tuberculosis	cdc.gov/mmwr/PDF/rr/rr6209.pdf
Updates on the Treatment of Drug-Susceptible and Drug-Resistant Tuberculosis: An Official ATS/CDC/ERS/EDSA Clinical Practice Guideline	pmc.ncbi.nlm.nih.gov/articles/PMC11755361/pdf/rccm.202410-2096ST.pTH
Sirturo Label Insert	accessdata.fda.gov/drugsatfda_docs/label/2012/204384s000lbl.pdf

Tuberculosis and Hansen's Disease Unit

dshs.texas.gov/tuberculosis-tb