TUBERCULOSIS AND HANSENS'S DISEASE UNIT

SIRTURO (BEDAQUILINE) ORDERING GUIDE

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

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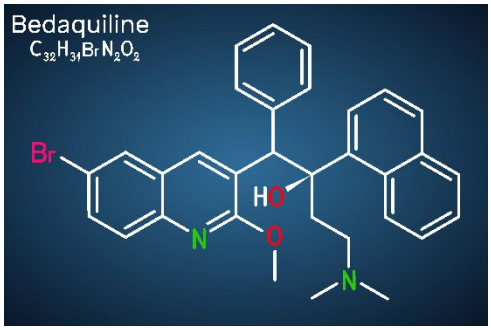
Sirturo (Bedaquiline) Ordering Guide

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 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 Program (J&JPAP)** - An independent, non-profit organization which covers the cost of designated medications to eligible patients *without* insurance or those with *inadequate prescription coverage* who meet eligibility criteria.

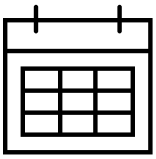
2) **Johnson and Johnson withMe (J&J withMe)** - Provides up to $7,500 assistance per calendar year for patients *with* private insurance *who incur costs* associated with copays.

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 <u>two-weeks</u> 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**.**

BDQ Ordering Steps

Step 1: Seek Medical Consultation and Obtain a Medical Order

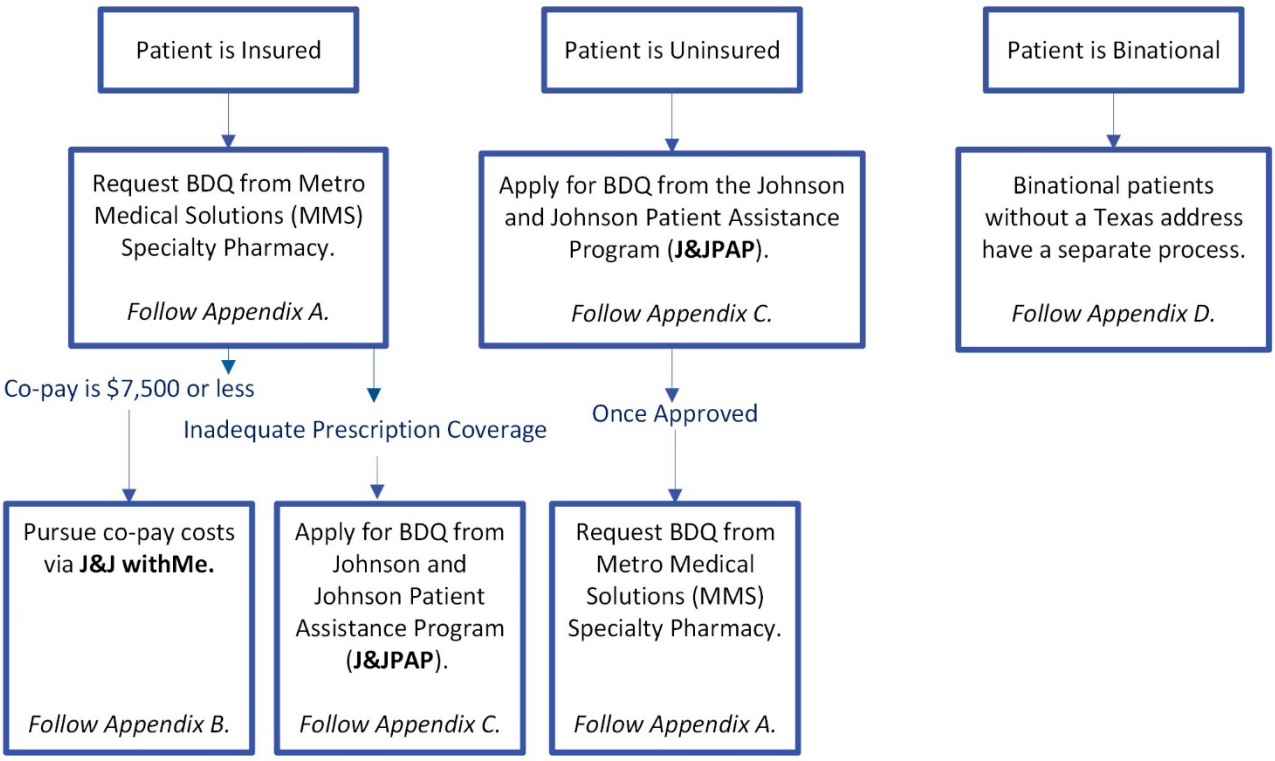
- BDQ is only available after a consult with a **DSHS-Recognized TB Medical Consultant**.
- Once recommended, obtain a medical order for BDQ from the patient's licensed healthcare provider. *Note: Consultant recommendations and/or discharge summaries from the Texas Center for Infectious Disease (TCID) 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 **J&J withMe** (Appendix B).
- For patients who are uninsured or have inadequate prescription coverage, request BDQ from **J&JPAP** 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 without residency in Texas, skip to **Appendix D**.

Figure 1: Determination of Patient Assistance



Step 3: Notify the DSHS TB Unit

Notify the TB Unit outlining the plan of care and when necessary, request BDQ 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,** Regional Medical Director [RMD], 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: ____/____/_____
    ☐ J&JPAP 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, an email with approval to order via the DSHS pharmacy unit's medication ordering system will be sent. **NOTE: BDQ may only be ordered in one-week increments 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").
- For refill requests, include the reason for needing continued DSHS-purchased medication (i.e., explain reason for delay in patient assistance).

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.

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.

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 Manual Chapter VI**.

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

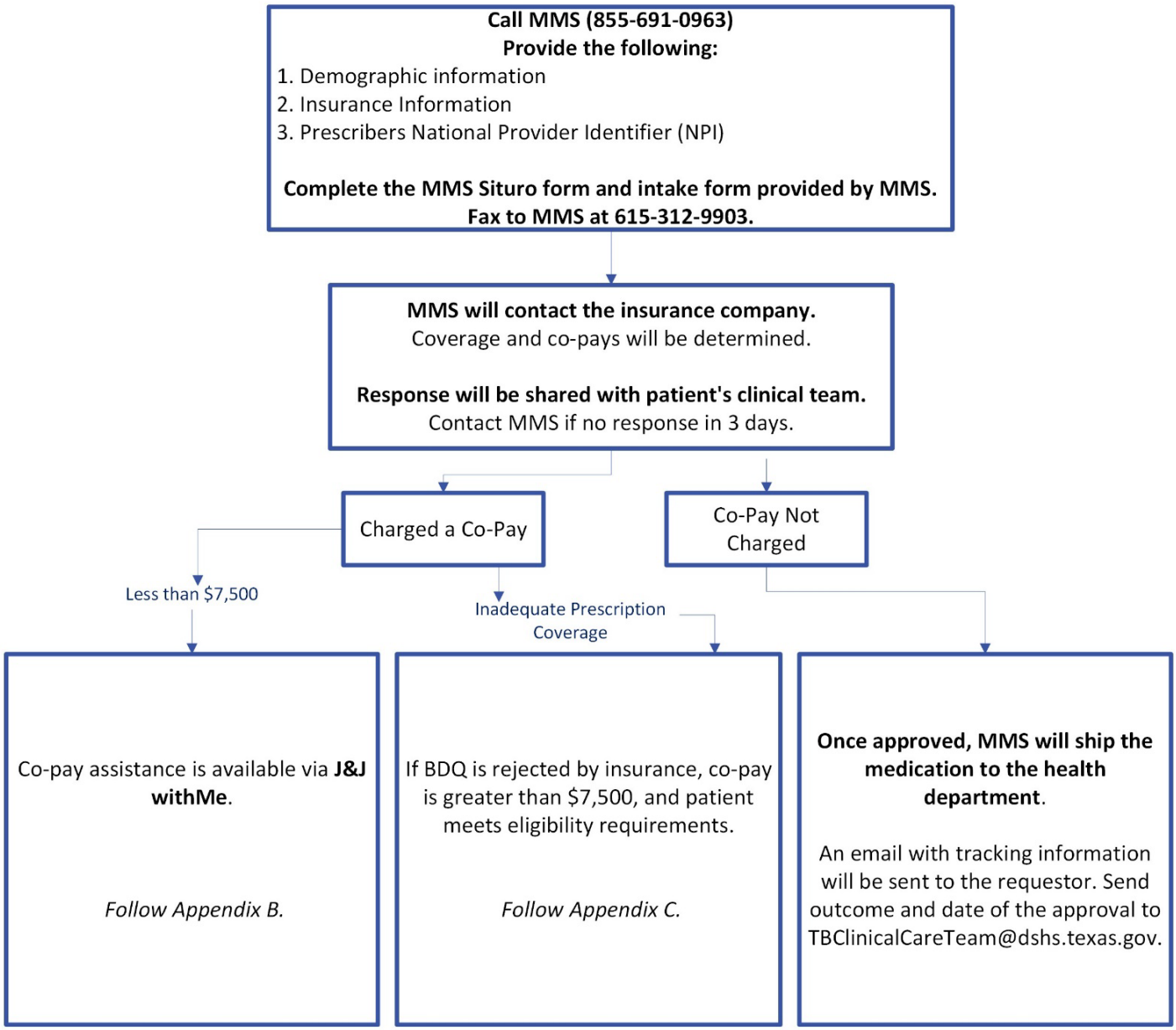
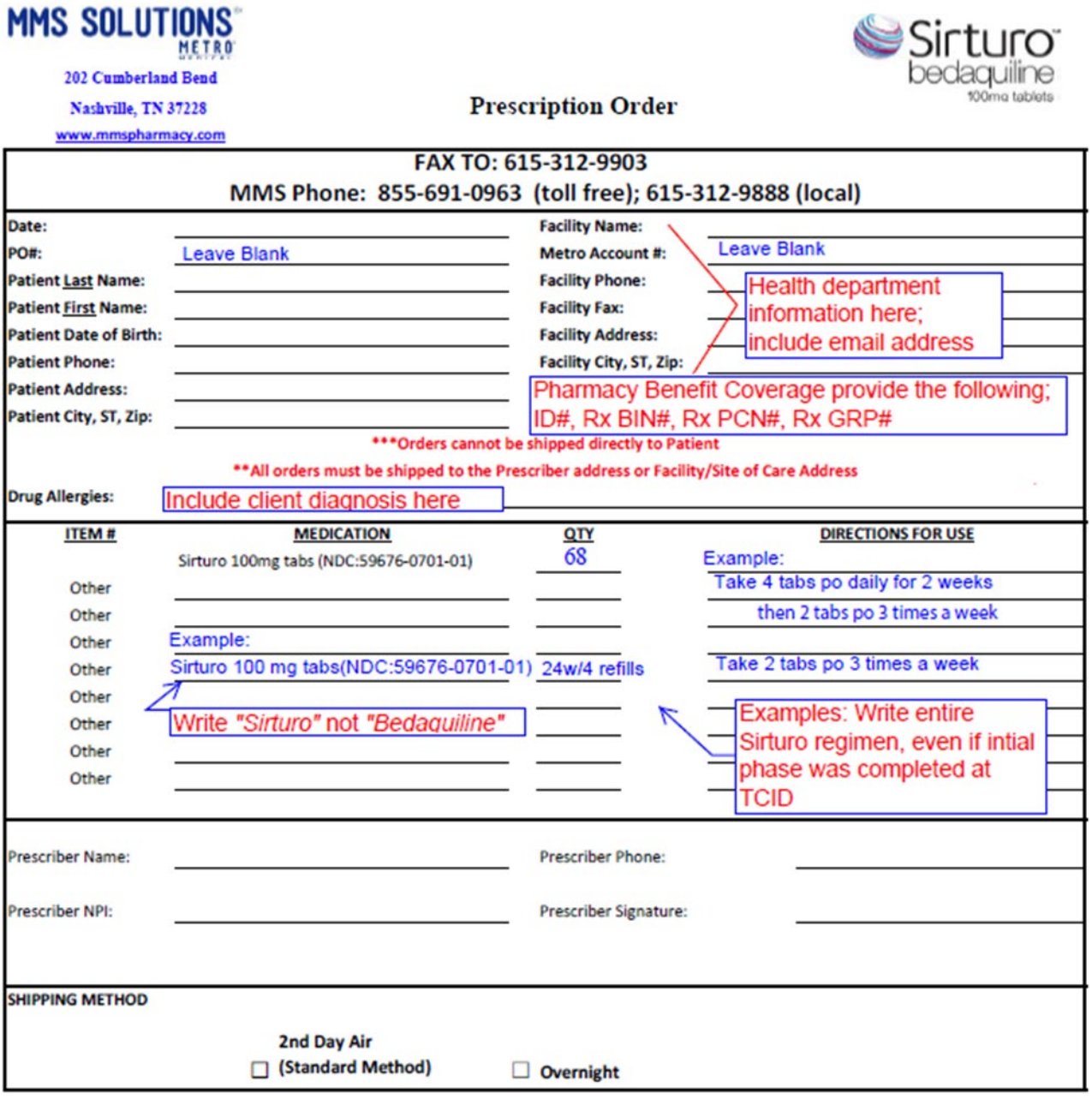


Figure 3: Metro Medical Solutions Prescription Instructions



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: _____

Prescriber NPI: _____ Prescriber Signature: _____

SHIPPING METHOD

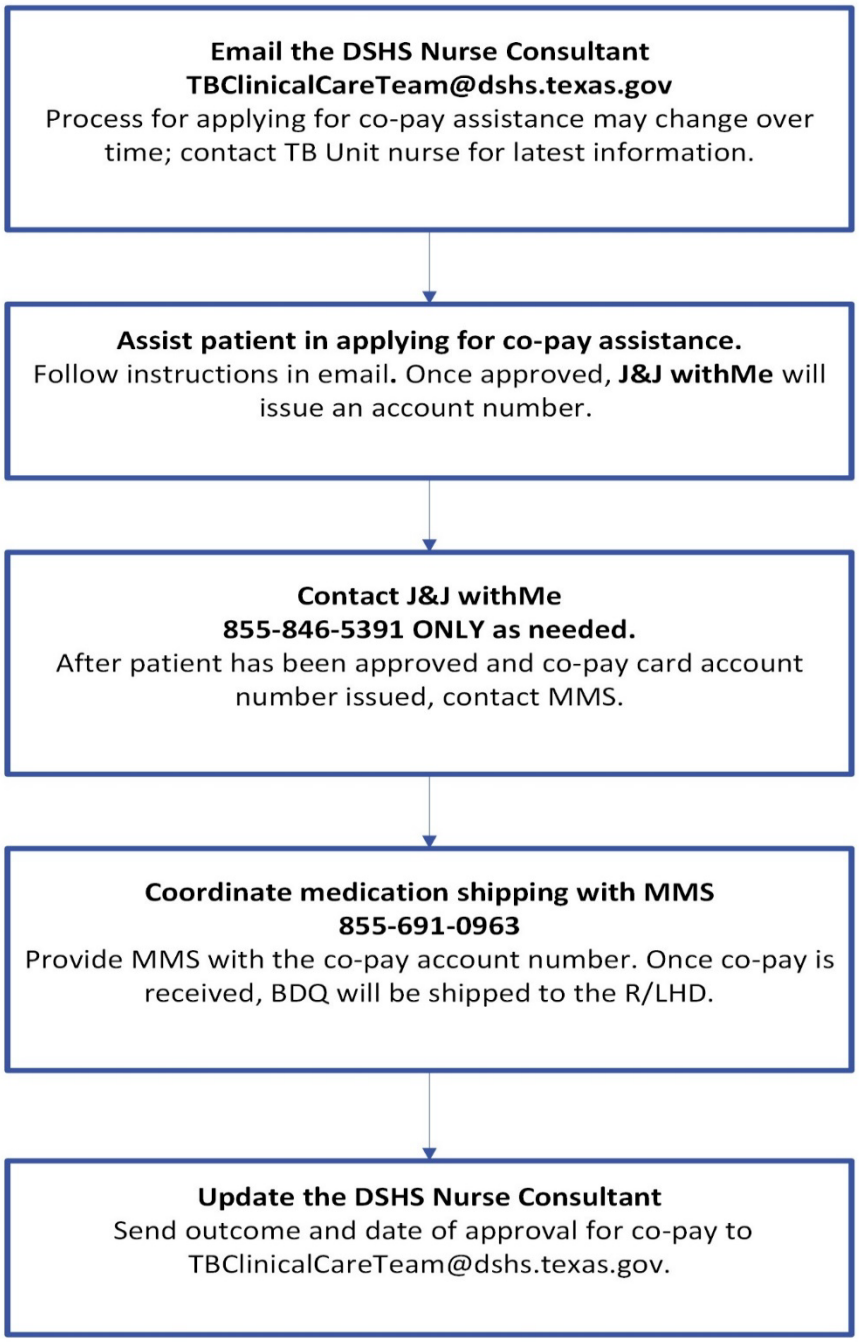
☐ **2nd Day Air (Standard Method)** ☐ **Overnight**

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)

J&J withMe 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: J&J will cover up to $7,500 per calendar year through a co-pay card. If the patient has been given a co-pay of greater than $7,500, ***STOP*** and apply to **J&JPAP**, see **Appendix C**.

Figure 4: Process for applying through J&J withMe



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

Refer to Figures 5 and 6 when applying for the **J&JPAP**.

- Eligibility requirements:
  - **myjanssencarepath.com/resource/1725877684000/janssen_quick_reference_guide_other_medications_other**.
- Application (refer to page 1 for enrollment instructions):
  - **janssencarepathportal.com/resource/1726928143000/Janssen_Patient_Assistance_Enrollment_Form_English**.

Figure 5: Process for applying through J&JPAP

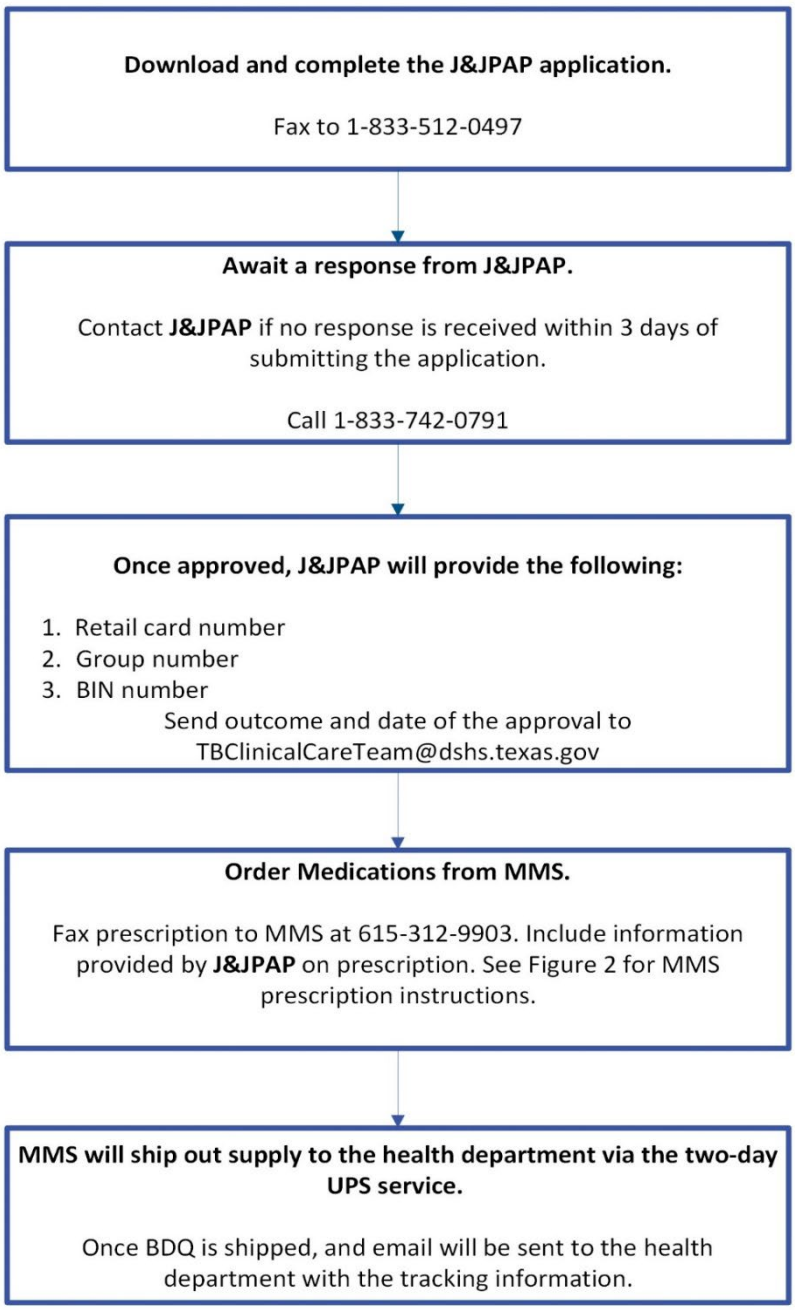


Figure 6: Johnson and Johnson Patient Assistance Application Example

Fill out and submit page 2 and 3.

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 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: Herman *Last Name: Munster *Primary Phone: (555) 444-7777
Email: herman.munster@email.com *Date of Birth (mm/dd/yyyy): 01/01/1999 *Sex: Male
*Address Line 1: 1313 Mockingbird Lane Address Line 2:
*City: Mockingbird Heights *State: Texas *ZIP Code: 77777
*Product Name: Sirturo
This is the address that all self-administered medication 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 #: for existing patients only

Primary Prescription Insurance (PPI): 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: Gateman, Goodbury, and Graves *Cardholder Employer Phone: (222) 333-4444
*Cardholder Employer Address: 999 Graves Drive
*Cardholder Employer City: Mockingbird Heights *Cardholder Employer State: Texas *Cardholder Employer ZIP Code: 77777

3. FINANCIAL INFORMATION

***Total Gross Annual Income**
Entire household: $ Enter income here

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

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

4. OPTIONAL COMMUNICATIONS Check appropriate box below if patient opts for communication

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 janssen.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:

5. TERMS OF PARTICIPATION AND TERMS & CONDITIONS CONSENT *(Please review Terms & Conditions and Terms of Participation on pages 6-7.)*

My signature below certifies that I have provided accurate and complete information and that I have read, understood, and agree to the Terms & Conditions and Terms of Participation on pages 6-7. Your signature also allows Johnson & Johnson to perform a credit check. This will not impact your credit score.

*Print Patient Name: Herman Munster
*Patient or legally authorized representative† sign here: See definition below and sign accordingly *Date: 10/21/2024
†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.

6. PATIENT AUTHORIZATION FORM CONSENT *(Please review Patient Authorization Form on pages 4-5.)*

By signing below, I certify that I have read, understand, and agree to the Johnson & Johnson Patient support program patient authorization form on pages 4-5.

*Print Patient Name: Herman Munster
*Patient or legally authorized representative† sign here: Patient signature or see definition below and sign accordingly *Date: 10/21/2024
†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: Fill out accordingly

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 Patient Programs may assist pateint fill out this section — Fields marked with an (*) are required

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

*Patient First Name: Herman *Patient Last Name: Munster *Patient Primary Phone: (555) 444-7777
*Patient Address Line 1: 1313 Mockingbird Lane Patient Address Line 2:
*Patient City: Mockingbird Heights *Patient State: Texas *Patient ZIP Code: 77777
*Patient Date of Birth (mm/dd/yyyy): 01/01/1999 Patient Weight: Patient Height: *Patient Sex: Male
*ICD Code: Enter ICD code here *Name of Product: Sirturo *Strength: 100 mg
*Sig: 400 mg daily x14 days, then 200 mg trice weekly X24 weeks *Quantity: 200 *Day Supply: 86
First Time Fill: ☑ Yes ☐ No *Number of Refills (maximum 11): 11 *Need by Date: Enter date here

***Ship to Location:** Always Check Prescriber Office

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

Fill out regional or local health department here where medication will be shipped.

Site Name: 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: List or check none box or ☐ none
*List of Patient's Current Medications: List or check none box or ☐ none

For RYBREVANT® (amivantamab-vmjw) in combination with LAZCLUZE™ (lazertinib): Complete a copy of this page for each medicine.

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 medications. Self-administered medications will be shipped directly to the Patient.)*

*HCP First Name: Healthcare Provider Name *HCP Last Name: *HCP Site Name: Name of Health Department Here
HCP Site Contact: Name of Contact Person, i.e., nurse HCP Business Hours:
*HCP Address Line 1: This is where medication will be mailed. Fill our entire section below *
*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 Licensed Heathcare Provider signs and dates *HCP Authorization Date (mm/dd/yyyy):

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

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.**
    Notification to the TB Unit includes outlining the plan of care prior to ordering BDQ via the DSHS Pharmacy Unit ordering system. 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 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) Date COEFAR/GANAFAR notified by the Mexico BNTB program:
    6) 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: _____/_____/_____
    7) Describe the plan of care for the patient's access to routine follow-up, including but not limited to obtaining ECGs:

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 to proceed with ordering BDQ from the DSHS pharmacy unit's medication ordering system.
    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 **TB Unit Clinical Care Team** indicating the progress made with the COEFAR/GANAFAR.
        c) Once received and reviewed, the TB Unit Clinical Care Team 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 or attach it to the patient's case identification in the Unit's surveillance and reporting database and notify by email the **TB Unit Clinical Care Team** indicating the receival 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; 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.
    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 adjusted depending on phase of therapy and duration of interruption. Seek consultation when needed.***
    6) Enter BDQ start and stop dates in the TB Unit's surveillance and reporting database. 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.

Appendix E: Contacts and Resources

DSHS TB Unit	
Main phone: 737-255-4300 **Email Address:** TBClinicalCareTeam@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: 855-846-5391 janssencarepath.com/hcp myjanssencarepath.com/user/register?flow=express&product
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
Provisional CDC Guidance for the Use of Pretomanid as part of a Regimen (Bedaquiline, Pretomanid, and Linezolid [BPaL]) to Treat Drug-Resistant Tuberculosis Disease. CDC, 2022.	cdc.gov/tb/hcp/treatment/bpal.html
Sirturo Label Insert	accessdata.fda.gov/drugsatfda_docs/label/2012/204384s000lbl.pdf

Tuberculosis and Hansen's Disease Unit

dshs.texas.gov/tuberculosis-tb