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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.
**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**

- **Patient is Insured**
  - Request BDQ from Metro Medical Solutions (MMS) Specialty Pharmacy
  - *Follow Appendix A*
- **Patient is Uninsured**
  - Apply for BDQ from the Johnson and Johnson Patient Assistance Foundation (JJPAF)
  - *Follow Appendix C*
- **Patient is Binational**
  - Binational patients without a Texas address have a separate process
  - *Follow Appendix D*

**Co-pay is $7500 or less**
- Inadequate Prescription Coverage
- **Pursue co-pay costs via the Janssen CarePath program, if applicable**
  - *Follow Appendix B*
- **Once Approved**
  - **Applying to the Johnson and Johnson Patient Assistance Foundation (JJPAF)**
    - *Follow Appendix C*
  - **Request BDQ from Metro Medical Solutions (MMS) Specialty Pharmacy**
    - *Follow Appendix A*
Tuberculosis and Hansen’s Disease Unit

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**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: ____/____/_______
   ☐ JIPAF 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.
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

Call MMS (855-691-0963)
Provide the following:
1. Demographic information
2. Insurance information
3. Prescribers National Provider Identifier (NPI)

Complete the MMS Situro form and intake form provided by MMS.
Fax to MMS at 615-312-9903.

MMS will contact the insurance company.
Coverage and co-pays will be determined.

Response will be shared with patient’s clinical team.
Contact MMS if no response in 3 days.

Charged a Co-Pay
Co-Pay Not Charged

Less than $7500
Inadequate Prescription Coverage

Co-pay assistance is available via Janssen’s Care Path program. See Appendix B.

If BDQ is rejected by insurance or co-pay is greater than $7,500, follow inadequate prescription coverage steps for JJPAF, see Appendix C.

Once approved, MMS will ship the medication to the health department.
An email with tracking information will be sent to the requestor.
Send outcome and date of the approval to TBClinicalCareTeam@dshs.texas.gov.

Bedaquiline Ordering Guide, created December 3, 2020; revised September 19, 2023
**Figure 3: Metro Medical Solutions Prescription Instructions**

![Prescription Order Form](image)

- **Date:** Leave Blank
- **PO:** Leave Blank
- **Patient Last Name:** Leave Blank
- **Patient First Name:** Leave Blank
- **Patient Date of Birth:** Leave Blank
- **Patient Phone:** Leave Blank
- **Patient Address:** Leave Blank
- **Patient City, ST, Zip:** Leave Blank
- **Drug Allergies:** Include client diagnosis here

**Pharmacy Benefit Coverage provide the following:**
- ID#, Rx BIN#, Rx PCN#, Rx GRP#

**Orders cannot be shipped directly to Patient**
- **Provider 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: 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

1. Contact Janssen’s CarePath Program at: 1-855-846-5392
   Patient must be available to speak with the representative.

2. Patient will receive an account number.
   This number will be used for co-pays.

3. Call and provide MMS the patient’s account number.
   MMS Phone Number: 855-691-0963

4. Once MMS receives the co-pay, medication will be shipped to the health department.
   Once medication has been approved and shipped, email with tracking information will be sent.

5. Send outcome and date of the approval to TBClinicalCareTeam@dshs.texas.gov.
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. Refer to Figure 5 and 6 for application details.

Figure 5: Process for applying for assistance through JJPAF

1. Download and complete the JJPAF Application.
2. Fax to 740-966-1797.
3. Await a response from JJPAF.
   - Contact JJPAF if no response is received within 3 days of submitting the application.
4. Once approved JJPAF will provide the following:
   - Retail card number
   - Group Number
   - BIN Number
   - Send outcome and date of the approval to TBClinicalCareTeam@dshs.texas.gov.
5. Order Medication from MMS.
   - Fax prescription to MMS at 615-312-9903. Include information provided by JJPAF on prescription. See Figure 2 for MMS prescription instructions.
6. MMS will ship out supply to the health department via the two-day UPS service.
   - Once BDQ is shipped, an email will be sent to the health department with the tracking information.

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. Refer to Figure 5 and 6 for application details.

Once approved JJPAF will provide the following:
1. Retail card number
2. Group Number
3. BIN Number
Send outcome and date of the approval to TBClinicalCareTeam@dshs.texas.gov.

Order Medication from MMS.
Fax prescription to MMS at 615-312-9903. Include information provided by JJPAF on prescription. See Figure 2 for MMS prescription instructions.

MMS will ship out supply to the health department via the two-day UPS service.
Once BDQ is shipped, an email will be sent to the health department with the tracking information.
Figure 6: Johnson and Johnson Application Instructions/Example

Download the application at https://www.jjpaf.org/resources/JJPAF_Application_INS.pdf

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

Read section carefully and check appropriate box.
If applicable, fill this section with patient insurance information. If insurance is denied, attach the insurance refusal letter with the application.

If an authorized representative is listed, both the patient and the representative must sign and date.
## Bedaquiline Ordering Guide

**Patient Assistance Program (PAP) Application**

*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
- **ICD Code:**
- **Name of Product:** Sirutro
- **Strength:** 100mg
- **Sig:** 400mg daily X 14 days, then 200mg twice weekly X 24 weeks
- **Quantity:** 200
- **Days’ Supply:** 86
- **Number of Refills (maximum II):** 11
- **List any patient allergies:**
- **List all allergies here:**
- **List patient’s current medications:**
- **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 med local 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:**
- **Healthcare Professional Signature**
- **Date:**

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*Bedaquiline Ordering Guide, created December 3, 2020; revised September 19, 2023*
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: ____________________________________________________________

Bedaquiline Ordering Guide, created December 3, 2020; revised September 19, 2023
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 COEFA/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 COEFA/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 recieval 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 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.
Appendix E: Contacts and Resources

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<tbody>
<tr>
<td><strong>Main phone:</strong> 737-255-4300</td>
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<tr>
<td><strong>Email Address:</strong> <a href="mailto:TBClinicalCareTeam@dshs.texas.gov">TBClinicalCareTeam@dshs.texas.gov</a></td>
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<th>DSHS Pharmacy Unit</th>
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<tr>
<td><strong>Main phone:</strong> 512-776-7500</td>
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<tr>
<td><strong>Website:</strong> <a href="https://www.dshs.texas.gov/pharmacy">https://www.dshs.texas.gov/pharmacy</a></td>
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