Bedaquiline (Situro) Ordering Process

Process Overview

Bedaquiline (BDQ), a medication used to treat drug-resistant tuberculosis (DR-TB), is a non-first line oral anti-TB medication. This medication is typically prescribed for at least six months of therapy.

The outpatient ordering process is different from other medications that are available through the DSHS Pharmacy Branch via ITEAMS, and additional planning and preparation are required. This medication is very costly, and therefore DSHS will work with local and regional health departments to obtain the medication through no-cost assistance programs. Ordering BDQ from DSHS will be allowed only as a last resort.

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

<table>
<thead>
<tr>
<th>Medical Consultation</th>
<th>Discharge Planning</th>
<th>DSHS DR-TB Monitoring Program Notification</th>
<th>Insurance Verification</th>
</tr>
</thead>
</table>
| • A consult from a DSHS recognized medical TB consultant is required for patients with drug-resistant TB: [dshs.texas.gov/idcu/disease/tb/consultants/](http://dshs.texas.gov/idcu/disease/tb/consultants/) | • If patient was started on BDQ while at the Texas Center for Infectious Disease (TCID), they will be provided **two weeks’** of BDQ at discharge.  
• Medication will be mailed to the health department prior to patient’s discharge. | • Notify DSHS TB and Hansen’s Disease Nurse Consultant prior to ordering BDQ from DSHS pharmacy.  
• See Texas TB Work Plan for ordering second line medications: [dshs.texas.gov/idcu/disease/tb/policies/](http://dshs.texas.gov/idcu/disease/tb/policies/) | • Local/regional TB programs must determine if client is privately insured or is uninsured.  
• Private insurance may include Medicare/ Medicaid.
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**STEPS**

**Step 1: Request BDQ from the TB and Hansen’s Disease Branch**

Email the DSHS DR-TB Monitoring Program nurse consultant a request for BDQ with the answers to the following questions *(for binational TB program clients, skip to page 7)*:

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

*After emailing the answers above, send securely a copy of the consult or discharge summary (if applicable) to the TB and Hansen’s Disease Branch Nurse Consultant.*

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Once approved, an email will be sent to the program contact (the person listed in #3 above) instructing the health department to order BDQ from DSHS pharmacy.

**Step 2: Order BDQ from ITEAMS**

BDQ may be obtained from DSHS for short-term use while the local or regional TB program is pursuing other client coverage options

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

2. Order in one-week supply increments. Ensure medication order is verified and request only the number of doses needed per week. *(Note: Ensure that patient ID# and specific instructions are noted in ITEAMS regarding how the patient should take the medication).*
Step 3: Pursue Patient Assistance Options

Knowing whether the patient is insured or uninsured will guide which patient assistance program local and regional TB programs may pursue.

Patient is Insured
- Pursue BDQ from Metro Medical Solutions (MMS)
  - Follow Step 3a

Patient is Uninsured
- Pursue BDQ from the Johnson and Johnson Patient Assistance Foundation (JJPAF)
  - Follow Step 3b

Patient is Binational
- Regardless of insurance status, binational patients have a separate process
  - Follow Step 3d

Manage Co-Pays

Pursue co-pay costs via the Janssen CarePath program, if applicable
- Follow Step 3c

JJPAF will provide the medication with no co-pay cost
Step 3a: Request BDQ from Metro Medical Solutions (MMS)

Ensure patient is covered through a private or state insurance program (i.e. Medicare/Medicaid) and document coverage prior to initiating this process. After verification, the steps for requesting from Metro Medical Solutions are the same regardless of insurance type.

Privately Insured Patients

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

Medicare/Medicaid Insured Patients

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

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

2. Complete a MMS Sirturo order form; fax to MMS.
   Fax#: 615-312-9903

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

4. Response will be shared with patient’s clinical team. Contact MMS if no response in 3 days
   If rejected, skip to #6

5. Private Insurance: Co-pay assistance is available via Janssen’s CarePath program. See step 3c
   State Insurance: If patient is charged co-pay, stop MMS application and move to JJPAF. See step 3b

6. If BDQ is rejected by insurance, follow steps for JJPAF process, see step 3b
   Write on application that BDQ was rejected by insurance company.
Step 3b: Request BDQ from the Johnson and Johnson Patient Assistance Foundation (JJPAF)

jjpaf.org/resources/jjpaf-application.pdf

BDQ is provided free of cost to uninsured patients via JJPAF and may be available to insured patients whose insurance was rejected by the MMS insurance request program.

1. **Complete the Patient Assistance Program Application, and fax it to Johnson and Johnson at: Phone 1-888-526-5168.**
   a. Ensure patient signs the *Patient Declaration* (page 2 of application) and the prescribing physician will need to sign the *Prescription* (page 3 of application).
   b. Complete section 3 in its entirety.
   c. Ensure health department contact number is correct.
   *Note: A social security number or a copy of a federal tax form are not necessary for Bedaquiline (Sirturo) requests*

2. **Await response.**
   a. Contact JJPAF if no response is received within 2-3 days of submitting application.

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

4. **Fill out the MMS Sirturo Prescription Order Form** (separate from the one sent to DSHS pharmacy while awaiting this approval, as the funding source will change to JJPAF; complete a new MMS form) and fax to Metro Medical Solutions (MMS) at 615-312-9903.

5. **Metro Medical will ship out supply the same day via 2 days UPS service.** The medication will be mailed to the Health Department, not the patient.

6. **Once the drug is shipped, requestor will receive an email with tracking information.**
Step 3c: Request co-pay coverage with Janssen’s CarePath Program

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

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

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

3. Provide Metro Medical Solutions (MMS) patient’s account number
   855-691-0963

4. Once MMS receives the co-pay, medication will be shipped to the clinic.
   Once medication has been approved and shipped, email with tracking information will be sent
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Step 3d: Request BDQ for Binational (BN) Patients

BDQ may be available to BN patients managed by DSHS Binational TB Program

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

1. **Submit answers to the DR-TB Monitoring Program nurse consultant with the following responses:**
   1. Explain what qualifies this patient for care under the Binational TB Program *(check all that apply)*:
      - ☐ The client lives in Mexico but has relatives in the U.S.;
      - ☐ The client has dual residency in the U.S. and Mexico;
      - ☐ The client has contacts on both sides of the border, in the U.S. and Mexico
      - ☐ The client started treatment in the U.S. but returns to live in Mexico; or
      - ☐ The client is referred from the U.S. for treatment or follow-up in Mexico
   2. Name of U.S. prescribing physician: *(must be a DSHS physician or physician working directly with health department)*
   3. Name of Mexico’s TB program and physician:
   4. Name of consulting physician: *(must be a DSHS-recognized medical TB consultant)*
   5. Name of binational TB program requesting BDQ (with best contact phone numbers):
   6. Describe plan of care for client’s access to routine follow up, including but not limited to ECGs:
   7. Has the approval letter for BDQ use been verified by the Binational TB Program Officer? *(If not, contact the Binational TB Program Officer (BPO) for coordination.)*

2. **Once the approval letter is verified, the binational TB coordinator will notify Heartland National TB Center, the prescribing physician and the DSHS Nurse Consultant.**
   - Send securely a copy of the Heartland consult and approval letter to the TB and Hansen’s Disease Branch Nurse Consultant.

3. **Once all the above have been met, the DSHS Nurse Consultant will send an email with approval to proceed with ordering BDQ from ITEAMS:**
   1. Fill out the Metro Medical Solutions (MMS) *Sirturo Prescription Order Form* (Note: form will be emailed to requestor when approved).
   2. Fax the form to the DSHS Pharmacy Branch: **Fax: 512-776-7489**  **Phone: 512-776-7500**
   3. Order **1 month-supply** at a time. Notify Pharmacy Branch 1-2 weeks before next order is needed.
**Metro Medical Solutions (MMS) Sirturo Prescription Order Form Instructions**

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**Prescription Order**

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

<table>
<thead>
<tr>
<th>Item #</th>
<th>Medication</th>
<th>Qty</th>
<th>Directions for Use</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sirturo 100mg tabs (NDC:59676-0701-01)</td>
<td>63</td>
<td>Example: Take 4 tabs po daily for 2 weeks then 2 tabs po 3 times a week</td>
</tr>
<tr>
<td></td>
<td>Other</td>
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<td></td>
<td>Other</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Sirturo 100 mg tabs (NDC:59676-0701-01)</td>
<td>24w/4 refills</td>
<td>Take 2 tabs po 3 times a week</td>
</tr>
</tbody>
</table>

Include client diagnosis here

Leaves Blank

Health department information here

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

**Orders cannot be shipped directly to Patient**

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

Examples: Write entire Sirturo regimen, even if initial phase on was completed at TCID

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Contacts and Resources

Client Assistance Programs for BDQ

- **Metro Medical Central Contact**, Phone: 855-691-0963
  metromedical.com

- **Johnson & Johnson Patient Assistance Foundation (JJPAF)**, Phone: 800-652-6227
  jjpaf.org

- **Janssen CarePath**, Phone: 855-846-5392
  janssencarepath.com/hcp

Additional Resources

- **Sirturo Product Guide**

- **TB Controllers Bedaquiline Access Guide**
  tbcontrollers.org/docs/bedaquiline/Bedaquiline_Access_Guide_v2.0_04June2019.pdf

- **CDC Bedaquiline Factsheet**
  cdc.gov/tb/publications/factsheets/treatment/bedaquiline.htm

- **CDC Guidelines for the Use and Safety Monitoring of Bedaquiline Furmarate (Sirturo) for the Treatment of Multidrug-Resistant Tuberculosis**
  cdc.gov/mmwr/PDF/rr/rr6209.pdf

- **Sirturo Label Insert**
  accessdata.fda.gov/drugsatfda_docs/label/2012/204384s000lbl.pdf

- **Medicare.gov**
  medicare.gov/claims-appeals/how-do-i-file-an-appeal

- **Medicare 2019 Drug Finder**
  q1medicare.com/PartD-SearchPDPMedicarePartDDrugFinder.php

- **Texas Statues, Health and Safety Code** - if requested for assistance program justification
  statutes.capitol.texas.gov/Docs/HS/htm/HS.81.htm