

Non-JJPAF Case Studies

ID	Days	Findings	Type of Insurance	Outcomes
MI-1	~14 days	“There is no affordability option in Michigan and that they would call her back if they hear anything.”	Express Scripts for prescriptions, United Health for care	Co-pay covered by CarePath, paid for by insurance
VA-1	Varies	Two separate prescribing physicians – health department representative and private insurance representative	Private	Fully covered previously and now paid by insurance with co-pay coverage
NY-1	Varies	Used to pay for the drug – those without insurance and those on Medicaid. Very time consuming to deal with insurance companies.	Private, state funds	Fully covered, insurance with full copay coverage
KY-1	Varies	Four different patient profiles, with each patient accessing bedaquiline based on payer-type	Medicaid, private, and federal government	All have successfully obtained bedaquiline – Medicaid covered two patients, private insurance covered all of the cost.

Case Study for
MI-1
(Insured Patient)



Insured Patient (MI-1)

Email from Metro Medical Patient Care Specialist May 30th 2018 in response to query, includes detailed instructions on filling prescription order

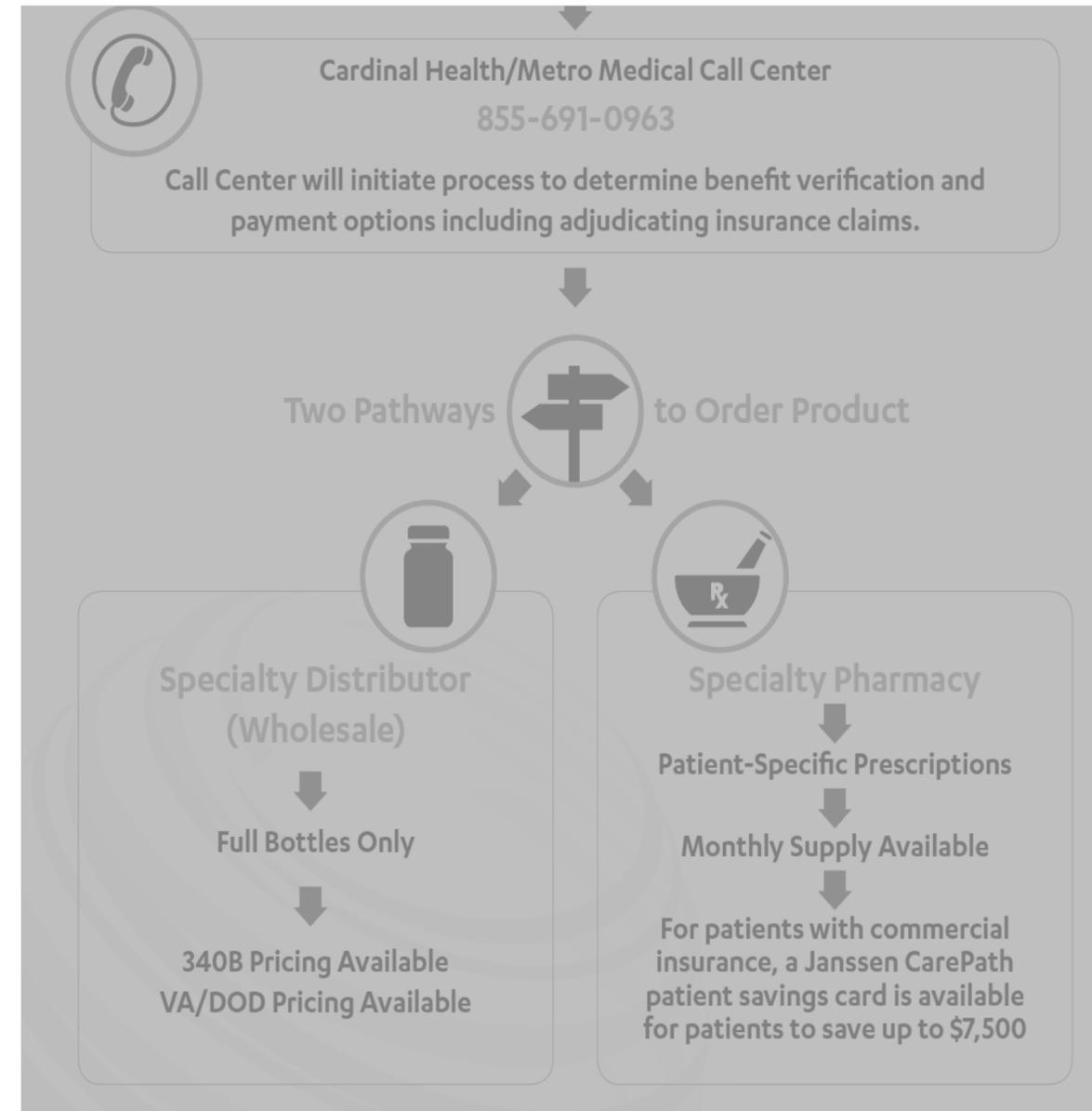
Bdq not received as expected – patient contacts PAP, told “there is no affordability option in Michigan and that they would call her back if they hear anything.”

Controller contacts Patient Care Specialist at Metro Medical, requests help on July 26th

Advised to call Janssen CarePath at 855-846-5392. State that she needs assistance with her copay for Sirturo. They will provide her with an ID#, BIN#, and GRP#.

Controller forwards Metro Medical insurance information on July 27th, confirms process does not need to be repeated every month

Metro Medical confirms delivery for July 31st 2018



Insured Patient (MI-1)



- Detailed prescription instructions from Metro Medical
- Excellent turn-around-time and assistance from MM
- No paperwork required for CarePath to cover the co-pay – was taken care of through phone calls



- Initial feedback from Patient Assistance program was incorrect and confusing

Insured Patient (MI-1) Key Quotes

“It’s a different ballgame [for us], in some respects - states like California or New York or Texas where they’re used to dealing with MDR-TB...for states that tend to be lower incidence, they don't see it very often...there's an extra layer of complexity when you're not just dealing with drug-resistant TB to begin with but you are using a drug like bedaquiline...it's important clinically and it's effective but at the same time it has a bad slew of side effects...you’ve got to do due diligence, it’s not just saying call me in a few days if you feel bad, you really have to be on top of it”

Case Study for
VA-1
(Insured Patient)



Insured Patient (VA-1)

Physician representing insurance company must write bedaquiline prescription in order to be covered through insurance. Health Department physician prescribes other MDR-TB meds.

Unsure of plan if the physician representing the insurance company refused to write the prescription for Sirturo.

Plan for insurance application:

1. Complete the Metro Medical Sirturo prescription order form and fax to Metro Medical pharmacy.
2. Pharmacy/clinician sends pt. demographic and payment information to Metro Medical
3. Metro Medical contacts insurance to determine coverage and co-pay
4. Metro Medical shares insurance response with patient's pharmacy/clinical team and the clinical team decides whether to order
5. If high co-pay, pt. may apply for Johnson & Johnson patient assistance program (up to \$7,000) at <<http://www.jjpaf.org>>



Insured Patient (VA-1)



- Smoother process than Patient Assistance Program at least for the Health Department
- Only have experience dealing with one insurance company (Kaiser Permanente) who offer Bedaquiline coverage

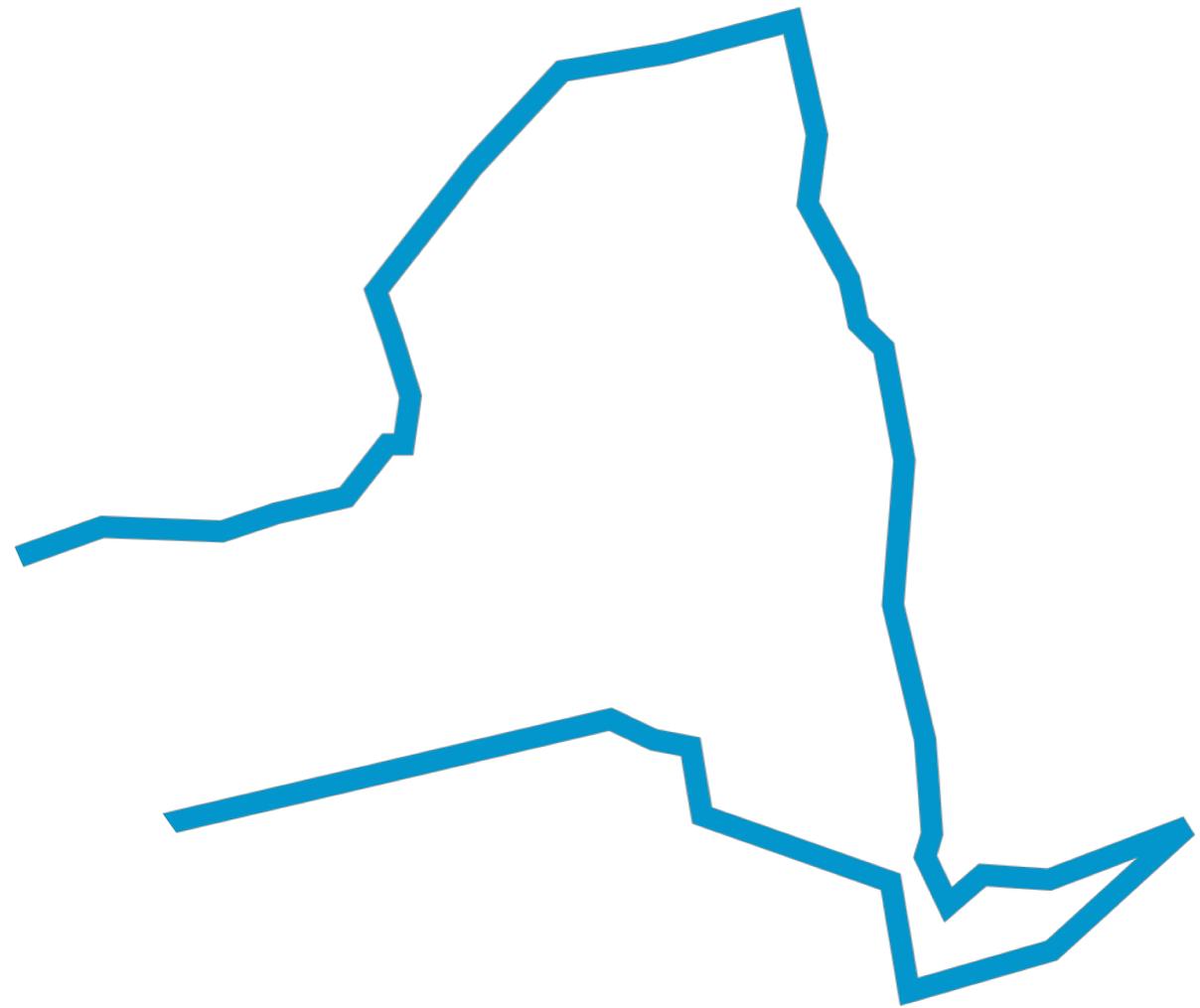


- Health Department physician has to work with the private (insurance rep) physician to help them understand why bedaquiline is a drug of choice compared to an injectable – logistical hurdle.
- Change from the norm for physicians who cannot now write a script and get the medications started right away.

Insured Patient (VA-1) Key Quotes

"The insurance route should be smoother...however, the health department physician has to really work with the private physicians to help them understand why Sirturo is a drug of choice as compared to maybe an injectable in the past...Our health department physicians might need some help in learning how to talk to the private physician in a more expedient way..."

Case Study for NYC-1 (Mixed)



Mixed (NYC-1)

12 patients who have had Bedaquiline. 1 compassionate use early on. 1 payed for by the health agency. 10 paid for by the patient insurance.

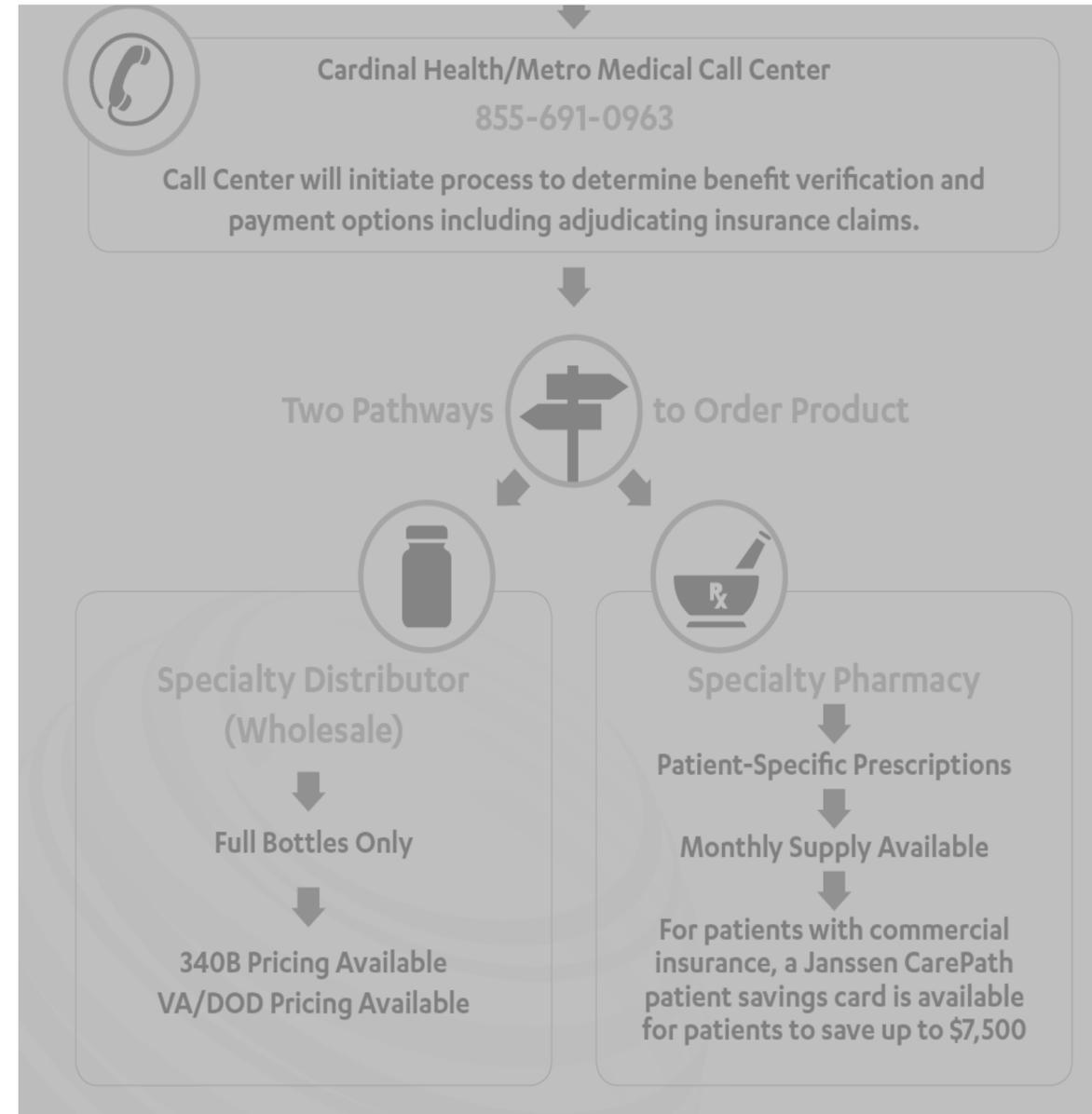
Difficult to figure out who exactly to speak to at the insurance/pharmacy to get the application completed

Spent hours on the phone dealing with insurance companies to get prior approval.

Insurance company medical/pharmacy consultant needed to approve the Bedaquiline request.

Because the vendor (Cardinal Health – sole distributor) is outside of NYState, when it comes to Medicaid the vendor needs to apply to the individual insurance company so that Medicaid will cover the medication.

Have to have NPI number handy when dealing with insurance companies – every insurance agent requests the NPI before speaking to you.



Mixed (NYC-1)



- JJPAF was helpful
- Pharmacy sending reminders to fill out prescriptions and following up to receive the next months supply is very useful



- Dealing with insurance companies was time consuming. All had different requirements, different paperwork and some needed multiple calls to work out.
- Calling the insurance company results in speaking to a different person every time. Have to speak to someone in the general claims to then get transferred to other departments.

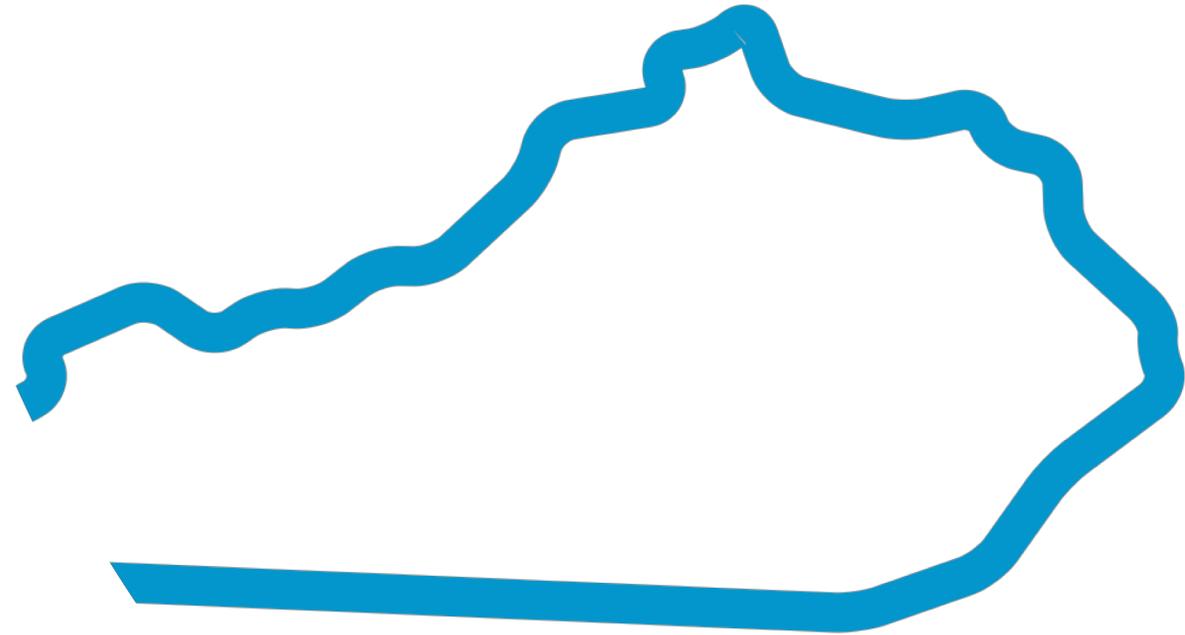
Mixed (NYC-1) Key Quotes

“In the beginning...we used to get it through compassionate use directly through Johnson & Johnson. Once it became available...in the first year it was used, we had to go through and purchase it for ourselves. Insurance was virtually impossible...and a lot of patients don't have insurance.”

“In the beginning, it would take three days [to figure out the insurance paperwork]...the problem is, our department is not private practice, so we are not enrolled in a lot of insurance programs...I would give them my NPI number, and they'd have to tell me that I'm not affiliated with them.”

“I foresee us in the future having to use [the Patient Assistance Program] more, because the patients we've put on it in the refugee or ICE detention with no insurance at all...we are starting to see more and more of those patients that have no insurance and no income.”

Case Study for KY-1 (Medicaid and Private)



Medicaid and Private (KY-1)

Since 2013, KY has had n=11 MDR TB cases that are covered through managed-care organizations (3-4)

Once a drug meets FDA-approval, Medicaid checks to see if it is added to the state formularies. Each managed-care organization makes a decision on acceptance.

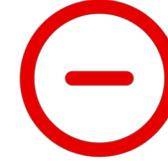
Recently, for a pre-XDR case in 2018, private insurance covered the cost. This is the 4th patient who has successfully obtained bedaquiline – two through Medicaid, one through private, and one through the government as a federal employee.



Medicaid and Private (KY-1)



- Even with different payer types, all four patients who have tried to access bedaquiline have done so successfully.
 - Two patients had existing Medicaid status



- Rural health departments have to deal with the current patient load, and it is only luck that they have had Medicaid or private insurance – if they had to cover costs it would put that health department in a precarious position

Medicaid and Private (KY-1) Key Quotes

“It’s been luck, it truly has. If we had a patient that had been uninsured, of course we would assist that local health department with information on how to possibly get the patient on Medicaid. If they [could not get Medicaid coverage], we would have a true barrier at that point. Or let’s say they were underinsured, and they did not meet criteria, we would definitely have an issue with pricing.”

“Well if we had a patient who was underinsured or for whatever reason was not eligible for Medicaid, and that would be a student, or let’s say a visitor who has not returned to their native country because of infectiousness, then most definitely the resources would fall upon that local health department and that would be very devastating. We have very limited resources”

Lessons Learned

- Confirm as much detail ahead of time as possible – NIPs, Medicaid information, insurance information, family size, yearly income, etc.
- Use Metro Medical as a resource to move things along, especially in concert with the JJPAF
- Always call 24 hours after submitting anything to JJPAF, and engage in very active follow up
- Need to have protocols written on how to deal with each insurance company to ease future claims
- Having a pre-filled PDF prescription form excluding patient information will save time

For Applications NOT going through JJPAF

1. Gather patient's insurance information, and any additional information you can
2. Obtain internal permissions
3. Call the Metro Medical number to verify payment status
 - For private insurance, be prepared to justify why bedaquiline over injectables
 - May need to coordinate between TB program docs and insurance docs, depending on insurance
4. Complete the prescription form and send to Metro Medical
 - Bedaquiline 100 mg: Take 4 tabs q day X 2 wks, followed by
 - Bedaquiline 200 mg 3 X a week (refill is limited to 4 refills)
5. Maximum time to hear back should be ~4 days
6. Be prepared to justify why bedaquiline over injectables
7. If the patient has a co-pay, call Janssen CarePath at 855-846-5392. State that patient needs assistance with copay for Sirturo. They will provide her with an ID#, BIN#, and GRP#.

Filling the Prescription

Complete the prescription form and send to Metro Medical

- a. Bedaquiline 100 mg: Take 4 tabs q day X 2 wks, followed by
- b. Bedaquiline 200 mg 3 X a week (refill is limited to 4 refills)

SAMPLE Prescription Order

FAX TO: 615-312-9903			
MMS Phone: 855-691-0963 (toll free); 615-312-9888 (local)			
Date:	<input type="text"/>	Facility Name:	<input type="text"/>
VDPO#:	<input type="text"/>	Metro Account #:	Health Pharmacy Services
Patient Last Name:	<input type="text"/>	Facility Phone:	Shipping Contact: Director of Pharmacy
Patient First Name:	<input type="text"/>	Facility Fax:	Metro Account #
Patient Date of Birth:	<input type="text"/>	Facility Address:	Phone:
Patient Phone:	<input type="text"/>	Facility City, ST,	Fax:
Zip: Patient Address:	<input type="text"/>		Pharmacy Services
Patient City, ST, Zip:	<input type="text"/>		
***Orders cannot be shipped directly to Patient **All orders must be shipped to the Prescriber address or Facility/Site of Care Address			
Drug Allergies: <input type="text"/>			
ITEM #	MEDICATION	QTY	DIRECTIONS FOR USE
	Sirturo, 100mg tabs (NDC:59676-0701-01)	68	Take 4 tabs po, daily for 2 weeks, then 2 tabs po, 3 times a week
Other	<input type="text"/>	<input type="text"/>	<input type="text"/>
Other	<input type="text"/>	<input type="text"/>	<input type="text"/>
Other	<input type="text"/>	<input type="text"/>	<input type="text"/>
Other	<input type="text"/>	<input type="text"/>	<input type="text"/>
Other	<input type="text"/>	<input type="text"/>	<input type="text"/>
Other	<input type="text"/>	<input type="text"/>	<input type="text"/>
Other	<input type="text"/>	<input type="text"/>	<input type="text"/>
Prescriber Name: <input type="text"/>		Prescriber Phone: <input type="text"/>	
Prescriber NPI: <input type="text"/>		Prescriber Signature: <input type="text"/>	

This is an image of how to write the two quantities.

ITEM #	MEDICATION	QTY	DIRECTIONS FOR USE
	Sirturo 100mg tabs (NDC:59676-0701-01)	68	Take 4 tabs po daily for 2 weeks, then 2 tabs po 3 times a week
Other	<input type="text"/>	<input type="text"/>	<input type="text"/>
Other	<input type="text"/>	<input type="text"/>	<input type="text"/>
Other	Sirturo 200mg tabs (NDC:59676-0701-01)	24 w/4 refills	Take 2 tabs po 3 times a week
Other	<input type="text"/>	<input type="text"/>	<input type="text"/>
Other	<input type="text"/>	<input type="text"/>	<input type="text"/>
Other	<input type="text"/>	<input type="text"/>	<input type="text"/>

Suggestions – Insured Patients

- **Insured Patients (MI-1)**

- Guide for filling out the application
- Due diligence for preparing patients and clinicians for use – not an easy drug

- **Insured Patients (KY-1)**

- Have a toolkit available to fill out all of the various paperwork
- Having medical consultants be familiar with ability to access bedaquiline is really critical

- **Insured Patients (VA-1)**

- Create a template prescription form PDF pre-filled with relevant numbers and information apart from patient data to have on hand – reduce time for future prescription.

- **Insured Patients (IN-1)**

- Key contact
- Bridging regimen

Suggestions – Underinsured or Uninsured

- **Under Insured Patients (CA-1)**

- Source NPI and MediCal PIN numbers
- Develop guidelines for what to do when a patient is transferred while taking BDQ
 - E.g. Patient started bedaquiline through federal government while in ICE detention, transferred to local TB department, controller completed Prescription Form and JJPAF application and secured medication for the patient

- **JJPAF (AZ-1)**

- Document state statutes and laws
- Have a direct point of contact at JJPAF who can take questions, and improve communication time
- Have consent forms and information in Spanish and Filipino

- **JJPAF (VA-1)**

- Call 24 hours after submission of application to JJPAF to confirm receipt.



Thank you!

All of the controllers and TB program staff we spoke to were giving of their time, experience, and expertise. Thank you!!!

Thanks also to Donna Wegener and her team at the NTCA, and Lindsay McKenna and her team at the Treatment Action Group who are leading our engagement with Janssen and the Johnson & Johnson representatives so effectively!