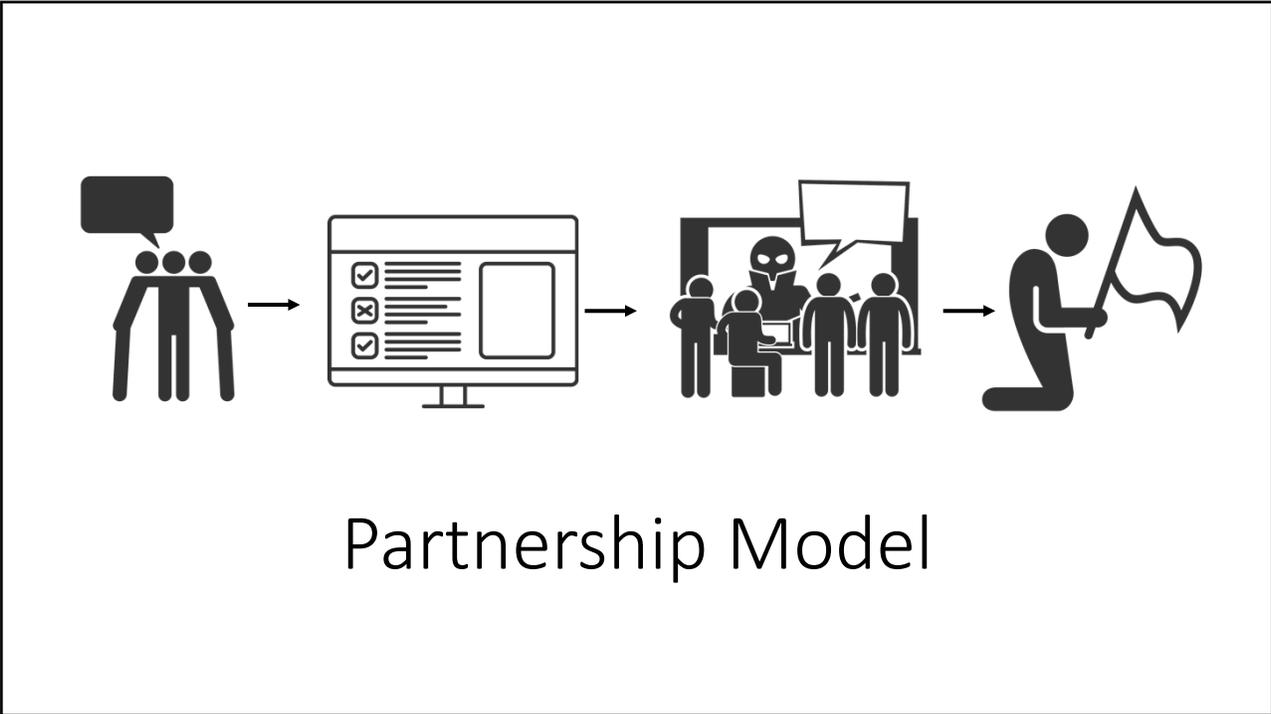


### History of Bedaquiline Pricing

- 2012 – bedaquiline approved by FDA, offered at \$30,000 in US
- 340b pricing available at ~\$23k, ordering through Metro Medical, full course
- Globally, donation program covered 60,000 courses sponsored by USAID and Janssen (through 2019 or until all claimed)
- 2018 - South Africa has negotiated a price of \$400 per course, should be available to all countries purchasing drugs from the Global Drug Facility



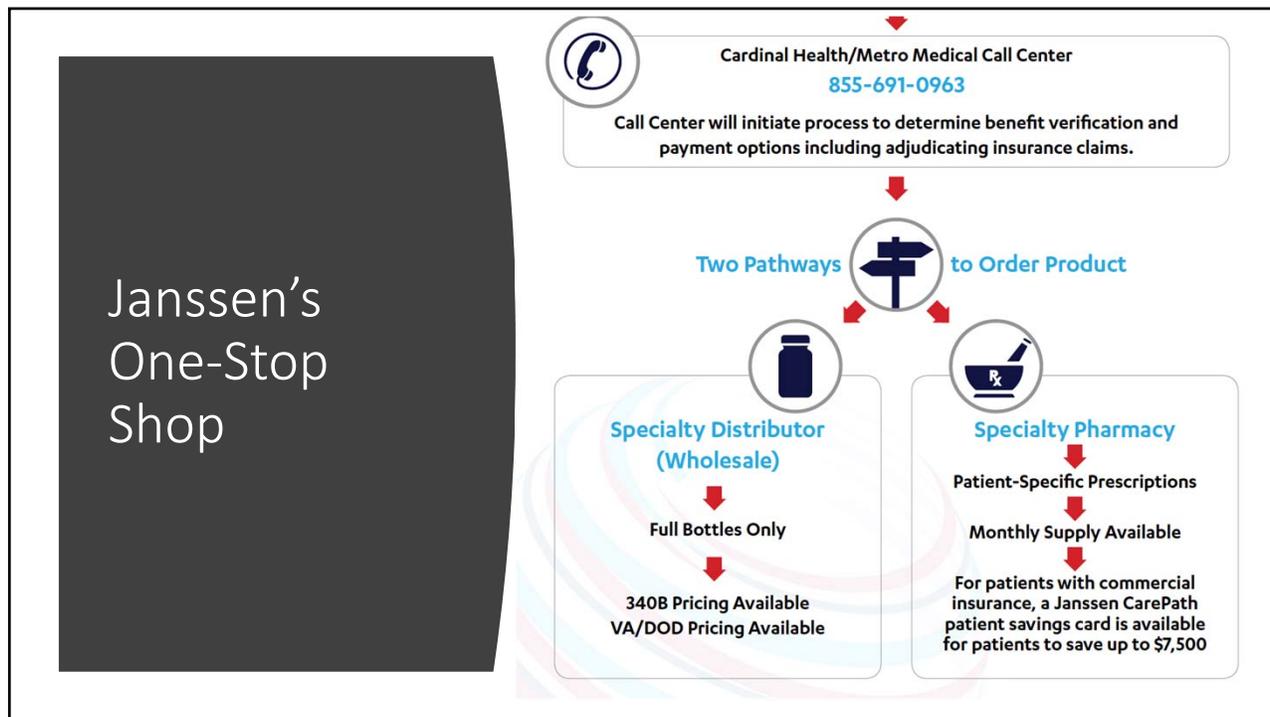
## Current bedaquiline campaign

- Controllers reported barriers to use, particularly cost
- Survey and focus groups found cost was barrier but other issues abound
  - Requirement to purchase course up front
  - Paperwork/contract issues with insurance companies and Metro Medical
- Contacted Janssen via closed letter and series of meetings
- Concessions on drug repackaging (still in process) and urgent improvements to the JJPAF. Also working with Janssen for Speed-to-Impact for in-patients.



## Definitions

- **CarePath:** Savings program offered by Janssen to help cover medical expenses for patient's with commercial or private health insurance. Ideal for covering co-pays. Contact point is Metro Medical.
- **Janssen:** Manufacturer of Sirturo (Bedaquiline) and a member of the Johnson & Johnson Pharmaceutical Companies.
- **Johnson and Johnson Patient Assistance Foundation (JJPAF):** JJPAF is a non-profit organization that helps eligible patients residing in the United States or U.S territories who have no insurance coverage receive certain prescription medications that are donated by Johnson & Johnson Pharmaceutical Companies.
- **Metro Medical:** National specialty pharmaceutical distributor
- **NPI:** The National Provider Identifier (NPI) is the standard unique 10-digit identifier for health care providers adopted by the Secretary of Health and Human Services in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA).
- **340B Pricing:** Enables covered entities to attain medication at reduced prices to be able to stretch federal resources, potentially reach more eligible patients and provide more comprehensive services.



So What's It Been Like IRL?

Non-JJPAF and JJPAF Patient Case Studies

Case Study for  
MI-1  
(Insured Patient)



### Insured Patient (MI-1)

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

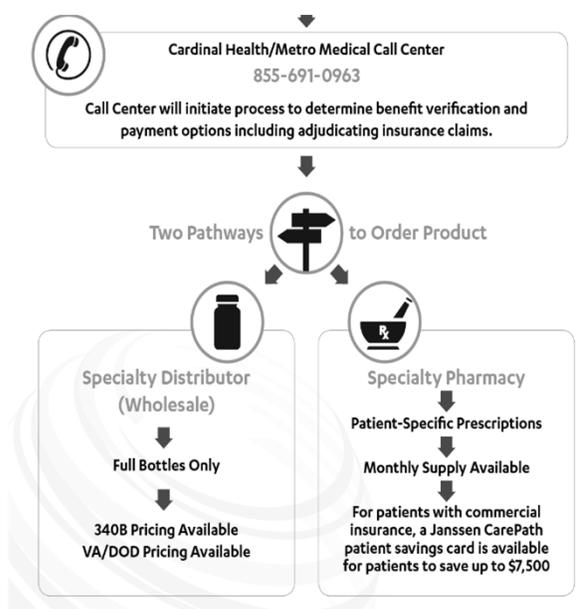
Bdq not received as expected – patient contacts JJPAF, told “there is no affordability option in Michigan and that they would call her back if they hear anything.”

TB nurse contacts Patient Care Specialist at Metro Medical, requests help on July 26<sup>th</sup>

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

TB nurse forwards Metro Medical insurance information on July 27<sup>th</sup>, confirms process does not need to be repeated every month

Metro Medical confirms delivery for July 31<sup>st</sup> 2018



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graph TD; A["Cardinal Health/Metro Medical Call Center  
855-691-0963  
Call Center will initiate process to determine benefit verification and payment options including adjudicating insurance claims."] --> B["Two Pathways to Order Product"]; B --> C["Specialty Distributor (Wholesale)"]; B --> D["Specialty Pharmacy"]; C --> E["Full Bottles Only"]; E --> F["340B Pricing Available  
VA/DOD Pricing Available"]; D --> G["Patient-Specific Prescriptions"]; G --> H["Monthly Supply Available"]; H --> I["For patients with commercial insurance, a Janssen CarePath patient savings card is available for patients to save up to $7,500"];
```

## 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

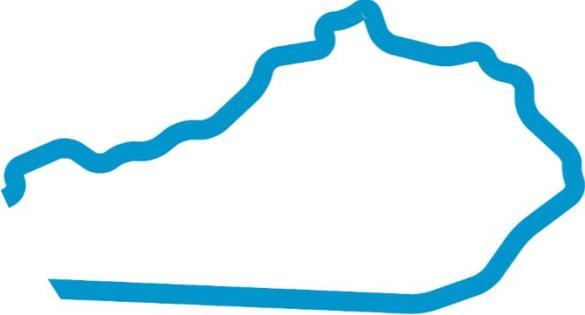


- Initial feedback from JJPAF was incorrect and confusing

## 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 they’re really saying is 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 really a potentially 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  
KY-1  
(Medicaid and  
Private)

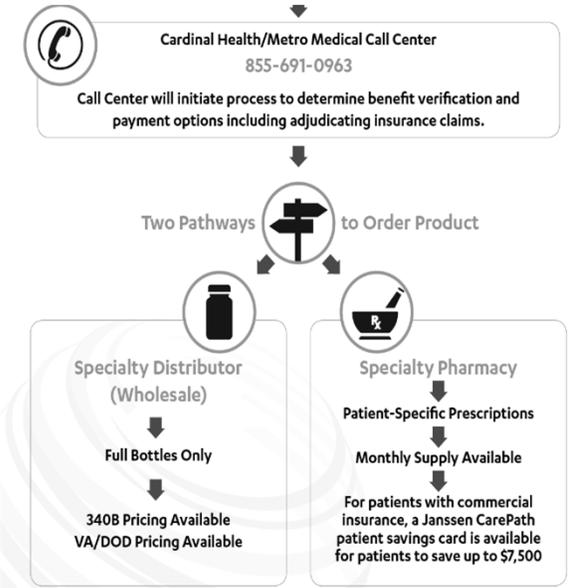


### Medicaid and Private (KY-1)

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 organization makes a decision on acceptance.

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



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graph TD; A["Cardinal Health/Metro Medical Call Center  
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## 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



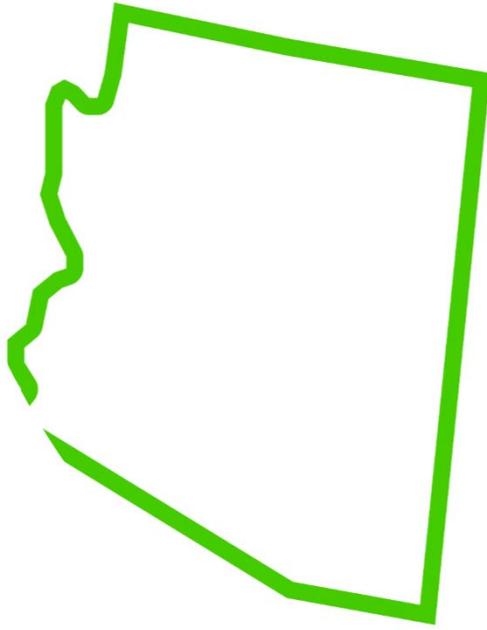
- Rural health departments have to deal with the current patient load, and it is only luck that they have had Medicaid or private insurance – if they had to cover costs it would put that health department in a precarious position

## 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”*

## Case Study for AZ-1 (Insured but State-Statute Covered Patient)



### JJPAF1 (AZ-1)

Original request to JJPAF rejected due to patient’s insurance status – would have covered the medication (took 1.5 weeks)

Local public health pays for all TB medications and health care by law (no services billed to patients).

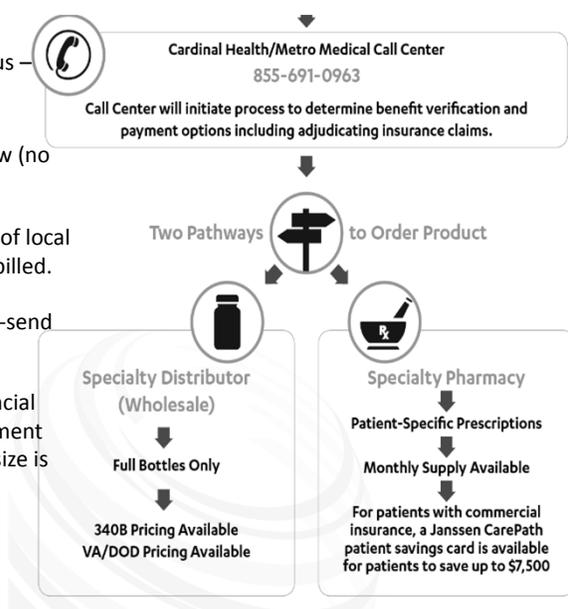
Controllers explained that payment for the drug would come out of local health department budget – explained insurance could not be billed.

State statute sent to JJPAF – received indication that they should re-send JJPAF application

Local health department completed the application without financial information. After one week with no contact, local health department contacted JJPAF, and were told that yearly income and household size is required information.

Application was amended and sent back to JJPAF.

Application approved.



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    A["Cardinal Health/Metro Medical Call Center  
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```

## JJPAF1 (AZ-1)



- Donna was the intermediary between JJPAF and controllers
- After receiving justification for providing drug for free, agreed and process ran smoothly from there



- Experienced initial rejection
- Had to source information on state statutes and use 'powers of persuasion' to justify JJPAF assistance
- Didn't hear back for a week, had to figure out what the delay was and source information that they were initially told wasn't needed

## Insured but covered by JJPAF (AZ-1) Key Quotes

*"Prior to obtaining free bedaquiline through the Foundation, we procured bedaquiline at retail price a handful of times. The process seemed pretty smooth for the most part, but due to the cost of the drug it was rarely prescribed. I know our local providers have wanted to prescribe bedaquiline, and have received consults from other TB experts suggesting a regimen including bedaquiline, but due to the cost they found other regimens and did not pursue obtaining bedaquiline." (KI 1)*

*"If the prescribing physician or local TB Control Officer could discuss directly with the Foundation member that will be reviewing this request, so they can discuss why this patient would need this medication for free, that would improve timeliness in medication acquisition." (KI 1)*

*"We've engaged with local jurisdictions to make sure they are aware that if they have a patient that requires bedaquiline, don't let the cost be prohibitive right now." (KI 1)*

## Insured but covered by JJPAF (AZ-1) Key Quotes

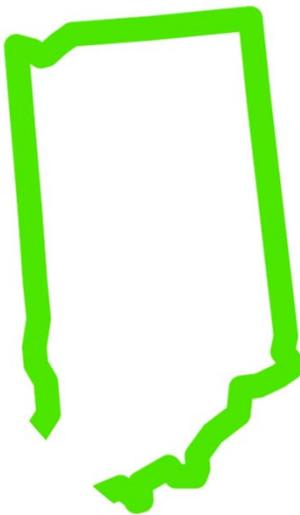
*“If I was able to talk directly to the Foundation, I would make the plea that making this medication available for free is life changing for our patients. Prescribing and paying full price for this medication would decimate local health department budgets. Currently, without the Foundation, one six-month prescription of bedaquiline is up to five times the annual budget for a rural local health department. Paying for bedaquiline would just completely ruin their budget and may require the patient to transfer care elsewhere, where it just puts the burden monetarily on someone else in our public health system. **Allowing us to procure this medication for free and has been lifesaving.**” (KI 1)*

## Insured but covered by JJPAF (AZ-1) Key Quotes

*“In the beginning, for all of our cases who need bedaquiline we’ve just been paying for it...it was pretty expensive, and it was draining my budget for TB. But this certainly helped a lot with this last patient that we had, in terms of the medication cost.” (KI 2)*

*“We figure out a way to cover because it is not something that we can predict. Knock on wood we haven’t had spent any for this fiscal year, but at any moment when we get a new drug resistant case who is going to be started on bedaquiline...I would have to either move money from elsewhere or request the higher ups for additional funding.” (KI 2)*

# Case Study for IN-1



## Patient (IN-1)

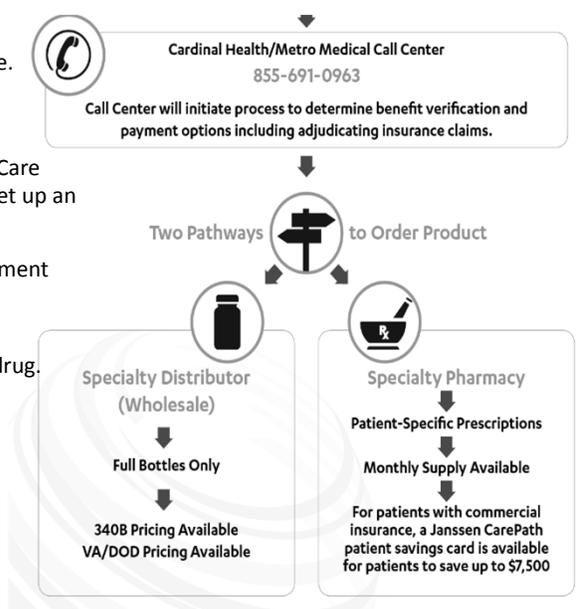
Center for Excellence advises bedaquiline as best drug of choice. Controller applied for internal approval (required because program covers cost).

Controller contacted Metro Medical directly, spoke to Patient Care Specialist. Requested to place prescription order form, and then set up an account with Cardinal.

Required a separate account with Cardinal – even though department already had contract with Cardinal for other TB drugs.

Contract and prescription sent back to Metro Medical to get the drug.

Patient initiated bedaquiline after six weeks.



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graph TD; A["Cardinal Health/Metro Medical Call Center  
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```

## Patient (IN-1)



- Many steps and delays associated with most
- Double contracting work required with Cardinal health
- Six week turn-around-time

## Timeline of Bedaquiline acquisition- *TB controller in IN took over a dozen steps to obtain drug*

1/16/18 – ISDH received request from local health department (LHD) for consult to obtain clofazimine for MDR patient. ISDH reached out to CDC to discuss process and was informed to set up a consult with COE. Email request to GTBI for consult on patient to obtain clofazimine submitted.

1/17/18 – Received confirmation from GTBI that consult request was received and began scheduling conference call with all parties.

1/24/18 – Conference call with GTBI, treating physicians, CDC, LHD, and ISDH to discuss patient's status and possibility of obtaining clofazimine. Per discussion, determined to try bedaquiline first. Internal approval of cost and ability to purchase at ISDH in afternoon.

1/25/18 – Initial inquiry to Metro Medical on ordering bedaquiline and email received from patient care rep with prescription order form.

1/26/18 – Credit application received from Metro Medical by ISDH

1/30/18 – ISDH submits cardinal credit application to Metro Medical

2/5/18 – Completed prescription form emailed to Metro Medical.

2/6/18 – Notification from Metro Medical that order form cannot be submitted without Metro account number and that status of account was pending

2/9/18 – ISDH conversation with Metro Medical regarding status of order and issue with shipment location (contracted pharmacy through 340B vs. paying entity). Notification that drug was being shipped.

2/12/18 – ISDH received drug and shipped out to contracted pharmacy same day.

2/19/18 – Received invoice from Metro Medical for \$22,809.27 and sent to ISDH finance

2/23/18 – Medication orders received at contracted pharmacy from treating physician

3/1/18 – Patient begins treatment with bedaquiline

8/15/18 – Patient discontinued bedaquiline. No side effects or issues noted during treatment.

## Insured by State Statutes (IN-1) Key Quotes

*“The one thing that would have been helpful was to have maybe a dedicated person that kind of understood the severity of needing this drug quickly and maybe the ‘guru’ for bedaquiline access at Johnson & Johnson or Metro Medical would have made it easier...”*

*“The biggest issue is that when you are talking to a random patient service representative or random person working for a very large company that has many drugs, they may not always understand the importance of, we need to get this really quickly...[so there may be] additional issues.”*

## 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 State medical consultants be familiar with ability to access bedaquiline is really critical
- **Insured Patients (IN-1)**
  - Key contact
  - Bridging regimen

## Suggestions – Underinsured or Uninsured

- **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

## What's Next?

1

Guide to Bedaquiline Access – review underway, to be launched in early 2019 on NTCA's website

2

Case Studies summarized and added to NTCA's website

3

Final (we hope) round of data collection for access issues and requests to Janssen



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, Lindsay McKenna and her team at the Treatment Action Group, and Marco Salerno and Michelle Macaraig who are leading our engagement with Janssen and the Johnson & Johnson representatives so effectively!