Obsessed with Abscessus (and other Non-Tuberculous Mycobacteria)

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March 2026

Beth Israel Lahey Health
Beth Israel Deaconess Medical Center

Objectives

1. Identify resources for contemporary non-tuberculous mycobacteria (NTM) treatment options

Disclosures

Abbreviations

- AMK amikacin
- AMX amoxicillin
- AZM azithromycin
- BDQ bedaquiline
- CIP ciprofloxacin
- CLO clofazimine
- CLR clarithromycin
- CZA ceftazidime/avibactam
- DOX doxycycline
- EMB ethambutol
- ERV eravacycline
- ETO ethionamide
- FOX cefoxitin
- IMR imipenem/relebactam
- INH isoniazid
- IPM imipenem
- LVX levofloxacin
- LZD linezolid
- MIN minocycline
- MXF moxifloxacin
- NTM nontuberculous mycobacterial
- OMC omadacycline
- PZA pyrazinamide
- RFB rifabutin
- RIF rifampin
- SXT sulfamethoxazole/trimethoprim
- TDM therapeutic drug monitoring
- TET tetracycline
- TGC tigecycline
- TOB tobramycin
- TZD tedizolid

NTM Resources

Clinical Infectious Diseases

IDSA FEATURES

Treatment of Nontuberculous Mycobacterial Pulmonary Disease: An Official ATS/ERS/ESCMID/IDSA Clinical Practice Guideline

Charles L. Daley, Jonathan M. Iaccarino, Christoph Lange, Emmanuelle Cambau, Richard J. Wallace, Jr, Claire Andrejak, Erik C. Böttger, Jan Brozek, David E. Griffith, Lorenzo Guglielmetti, Gwen A. Huitt, Shandra L. Knight, Philip Leitman, Theodore K. Marras, Kenneth N. Olivier, Miguel Santin, Jason E. Stout, Enrico Tortoli, Jakko van Ingen, Dirk Wagner, and Kevin L. Winthrop

Nontuberculous mycobacteria (NTM) represent over 190 species and subspecies, some of which can produce disease in humans of all ages and can affect both pulmonary and extrapulmonary sites. This guideline focuses on pulmonary disease in adults (without cystic fibrosis or human immunodeficiency virus infection) caused by the most common NTM pathogens such as *Mycobacterium avium* complex, *Mycobacterium kansasii*, and *Mycobacterium xenopi* among the slowly growing NTM and *Mycobacterium abscessus* among the rapidly growing NTM. A panel of experts was carefully selected by leading international respiratory medicine and infectious diseases societies (ATS, ERS, ESCMID, IDSA) and included specialists in pulmonary medicine, infectious diseases and clinical microbiology, laboratory medicine, and patient advocacy. Systematic reviews were conducted around each of 22 PICO (Population, Intervention, Comparator, Outcome) questions and the recommendations were formulated, written, and graded using the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) approach. Thirty-one evidence-based recommendations about treatment of NTM pulmonary disease are provided. This guideline is intended for use by healthcare professionals who care for patients with NTM pulmonary disease, including specialists in infectious diseases and pulmonary diseases.

Keywords. nontuberculous; *Mycobacterium avium* complex; *Mycobacterium kansasii*; *Mycobacterium abscessus*; *Mycobacterium xenopi*.

EXECUTIVE SUMMARY

The American Thoracic Society (ATS), European Respiratory Society (ERS), European Society of Clinical Microbiology and Infectious Diseases (ESCMID), and Infectious Diseases Society of America (IDSA) jointly sponsored the development of this Guideline to update the treatment recommendations for nontuberculous mycobacterial (NTM) pulmonary disease in adults. NTM represent over 190 species and subspecies (http://www.bacterio.net/mycobacterium.html), many of which can produce disease in humans of all ages and can affect both pulmonary and extrapulmonary sites. Attempting to cover such a broad array of species and disease in a guideline using current guideline development methods is impossible. Therefore, this guideline focuses on pulmonary disease in adults (without cystic fibrosis or human immunodeficiency virus [HIV] infection) caused by the most common NTM pathogens comprising *Mycobacterium avium* complex (MAC), *Mycobacterium kansasii*, and *Mycobacterium xenopi* among the slowly growing

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*C. L. D., C. L., E. C., R. J. W. are cochairs of this guideline committee.
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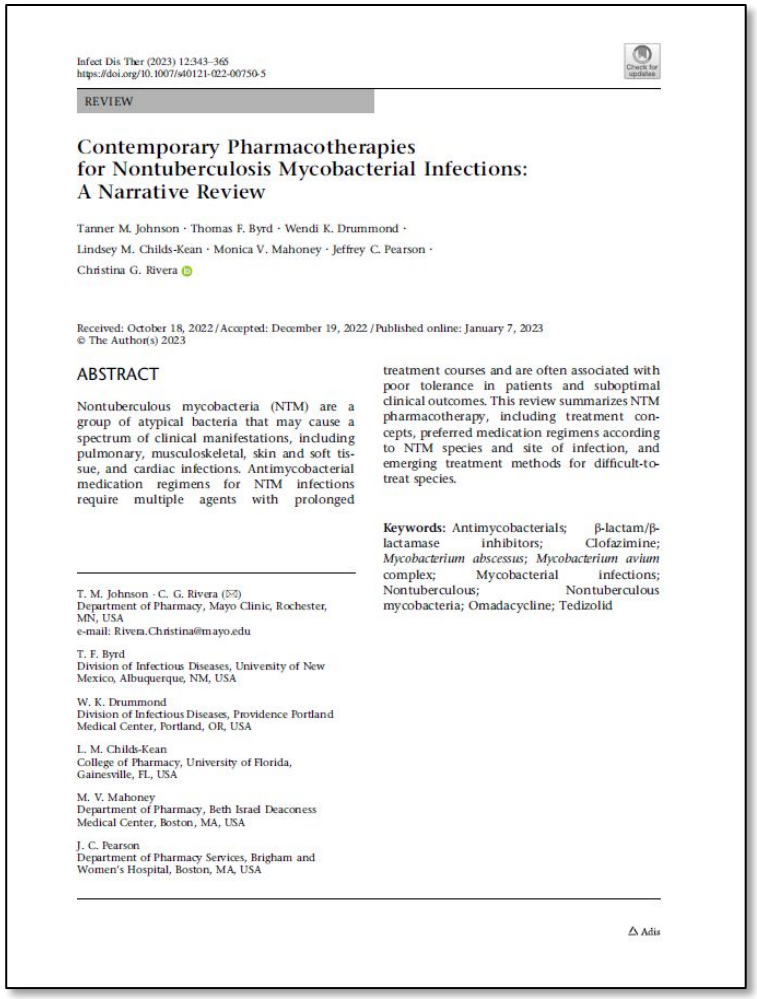

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REVIEW

Contemporary Pharmacotherapies for Nontuberculosis Mycobacterial Infections: A Narrative Review

Tanner M. Johnson · Thomas F. Byrd · Wendi K. Drummond · Lindsey M. Childs-Kean · Monica V. Mahoney · Jeffrey C. Pearson · Christina G. Rivera

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ABSTRACT

Nontuberculous mycobacteria (NTM) are a group of atypical bacteria that may cause a spectrum of clinical manifestations, including pulmonary, musculoskeletal, skin and soft tissue, and cardiac infections. Antimycobacterial medication regimens for NTM infections require multiple agents with prolonged treatment courses and are often associated with poor tolerance in patients and suboptimal clinical outcomes. This review summarizes NTM pharmacotherapy, including treatment concepts, preferred medication regimens according to NTM species and site of infection, and emerging treatment methods for difficult-to-treat species.

Keywords: Antimycobacterials; β-lactam/β-lactamase inhibitors; Clofazimine; *Mycobacterium abscessus*; *Mycobacterium avium* complex; Mycobacterial infections; Nontuberculous; Nontuberculous mycobacteria; Omadacycline; Tedizolid

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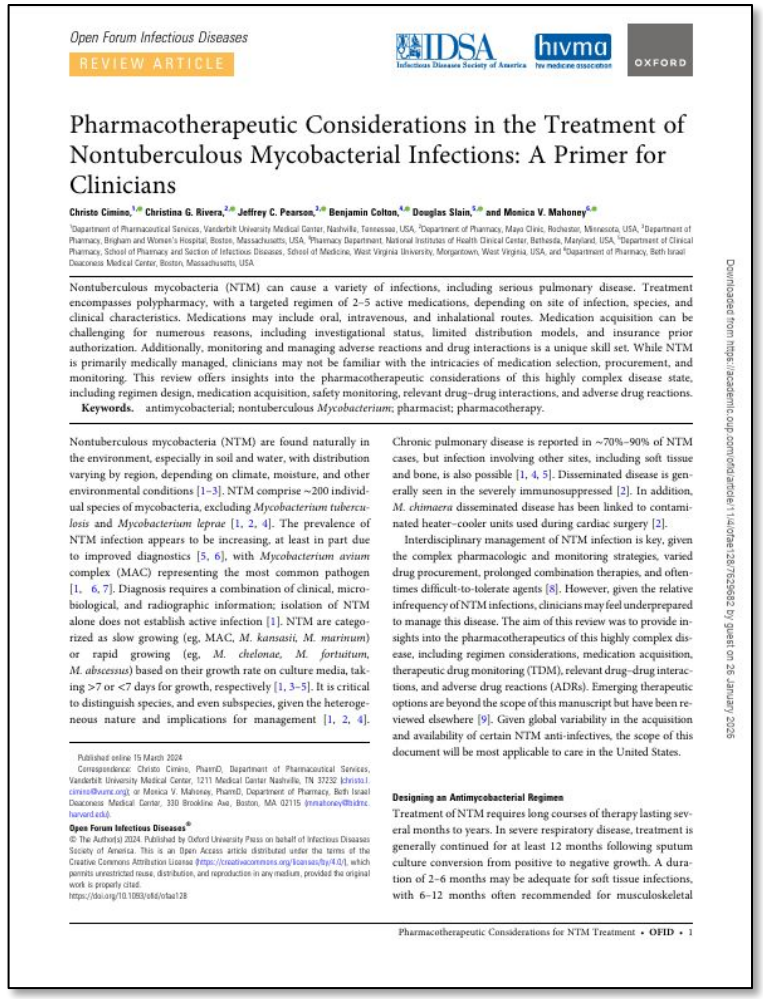

Open Forum Infectious Diseases

REVIEW ARTICLE

Pharmacotherapeutic Considerations in the Treatment of Nontuberculous Mycobacterial Infections: A Primer for Clinicians

Christo Cimino, Christina G. Rivera, Jeffrey C. Pearson, Benjamin Colton, Douglas Slain, and Monica V. Mahoney

Nontuberculous mycobacteria (NTM) can cause a variety of infections, including serious pulmonary disease. Treatment encompasses polypharmacy, with a targeted regimen of 2–5 active medications, depending on site of infection, species, and clinical characteristics. Medications may include oral, intravenous, and inhalational routes. Medication acquisition can be challenging for numerous reasons, including investigational status, limited distribution models, and insurance prior authorization. Additionally, monitoring and managing adverse reactions and drug interactions is a unique skill set. While NTM is primarily medically managed, clinicians may not be familiar with the intricacies of medication selection, procurement, and monitoring. This review offers insights into the pharmacotherapeutic considerations of this highly complex disease state, including regimen design, medication acquisition, safety monitoring, relevant drug–drug interactions, and adverse drug reactions.

Keywords. antimycobacterial; nontuberculous *Mycobacterium*; pharmacist; pharmacotherapy.

Nontuberculous mycobacteria (NTM) are found naturally in the environment, especially in soil and water, with distribution varying by region, depending on climate, moisture, and other environmental conditions [1–3]. NTM comprise ~200 individual species of mycobacteria, excluding *Mycobacterium tuberculosis* and *Mycobacterium leprae* [1, 2, 4]. The prevalence of NTM infection appears to be increasing, at least in part due to improved diagnostics [5, 6], with *Mycobacterium avium* complex (MAC) representing the most common pathogen [1, 6, 7]. Diagnosis requires a combination of clinical, microbiological, and radiographic information; isolation of NTM alone does not establish active infection [1]. NTM are categorized as slow growing (eg, MAC, *M. kansasii*, *M. marinum*) or rapid growing (eg, *M. chelonae*, *M. fortuitum*, *M. abscessus*) based on their growth rate on culture media, taking >7 or <7 days for growth, respectively [1, 3–5]. It is critical to distinguish species, and even subspecies, given the heterogeneous nature and implications for management [1, 2, 4].

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Chronic pulmonary disease is reported in ~70%–90% of NTM cases, but infection involving other sites, including soft tissue and bone, is also possible [1, 4, 5]. Disseminated disease is generally seen in the severely immunosuppressed [2]. In addition, *M. chimaera* disseminated disease has been linked to contaminated heater–cooler units used during cardiac surgery [2].

Interdisciplinary management of NTM infection is key, given the complex pharmacologic and monitoring strategies, varied drug procurement, prolonged combination therapies, and oftentimes difficult-to-tolerate agents [8]. However, given the relative infrequency of NTM infections, clinicians may feel underprepared to manage this disease. The aim of this review was to provide insights into the pharmacotherapeutics of this highly complex disease, including regimen considerations, medication acquisition, therapeutic drug monitoring (TDM), relevant drug–drug interactions, and adverse drug reactions (ADRs). Emerging therapeutic options are beyond the scope of this manuscript but have been reviewed elsewhere [9]. Given global variability in the acquisition and availability of certain NTM anti-infectives, the scope of this document will be most applicable to care in the United States.

Designing an Antimycobacterial Regimen

Treatment of NTM requires long courses of therapy lasting several months to years. In severe respiratory disease, treatment is generally continued for at least 12 months following sputum culture conversion from positive to negative growth. A duration of 2–6 months may be adequate for soft tissue infections, with 6–12 months often recommended for musculoskeletal

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IDSA Guidelines: CID 2020;71:e1-36, ciaa241; Johnson et al, Infect Dis Ther 2023;12:343-65; Cimino et al OFID 2024, ofae128

Diagnosis

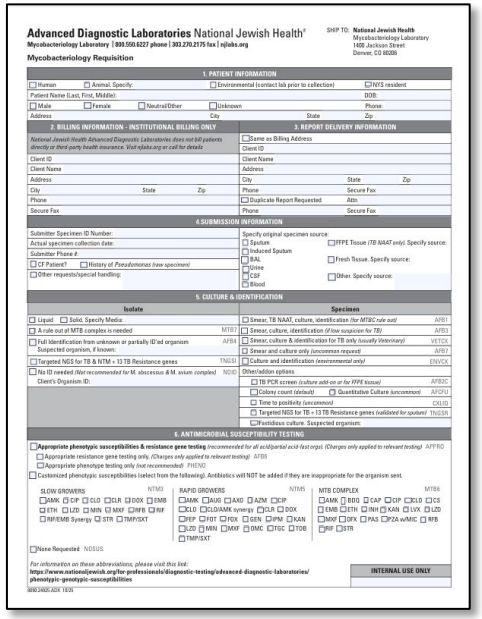
Category	Description
Clinical	Pulmonary or systemic symptoms
Radiologic	Nodular or cavitary opacities on chest radiograph or a high-resolution CT scan that shows bronchiectasis with multiple small nodules
Microbiologic	• Positive culture results from ≥ 2 expectorated sputum samples (if non-diagnostic, consider repeat sputum AFB smears and cultures) or • Positive culture results from ≥ 1 bronchial wash or lavage or • Transbronchial or other lung biopsy with mycobacterial histologic features (granulomatous inflammation or AFB) and positive culture for NTM or biopsy showing mycobacterial histologic features (granulomatous inflammation or AFB) and ≥ 1 sputum or bronchial washings that are culture positive for NTM

- Need all 3: clinical + radiologic + microbiologic
- Exclusion of other diagnoses

IDSA Guidelines: CID 2020;71:e1-36, ciaa241

Susceptibility Testing

- IDSA recommends treatment guided by susceptibilities (*M. avium* complex, *M. kansasii, M. xenopi, M. abscessus*)
- Correlation between *in vitro* MICs and clinic outcomes is not established for all agents



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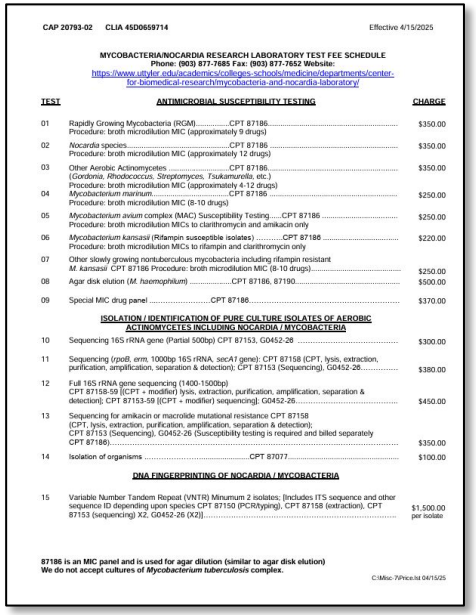

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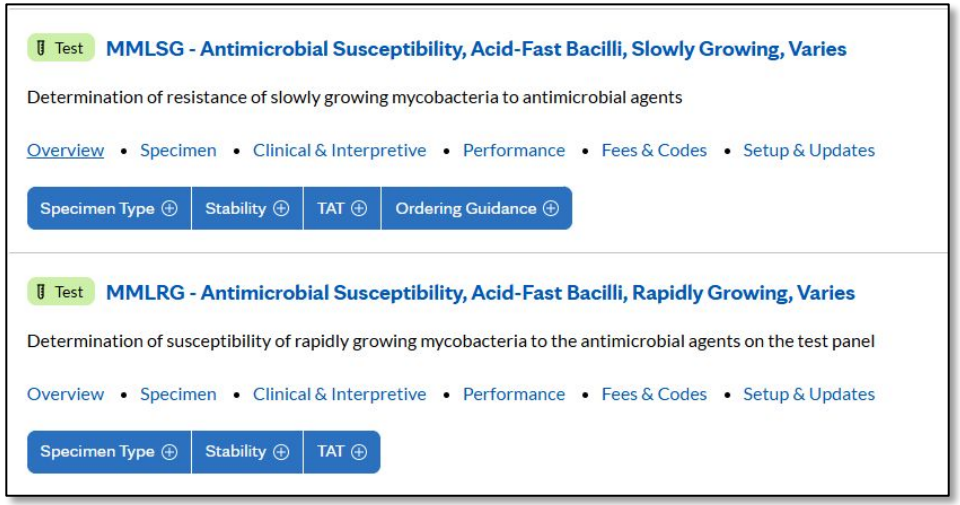


Mayo Clinic

IDSA Guidelines: CID 2020;71:e1-36, ciaa241; (See references for above website)

Susceptibility Testing Examples

SOURCE: LUNG
SUSC, AFB, SLOWLY GROWING **FINAL**

MYCOBACTERIUM KANSASII
Organism identified by client.

There are no established interpretive guidelines for agents reported without interpretations.

Organism: MYCOBACTERIUM KANSASII		
Antibiotic	**MIC (mcg/mL)**	**Interpretation**
Clofazimine	0.25	
Ciprofloxacin	1	S
Moxifloxacin	0.12	S
Clarithromycin	0.5	S
Amikacin	4	S
Doxycycline	2	I
Minocycline	1	S
TMP/SMX	1/19	S
Linezolid	16	I
Rifampin	0.06	S
Rifabutin	0.5	S

Ciprofloxacin: Ciprofloxacin and levofloxacin are interchangeable, but both are less active in vitro than moxifloxacin.
Clarithromycin: Clarithromycin is the class drug for macrolides and the only macrolide that needs to be tested.

SOURCE: SPUTUM
SUSC, AFB, SLOWLY GROWING **FINAL**

MYCOBACTERIUM AVIUM COMPLEX
Organism identified by client.

There are no established interpretive guidelines for agents reported without interpretations.

Organism: MYCOBACTERIUM AVIUM COMPLEX		
Antibiotic	**MIC (mcg/mL)**	**Interpretation**
Clofazimine	0.25	
Moxifloxacin	0.12	S
Clarithromycin	0.5	S
Amikacin (IV)	4	S
Amikacin (liposomal, inhaled)	4	S
Linezolid	4	S

Moxifloxacin: The in vivo effectiveness of this agent for MAC disease is unproven.
Clarithromycin: Clarithromycin is the class drug for macrolides and the only macrolide that needs to be tested.
Linezolid: The in vivo effectiveness of this agent for MAC disease is unproven.

SOURCE: SPUTUM
SUSC, AFB, RAPIDLY GROWING **FINAL**

MYCOBACTERIUM FORTUITUM
Organism identified by client.

There are no established interpretive guidelines for agents reported without interpretations.

Organism: MYCOBACTERIUM FORTUITUM		
Antibiotic	**MIC (mcg/mL)**	**Interpretation**
Cefoxitin	4	S
Imipenem	0.25	S
Clofazimine	0.25	
Ciprofloxacin	1	S
Moxifloxacin	0.25	S
Clarithromycin	0.5	S
Amikacin	4	S
Tobramycin	1	S
Doxycycline	1	S
Tigecycline	0.5	
TMP/SMX	2/38	S
Linezolid	16	I

Ciprofloxacin: Ciprofloxacin and levofloxacin are interchangeable, but both are less active in vitro than moxifloxacin.
Clarithromycin: Clarithromycin is the class drug for macrolides and the only macrolide that needs to be tested.
Tobramycin: Tobramycin results intended for use with M. chelonae only.

Examples available at: https://www.mayocliniclabs.com/search#q=mycobacteria Accesses 2/1/26

Treatment Options – Slow Growers*

Species	Preferred Agents	Alternative Agents
M. avium complex	AMK, AZM, EMB, RFB, RIF	BDQ, CLO, CLR, CZA, ETO, LZD, MXF, SXT, TGC, TZD
M. kansasii	AZM, CIP, EMB, INH, LVX, MXF, RFB, RIF	AMK, BDQ, CLO, CLR, LZD, SXT, TGC, TZD
M. marinum	AZM, EMB, RFB, RIF	AMK, CIP, CLR, DOX, INH, IPM, LVX, LZD, MIN, MXF, SXT, TZD
M. scrofulaceum	AZM, CIP, CLR, LVX, MXF	EMB, LZD, MIN, RFB, RIF
M. haemophilum	AZM, CIP, CLR, RFB, RIF	AMK, CLO, DOX, SXT
M. terrae complex	AZM, CLR, EMB, RIF	AMK, CIP, ETO, LVX, LZD, MXF, SXT
M. xenopi	AZM, CLR, EMB, RFB, RIF	AMK, INH, LVX, MXF
M. ulcerans	AMK, AZM, EMB, RFB, RIF	CLR, MXF, SXT, TET
M. malmoense	AZM, EMB, LVX, MXF, RFB, RIF	CLR, INH
M. celatum	AZM, EMB, LVX, MXF, RFB	AMK, CLR, INH, PZA
M. genavense	AZM, RFB, RIF	AMK, CLO, CLR, EMB, LVX, MXF
M. simiae complex	CLR, EMB, MXF, RFB, RIF, SXT	AMK, CLO, LZD
M. szulgai	AZM, EMB, RIF	AMK, CLR, INH, LVX, MXF, PZA
M. gordonae	AZM, CLR, EMB, RIF	INH, LVX, LZD, MXF, RFB, SXT

*Grow > 7 days

M. avium complex: *M. avium, M. intracellulare, M.* subspecies *chimaera*

Johnson et al, Infect Dis Ther 2023;12:343-65

Treatment Options – Rapid Growers*

Species	Preferred Agents	Alternative Agents
M. fortuitum complex	AMK, CIP, DOX, IPM, LVX, MIN, MXF, SXT	FOX, LZD, OMC, TGC, TOB
M. chelonae	AZM, IPM, LZD, TOB	CIP, CLO, CLR, DOX, LVX, MIN, MXF, OMC, SXT, TGC
M. abscesssus complex	AMK, AZM, FOX, IPM	BDQ, CIP, CLO, CLR, ERV, IMR, LVX, LZD, MXF, OMC, TGC, TZD
M. smegmatis group	AMK, CIP, DOX, MXF, SXT	AZM, CLO, CLR, EMB, FOX, IPM
M. immunogenum	AMK, AZM, TGC	CLR, IPM, LZD, TZD
M. mucogenicum	AMK, AZM, CIP, FOX, IPM, LVX, MXF, SXT	AMX, CLR, DOX, LZD, MIN

M. abscessus complex: *M. abscessus* subspecies *abscessus, M. abscessus* subspecies *massiliense, M. abscessus* subspecies *bolletii*

*Grow within 7 days

Drug Dosing

Drug	Dosing	Comment
Amikacin	• 15 mg/kg IV daily or 5 x week • 15-25 mg/kg 3 x week	• Peak 35-45 mcg/mL (15 mg/kg) • Peak 65-80 mcg/mL (25 mg/kg) • Trough: undetectable • Audiology exams
Amikacin liposomal	590 mg inhaled once daily	
Bedaquiline	• Induction: 400 mg PO daily x 2 weeks • Maintenance: 200 mg PO 3 x week	
Cefoxitin	2-4g IV every 8-12h (max: 12g/day)	
Clofazimine	100 mg PO daily	May consider TDM: peak 0.5-2 mcg/mL (2h level)
Ethambutol	• 15-20 mg/kg PO daily • 25 mg/kg PO 3x week	• Consider TDM: refer to reference lab ranges • Dose on lean body weight in obesity
Fluoroquinolones	• Ciprofloxacin 500-750 mg PO BID • Levofloxacin 500-750 mg PO daily • Moxifloxacin 400 mg PO daily	
Imipenem-cilastatin	500-1000 mg IV q8-12h	
Isoniazid	5 mg/kg PO daily (max: 300 mg)	• Administer with pyridoxine • Consider TDM: peak 3-6 mcg/mL (1-2h level)

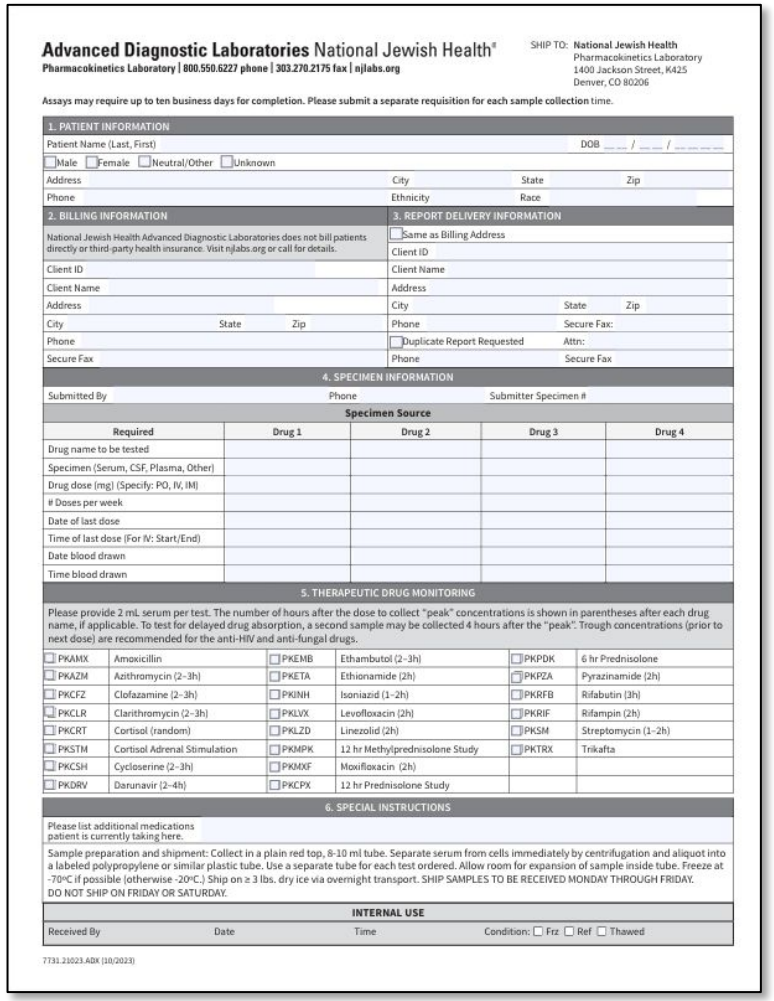
Cimino et al OFID 2024, ofae128

Drug Dosing

Drug	Dosing	Comment
Macrolides	• Azithromycin 250-500 mg PO/IV daily • Azithromycin 500 mg PO/IV 3x week • Clarithromycin 500 mg PO q12h	• Consider TDM: • AZM peak 0.2-0.7 mcg/mL (2-3h level) • CLR peak 2-7 mcg/mL (2-3h level)
Omadacycline	• 300 mg PO once daily • 100 mg IV once daily	No need to giving loading dose
Oxazolidinone	• Linezolid 600 mg PO/IV once daily • Tedizolid 200 mg PO/IV once daily	Consider LZD TDM: trough 2-8 mcg/mL or <2 mcg/mL (long-term use)
Rifamycins	• Rifabutin 5 mg/kg PO daily (max: 300 mg) • Rifabutin 300 mg PO 3x week • Rifampin 10 mg/kg PO daily (max: 600 mg) • Rifampin 600 mg PO 3x week	• Consider TDM: • Rifabutin peak 0.45-0.9 mcg/mL (3h level) • Rifampin peak 8-24 mcg/mL (2h level)
Trimethoprim-sulfamethoxazole	160mg/800 mg PO/IV twice daily	
Tetracyclines	• Doxycycline 100 mg PO/IV twice daily • Minocycline 100 mg PO/IV twice daily	
Tigecycline	• 25-50 mg IV q12-24h	May not need loading dose

Cimino et al OFID 2024, ofae128

Therapeutic Drug Monitoring



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Assays may require up to ten business days for completion. Please submit a separate requisition for each sample collection time.

1. PATIENT INFORMATION

Patient Name (Last, First) DOB ___ / ___ / _____

☐ Male ☐ Female ☐ Neutral/Other ☐ Unknown

Address City State Zip

Phone Ethnicity Race

2. BILLING INFORMATION

National Jewish Health Advanced Diagnostic Laboratories does not bill patients directly or third-party health insurance. Visit njlabs.org or call for details.

Client ID

Client Name

Address

City State Zip

Phone

Secure Fax

3. REPORT DELIVERY INFORMATION

☐ Same as Billing Address

Client ID

Client Name

Address

City State Zip

Phone Secure Fax:

☐ Duplicate Report Requested Attn:

Phone Secure Fax

4. SPECIMEN INFORMATION

Submitted By Phone Submitter Specimen #

Specimen Source

Required	Drug 1	Drug 2	Drug 3	Drug 4
Drug name to be tested				
Specimen (Serum, CSF, Plasma, Other)				
Drug dose (mg) (Specify: PO, IV, IM)				
# Doses per week				
Date of last dose				
Time of last dose (For IV: Start/End)				
Date blood drawn				
Time blood drawn				

5. THERAPEUTIC DRUG MONITORING

Please provide 2 mL serum per test. The number of hours after the dose to collect "peak" concentrations is shown in parentheses after each drug name, if applicable. To test for delayed drug absorption, a second sample may be collected 4 hours after the "peak". Trough concentrations (prior to next dose) are recommended for the anti-HIV and anti-fungal drugs.

☐ PKAMX	Amoxicillin	☐ PKEMB	Ethambutol (2-3h)	☐ PKPDK	6 hr Prednisolone
☐ PKAZM	Azithromycin (2-3h)	☐ PKETA	Ethionamide (2h)	☐ PKPZA	Pyrazinamide (2h)
☐ PKCFZ	Clofazamine (2-3h)	☐ PKINH	Isoniazid (1-2h)	☐ PKRFB	Rifabutin (3h)
☐ PKCLR	Clarithromycin (2-3h)	☐ PKLVX	Levofloxacin (2h)	☐ PKRIF	Rifampin (2h)
☐ PKCRT	Cortisol (random)	☐ PKLZD	Linezolid (2h)	☐ PKSM	Streptomycin (1-2h)
☐ PKSTM	Cortisol Adrenal Stimulation	☐ PKMPK	12 hr Methylprednisolone Study	☐ PKTRX	Trikafta
☐ PKCSH	Cycloserine (2-3h)	☐ PKMXF	Moxifloxacin (2h)		
☐ PKDRV	Darunavir (2-4h)	☐ PKCPX	12 hr Prednisolone Study		

6. SPECIAL INSTRUCTIONS

Please list additional medications patient is currently taking here.

Sample preparation and shipment: Collect in a plain red top, 8-10 ml tube. Separate serum from cells immediately by centrifugation and aliquot into a labeled polypropylene or similar plastic tube. Use a separate tube for each test ordered. Allow room for expansion of sample inside tube. Freeze at -70ºC if possible (otherwise -20ºC.) Ship on ≥ 3 lbs. dry ice via overnight transport. SHIP SAMPLES TO BE RECEIVED MONDAY THROUGH FRIDAY. DO NOT SHIP ON FRIDAY OR SATURDAY.

INTERNAL USE

Received By Date Time Condition: ☐ Frz ☐ Ref ☐ Thawed

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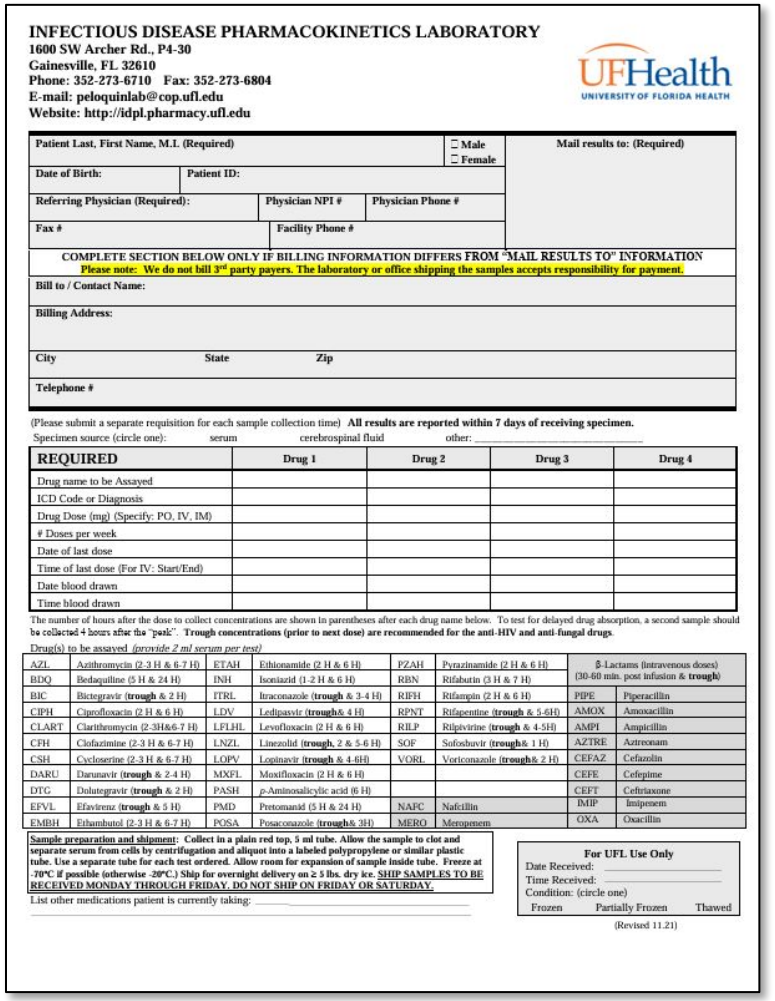
National Jewish Health



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Website: http://idpl.pharmacy.ufl.edu

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Patient Last, First Name, M.I. (Required)		☐ Male ☐ Female	**Mail results to: (Required)**
Date of Birth:	**Patient ID:**		
Referring Physician (Required):	**Physician NPI #**	**Physician Phone #**	
Fax #	**Facility Phone #**		

COMPLETE SECTION BELOW ONLY IF BILLING INFORMATION DIFFERS FROM "MAIL RESULTS TO" INFORMATION
Please note: We do not bill 3rd party payers. The laboratory or office shipping the samples accepts responsibility for payment.

Bill to / Contact Name:

Billing Address:

City **State** **Zip**

Telephone #

(Please submit a separate requisition for each sample collection time) **All results are reported within 7 days of receiving specimen.**
Specimen source (circle one): serum cerebrospinal fluid other: _____

REQUIRED	**Drug 1**	**Drug 2**	**Drug 3**	**Drug 4**
Drug name to be Assayed				
ICD Code or Diagnosis				
Drug Dose (mg) (Specify: PO, IV, IM)				
# Doses per week				
Date of last dose				
Time of last dose (For IV: Start/End)				
Date blood drawn				
Time blood drawn				

The number of hours after the dose to collect concentrations are shown in parentheses after each drug name below. To test for delayed drug absorption, a second sample should be collected 4 hours after the "peak". **Trough concentrations (prior to next dose) are recommended for the anti-HIV and anti-fungal drugs.**

Drug(s) to be assayed *(provide 2 ml serum per test)*

						β-Lactams (intravenous doses) (30-60 min. post infusion & **trough**)	
AZL	Azithromycin (2-3 H & 6-7 H)	ETAH	Ethionamide (2 H & 6 H)	PZAH	Pyrazinamide (2 H & 6 H)		
BDQ	Bedaquiline (5 H & 24 H)	INH	Isoniazid (1-2 H & 6 H)	RBN	Rifabutin (3 H & 7 H)		
BIC	Bictegravir (**trough** & 2 H)	ITRL	Itraconazole (**trough** & 3-4 H)	RIFH	Rifampin (2 H & 6 H)	PIPE	Piperacillin
CIPH	Ciprofloxacin (2 H & 6 H)	LDV	Ledipasvir (**trough**& 4 H)	RPNT	Rifapentine (**trough** & 5-6H)	AMOX	Amoxacillin
CLART	Clarithromycin (2-3H&6-7 H)	LFLHL	Levofloxacin (2 H & 6 H)	RILP	Rilpivirine (**trough** & 4-5H)	AMPI	Ampicillin
CFH	Clofazimine (2-3 H & 6-7 H)	LNZL	Linezolid (**trough,** 2 & 5-6 H)	SOF	Sofosbuvir (**trough**& 1 H)	AZTRE	Aztreonam
CSH	Cycloserine (2-3 H & 6-7 H)	LOPV	Lopinavir (**trough** & 4-6H)	VORL	Voriconazole (**trough**& 2 H)	CEFAZ	Cefazolin
DARU	Darunavir (**trough** & 2-4 H)	MXFL	Moxifloxacin (2 H & 6 H)			CEFE	Cefepime
DTG	Dolutegravir (**trough** & 2 H)	PASH	*p*-Aminosalicylic acid (6 H)			CEFT	Ceftriaxone
EFVL	Efavirenz (**trough** & 5 H)	PMD	Pretomanid (5 H & 24 H)	NAFC	Nafcillin	IMIP	Imipenem
EMBH	Ethambutol (2-3 H & 6-7 H)	POSA	Posaconazole (**trough**& 3H)	MERO	Meropenem	OXA	Oxacillin

Sample preparation and shipment: Collect in a plain red top, 5 ml tube. Allow the sample to clot and separate serum from cells by centrifugation and aliquot into a labeled polypropylene or similar plastic tube. Use a separate tube for each test ordered. Allow room for expansion of sample inside tube. Freeze at -70ºC if possible (otherwise -20ºC.) Ship for overnight delivery on ≥ 5 lbs. dry ice. SHIP SAMPLES TO BE RECEIVED MONDAY THROUGH FRIDAY. DO NOT SHIP ON FRIDAY OR SATURDAY.

List other medications patient is currently taking: _____

For UFL Use Only
Date Received: _____
Time Received: _____
Condition: (circle one)
Frozen Partially Frozen Thawed

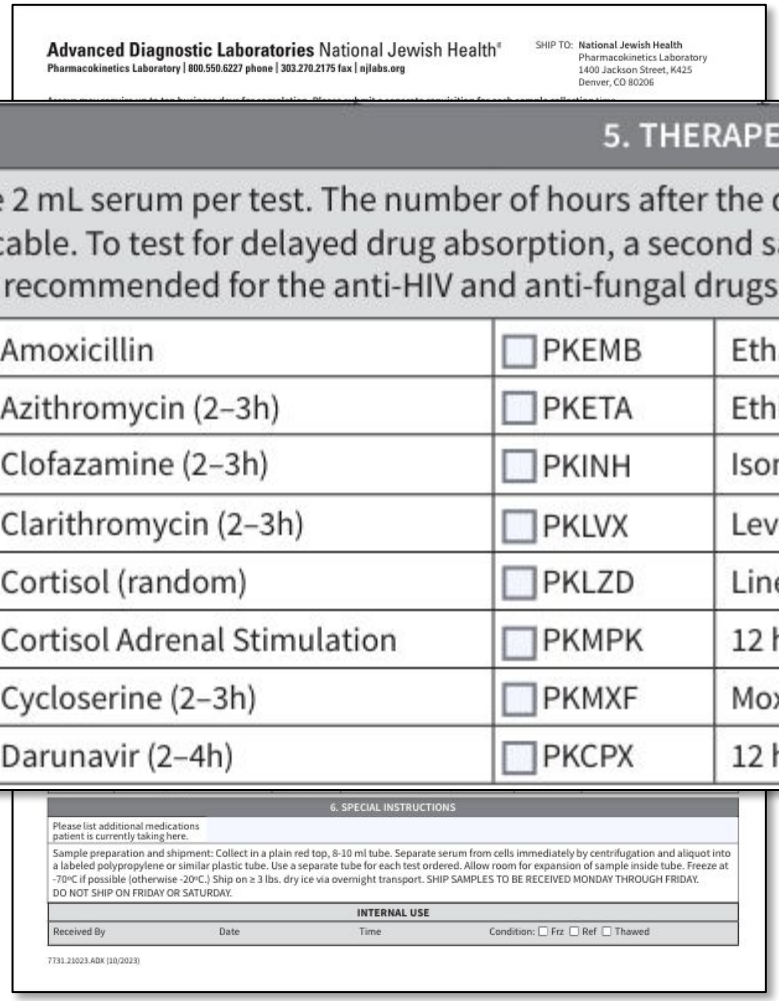
(Revised 11.21)

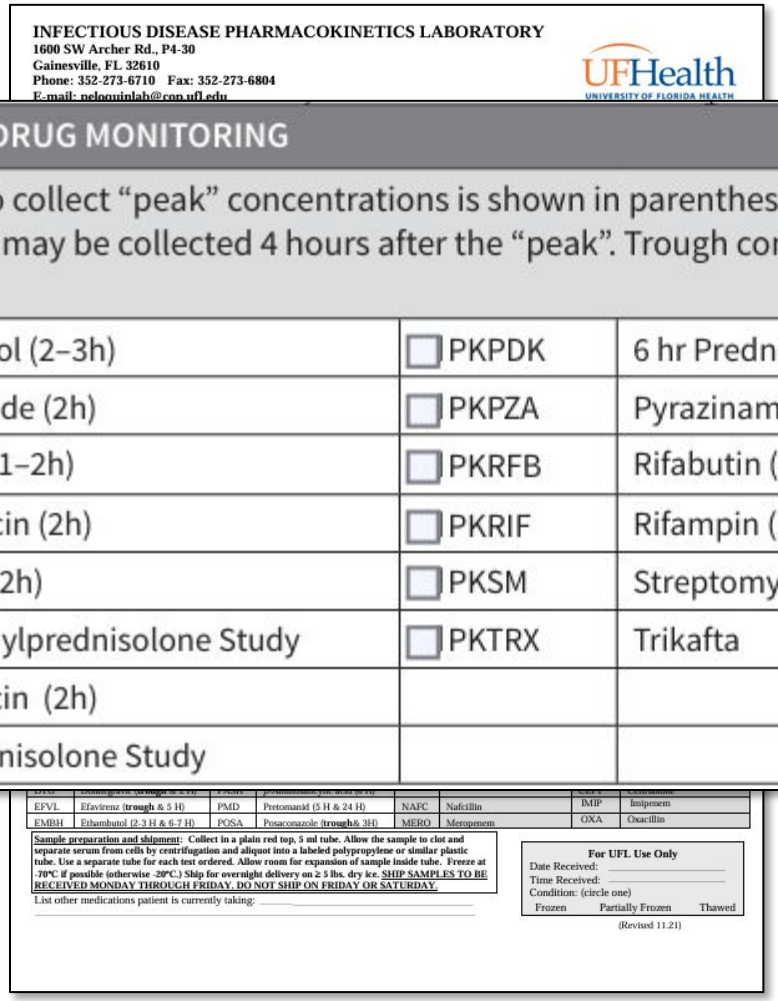
University of Florida

(See references for above website links)

Beth Israel Lahey Health
Beth Israel Deaconess Medical Center

Therapeutic Drug Monitoring





5. THERAPEUTIC DRUG MONITORING

Please provide 2 mL serum per test. The number of hours after the dose to collect "peak" concentrations is shown in parentheses after each drug name, if applicable. To test for delayed drug absorption, a second sample may be collected 4 hours after the "peak". Trough concentrations (prior to next dose) are recommended for the anti-HIV and anti-fungal drugs.

☐ PKAMX	Amoxicillin	☐ PKEMB	Ethambutol (2–3h)	☐ PKPDK	6 hr Prednisolone
☐ PKAZM	Azithromycin (2–3h)	☐ PKETA	Ethionamide (2h)	☐ PKPZA	Pyrazinamide (2h)
☐ PKCFZ	Clofazamine (2–3h)	☐ PKINH	Isoniazid (1–2h)	☐ PKRFB	Rifabutin (3h)
☐ PKCLR	Clarithromycin (2–3h)	☐ PKLVX	Levofloxacin (2h)	☐ PKRIF	Rifampin (2h)
☐ PKCRT	Cortisol (random)	☐ PKLZD	Linezolid (2h)	☐ PKSM	Streptomycin (1–2h)
☐ PKSTM	Cortisol Adrenal Stimulation	☐ PKMPK	12 hr Methylprednisolone Study	☐ PKTRX	Trikafta
☐ PKCSH	Cycloserine (2–3h)	☐ PKMXF	Moxifloxacin (2h)		
☐ PKDRV	Darunavir (2–4h)	☐ PKCPX	12 hr Prednisolone Study		

National Jewish Health

University of Florida

(See references for above website links)

Targeted Treatment Recommendations

***M. avium* complex**

- 3 drug regimen preferred
- AZM-based regimen preferred
- 3x week dosing unless severe/cavitary disease
- Add inhaled amikacin if failed txt x 6 months
- 12 months of txt after culture-conversion

M. xenopi

- 3 drug regimen preferred
- FQ or macrolide-based regimen preferred
- Daily dosing preferred
- Add IV amikacin in cavitary disease
- 12 months of txt after culture-conversion

M. kansasii

- 3 drug regimen preferred
- RIF/EMB-based regimen preferred
  - Macrolide vs. INH
- 3x week dosing unless cavitary disease or INH-based
- 12 months txt ***total***

M. abscessus

- 3 drug regimen preferred
- Macrolide-based regimen preferred
- No consensus on duration of txt

IDSA Guidelines: CID 2020;71:e1-36, ciaa241

Drug Acquisition

Medication	Pharmacy Availability	Prescription Requirements	Patient Acquisition
Amikacin IV	Home infusion or infusion center	Home infusion company forms	Home delivery
Amikacin liposomal inhaled	Specialty pharmacy (N=3)	Company-provided form or routine prescribing	Home delivery
Bedaquiline PO	Specialty pharmacy (N=1)	Company-provided form	Clinic pick-up
Cefoxitin IV	Home infusion or infusion center	Home infusion company forms	Home delivery
Clofazimine PO	Investigational	Drug company portal and research pharmacy protocol	Clinic pick up (home delivery may be possible)
Ethambutol PO	Community	Routine prescribing	Pharmacy pick up or home deliver
Fluoroquinolones PO	Community	Routine prescribing	Pharmacy pick up or home deliver
Imipenem-cilastatin IV	Home infusion or infusion center	Home infusion company forms	Home delivery
Macrolides PO	Community	Routine prescribing	Pharmacy pick up or home deliver
Omadacycline PO	Community or specialty	Routine prescribing	Pharmacy pick up or home deliver
Oxazolidinones PO	Community or specialty	Routine prescribing	Pharmacy pick up or home deliver
Rifamycins PO	Community	Routine prescribing	Pharmacy pick up or home deliver
Trimethoprim-sulfamethoxazole PO	Community	Routine prescribing	Pharmacy pick up or home deliver
Tetracyclines PO	Community	Routine prescribing	Pharmacy pick up or home deliver
Tigecycline IV	Home infusion or infusion center	Home infusion company forms	Home delivery

Cimino et al OFID 2024, ofae128

Amikacin Liposomal Inhaled Prescribing

ARIKAYCE Prescription

Page 1 of 4

Fax: (800) 604-6027 or email: enrollment@inlightensupport.com

To prevent delays, please:
1. Complete all required fields (marked with an asterisk) on pages 1 and 3
2. Include scanned copies of both sides of the patient's pharmacy insurance card(s)

ARIKAYCE® (amikacin liposome inhalation suspension) 590 mg/8.4 mL
Limited Population

inLighten® Patient Support

HEALTHCARE PROFESSIONAL & PRESCRIPTION INFORMATION

Patient Information:
*Patient First Name: *Patient Last Name:
*DOB: *Gender: ☐ Male ☐ Female ☐ Non-Binary ☐ Unknown
*Physical Address (no PO boxes):
*Physical City: *Physical State: *Physical ZIP: *Mobile Phone:

Prescriber Information:
*Prescriber First Name: *Prescriber Last Name:
*Practice Name: Specialty:
*Address: *City: *State: *ZIP:
*Phone: Extension Line: *Fax: *NPI #:
Office Contact Name: Office Contact Phone:
Office Contact Email: Best Time to Contact Office: ☐ AM ☐ PM

This **Prescription does not need** to be sent to a pharmacy because it was already sent directly to a:
☐ SP checked below ☐ VA pharmacy ☐ 340B entity

ARIKAYCE is fulfilled by 3 in-network pharmacies. Check box below to indicate preference. ☐ No Preference
☐ Amber Specialty Pharmacy ☐ PANTHERx RARE Pharmacy ☐ VytlOne Specialty Pharmacy

Current medications:
Known drug allergies:

Official Prescription Information

Product: ARIKAYCE® (amikacin liposome inhalation suspension)
Quantity: 28-Day Supply: 28-Vial Pack (28 Vials of Medication, 4 Aerosol Heads, and 1 Handset) (First shipment includes Lamira® system)
Dosing Info: Once-daily 590 mg/8.4 mL
*Number of refills:

New York prescribers, please submit prescription on an original NY State prescription blank. The prescriber is to comply with his or her state-specific form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to the prescriber. ***Substitution permitted?** ☐ Yes ☐ No

Prescriber Certification

I certify that the above therapy is medically necessary, and that the information provided is accurate to the best of my knowledge. By submitting this form, I certify that I am the prescriber who has prescribed ARIKAYCE to the previously identified patient, that the patient authorized the disclosure of their personal health information to Insmed, that I provided the patient with a description of the *inLighten® Patient Support* program, and that the patient has given permission to be contacted by Insmed regarding the *inLighten Patient Support* program. I authorize the *inLighten Patient Support* program to act on my behalf for the purposes of transmitting this prescription to the appropriate pharmacy.

Prescriber Signature *Date
No stamped or electronic signatures accepted

Special Instructions
☐ Pre-treatment with inhaled bronchodilator due to history of hyperreactive airway disease

Please see Indication and Important Safety Information for ARIKAYCE, including Boxed Warning, on page 2 and accompanying full Prescribing Information.

Questions? Phone: 833-LIGHT-00 (833-544-4800)

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- Provider fill out page 1 – this is the Rx
- Send to inLIGHTen → sends to 1 of 3 specialty pharmacies

Patient Support Program Enrollment Form

Page 3 of 4

Fax: (800) 604-6027 or email: enrollment@inlightensupport.com

To prevent delays, please:
1. Complete all required fields (marked with an asterisk) on pages 1 and 3
2. Include scanned copies of both sides of the patient's pharmacy insurance card(s)

ARIKAYCE® (amikacin liposome inhalation suspension) 590 mg/8.4 mL
Limited Population

inLighten® Patient Support

PATIENT INFORMATION

*Patient First Name: *Patient Last Name: *MI:
*DOB: *Gender: ☐ Male ☐ Female ☐ Non-Binary ☐ Unknown
*Physical Address (no PO boxes):
*Physical City: *Physical State: *Physical ZIP:
*Mailing Address: ☐ Same as Physical Address
*Mailing City: *Mailing State: *Mailing ZIP:
*Mobile Phone: Home Phone: Patient Email:
Preferred Time to Contact: ☐ Morning ☐ Afternoon ☐ Evening
Preferred Contact Language: ☐ English ☐ Spanish ☐ Other:
Authorized Alternate Contact (or parent/guardian) First Name: Last Name:
Alternate Contact Phone: Relationship to Patient:

Authorization for Use and Disclosure of My Health Information: I have read and agree to the Authorization for Use and Disclosure of My Health Information on page 4. By signing below, I authorize the disclosure of my PHI to the *inLighten Patient Support* program as described in the Authorization for Use and Disclosure of My Health Information on page 4.

***Patient Signature 1** ***Date**
PATIENT / LEGAL REPRESENTATIVE

Patient Support Program Enrollment and Data Collection Consent: I have read and agree to the Patient Support Program Enrollment and Data Collection Consent on page 4. By signing below, I agree to enroll in the *inLighten Patient Support* program and consent to processing of my Health Information as described in the Patient Support Program Enrollment and Data Collection Consent on page 4.

***Patient Signature 2** ***Date**
PATIENT / LEGAL REPRESENTATIVE

If signed by legal representative:
Printed name: Relationship to patient:

Prescription Insurance Information (Please Fax a Copy of Insurance Card)

Primary Pharmacy Insurance:
*Prescription Coverage Plan Name:
Beneficiary/Cardholder: Relationship to Cardholder:
*Primary Insurance ID #: *Group #:
*BIN: *PCN: *Phone:
*Primary Rx Plan Type: ☐ Private/Commercial ☐ Medicare Advantage ☐ Medicare Part D ☐ Medicaid ☐ TRICARE ☐ Other

Secondary Pharmacy Insurance:
Secondary Prescription Coverage Plan Name:
Beneficiary/Cardholder: Relationship to Cardholder:
Secondary Insurance ID #: Secondary Group #:
Secondary BIN: Secondary PCN: Secondary Phone:
Secondary Rx Plan Type: ☐ Private/Commercial ☐ Medicare Advantage ☐ Medicare Part D ☐ Medicaid ☐ TRICARE ☐ Other

Patient Does Not Have Insurance ☐

Please see Indication and Important Safety Information for ARIKAYCE, including Boxed Warning, on page 2 and accompanying full Prescribing Information.

Questions? Phone: 833-LIGHT-00 (833-544-4800)

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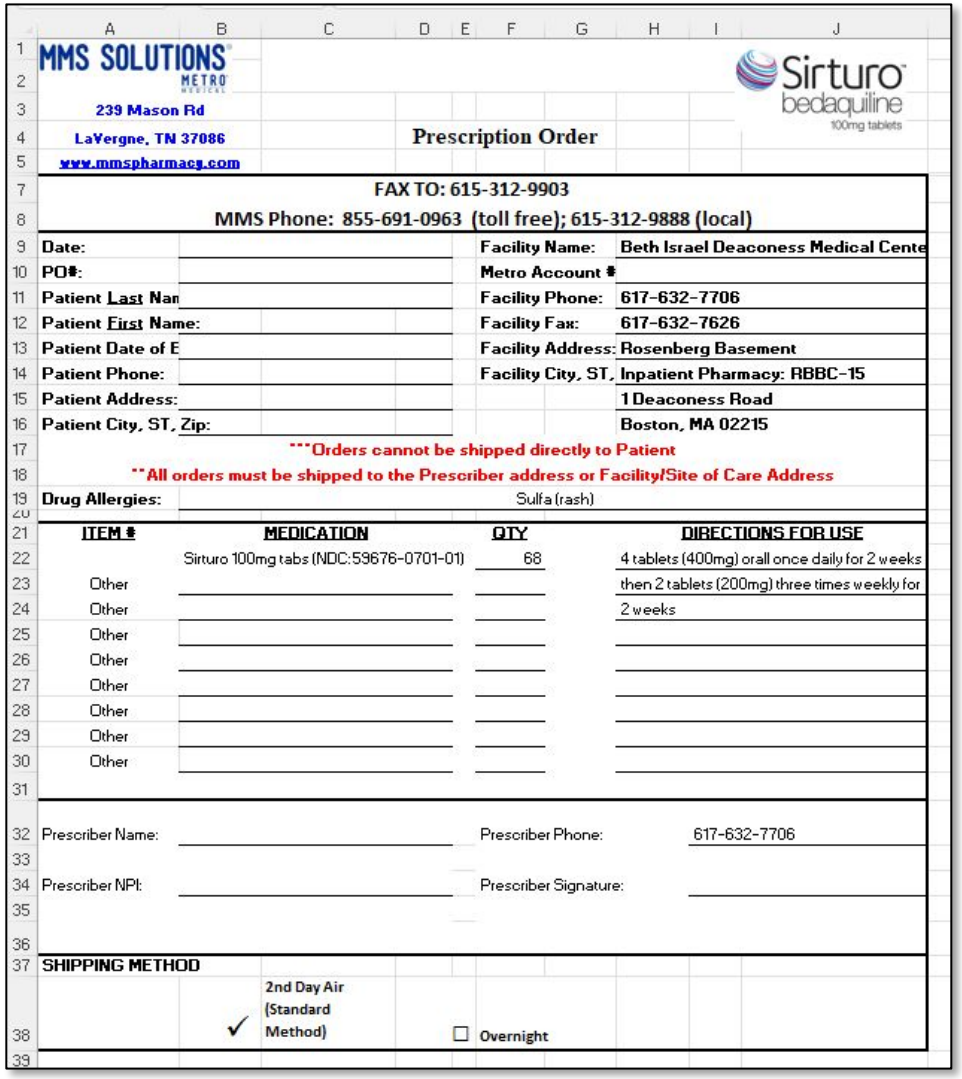
- Patient signs page 3
- Authorizes RN to go to patient's home for in-house teaching with 1st delivery

https://www.arikaycehcp.com/ Accessed 2/1/26

Bedaquiline Prescribing



MMS SOLUTIONS METRO

239 Mason Rd
LaVergne, TN 37086
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:	Beth Israel Deaconess Medical Cente
PO#:		Metro Account #	
Patient Last Nam		Facility Phone:	617-632-7706
Patient First Name:		Facility Fax:	617-632-7626
Patient Date of B		Facility Address:	Rosenberg Basement
Patient Phone:		Facility City, ST,	Inpatient Pharmacy: RBBC-15
Patient Address:			1 Deaconess Road
Patient City, ST, Zip:			Boston, MA 02215

***Orders cannot be shipped directly to Patient
**All orders must be shipped to the Prescriber address or Facility/Site of Care Address

Drug Allergies: Sulfa (rash)

ITEM #	MEDICATION	QTY	DIRECTIONS FOR USE
	Sirturo 100mg tabs (NDC:59676-0701-01)	68	4 tablets (400mg) orall once daily for 2 weeks
Other			then 2 tablets (200mg) three times weekly for
Other			2 weeks
Other			
Other			
Other			
Other			
Other			
Other			

Prescriber Name: Prescriber Phone: 617-632-7706

Prescriber NPI: Prescriber Signature:

SHIPPING METHOD

✓ 2nd Day Air (Standard Method) ☐ Overnight

- Order form is an excel sheet/pdf
- Rx must be faxed or emailed with insurance info and a patient intake form to MMS Solutions
- Only available from one specialty pharmacy
- Can only be delivered to an office/clinic – CANNOT be delivered to the patient's home

- Helpful hints:
  - Save one copy as the loading dose
  - Save a second copy as the maintenance dose with refills
  - Pre-fill with the clinic/inpatient pharmacy address
  - Keep a proactive file of patient names, MRN, order dates, and next due dates to avoid lapses

Personal resources; Cimino et al OFID 2024, ofae128

Clofazimine Prescribing

1. **Clinical trial via institution**
   - Trail eligibility: https://clinicaltrials.gov/study/NCT04334070
   - Enroll with Novartis
   - Obtain IRB approval – include all potentially prescribing attendings
   - Obtain patient consent – clinical trial enrollment

2. **Single patient IND (SPIND)**
   - Obtain IRB approval
   - Obtain patient consent – investigational drug use
   - Submit to FDA

- Medication requested through Novartis portal
  - Delivered to research pharmacy
  - Patient picks up medication from research pharmacy/clinic
- Keep a proactive file of patient names, MRN, order dates, and next due dates to avoid lapses

Cimino et al OFID 2024, ofae128 ; https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/expanded-access-clofazimine Accessed 2/1/26

Other Odds & Ends

- Consulting colleagues: pulmonary & audiology
- Prior authorization requests
- Financial assistance programs
  - The Assistance Fund
  - HealthWell Foundation
- Follow-up appointments
  - While on therapy
  - When completed therapy

https://tafcares.org/; https://www.healthwellfoundation.org/ Accessed: 2/1/26

Susceptibility Lab References

National Jewish Health:

- https://www.nationaljewish.org/for-professionals/diagnostic-testing/advanced-diagnostic-laboratories/phenotypic-susceptibilities-antimicrobial-susceptibility-testing

University of Texas at Tyler:

- https://www.uttyler.edu/academics/colleges-schools/medicine/departments/center-for-biomedical-research/mycobacteria-and-nocardia-laboratory/

Mayo Clinic:

- Rapid Growers: https://www.mayocliniclabs.com/test-catalog/overview/81601
  Slow Growers: https://www.mayocliniclabs.com/test-catalog/overview/34805

Therapeutic Drug Monitoring References:

National Jewish Health:

- https://www.nationaljewish.org/for-professionals/diagnostic-testing/advanced-diagnostic-laboratories/search-for-tests?searchText=mycobacteria&availability=both

University of Florida:

- https://idpl.pharmacy.ufl.edu/forms-and-catalog/

Obsessed with Abscessus (and other Non-Tuberculous Mycobacteria)

Monica V. Mahoney, PharmD

March 2026

Beth Israel Lahey Health
Beth Israel Deaconess Medical Center