

## Antimicrobial Medication Guide for Pediatric Cystic Fibrosis Patients

### Oral Antibiotics

\*See NTM section for organism-specific dosing for mycobacterial infections.

Drug	Dosing	Maximum single dose	Available preparations	Other considerations
Amoxicillin/ clavulanic acid	15 mg/kg TID (standard dose) or 45 mg/kg BID (high dose)	2000 mg	250mg, 500mg*, 875mg tablets* 200mg, 400mg chewables XR tablets 1000mg 200mg/5mL, 250mg/5mL, 400 mg/5mL suspension* ES suspension: 600 mg/5mL* (less clavulanic acid)	600mg/5mL for high dose only
Cefpodoxime	5 mg/kg BID	200 mg	100mg, 200mg tablets 50mg/5mL, 100mg/5mL suspension	
Cefuroxime axetil	10-15 mg/kg BID (suspension) or 250-500mg BID (tablet)	500 mg	125mg, 250mg*, 500mg tablets* 125mg/5mL, 250mg/5mL suspension	Suspension and tablet are <i>not</i> interchangeable Suspension must be administered with food
Cephalexin	25 mg/kg QID	1000 mg	250*, 500mg*, 750mg capsules 250mg, 500mg tablets 125mg/5mL, 250mg/5mL suspension*	
Ciprofloxacin	20 mg/kg BID	1000 mg	250mg*, 500mg*, 750mg tablets 250mg/5mL, 500mg/5mL suspension* 500mg, 1000mg XR tablets	Do not give oral suspension via G-tube or NG tube Hold tube feeds 1 hr before and 2 hrs after administration
Clindamycin	40 mg/kg/day divided TID	600 mg	75mg, 150mg*, 300mg capsules 75mg/5mL suspension*	
Dicloxacillin <sup>2</sup>	6.25-12.5mg/kg QID	500 mg	250mg*, 500mg capsules	
Doxycycline	1-2 mg/kg BID	100 mg	50mg, 100mg capsules* 25mg/5mL suspension*	Avoid within 2hrs of antacids, Ca, Fe, Mg, and cholestyramine
Levofloxacin	< 5 yo: 10 mg/kg BID ≥ 5 yo: 10 mg/kg daily	750 mg	250mg*, 500mg*, 750mg tablets* 25mg/mL solution*	Suspension should be administered 1 hr before or 2hrs after eating
Linezolid	< 12 yo: 10 mg/kg Q8 ≥ 12yo: 10 mg/kg Q12	600 mg	600mg tablet* 100mg/5mL suspension*	Consider continuing q8 hour dosing if > 12 yr but less than 45 kg
Minocycline	4 mg/kg once, then 2 mg/kg Q12	100 mg	50mg*, 75mg, 100mg capsules*	Avoid within 2hrs of antacids, Ca, Fe, Mg, and cholestyramine
Sulfamethoxazole/ Trimethoprim (SMX/TMP)	15-20 mg TMP/kg/day divided Q8-Q12	320mg TMP	80 mg TMP+400 mg SMX tab*, 160 mg TMP+800 mg SMX DS tab* 40mg TMP+200mg SMX/5mL suspension*	
Tedizolid <sup>^</sup>	200 mg once daily*	200 mg	200 mg tablet	

<sup>^</sup>Requires approval by ID consult or Pediatric ID Stewardship for inpatient use

\*Indicates UNC formulary item

\* Adult dosing (pediatric dosing not available): for patients <40kg, consult pediatric pulmonary and/or ID/ASP pharmacist for dosing

## Intravenous Antibiotics

\*See NTM section for organism-specific dosing for mycobacterial infections.

- Double-cover Pseudomonas, but do not combine anti-pseudomonal beta lactams, as they can be antagonistic
- **Initial doses for Tobramycin and Amikacin should be based on patients' previous doses within the last year;** see pharmacist consult note for past dosing information
- If patient has not received aminoglycosides in the past or since starting a CFTR modulator, use the following guide for dosing

Consider alternative dosing regimens for patients with lack of response to antibiotic expected to have activity – consult service pharmacist for appropriateness and availability

Drug	Traditional Dosing	Alternative Dosing	Maximum single dose	Other considerations
Aztreonam <sup>1,2*</sup>	50-75 mg/kg Q6	Extended: 50-75 mg/kg (infused over 4 hours) <sup>27</sup>	8-12 g/day	
Cefepime <sup>1,3*</sup>	50 mg/kg Q8	Intermittent: 50 mg/kg Q6 Extended: 50 mg/kg Q8 (infused over 4 hours)	2000 mg	
Ceftaroline <sup>4*</sup>	≤33 kg: 15 mg/kg Q8 > 33 kg (adolescent/adult): 600 mg Q8		600mg	
Ceftazidime <sup>1,3*</sup>	200-400 mg/kg/day divided Q6-8	Extended: infused over 4 hours <sup>27</sup> Continuous: 200 mg/kg/day <sup>27,28</sup>	8-12 g/day	
Ceftazidime/ avibactam <sup>*^</sup>	50 mg/kg ceftazidime infused over 2h Q8		2.5 g (2g ceftazidime/500 mg avibactam)	Only for MDR Gram negative pathogens; susceptibility must be documented prior to use
Ceftolozane/ tazobactam <sup>5*^</sup>	40-50 mg/kg ceftolozane infused over 3h Q8		3 g (2g ceftolozane/1 g tazobactam)	Only for MDR Gram negative pathogens; susceptibility must be documented prior to use
Cefiderocol <sup>*^</sup>	60mg/kg infused over 3h Q6-8		2000mg	Only for MDR Gram negative pathogens; susceptibility must be documented prior to use More frequent dosing recommended for patients with augmented clearance >120mL/min
Cefuroxime <sup>*</sup>	75 mg/kg Q8		1500 mg	
Ciprofloxacin <sup>1,6*</sup>	10 mg/kg Q8		400 mg	
Clindamycin <sup>*</sup>	40 mg/kg/day divided Q8		2700 mg/day	
Imipenem/ Cilastatin <sup>1,2*</sup>	25 mg/kg Q6	Extended: infused over 4 hours <sup>27</sup>	1000 mg	
Imipenem/cilastatin/ relebactam <sup>*^</sup>	25 mg imipenem/kg Q6		1000 mg imipenem (1g imipenem / 0.5g relebactam)	Only for MDR Gram negative pathogens; susceptibility must be documented prior to use Dose based on the imipenem component
Levofloxacin <sup>1,6*</sup>	< 5 yo: 10 mg/kg Q12 ≥ 5 yo: 10 mg/kg daily		750 mg	
Linezolid <sup>*</sup>	< 12 yo: 10 mg/kg Q8 ≥ 12 yo: 10 mg/kg Q12		600 mg	Consider continuing Q8 hour dosing if > 12 yr but less than 45 kg
Meropenem <sup>1,2*</sup>	40 mg/kg Q8	Extended: 40 mg/kg	2000 mg	

		q8h (infused over 3 hours)		
Nafcillin <sup>1*</sup>	50 mg/kg Q6	Continuous: 200mg/kg/day	2000 mg; 12g/day	
Piperacillin/ Tazobactam <sup>1,3,25*</sup>	100 mg/kg Q6	Extended: 100 mg/kg Q6 (infused over 3 hours) Continuous: 300-400 mg/kg/day	4000mg piperacillin (4g piperacillin/0.5g tazobactam)	All doses are based on piperacillin component
Tedizolid <sup>^</sup>	200mg Q24		200mg	
Tobramycin* (extended interval)	10 mg/kg Q24 or previous total daily dose			Draw levels at 2 and 8 hours after 2 <sup>nd</sup> dose started
Vancomycin <sup>11,22*</sup>	15-20 mg/kg Q6-8	Continuous: 55-60 mg/kg/day	2000 mg (intermittent)	Intermittent: Draw trough prior to 4 <sup>th</sup> dose; goal 15-20 mg/L Continuous: Draw random level after 24 hours; goal 20-25 mg/L

<sup>^</sup>Requires approval by ID consult or Pediatric ID Stewardship for inpatient use

\*Indicates UNC formulary item

\*Adult dosing (pediatric dosing not available): for patients <40kg, consult pediatric pulmonary and/or ID/ASP pharmacist for dosing

## **Nontuberculous Mycobacterium – Antibiotics**

*\*Typically start only one drug each day to assess for adverse effects from each drug*

### **Recommended Initial Regimen for *Mycobacterium abscessus*:**

1. Azithromycin
2. Amikacin
3. Cefoxitin, imipenem/cilastatin, tigecycline, or linezolid

### **Recommended Initial Regimen for *Mycobacterium avium complex (MAC)*:**

1. Azithromycin
2. Ethambutol
3. Rifampin

<b>Drug</b>	<b>Dosing</b>	<b>Maximum dose</b>	<b>Other considerations</b>
Amikacin <sup>13</sup> (IV)*	10-15 mg/kg IV daily	1500mg/dose	Draw 2 and 8 hour levels with 2 <sup>nd</sup> or 3 <sup>rd</sup> dose; goal peak = 20-30 mg/L Audiology consult required at initiation Thrice weekly dosing can be considered for unique patient cases
Amikacin <sup>21</sup> (IV solution for inhalation)*	250-500 mg inhaled daily-BID	500mg/dose	
Arikayce <sup>®</sup> ^	590mg inhaled daily	590mg	
Azithromycin <sup>13,21</sup>	10-12 mg/kg PO daily	500mg/dose	Consider obtaining drug levels at 2 and 6 hours
Bedaquiline <sup>24</sup> ^	Weeks 1-2: 400 mg PO daily Weeks 3 and onward: 200 mg TIW <u>Weight 20-32 kg:</u> 200 mg PO daily x 2 weeks, then 100 mg TIW <u>Weight &gt; 32 kg:</u> 400 mg PO daily x 2 weeks, then 200 mg TIW		Reserve for refractory NTM cases
Cefoxitin <sup>13,21</sup> *	Children: 50mg/kg IV TID Adults: 200 mg/kg/day IV divided TID	12g/day	
Clarithromycin <sup>13,21</sup> *	7.5 mg/kg PO BID	500mg/dose	Consider obtaining drug levels at 2 and 6 hours
Clofazimine^	50-100 mg PO daily	150 mg	Reserve for refractory NTM cases (requires an IRB and IND)
Ethambutol <sup>21</sup> *	15 mg/kg PO daily		Consider obtaining drug levels at 2 and 6 hours
Eravacycline <sup>^*</sup>	1 mg/kg IV BID <sup>+</sup>	Unknown	Replaced tigecycline on UNC formulary; consult ID if needing to use advanced tetracycline derivative
Imipenem/cilastatin <sup>13,21</sup> (IV)*	15-20 mg/kg IV BID	1000mg/dose	
Linezolid <sup>13,21</sup> (PO, IV)*	< 12 yo: 10 mg/kg Q8 ≥ 12 yo: 10 mg/kg daily-BID	600mg	1:1 PO to IV conversion Consider concomitant vitamin B6
Minocycline <sup>21</sup> *	Children: 2 mg/kg PO daily Adults: 100mg PO BID	200mg/dose	
Moxifloxacin <sup>21</sup> ^	7.5-10 mg/kg PO daily	400mg/dose	
Omadacycline^	300 mg PO daily; consider loading dose of 450 mg daily x2 days	300 mg daily	Consult ID if needing to use advanced tetracycline derivative
Rifabutin <sup>21</sup> *	5-10 mg/kg daily	150-300mg daily	Refer to NTM guidelines for dose adjustments with strong CYP3A4 inhibitors or inducers
Rifampin <sup>21</sup> *	10-20 mg/kg PO daily	< 50 kg: 450mg/day > 50 kg: 600mg/day	Significant potential for drug interactions Consider obtaining drug levels at 2 and 6 hours
SMX/TMP <sup>21</sup> (PO, IV)*	10-20 mg TMP/kg BID	240mg TMP/dose	Consider fluid status of patient when utilizing IV formulation
Tedizolid^ (PO, IV)	200 mg once daily	PO/IV: 200 mg	
Tigecycline <sup>13,14,21</sup> ^	Eravacycline has replaced tigecycline on UNC formulary; consult ID if needing to use advanced tetracycline derivative		

^Requires approval by ID consult or Pediatric ID Stewardship for inpatient use

\*Indicates UNC formulary item

+ Adult dosing (pediatric dosing not available)

**Antifungals**

\*These have lots of drug interactions!

\*Consult pharmacy for assistance transitioning between dosage forms.

Drug	Dosing	Maximum initial single dose	Available oral preparations
Fluconazole	12 mg/kg x 1, then 6-12 mg/kg IV/PO Q24	800mg	50mg*, 100mg*, 150mg*, 200 mg tablets* 40mg/mL suspension*
Itraconazole	5 mg/kg PO Q12	200 mg	100mg capsules* 50mg/5mL solution*
Voriconazole (PO/IV)	<u>Loading doses:</u> < 12 yo OR 12-14 yo AND < 50 kg: 9 mg/kg IV Q12 x 2 doses ≥ 12 yo AND ≥ 50kg: 6 mg/kg IV Q12 x 2 doses <u>Maintenance doses:</u> < 12 yo: 9 mg/kg IV Q12 ≥ 12 yo AND ≥ 50kg: 4 mg/kg IV Q12	350 mg	50mg*, 200mg tablets* 40mg/mL suspension*
Posaconazole <sup>20</sup>	<u>Immediate Release Suspension:</u> 18-24 mg/kg/day divided QID  <u>Delayed Release Suspension (non-formulary):</u> <i>Contact pharmacist for dosing</i>  <u>Tablets (preferred):</u> <13 yo: 10-15 mg/kg/day divided BID ≥ 13 yo: 6-8 mg/kg BID x 1 day, then 6-8 mg/kg daily <u>IV:</u> 10-12 mg/kg BID x 1 day, then 10-12 mg/kg daily	Suspension: 400mg  Tablets: 300mg	40mg/mL suspension* 100mg DR tablet* - tablets can be crushed Suspension and tablets are not 1:1  IR suspension requires administration with high fat food or acidic carbonated beverage
Isavuconazonium sulfate, prodrug (Isavuconazole)	<u>10mg isavuconazonium sulfate/kg/DOSE IV/PO q8h x6 doses followed by 10mg isavuconazonium sulfate/kg/DOSE q24h</u>	372mg <u>isavuconazonium sulfate</u>	186mg isavuconazonium sulfate capsule = 100mg isavuconazole

Considerations for antifungal therapies:

	<b>Fluconazole</b>	<b>Itraconazole</b>	<b>Posaconazole</b>	<b>Voriconazole</b>	<b>Isavuconazole</b>
<b>Renally Dose Adjust</b>	Yes	No	No	No; caution if long-term use of IV if CrCl<50 due to risk of cyclodextrin accumulation	No
<b>Drug Interactions</b>	Significant drug-drug interactions exist. Consult with pharmacist.				
<b>Meals</b>	Administer without regard to meals	Capsules: food increases absorption  Solution: food decreases absorption. Take on empty stomach	Suspension: best absorption with a high-fat meal and acidic beverage	Food may decrease voriconazole absorption  Give 1 hour before or 1 hour after a meal	Administer without regard to meals
<b>Steady State / When to Order Therapeutic Drug Monitoring (TDM)</b>	Day 5-7 of therapy; no TDM indicated	Day 5-7 of therapy (consider repeat level at 14 days if not at goal)	Day 5-7 of therapy (PO tab / IV)  Day 7-10 of therapy (PO suspension)	Day 5 – 7 of therapy in the absence of a loading dose	Not routinely indicated; consult ID Day 5-7 of therapy (consider repeat at 21 days if subtherapeutic)  Day 10-14 of therapy if no loading dose
<b>Goal Trough Concentrations (30 min prior to dose)</b>	N/A	Prophylaxis: Itraconazole + hydroxyitraconazole > 0.5 mcg/mL  Treatment: Itraconazole + hydroxyitraconazole > 1 and < 10 mcg/mL	Prophylaxis: > 700 ng/mL  Treatment: > 1000 ng/mL	1 – 5.5 mcg/mL	Not routinely indicated; consult ID  1-5 mcg/mL
<b>Recommend Adjustments</b>	N/A	< 1 mcg/mL – increase dose by 50%  > 10 mcg/mL – decrease dose by 25-50%	Increase dose by 50% if less than goal trough  Consider decrease in dose by 25-50% if trough >3750 ng/mL	< 1 mcg/mL – increase dose by 50%  ≥ 5.5 mcg/mL – decrease dose by 25-50% (may consider alternative agents if clinically significant toxicities)	No set dose adjustments; consult with ID

## **Pharmacokinetic Monitoring for Aminoglycosides and Vancomycin**

Timed amikacin and tobramycin levels should be drawn at 2 hours and 8 hours after the 2<sup>nd</sup> (tobramycin) or 3<sup>rd</sup> (amikacin) dose is started. The service pharmacist will use these to extrapolate peak and trough concentrations.

Desired parameters are as follows:

**Tobramycin (extended interval):** trough < 1 mcg/mL; extrapolated peak 20-30 mcg/mL

**Amikacin (for *Mycobacterium abscessus*):**

Traditional daily dosing: trough < 5 mcg/mL; extrapolated peak 20-30 mcg/mL

Thrice weekly dosing: trough <5 mcg/mL, extrapolated peak 65-80 mcg/mL

For vancomycin, the timing of the level depends on the dosing strategy utilized:

**Vancomycin (intermittent):** Obtain trough immediately before the fourth dose is due

Goal trough: 15-20 mcg/mL

**Vancomycin (continuous):** Obtain random level 24 hours after initiation of therapy

Goal random: 20-25 mcg/mL

BUN/SCr should be obtained **twice** weekly while on these medications. Ensure adequate hydration and discontinue all other nephrotoxic drugs (including **ibuprofen** at any dose). Patients should also receive an annual hearing evaluation to evaluate for ototoxicity from aminoglycosides.

If on vancomycin + aminoglycoside or other nephrotoxic medication, consider obtaining BUN/SCr more frequently per the UNC AKI monitoring protocol.

## **Nebulized Medications**

*Airway clearance:*

**Albuterol:** 2.5-5 mg nebulized BID-QID or 2-4 puffs inhaled BID-QID

**Hypertonic Saline:** 4mL nebulized BID-QID

3%, 7%, and 10% commercially available

Can make 5%: 2mL 3% sodium chloride + 2mL 7% sodium chloride

Discourage other combinations due to potential for mixing errors

**Dornase Alfa (Pulmozyme®):** 2.5mg ampule nebulized daily-BID

*Antimicrobials:*

<b>Drug</b>	<b>Dosing</b>	<b>Other considerations</b>
Amikacin, traditional (IV for inhalation) <sup>21</sup>	250-500 mg inhaled daily-BID	
Amikacin, liposomal (Arikayce®)	590mg/8.4mL nebulized daily	Must be nebulized with Lamira® nebulizer For inpatient use, patient must supply medication, nebulizer, and cleaning supplies
Aztreonam	75mg nebulized TID	Must be nebulized with Altera® nebulizer For inpatient use, patient must supply medication, nebulizer, and cleaning supplies
Colistin	< 6 years: 75 mg nebulized BID ≥ 6 years: 150 mg nebulized BID	
Imipenem/cilastatin	250mg nebulized BID	Restricted to outpatient refractory <i>M. abscessus</i> cases only with clinic pharmacist input
Tobramycin	300mg nebulized BID <i>or</i> 112mg inhaled BID (TOBI Podhaler)	For inpatient use of TOBI Podhaler, patient must supply medication and Podhaler device
Vancomycin	4 mg/kg (max 250mg) nebulized BID	Restricted to outpatient MRSA management only with clinic pharmacist input



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