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# UT Southwestern Medical Center

## Cystic Fibrosis Clinic

5939 Harry Hines Blvd.  
POB II, Suite 334  
Dallas, TX 75390-9258

**Tel:** 214-645-0599  
**Fax:** 214-645-3297  
**Web:** [www.utsouthwestern.edu](http://www.utsouthwestern.edu)

## Facsimile Cover Sheet

<b>To</b>	OPTUMRX	<b>From</b>	Karen Lowe, PA-C
<b>Dept</b>	ATTN: Second level APPEALS	<b>Tel</b>	214-645-0599
<b>Tel</b>		<b>Fax</b>	214-645-3297
<b>Fax</b>	801-938-2100	<b>Date</b>	Tuesday, May 4, 2021 11:59:18 AM
<b>Pages</b>	73		

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### Comments:

Please see attached URGENT second-level appeal request for case number: R1061755002. Please call with any questions. Please fax determination to 214-645-3297.

Thank you,

Karen Lowe, PA-C

**Confidential Information:** If you have any problems receiving this telecopy, please call 214-645-0599. Unless otherwise indicated, the information contained in this fax is privileged and confidential, intended for use by the intended recipient named above. If the reader of this message is not the intended recipient (or the employee or agent responsible for delivering it to the intended recipient), you are hereby notified that any dissemination, distribution or copying of this communication is prohibited. If you have this communication in error, please notify us immediately and return the original message to us at the address above at our expense.

**UT Southwestern**  
Medical Center**Cystic Fibrosis Clinic**

Clinic Phone: 214-645-0599

May 3, 2021

Re: Pam Simpson  
DOB: 11/10/1976  
Member ID: 904030334-01  
Group #: 192086

Dear Sir/Madam:

Ms. Pam Simpson is a patient whom I treat in the cystic fibrosis clinic in collaboration with National Jewish Health for her multidrug-resistant pulmonary non-tuberculous mycobacterium (NTM) infections: *Mycobacterium abscessus* group and *Mycobacterium avium* complex. Ms. Simpson has been on both intravenous (IV) and oral antibiotic therapy since February 2019. She continues to have positive sputum cultures for *Mycobacterium abscessus* though she has not grown *Mycobacterium avium* in her sputum since April 2019. She most recently had a positive acid fast bacilli (AFB) culture, smear negative which is still pending identification from 3/23/2021. I am writing this letter to request an urgent benefit appeal for Nuzyra (omadacycline) 300 mg once daily. Ms. Simpson's current NTM therapy includes the following regimen: Amikacin 500 mg nebulized every Monday, Wednesday, Friday; Azithromycin 250 mg every other day (dose was lowered due to hearing loss); Ethambutol 400 mg daily (reduced dose due to neurologic side effects); Clofazimine 50 mg daily, Sirturo (bedaquiline) 100 mg every Monday, Wednesday, Friday; and Cefoxitin 2 g IV every 8 hours.

I am requesting approval for Nuzyra (omadacycline) to replace Ms. Simpson's Cefoxitin as she has failed to clear the M abscessus from her sputum culture on her current regimen. I strongly believe switching Cefoxitin to Nuzyra (omadacycline) 300mg once daily will not only help her clear the M abscessus, ease her treatment burden but will also reduce the overall healthcare costs associated with home IV antibiotic therapies. Ms. Simpson has previously tried and failed the following antibiotics Arikayce (2/12/2019 – 2/25/2019), Rifampin (2/2019 – 4/2019), Rifabutin (4/2019 – 12/2019), Imipenem (2/2019 – 7/2019), Avycaz (3/2019 – 6/2019). Patient reported she had also previously tried Tedizolid but was unable to tolerate it due to side effects.

Nuzyra (omadacycline), was approved by the US Food and Drug Administration (FDA) in 2018 for community acquired pneumonia and acute bacterial skin and skin structure infections. I have included 2 case series reports in support of this urgent benefit appeal. "Preliminary, Real-World, Multicenter Experience with Omadacycline for *Mycobacterium abscessus* Infections" and "Omadacycline for the Treatment of *Mycobacterium abscessus* Disease: A Case Series [1, 2]." There have been recent studies showing potent *in vitro* activity of Nuzyra (omadacycline) against drug-resistant M. abscessus complex clinical isolates [1, 3]. Patients in both case series received the maintenance oral dose of Nuzyra (omadacycline) 300 mg once daily and the majority seemed to tolerate it well and clinical success occurred in 75% of patients in one of the studies [1, 4]. Based upon this along with the prescribing guidelines, I would not recommend decreasing the dose to 150 mg once daily and risk having her develop further antibiotic resistance.

PAM L SIMPSON (MR# 93071847)

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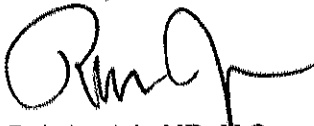
I am attaching a copy of the antimicrobial susceptibilities from 11/03/2020 below (Table 1)

	Mycobacterium abscessus group
	Not Specified
Cefoxitin	128 mcg/mL Resistant
Ciprofloxacin	>4 mcg/mL Resistant
Clarithromycin	>16 mcg/mL Resistant (C)
Doxycycline	>16 mcg/mL Resistant
Imipenem	64 mcg/mL Resistant
Linezolid	32 mcg/mL Resistant
Minocycline	>8 mcg/mL Resistant
Moxifloxacin	>8 mcg/mL Resistant
Tigecycline	0.5 mcg/mL
Tobramycin	>16 mcg/mL Resistant
Trimethoprim + Sulfamethoxazole	>8/152 mcg/mL Resistant

Table 1. Antimicrobial susceptibility testing of *Mycobacterium abscessus* isolated on sputum culture for patient in November 2020.

As you can see in review of Ms. Simpson's medical history and documentation provided, she has multi-drug resistant *M. abscessus* infection and has been on oral and IV antibiotic therapy for over two years without clearing the *M. abscessus*. She desperately needs an alternative treatment regimen and after careful review of the literature along with my previous experience in conjunction with the UT Southwestern Infectious Disease physicians, I feel strongly that the use of Nuzyra (omadacycline) 300 mg once daily would greatly benefit Ms. Simpson's health. I would like you to consider approving Nuzyra (omadacycline) 300 mg once daily for Ms. Simpson.

Sincerely,



Raksha Jain MD, M.Sc.  
 Director, Adult Cystic Fibrosis Program  
 UT Southwestern Medical Center  
 5939 Harry Hines Blvd. POB 2, Suite 334  
 Dallas, TX 75390 (mail code: 9307)

#### References:

1. Pearson, J. C., Dionne, B., Richterman, A., Vidal, S. J., Weiss, Z., Velásquez, G. E., Marty, F. M., Sax, P. E., & Yawetz, S. (2020). Omadacycline for the Treatment of *Mycobacterium abscessus* Disease: A Case Series. *Open forum infectious diseases*, 7(10), ofaa415. <https://doi.org/10.1093/ofid/ofaa415>
2. Morrisette, T., Alosaimy, S., Philley, J. V., Wadle, C., Howard, C., Webb, A. J., Veve, M. P., Barger, M. L., Bouchard, J., Gore, T. W., Lagnf, A. M., Ansari, I., Mejia-Chew, C., Cohen, K. A., & Rybak, M. J. (2021). Preliminary, Real-world, Multicenter Experience With Omadacycline for *Mycobacterium abscessus* Infections. *Open forum infectious diseases*, 8(2), ofab002. <https://doi.org/10.1093/ofid/ofab002>
3. Brown-Elliott, B. A., & Wallace, R. J., Jr (2021). *In Vitro* Susceptibility Testing of Omadacycline against Nontuberculous Mycobacteria. *Antimicrobial agents and chemotherapy*, 65(3), e01947-20. <https://doi.org/10.1128/AAC.01947-20>
4. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2018/209816\\_209817lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209816_209817lbl.pdf)

Simpson, Pam L (MRN 93071847) DOB: 11/10/1976

Encounter Date: 03/23/2021

**Simpson, Pam L**

MRN: 93071847

Office Visit 3/23/2021

Provider: Jain, Raksha, MD (PULMONARY DISEASE)

Cystic Fibrosis Clinic

Primary diagnosis: Therapeutic drug monitoring

Reason for Visit: Referred by Referral, Follow-Up No

**Progress Notes**

Jain, Raksha, MD (Physician) - PULMONARY DISEASE

**CF CLINIC VISIT****DOB: 3/23/2021****PROBLEM LIST:**

1. CF dx in 2010 because of recurrent pneumonia
2. CFTR mutations F508del/T1246I - started Trikafta Dec 25, 2019
3. Pancreatic status - sufficient. Has normal elastase in 9/2017
4. Sinusitis with hx of sinus surgery last in 6/2015
5. Chronic constipation
6. CF sputum with MSSA, recent steno-trophomonas
7. M. Abscessus (previously treated and on treatment currently as well). Also MAI recently
8. Osteopenia with rib fractures
9. Numerous drug allergies including allergies to betadine
10. Hx of SVT with ablation in 2003
11. Mild airflow obstruction (baseline FEV1 80s)
12. GERD - on pepcid

**HPI**

Pam L. Simpson is a 44y/o female being seen for follow up. She has been on NTM treatment since spring of 2019 and is feeling well overall from a lung standpoint. She is no longer growing MAI, but she continues to grow abscessus. She has been getting regular audiology, ECG and lab follow up on her antibiotics, however this is been increasingly challenging during the pandemic. She saw ophthalmology for an eye exam and was told that her retinal nerve was okay but she may have a retina problem and is due to follow up.

She started Trikafta on December 25, 2019 at an adjusted dose because of her cefazolin. She was changed to full dose, but actually recently self decreased this due to side effects that she reports were largely neurologic.

She has been doing great job keeping up with her ACT's. She had been in an open label GM-CSF clinical trial for her NTM infection (in early 2020), but the study and drug were discontinued. Her current NTM regimen includes inh amikacin MWF, Azithro 250mg every other day (lowered due to hearing loss), ethambutol 1200mg every day (now lowered by patient to 400mg), cefaz 500mg every day, sirturo MWF, and iv ceftazidime. She is tolerating this regimen well and we are keeping a close watch on her QTc, hearing and labs.

We have been working on evaluating her numbness symptoms, but MRI studies have been a challenge to get through her insurance. She recently had an MRI neck which did show multilevel cervical degenerative changes most pronounced at C5-6 with slight impression on the anterior surface of the cervical cord and mild central canal narrowing.

From respiratory standpoint she is feeling great, with minimal cough or mucous production. She will have some SOB when exercising on bike, but overall feels great. No fevers, chills or night sweats. She is pleased with her PFTs today, which have overall been quite stable.

**Respiratory**

- Sputum color varies from normal yellow to brown, but not bringing as much up since starting Trikafta