



August 24, 2021

Dr. Douglas Fish
Medicaid Medical Director
NY State Department of Health
Empire State Plaza, Corning Tower
Albany, NY 12237

Dear Dr. Fish,

On behalf of the 1,600 people living with cystic fibrosis (CF) in New York and their families, we write to express concerns with the New York State Medicaid Program's coverage guidelines for airway clearance devices, which are a critical component of CF care. The current guidelines inappropriately preclude certain CF care centers—particularly those that serve adult patients and do not have a pulmonologist on site—from ordering these devices, thereby making it more difficult for patients to access them.

We offer the following comments on the current coverage guidelines, and respectfully ask that New York Medicaid revise its coverage guidelines to allow any physician or advanced practice registered nurse at a CF Foundation-accredited care center to prescribe airway clearance devices for their patients with cystic fibrosis. We are available to assist in this revision.

About cystic fibrosis and airway clearance devices

Cystic fibrosis is a life-threatening genetic disease that causes the body to produce a thick, sticky mucus that clogs the lungs and digestive system, which can lead to serious lung infections. Cystic fibrosis is both serious and progressive; lung damage caused by infection can be irreversible and have a lasting impact on length and quality of life. As a complex, multi-system disease, CF requires targeted, specialized care and treatment to address its many manifestations; among those treatments is airway clearance.

Airway clearance devices help loosen the thick, sticky mucus characteristic of the disease so that it can be cleared from the lungs by coughing or huffing. Clearing the airways is critical as it may help reduce airway obstruction, prevent lung infections, and improve lung function: a primary health indicator for CF. The CF Foundation pulmonary guidelines, which are based on the latest research, medical evidence, and consultation with experts on best practices, recommend airway clearance for all individuals with CF.¹ While there are many ways to clear the airways, the most common clearance technique – used by over three-quarters of individuals with CF – is a device known as the high-frequency chest wall oscillation vest.²

NY Medicaid's coverage guidelines for airway clearance devices

As currently written, the New York State Medicaid Program's *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Procedure Codes and Coverage Guidelines Manual* states, "All airway clearance devices (E0480, E0481, E0482, and E0483) require an order from a Physically Handicapped Children's Program (PHCP)-approved Cystic Fibrosis Center or a board-certified pulmonologist."³

It is unreasonable for airway clearance devices to be the sole purview of pulmonologists and PHCP-approved cystic fibrosis centers. Instead, physicians and advanced practice nurses at all CF Foundation-accredited care centers should be able to order these devices for their patients who need them. These clinicians not only have expertise in cystic fibrosis, but have also been properly vetted by the CF Foundation through our accreditation process (see Appendix for more information on CF care centers and the CF Foundation's accreditation process), and are therefore eminently qualified to make determinations around the use of these devices and which one is best for each patient. Clinicians with expertise in CF, and who work in CF care centers, are better positioned to make these determinations than pulmonologists outside of the care center network who do not have this expertise.

Furthermore, the Physically Handicapped Children's Program (PHCP) designation included in Medicaid's guidelines makes an unnecessary distinction between pediatric and adult CF care centers without a clinical basis. It is our understanding that the PHCP designation is only available to CF care centers that treat pediatric patients;⁴ however, the same specialized and interdisciplinary model employed by pediatric centers is also used by adult CF care centers. Therefore, if clinicians not specialized in pulmonology at PHCP-approved CF centers are eligible to prescribe airway clearance devices, this standard should likewise apply to physicians who treat adult patients living with CF.

Adult CF care centers that do not have a pulmonologist on site, and that cannot obtain the PHCP designation, are currently unable to order airway clearance devices for their patients. Instead, they are having to refer to patients to off-site pulmonologists that may lack expertise in cystic fibrosis. Patients are having to schedule another clinical visit and pay an extra co-pay: a time-intensive and financially unnecessary step that could be avoided if the guidelines were revised. We fear that this extra step could lead to delays in patient access to these devices, and in Medicaid paying unnecessary costs for the extra clinical visit.

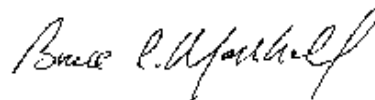
We urge New York Medicaid to revise its coverage guidelines to allow for any physician or advanced practice nurse at a CF Foundation-accredited care center to prescribe airway clearance devices for their patients living with cystic fibrosis who need them. This revision will ensure continuity of care for patients, prevent delays in treatment, and minimize unnecessary Medicaid costs.

We stand ready to answer any questions about this letter or the recommendations contained within. Please contact Adam Kellermann, State Policy Specialist, at akellermann@cff.org or (240) 200-3713. We would be happy to connect you with local CF experts to further discuss this important issue.

Sincerely,



Mary B. Dwight
Senior Vice President of Policy & Advocacy
Cystic Fibrosis Foundation



Bruce C. Marshall, MD
Senior Vice President of Clinical Affairs
Cystic Fibrosis Foundation

Appendix

About CF Foundation-accredited CF care centers

In order to manage their disease, most people with CF receive their care at accredited care centers where clinicians use evidence-based guidelines to deliver multi-disciplinary, coordinated care. The CF Foundation funds and accredits a nationwide network of more than 130 care centers located in hospitals across the country, including 21 programs in New York. These centers provide multidisciplinary, patient-centered care in accordance with systematically reviewed, data-driven clinical practice guidelines. Each center employs a team of dedicated health care professionals, including physicians who specialize in CF, respiratory therapists, dietitians, social workers, and program coordinators, among others. Together, care teams apply the latest medical evidence and guidelines, resulting in comprehensive, coordinated care. To maintain accreditation by the Foundation, each center undergoes an annual review and periodic re-accreditation peer site visits to ensure they provide a consistently high standard of care.

¹ Flume PA, Robinson KA, O'Sullivan BP, et al. Cystic fibrosis pulmonary guidelines: airway clearance therapies. *Respir Care*. 2009 Apr;54(4):522–537.

² <https://www.cff.org/Research/Researcher-Resources/Patient-Registry/2019-Patient-Registry-Annual-Data-Report.pdf>

³ https://www.emedny.org/ProviderManuals/DME/PDFS/DME_Procedure_Codes.pdf

⁴ <https://www.wadsworth.org/programs/newborn/screening/specialty-care-centers/cystic-fibrosis>