



April 16, 2020

Dave Richard
Secretary for Medical Assistance
State of North Carolina, Department of Health and Human Services
1985 Umstead Drive, 2501 Mail Service Center
Raleigh, NC 27699-2501

Dear Mr. Richard:

On behalf of people in North Carolina living with cystic fibrosis (CF), we write to urge North Carolina Medicaid to adopt necessary flexibility for care delivery to protect the health of patients during the COVID-19 public health emergency and give providers the tools they need to streamline care. It is essential that people with cystic fibrosis retain access to their regular care while following guidelines from the Centers for Disease Prevention and Control (CDC) for social distancing. The flexibilities outlined below will help minimize risk of contracting the virus for people with CF and may also prevent costly hospitalizations due to exacerbations or gaps in care. We urge North Carolina Medicaid ensure safe, timely access to care during this difficult time by expanding coverage for telemedicine, home care, and emergency supplies of medication while temporarily allowing flexibility in utilization management requirements.

Cystic fibrosis patients are at high risk of serious illness from COVID-19

Cystic fibrosis is caused by genetic mutations that result in the absence or malfunction of a protein known as the cystic fibrosis transmembrane conductance regulator (CFTR). CF causes the body to produce thick, sticky mucus that clogs the lungs and digestive system, which can lead to life-threatening infections. Cystic fibrosis is both serious and progressive; lung damage caused by infection is irreversible and can have a lasting impact on length and quality of life. Throughout the coronavirus public health emergency, it is important that people with CF continue to get their regular care as safely as possible to manage symptoms and prevent irreversible organ damage.

While there is no evidence to suggest that people with underlying health conditions are at higher risk of becoming infected, the CDC notes there is evidence to show that people with underlying health conditions, including lung disease, are at greater risk of developing serious illness from COVID-19 if they become infected. Given the continuous high risk of contracting a serious bacterial infection, people with CF regularly practice social distancing and stay at least six feet apart from each other every day – a practice that is maintained outside of pandemic situations. However, the CDC has issued guidelines extending beyond social distancing for high risk individuals (including people with cystic fibrosis): stay at home as much as possible, stock up on supplies, take everyday precautions to keep space between themselves and others, and when out in public, avoid crowds and keep away from others.ⁱ To align ongoing care needs with these recommendations, we propose the following flexibilities for individuals with CF.

Increase access to telemedicine for both COVID-19 treatment and regular care

The CF Foundation applauds your efforts to expand access to telemedicine by ensuring payment parity and expanding eligible providers, locations, and technologies.

Access to health care services via telemedicine, especially for people with CF and others at increased risk for complications from COVID-19, helps patients continue to receive care while keeping them out of health care settings where they may be exposed to the virus. As discussed above, people with CF can continue to monitor their weight, use hand-held spirometers to track changes in lung function, and discuss changes in symptoms with their care team through telemedicine. Recognizing the importance of telemedicine during this crisis, the federal government has temporarily relaxed restrictions on telemedicine services in Medicare.

North Carolina Medicaid should also ensure that telemedicine options are made available to its beneficiaries with cost-sharing obligations that do not exceed those for similar in-person visits. By removing potential additional costs, patients will be more likely to seek their care remotely than at in-person health care settings, where the risk of spreading and contracting coronavirus increases.

By expanding access to and availability of telemedicine services, and eliminating the aforementioned barriers, North Carolina Medicaid can ensure people with CF can continue to access vital care without risking exposure to the virus.

Enable options for at-home treatment

We request that coverage be expanded to allow for in-hospital treatments, such as intravenous (IV) antibiotic treatment for pulmonary exacerbations, to be performed in a home setting. This will help reduce hospital overcrowding and ensure people with CF are not exposed to sick persons.

Specifically, we are requesting coverage for the medications, supplies, and nursing visits necessary to treat pulmonary exacerbations. This includes coverage for home IV antibiotics and other medications prescribed by the treating physician, as well as medical equipment to administer these treatments (pumps, home port flushes, and PICC line dressing changes). We also request that providers have the option of using telemedicine to order home treatment. In addition to reducing COVID-19 risk for people with CF, this coverage may be a lower cost alternative to inpatient care.

We also request that you expand coverage for home spirometers and other remote monitoring devices, following the precedent set by the Center for Medicare & Medicaid Services (CMS) for Medicare enrollees. As providers move to greater use of telemedicine, coverage for monitoring devices is critical, particularly for individuals who may not otherwise be able to afford them. For example, spirometers are a valuable way for providers to check in with patients and understand their current lung function level, a key measure of health in cystic fibrosis. Home spirometers are currently the best indicator of pulmonary function available without using equipment in an office or hospital setting.

By providing coverage for these at-home treatments and supplies, North Carolina Medicaid provides patients and providers the tools they need to ensure patient safety and keeps people with cystic fibrosis out of the hospitals.

Enable access to an emergency supply of medication

Current CDC guidelines recommend that high-risk individuals have access to an emergency supply of medication and treatments in the event that they need to stay home for a prolonged period of time. We appreciate North Carolina's efforts to ensure patients can safely obtain their medications by allowing early refills and a 90-day supply of prescriptions.

We also urge flexibility in requirements for obtaining these medications by enabling use of mail order pharmacies (including out-of-state mail order pharmacies), and covering medication delivery by community-based pharmacies, by relaxing requirements for in-person visits for medication refills (by leveraging telehealth visits during the pandemic). These flexibilities will ensure that patients are able to follow CDC guidelines on emergency supplies without risking exposure through in-person visits to pharmacies or clinics and regardless of their financial situation.

Temporarily allow flexibility in utilization management requirements

As cystic fibrosis is a lifelong disease, many individuals currently take chronic medications, some of which have requirements to allow for initial and continued use. During the COVID-19 public health emergency, we ask that North Carolina Medicaid allow for flexibility in these requirements due to challenges obtaining the necessary clinical data needed to fulfill utilization management criteria.

We are specifically asking for this flexibility to allow for uninterrupted use of CFTR modulators. For eligible patients, CFTR modulators – ivacaftor (Kalydeco®), lumacaftor/ivacaftor (Orkambi®), tezacaftor/ivacaftor (Symdeko™), and elexacaftor/tezacaftor/ivacaftor (Trikafta™) – represent the most transformative therapeutic advances in CF. These therapies correct the CFTR protein malfunction, thereby restoring function to the protein and reducing the symptoms and progression of the disease.

CFTR modulators cannot reverse damage that has already occurred and, to prevent life-long organ damage, should be initiated as soon as patients and their physicians determine it is medically necessary and appropriate to begin therapy. Once begun, access to CFTR modulators must be taken chronically and without gaps in therapy. During this pandemic era it is critical that patients begin modulator therapies as soon as possible, as these therapies have the potential to stabilize or improve the health of eligible people with cystic fibrosis. We ask that, given Trikafta has not yet been reviewed by North Carolina Medicaid, case-by-case reviews of Trikafta reflect the importance of this medication.

During case-by-case reviews, we urge flexibility in initial authorization criteria. For patients who are beginning modulator therapy, we request that North Carolina Medicaid either use the patient's most recent clinical visit data as their baseline information or allow for home spirometry and BMI measures be used in lieu of an in-person clinical visit. This will allow for

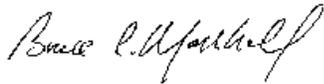
both North Carolina Medicaid and providers to have data to track stabilizations or improvement of clinical endpoints after initiation of modulator therapies, while also ensuring the patient minimizes risk and exposure to the coronavirus.

Policy Recommendations

The CF Foundation urges North Carolina Medicaid to adopt the above recommendations to increase flexibility in coverage of supplies, medications, and treatment needed for people with CF to continue to receive their regular care and maintain their health and wellbeing during this pandemic.

We stand ready to answer any questions about cystic fibrosis and the needs of patients during the COVID-19 public health emergency. Should you have any questions regarding our requests, please contact Lauren Ryan, CFF Senior Policy Specialist, at lryan@cff.org or (301) 841-2632. We thank you for all you do for people with cystic fibrosis.

Sincerely,



Bruce C. Marshall, MD
Chief Medical Officer
Executive Vice President of Clinical Affairs



Mary B. Dwight
Chief Policy & Advocacy Officer
Senior Vice President of Policy and Advocacy

ⁱ Coronavirus Disease 2019 (COVID-19). (2020, March 31). Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/index.html>