



April 15, 2020

Ms. Kate Massey
333 S. Grand Ave
P.O. Box 30195
Lansing, Michigan 48909

Dear Director Massey:

On behalf of people in Michigan living with cystic fibrosis (CF), we write to urge Michigan 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 Michigan 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 in order 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, according to the CDC, 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.¹ To align ongoing care needs with these recommendations, we propose the following flexibilities for individuals with CF.

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, Michigan Medicaid provides patients and providers the tools they need to ensure patient safety and keeps people with cystic fibrosis out of the hospitals.

Expand access to telemedicine services

The CF Foundation applauds your efforts to expand access to telemedicine by allowing patients to receive care in the home and providers to deliver telemedicine services outside of the traditional care setting. We also appreciate that Michigan Medicaid has increased the modalities through which telemedicine can be offered and provide reimbursement for services delivered by telephone, in addition to video-capable devices. However, we urge you to implement the following additional policies to ensure individuals in your state, including those with CF, are protected from infection while accessing the critical services they need.

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. We encourage Michigan Medicaid to use existing authorities to likewise expand access to telemedicine services at the state level.

Reimbursement and cost-sharing

We urge Michigan Medicaid to act swiftly to expand access to telemedicine by reimbursing providers for these services at the same rate as similar in-person visits to ensure patients can access these services.

In a document outlining state flexibilities related to telemedicine coverage, CMS clarified that states already have this authority, even without federal approval.ⁱⁱ Michigan 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.

Provider eligibility and licensing requirements

Furthermore, we request that Michigan Medicaid remove existing barriers that prevent providers from delivering telemedicine services; these include lifting restrictions on the types of providers who can be reimbursed for telemedicine and encouraging Governor Whitmer and the state medical boards to relax state-specific licensure requirements that prohibit interstate delivery of care. Broadening provider eligibility to include more provider types is especially important for the CF community as our care centers use a multidisciplinary team of providers, including pulmonologists, respiratory therapists, dietitians and others to treat this complex disease. Allowing for license portability across state lines is also important as 11 percent of people with CF seek care across state lines and without such changes, may not be able to get remote care from their regular care team.ⁱⁱⁱ

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

Temporarily allow flexibility in utilization management requirements

As cystic fibrosis is a lifelong disease, many individuals currently take chronic medications, some of which have prior authorization and reauthorization requirements to allow for initial and continued use. During the COVID-19 public health emergency, we ask that Michigan Medicaid allow for flexibility in these requirements due to challenges obtaining the necessary clinical data needed to fulfill authorization and reauthorization 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. Current reauthorization criteria threaten modulator usage during this pandemic, specifically criterion requiring proof of stabilization or improvement of clinical endpoints (e.g. FEV₁, body mass index, sweat chloride). This is especially true of pulmonary function test (PFT) requirements as PFT labs are closed due to the high risk of spreading the coronavirus and home PFT testing results are not reliably comparable to baseline measurements taken in-clinic (although, as stated earlier, home spirometers are an important way for clinicians to track trends and determine when patients need to have an in-person clinic visit). We ask Michigan Medicaid to temporarily suspend

reauthorization requirements in order to allow for continuous use of modulators during the current public health emergency.

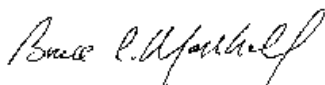
We also urge similar flexibility in initial authorization criteria. During this pandemic era it is critical that patients begin modulator therapies as soon as possible, as these therapies have the potential to stabilize or improve the health of eligible people with cystic fibrosis. For patients who are beginning modulator therapy, we request that Michigan 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 Michigan 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 Michigan 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. Given the urgency of this issue and the quickly changing health care landscape, we ask for you to please respond upon receipt of this letter. Should you have any questions regarding our requests, please contact Sarah Webster-Mellon, Senior State Policy Specialist, at swebster-mellon@cff.org or (240) 200-3712. 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>

ⁱⁱ Medicaid State Plan Fee-for-Service Payments for Services Delivered Via Telehealth. Retrieved from <https://www.medicaid.gov/medicaid/benefits/downloads/medicaid-telehealth-services.pdf>

ⁱⁱⁱ 2018 Patient Registry Annual Data Report. Cystic Fibrosis Foundation. Cystic Fibrosis Foundation. Retrieved from <https://www.cff.org/Research/Researcher-Resources/Patient-Registry/2018-Patient-Registry-Annual-Data-Report.pdf>