Vicki Goethals
Bureau of Medicaid Care Management & Customer Service
Medical Services Administration
P.O. Box 30479
Lansing, Michigan 48909-7979

November 4, 2019

Re: Medicaid Health Plan Pharmacy Drug Coverage Transition

Dear Ms. Goethals,

On behalf of people with cystic fibrosis (CF) living in Michigan, the Cystic Fibrosis Foundation is grateful for the opportunity to comment on the Michigan Department of Health and Human Services' (MDHHS) proposal to transition pharmacy drug coverage from the Medicaid Health Plans (MHPs) to fee-for-service Medicaid. We urge the state to provide access to all cystic fibrosis therapies so people with CF can maintain their health to the fullest extent possible. We also ask the state to exempt all people with CF from Medicaid prescription co-pay requirements.

Cystic fibrosis is a rare, life-threatening genetic disease that affects approximately 1,150 people in Michigan, including over 230 adults who rely on Medicaid for some or all of their health coverage. 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.

Access to CF medications:
As a complex, multi-system condition, CF requires targeted, specialized treatments and medications, including:

- *CFTR Modulators:* CFTR modulators, a relatively new class of CF therapies, are the latest and most significant milestone in cystic fibrosis care. Ivacaftor (Kalydeco®), lumacaftor/ivacaftor (Orkambi®), tezacaftor/ivacaftor (Symdeko®), and elexacaftor/ivacaftor/tezacaftor (Trikafta™) are FDA-approved therapies that improve the function of CFTR protein for individuals with specific mutations in the CFTR gene. Different CFTR mutations cause different defects in the protein; therefore, modulators are effective only in people with specific mutations.

  Unlike other therapies that treat the symptoms of CF, CFTR modulators correct the genetic defect of the disease and exemplify the promise of precision medicine. Studies show that patients who take modulators experience significant improvements in lung function, body weight, and respiratory symptom-related quality of life. They also experience fewer pulmonary exacerbations. For some patients, these represent previously inconceivable improvements in their health.

As DHHS moves to transition drug coverage from the Medicaid Health Plan (MHP) benefit to fee-for-service Medicaid, we urge you to ensure that the preferred drug list reflects the FDA label for all CFTR modulators and does not place inappropriate restrictions on access to these drugs. In particular, the prior authorization request form for modulators currently available on DHHS' website[1] does not reflect the most current age requirements on the FDA label. As of 2019, Kalydeco's label was expanded to include people with CF who are age six months or older and Symdeko's label now includes children six years or older. Please ensure that prior authorization requirements reflect the most updated version of the FDA label.

- *Mucociliary Clearance*: People with cystic fibrosis have thick, sticky mucus that blocks passages in their lungs, making it difficult for them to breathe and predisposing them to infections. Access to mucociliary drugs, such as dornase alfa and hypertonic saline, is critical as these drugs help break up and hydrate mucus in the lungs to make it easier to clear.

  We ask that you continue to cover hypertonic saline and dornase alfa without step therapy. Treatment with mucolytic products is shown to help clear mucus from the lungs, resulting in fewer lung infections, improved lung function, and better quality of life for people with CF.[2] Long-term clinical trials also found that people who were treated with inhaled hypertonic saline experienced a reduction in antibiotic use for pulmonary exacerbations and subsequently missed fewer days of work and school due to illness.[3] Similarly, dornase alfa represents an important component of CF care as it produces sustained improvements in lung function, reduces infection rates, and improves patient quality of life.[4,5]

- *Anti-Infectives:* People with cystic fibrosis also use anti-infectives to treat the bacteria that get trapped and colonize in their airways. Anti-infectives, such as inhaled tobramycin and aztreonam, are used to improve respiratory symptoms in people with cystic fibrosis who have *Pseudomonas aeruginosa*, a bacterium that colonizes the lungs and is associated with increased morbidity and mortality in people with this disease. Use of CF-specific antibiotics has been shown to decrease *P. aeruginosa* in sputum and improve lung function and quality of life.[6,7,8]

  It is important that the preferred drug list continue to include access to both aztreonam for inhalation solution (Cayston®) and a tobramycin product, allowing for provider discretion in determining which antibiotic is most appropriate for the patient. Because the type of antibiotic, the dosage, and the length of time to take the drug all vary from person to person—and the fact

[1] https://michigan.magellanrx.com/provider/external/medicaid/mi/doc/en-us/MIRx_PAfaxform_Kalydeco_Orkambi_Symdeko.pdf

[2] Mogayzel, Peter, Jr., Naureckas, Edward, et al. Cystic Fibrosis Pulmonary Guidelines. American Journal of Respiratory and Critical Care Medicine, Vol. 187, 2013.

[3] Elkins MR, Robinson M, Rose BR, et al. A controlled trial of long-term inhaled hypertonic saline in patients with cystic fibrosis. N Engl J Med 2006;354:229–240.

[4] Cramer, Gena W., et al. "The role of dornase alfa in the treatment of cystic fibrosis." Annals of Pharmacotherapy 30.6 (1996): 656-661.

[5] Fisher, L. M. "Company news; Genentech's drug to treat cystic fibrosis is approved." The New York Times 1993, December 31.

[6] Retsch-Bogart GZ, Quittner AL, Gibson RL, Oermann CM, McCoy KS, Montgomery AB, Cooper PJ. Efficacy and safety of inhaled aztreonam lysine for airway Pseudomonas in cystic fibrosis. Chest 2009;135:1223-32.

[7] Ramsey BW, Pepe MS, Quan JM, Otto KL, Montgomery AB, Williams-Warren J, Vasiljev KM, Borowitz D, Bowman CM, Marshall BC, et al. Intermittent administration of inhaled tobramycin in patients with cystic fibrosis. Cystic Fibrosis Inhaled Tobramycin Study Group. N Engl J Med 1999;340:23-30.

[8] Quittner AL, Buu A. Effects of tobramycin solution for inhalation on global ratings of quality of life in patients with cystic fibrosis and Pseudomonas aeruginosa infection. Pediatr Pulmonol 2002;33:269-276.

that some people become resistant to antibiotics over time—it is critical that people with CF have access to all available inhaled antibiotics designed specifically for CF. Additionally, we ask that you provide coverage for both aztreonam and a tobramycin product in a continuous combination treatment regimen for people with CF when prescribed by their physician.[9,10]

- *Nutritional-GI Medications:* People with cystic fibrosis can experience complications in the pancreas, liver, and intestines that can lead to malnutrition, constipation, liver disease, CF-related diabetes, and other digestive issues—including abdominal pain and poor appetite. Taking pancreatic enzymes before meals and snacks helps people with CF digest carbohydrates, proteins, and fats, gain and maintain a healthy weight, and absorb essential nutrients such as vitamins and minerals.

  CF patients all respond differently to the various enzymes and it is therefore critical that the state include all these enzymes as preferred products on the state's preferred drug list. Currently, Creon and Zenpep are listed as preferred enzymes, while Pancreaze, Pertzye, and Viokace are non-preferred. Excluding any individual enzyme as a preferred product disregards the variable clinical responses of CF patients to pancreatic enzyme therapies and jeopardizes patient health. We strongly urge you to ensure that CF patients and providers have the ability to choose the most appropriate enzyme given the patient's unique health profile and thereby attempt to minimize the risk of further medical complications.

Co-payments for Prescription Drugs

We also ask the state to exempt people with CF from Medicaid prescription co-pay requirements to ensure equity across the CF population. The DHHS' policy bulletin notes that transitioning pharmacy drug coverage from managed care to fee-for-service Medicaid will result in pharmacy co-pays for current MHP enrollees ages 21 and older. We appreciate that many enrollees with cystic fibrosis are already exempt from these cost-sharing requirements due to their dual enrollment in Medicaid and Children's Special Health Care Services (CSHCS), Medicaid and Medicare, or through a chronic disease exemption for the Healthy Michigan Plan (HMP). However, for those living with CF who are not enrolled in HMP, Medicare, or CSHCS, we are concerned that implementing pharmaceutical co-pays would impact their access to necessary medications. Even nominal co-pays can be unmanageable for financially vulnerable and medically complex adults like those with cystic fibrosis. A survey conducted by George Washington University of 2,500 people living with CF found that while 98 percent of people with CF have insurance, almost 60 percent have delayed or skipped care due to cost concerns, which can jeopardize patient health and lead to costly hospitalizations and life-threatening lung infections. As such, we request that all people with CF be exempt from prescription co-pay requirements as the state transitions drug coverage to fee-for-service Medicaid.

[9] Flume PA, Mogayzel PJ, Robinson KA, Goss, CH, et.Al. Cystic Fibrosis Pulmonary Guidelines: Treatment of pulmonary exacerbations. Am J Respir Crit Care Med 2009;180:802-808.

[10] Flume PA, et al, Continuous alternating inhaled antibiotics for chronic pseudomonal infection in cystic fibrosis, J Cyst Fibros (2016).

The CF Foundation stands ready to be a resource on behalf of Michiganders with CF. Please do not hesitate to reach out to Sarah Webster-Mellon, Senior State Policy Specialist, at swebster-mellon@cff.org for any additional information. Thank you for the opportunity to comment on this proposed policy change.

Sincerely,

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