



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

August 19, 2019

Re: Transition Fills for Carved-In Drugs

Dear Ms. Goethals,

On behalf of people with cystic fibrosis (CF) living in Michigan, the Cystic Fibrosis Foundation urges the Michigan Department of Health and Human Services (MDHHS) to ensure continued access to CFTR modulators on the common formulary consistent with the Food and Drug Administration (FDA) label once these drugs are carved into coverage by Medicaid Health Plans. This class of medications represents a breakthrough in CF care by targeting the underlying cause of cystic fibrosis—rather than treating the symptoms—and may delay or prevent damage caused by the disease.

Cystic fibrosis is a rare, life-threatening genetic disease that affects approximately 1,150 people in Michigan and more than 30,000 children and adults in the United States. 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. As a complex, multi-system condition, CF requires targeted, specialized treatment and medications.

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®), and tezacaftor/ivacaftor (Symdeko®) 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, 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.

Bethesda Office

4550 Montgomery Avenue, Suite 1100N, Bethesda, Maryland 20814
301.951.4422 800.FIGHT.CF Fax: 301.951.6378
www.cff.org email: info@cff.org

It is critical that Michigan maintain open access to modulators for people with CF who are eligible, ensuring that those who can benefit from the drugs are able to get them. As DHHS moves to carve CFTR modulators into the MHP pharmacy benefit, we urge you to ensure that the common formulary reflects the FDA label and does not place inappropriate restrictions on access to these drugs.

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,

A handwritten signature in black ink, appearing to read "Mary Dwight". The signature is fluid and cursive, with a large initial "M" and "D".

Mary Dwight
Senior Vice President
Policy and Advocacy

Bethesda Office

4550 Montgomery Avenue, Suite 1100N, Bethesda, Maryland 20814
301.951.4422 800.FIGHT.CF Fax: 301.951.6378
www.cff.org email: info@cff.org