November 12, 2020

Iowa Medicaid Pharmaceutical and Therapeutics Committee
c/o Iowa Medicaid
611 5th Avenue
Des Moines, IA 50309

Dear Members of the Iowa Medicaid Pharmaceutical and Therapeutics Committee:

On behalf of patients and families with cystic fibrosis (CF) living in Iowa, we write to recommend that Iowa Medicaid make all Food and Drug Administration (FDA) approved pancreatic enzyme products available to patients with CF on the preferred drug list (PDL). Specifically, we are writing to request that Iowa Medicaid continue to include Zenpep, in addition to Creon and pancrelipase, as a preferred product on the PDL. While pancreatic enzyme replacement products (PERTs) may be interchangeable in some populations, people with CF experience variable responses to PERTs and patients who are stable on one product should not be forced to switch. This could place CF patients at serious risk for negative health outcomes.

About Cystic Fibrosis & the CF Foundation
Cystic fibrosis is caused by genetic mutations that result in the malfunction of a protein known as the cystic fibrosis transmembrane conductance regulator (CFTR). Decreased CFTR function causes irreversible organ damage and the associated symptoms of cystic fibrosis and leads to early death, usually by respiratory failure. As the world's leader in the search for a cure for CF and an organization dedicated to ensuring access to high quality, specialized CF care, the Cystic Fibrosis Foundation accredits 130 care centers, and 55 affiliate programs nationally that provide multidisciplinary, patient-centered care in accordance with systematically reviewed, data-driven clinical practice guidelines. Treatment options for this rare, life-threatening disease are limited.

About Pancreatic Enzyme Replacement Therapy
Pancreatic enzyme replacement therapy (PERT) is a life-sustaining therapy for people with CF as nutritional status is closely linked to pulmonary function and survival. Cystic fibrosis is a multi-system disease that causes the ducts in the pancreas to become clogged with thick, sticky mucus that blocks natural enzymes from reaching food in the small intestine. As a result, approximately 90 percent of CF patients have pancreatic insufficiency, making PERT a vital component of CF care. Decreased pancreatic function leads to malabsorption of calories and nutrients, and therefore, difficulty with growth and weight gain. Patients with pancreatic insufficiency require lifelong PERTs with each meal and snack to maintain adequate nutrition and prevent abdominal distress.

Although the drug substance is the same, the dissolution properties of the PERTs are not identical. The differences in enteric coating, delivery, and size of each FDA-approved product affect a patient's ability to absorb nutrients. The degree of acidification of the GI tract in each CF patient also varies, causing some patients to have a better clinical response to one product over another.

Changing any any individual enzyme's status to "non-preferred" on the PDL disregards the variable clinical responses of CF patients to pancreatic enzyme therapies and jeopardizes patient health.

Nutritional failure of any type places CF patients at risk for long-term health consequences and a patient's PERT regimen, once stable, should not be modified unless it is clinically indicated.

Limiting patient choice for enzymes can contribute even greater health difficulties to those already experienced by people with cystic fibrosis. We strongly urge Iowa Medicaid to ensure that CF patients and providers have the ability to choose the most appropriate treatment given the patient's unique health profile and thereby attempt to minimize the risk of further medical complications.

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