



July 22, 2019

Sumit Dutta M.D.
Chief Medical Officer
OptumRx
2300 Main St.
Irvine, CA 92614

Re: Coverage of pancreatic enzyme replacement therapies

Mr. Dutta,

Aimed Alliance is a nonprofit organization that works to protect and enhance the rights of health care consumers and providers. The Exocrine Pancreatic Insufficiency Coalition (EPIC) is a coalition of likeminded organizations, convened by Aimed Alliance, that advocates on behalf of patients who are living with enzyme deficiencies. The mission of EPIC is to ensure that patients living with enzyme deficiencies can access treatments and services that are appropriate for them.¹

We are writing to you today to express our gratitude for your choice to preserve access to multiple pancreatic enzyme replacement therapy (PERT) products. If you had chosen to exclude coverage for one or more PERT products, individuals with exocrine pancreatic insufficiency (EPI), a condition that impacts highly vulnerable patient populations, including those with cystic fibrosis and chronic pancreatitis, would have lost access to medically necessary enzyme treatments.

EPI is a condition that occurs when the human body is unable to provide an adequate supply of digestive enzymes.² The shortage of digestive enzymes is commonly caused by other conditions that affect the pancreas, such as cystic fibrosis, Shwachman-Diamond syndrome, pancreatic tumors, and chronic pancreatitis. Patients with this condition are unable to properly digest food, which causes gastrointestinal upset and difficulty absorbing nutrients from food. Patients with EPI rely on PERTs, which replace missing enzymes and help break down nutrients in food. If the body does not absorb enough nutrients, it can cause further complications. For example, Vitamin K insufficiencies can cause bleeding disorders and Vitamin D insufficiencies can cause bone pain.³ For individuals with cystic fibrosis in particular, lack of proper treatment can be life-threatening.⁴ Therefore, patients with EPI rely on these medications for survival.⁵

It is important that stable patients with EPI be allowed to remain on current medication to avoid any complications with their condition. While there are six FDA-approved PERT products available in the United States, the FDA has determined that none of these medications are interchangeable, meaning that they do not “produce the same clinical results as the reference

¹ <https://aimedalliance.org/epic/>

² <https://www.identifyepi.com/what-is-epi>

³ <https://www.webmd.com/digestive-disorders/exocrine-pancreatic-insufficiency#1>

⁴ <https://www.medicalnewstoday.com/articles/147960.php>

⁵ <https://www.pharmacytimes.com/publications/issue/2008/2008-12/p2ppeps-1208>

product in any given patient.”⁶ Removing coverage for one or more PERT products would have forced some patients to switch to an alternative option, which could cause them to experience negative health outcomes.

Each PERT product has a different formulation and different dosing.⁷ As such, forcing a patient to switch from one PERT to another could upset the patient’s stability and expose him or her to unnecessarily negative health outcomes, including abdominal pain, intestinal obstruction, increased incidence of steatorrhea, and rectal prolapse.⁸ If a patient with EPI is switched to a PERT that does not adequately manage his or her condition, the symptoms of the condition could become exacerbated and could progress into more serious health conditions. For example, a patient could develop osteoporosis as a result of inadequate Vitamin D levels, or a patient could experience ataxia and peripheral neuropathy as a result of inadequate Vitamin E levels.⁹ Furthermore, switching between these products carries the risk that the body will develop tolerance to the active ingredients and, consequently, the medication’s efficacy could be diminished.¹⁰

We would like to reiterate our gratitude for your choice to preserve access to multiple PERT options for patients with EPI.

Sincerely,

The Exocrine Pancreatic Insufficiency Coalition (EPIC)

Aimed Alliance

Attain Health

The Bonnell Foundation

CysticLife

Cystic Fibrosis Engagement Network (CFEN)

Neuroendocrine Cancer Awareness Network (NCAN)

Patients Rising Now

Rock CF

6

<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm>

⁷ <https://www.verywellhealth.com/pancrelipase-pancreatic-enzyme-replacement-998342>

⁸ <https://www.pharmacytimes.com/publications/issue/2008/2008-12/p2ppeps-1208>;

⁹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5873407/>

¹⁰ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5706924/>