AIMED ALLIANCE

June 4, 2019

Trent Haywood, M.D., J.D.
Chief Medical Officer
Blue Cross Blue Shield Association
225 North Michigan Avenue
Chicago, Illinois 60601

William Breskin
Senior Vice President, Government Programs
Blue Cross Blue Shield Association
225 North Michigan Avenue
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Re: Formulary coverage of pancreatic enzyme replacement therapy

Dear Dr. Haywood and Mr. Breskin:

Aimed Alliance is a nonprofit organization that works to protect and enhance the rights of health care consumers and providers. We are concerned about the Blue Cross Blue Shield's (BCBS) recent decision to exclude certain pancreatic enzyme replacement therapies (PERT) from formulary coverage in Federal Employee Program (FEP) plans. As a result, individuals with exocrine pancreatic insufficiency (EPI), a condition that impacts highly vulnerable patient populations including those with cystic fibrosis, could lose access to their medically necessary enzyme treatments.

I. What is EPI?

EPI is a condition that occurs when the human body is unable to provide an adequate supply of digestive enzymes.[1] 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 to replace the pancreatic enzymes that their body is not naturally producing to 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.[2] For individuals with cystic fibrosis in particular, lack of proper treatment can be life-threatening.[3] Therefore, patients with EPI rely on these medications for survival.[4]

II. BCBS Removes Coverage for PERT

Currently, there are six FDA-approved PERTs available in the United States. The FDA has determined that none of these medications are interchangeable, meaning that they do not "produce

[1] https://www.identifyepi.com/what-is-epi
[2] https://www.webmd.com/digestive-disorders/exocrine-pancreatic-insufficiency#1
[3] https://www.medicalnewstoday.com/articles/147960.php
[4] https://www.pharmacytimes.com/publications/issue/2008/2008-12/p2ppeps-1208

the same clinical results as the reference product in any given patient."[5] Last year, BCBS FEP plans covered five of the six available PERTs. On September 26, 2018, BCBS announced that its FEP formulary would only cover three of the six medications for PERT, thereby excluding two from coverage. As a result, patients currently taking and stable on the excluded PERT products are forced to switch medications.

III. Removal of a PERT from the FEP Formulary Can Jeopardize Patient Health

We are concerned that the decision to exclude coverage of a PERT product in the FEP formulary could result in nonmedical switching. Nonmedical switching occurs when an insurer requires a stable patient to switch from his or her current, effective medication to an alternative drug by excluding the original medication from coverage, elevating the drug to a higher cost tier, or otherwise limiting access to a treatment or increasing the patient's out-of-pocket costs. The patient is forced to switch to a "therapeutically equivalent" medication based on the actions of the payer rather than for medical reasons. Therapeutically equivalent drugs do not need to be chemically equivalent, bioequivalent, or generically equivalent.[6] They can be entirely different medications. We do not oppose switching a plan enrollee from a brand medication to a generic version that exhibits the same level of safety and effectiveness. However, we are opposed to policies that force stable plan enrollees to switch to a therapeutically equivalent medication for nonmedical reasons.

While BCBS FEP plans will continue to cover alternative PERT products, the lack of interchangeability between these products could result in negative health outcomes. Patients with chronic conditions like EPI must often try various doses of PERT before they find the dose that works for them, and doses vary from product to product.[7] Once stable on a therapy, it is critically important that these patients are able to remain on the same therapy to ensure that they can successfully manage their health. Forcing patients to switch to another medication can disrupt the patient's continuity of care, contribute to negative health outcomes, and increased costs for the health system. For example, 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, including abdominal pain, intestinal obstruction, and increased incidence of steatorrhea and rectal prolapse.[8] Additionally, 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]

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

6 http://www.gabionline.net/biosimilars/general/glossary-of-key-terms

7 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5301368/

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/

PERTs allow individuals with conditions such as cystic fibrosis to maintain or gain weight, which is vital, especially in pediatric populations.[11] Children with cystic fibrosis who are unable to reach the 50 weight-for-age percentile are at a greater risk of acute pulmonary exacerbations, impaired glucose tolerance, and cystic fibrosis-related diabetes; spend more days in the hospital; and have incrementally lower survival at age 18.[12] Without having access to several PERT options at this critical time in their development, this population is at risk of experiencing these long-term negative health outcomes. Given that PERT products are not interchangeable, patients may experience detrimental weight loss when they are switched and as they struggle to find the appropriate dose on the new product. Instead, the decision to switch treatments should remain within the discretion of the treating health care provider and patient, and it should be made on a case-by-case basis with the support of scientific evidence and the patient's full consent.[13]

IV. Need for Continuity of Care Between Plan Years

Although BCBS sent notice of the switch on September 26, 2018, a switch that occurs at the beginning of a plan year is just as harmful as one that occurs mid-plan year for stable patients. For anyone struggling to manage a complex or chronic condition, such as EPI, long-term stability is absolutely essential. For this reason, numerous states have introduced legislation that protect an enrollee's continuity of care between plan years by requiring health plans to provide continuous coverage of medications that they are currently stable on. For example, Texas has introduced legislation this year that would prohibit health plans from modifying an enrollee's level of coverage for any medication that was approved and covered for them during the previous year, as long as the prescribing provider attests to the appropriateness of the treatment.[14] In light of this, we recommend that BCBS voluntarily offer continued coverage for prescription medications in situations like these to ensure that enrollees are not subject to avoidable complications due to coverage for their medications being changed.

V. Documented Impact of Nonmedical Switching

The Alliance for Patient Access released a report in February 2019, titled *A Study of the Qualitative Impact of Non-Medical Switching*.[15] This report features the results of a national survey designed to gauge patient perspectives on nonmedical switching practices. This report revealed that after being switched, nearly 40 percent of patients indicated that the new medication was not as effective as the original medication. Furthermore, almost 60 percent of respondents indicated that they experienced a complication from taking the new medication. Almost 40 percent of

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[11] https://www.ncbi.nlm.nih.gov/pubmed/23062247
[12] https://www.ncbi.nlm.nih.gov/pubmed/23062247
[13] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5486595/
[14] https://legiscan.com/TX/votes/HB2099/2019
[15] http://allianceforpatientaccess.org/wp-content/uploads/2019/02/AfPA_Qualitative-Impact-of-Non-Medical-Switching_Report_Feb-2019.pdf

respondents indicated that the experience was so frustrating that they stopped taking their medication altogether.

The Global Healthy Living Foundation, in collaboration with the Indiana Stable Patient Protection Coalition, also released a report in February 2019 titled, *Indiana Patient Sentiment toward Non-Medical Prescription Drug Switching by Health Insurance Companies*.[16] This report highlights the results of a survey that was conducted in Indiana with the goal of analyzing how patients experience nonmedical switching. This report sheds light on the fact that over 60 percent of patients who were switched off of their medication for nonmedical reasons had to try multiple other medications before being able to find one that worked for them. When asked about how the side effects of the new medication compared to the side effects of the original medication, 92.8 percent of respondents indicated that side effects of the new medication were worse. We urge you to review these reports in their entirety to fully understand how nonmedical switching can negatively impact patient health, medication adherence, and outcomes.

VI. Conclusion

BCBS must allow stable patients with EPI to remain on their PERT. We recommend that BCBS reverse its policy decision to exclude vital PERT treatments from FEP coverage and allow patients who are stable on their current PERT treatment to remain on such treatment. Patients with EPI are typically battling severe conditions, such as cystic fibrosis, Shwachman-Diamond syndrome, pancreatic tumors, and chronic pancreatitis. They should not be subjected to the added difficulty of losing access to a life-saving treatment as well.

We would like to schedule a meeting or call with you to discuss this matter further and request that you provide us with your availability. You can reach us at (202) 559-0380 or jwylam@aimedalliance.org.

Sincerely,

John Wylam
Staff Attorney

[16] https://csro.info/docs/advocacy-news/in-nms-survey-executive-summary.aspx