



July 22, 2019

Troyen Brennan, M.D.  
Executive Vice President and Chief Medical Officer  
CVS Health  
One CVS Drive  
Woonsocket, Rhode Island 02895

Re: Formulary coverage of pancreatic enzyme replacement therapy

Dear Mr. Brennan:

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.<sup>1</sup>

We write to seek clarification from CVS Caremark about the current coverage status of ZENPEP on the CVS Caremark Commercial Value Formulary and to request that CVS allow stable patients to remain on their current medication. Our current findings suggest that CVS Caremark has excluded coverage of ZENPEP from the Commercial Value Formulary as of July 1, 2019. As a result, individuals with exocrine pancreatic insufficiency (EPI), a condition that impacts highly vulnerable patient populations, including those with cystic fibrosis and chronic pancreatitis, 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.<sup>2</sup> 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.<sup>3</sup> For individuals with cystic fibrosis

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<sup>1</sup> <https://aimedalliance.org/epic/>

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

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

in particular, lack of proper treatment can be life-threatening.<sup>4</sup> Therefore, patients with EPI rely on these medications for survival.<sup>5</sup>

## **II. CVS Caremark Changed Its Coverage of PERT Products**

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 the same clinical results as the reference product in any given patient.”<sup>6</sup> According to the CVS Caremark Value Formulary, effective on January 1, 2018, ZENPEP was covered, among other pancreatic enzyme options.<sup>7</sup> However, CVS Caremark published an updated Value Formulary on July 1, 2019, which excluded coverage of ZENPEP.<sup>8</sup> Furthermore, CVS Caremark published an accompanying document on July 1, 2019 that included details about medications that were excluded from coverage.<sup>9</sup> We have been unable to locate any documents indicating an update to the CVS Caremark Value Formulary between January 1, 2018, and July 1, 2019. If CVS Caremark has chosen to exclude coverage of ZENPEP on July 1, 2019, which is the middle of the plan year, notice of this should have been included in the July 2019 coverage exclusion document. Additionally, notice should have been sent to patients who are currently stable on this medication as well as their prescribers.

## **III. Removal of a PERT from Coverage Can Jeopardize Patient Health**

We are concerned that a decision to exclude coverage of a PERT product from CVS Caremark’s 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.<sup>10</sup> 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.

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

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

<sup>6</sup>

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

<sup>7</sup> [https://www.caremark.com/portal/asset/Value\\_Formulary\\_OE.pdf](https://www.caremark.com/portal/asset/Value_Formulary_OE.pdf)

<sup>8</sup> [https://www.caremark.com/portal/asset/Value\\_Formulary.pdf](https://www.caremark.com/portal/asset/Value_Formulary.pdf)

<sup>9</sup> [https://www.caremark.com/portal/asset/Value\\_Formulary\\_Non-Listed\\_Brands.pdf](https://www.caremark.com/portal/asset/Value_Formulary_Non-Listed_Brands.pdf)

<sup>10</sup> <http://www.gabionline.net/biosimilars/general/glossary-of-key-terms>

While CVS Caremark may 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.<sup>11</sup> 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.<sup>12</sup> 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.<sup>13</sup> 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.<sup>14</sup>

PERTs allow individuals with conditions such as cystic fibrosis to maintain or gain weight, which is vital, especially in pediatric populations.<sup>15</sup> 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.<sup>16</sup> 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.<sup>17</sup>

#### **IV. CVS Caremark's Formulary Exclusion Could Result in Health Plans Violating Illinois Law**

If CVS Caremark decided to exclude medications from coverage in the middle of the plan year, such a move would force health plans in Illinois, whose formularies are managed by CVS Caremark, to violate state law. Illinois has enacted the Managed Care Reform and Patient Rights Act, which prohibits health plans from removing drugs from their formularies or negatively changing their coverage status unless the health plan provides at least 60 days' advance notice to current and prospective enrollees. This notice must inform enrollees who are currently receiving

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<sup>11</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5301368/>

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

<sup>13</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5873407/>

<sup>14</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5706924/>

<sup>15</sup> <https://www.ncbi.nlm.nih.gov/pubmed/23062247>

<sup>16</sup> <https://www.ncbi.nlm.nih.gov/pubmed/23062247>

<sup>17</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5486595/>

coverage for such drugs that their provider can certify the medication's medical necessity, which will allow the enrollee to continue receiving the medication at the same level of coverage.<sup>18</sup> Similar notice must also be sent to providers for all enrollees who are currently being prescribed such medications.<sup>19</sup> If CVS failed to provide 60 days' notice to plan beneficiaries, it may have violated this provision. Moreover, the failure to provide such notice could have resulted in insufficient time to request an exemption to allow stable patients to remain on their medication, thereby disrupting continuity of care. We request confirmation from CVS that it did send such notice and a copy of a sample letter, with patient identifying information redacted.

## **V. Nonmedical Switching is an Unfair and Deceptive Trade Practice**

If CVS Caremark has chosen to exclude coverage of ZENPEP in the middle of the plan year, this action may violate state laws and regulations governing unfair and deceptive trade practices. For example, according to Illinois law, "a person engages in a deceptive trade practice when, in the course of his or her business . . . [that person] represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have."<sup>20</sup> The health plans to which CVS Caremark provides pharmacy benefit services were sold to consumers for the purpose of providing health benefits for the duration of the plan year. If CVS Caremark knew that it would be excluding coverage for a PERT product in the middle of the plan year, it could be an unfair and deceptive trade practice because CVS Caremark would have misled consumers about the year-long coverage status of the medications included on the health plan's formulary. CVS Caremark could have misled consumers by falsely having them believe that the medications on the health plan's formulary would be covered at a particular rate for the full plan year, which turned out not to be true.

Plan enrollees, therefore, may have been induced to enroll in a plan without adequate notice of proposed changes that could impact them. Without notice regarding the coverage exclusion, they would not have the opportunity to shop for a different plan that would have provided adequate coverage for their medications. As such, a mid-year change of this nature is essentially a bait-and-switch tactic that could violate unfair and deceptive trade practice laws and regulations.

## **VI. Conclusion**

We request that CVS Caremark provide us with additional details about the coverage status of ZENPEP. If this medication was excluded from coverage on the Value Formulary, we request information on when that change occurred and what notice was provided to impacted plan beneficiaries and prescribers, if any. We recommend that CVS Caremark maintain coverage of ZENPEP for stable patients. If CVS Caremark has elected to exclude coverage of ZENPEP, we recommend that CVS Caremark allow stable patients to remain on their medication for the duration of the plan year. 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.

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<sup>18</sup> <http://www.ilga.gov/legislation/publicacts/fulltext.asp?Name=100-1052>

<sup>19</sup> <http://www.ilga.gov/legislation/publicacts/fulltext.asp?Name=100-1052>

<sup>20</sup> <http://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=2357&ChapterID=67>

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](mailto:jwylam@aimedalliance.org).

Sincerely,

The Exocrine Pancreatic Insufficiency Coalition (EPIC)

Aimed Alliance

Attain Health

The Bonnell Foundation

CysticLife.org

Cystic Fibrosis Engagement Network (CFEN)

Neuroendocrine Cancer Awareness Network (NCAN)

Patients Rising Now

Rock CF