



Exocrine Pancreatic Insufficiency Patients

KNOW YOUR RIGHTS

Exocrine Pancreatic Insufficiency Diagnosis and Treatment

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, 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 pancreatic enzyme replacement therapies (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.² Patients with EPI rely on these medications for survival.³

Patients often try numerous PERT medications before finding one that works for them, which can present challenges when insurers restrict coverage of these medications.⁴ The U.S. Food and Drug

Administration (FDA) has determined that none of these medications are interchangeable with each other because each product has a unique formulation.⁵ Patients with EPI need access to a broad selection of these products to ensure that they can receive one that can successfully manage their condition.

Health insurance companies can take a number of steps to reduce their costs. This can mean your health plan may not cover certain PERT treatments prescribed by your doctor, or the plan may require you to take a number of steps before your treatment is approved.

The good news is that there are state and federal laws in place that may protect you from these practices.

To find out whether your insurer may have improperly delayed or denied access to your migraine treatment, ask yourself the following questions:

Step Therapy

Did my insurer make me try a different treatment before covering the PERT medication or therapy that my care team prescribed?

This practice is called “step therapy” or “fail first” because it requires patients to try other treatments first and demonstrate that they do not work or are intolerable. Your insurer may require you to try and fail on a different PERT treatment before covering the one prescribed by your care team.⁶ This can lead to delays in access to medically necessary treatment, which in turn, can result in disease progression. Step therapy policies may be against federal or state laws if your insurer treats you and others with similar diagnoses differently because of your health condition.⁷ Additionally, you may be entitled to an exception from the step therapy process.

Nonmedical Switching

Is my insurer forcing me to take a different medication, even though my current PERT treatment is working, by refusing to cover it any longer or increasing my co-pay?

This practice is referred to as “nonmedical switching.” It occurs when your insurer (not your health care professional or pharmacist) forces you to switch from your current PERT medication to a different (but not a generic equivalent) medication by either refusing to cover your drug any longer or increasing the out-of-pocket cost of your drug.⁸ This commonly occurs with PERT medications.⁹ However, these treatments may not be identical, and the switch can upset the patient’s stability and expose him or her to unnecessarily negative health outcomes, including abdominal pain, intestinal obstruction, and increased incidence of steatorrhea and rectal prolapse.¹⁰ Nonmedical switching may violate certain states’ consumer protection laws.¹¹



Prior Authorization

Do I need to get my insurer's approval before I can begin or continue my prescribed PERT treatment?

This practice is called “prior authorization.” It happens when your insurer requires you or your doctor to contact your insurer and get approval before the treatment is covered. Prior authorization policies can delay or interrupt care, waste time, and complicate medical decisions, as well as negatively impact clinical outcomes.¹² These policies can violate state and federal laws if applied in a certain manner.¹³



Copayment Accumulators

If I receive coupons or discounts to help pay for my medication copays, does my insurer prohibit those coupons or discounts from counting toward my annual deductible?

This policy is known as a “copayment accumulator.” There have been reports that insurers are refusing to apply drug manufacturer coupons used by patients with EPI to help pay for their medication out of pocket against a patient’s annual deductible.¹⁴ Copayment accumulators force patients to pay more out-of-pocket when copayment assistance runs out and the insurance deductible has not been met. These policies are frequently buried in the fine print of insurance contracts and may violate state consumer protection laws.¹⁵

My insurer refuses to cover a PERT treatment or therapy that my health care professional prescribed to me. **What can I do?**

If your insurer refuses to cover your treatment, here are three steps you can take to change your insurer's decision:

- Appeal the decision;
- Request an external review; or
- File a complaint.

How do I appeal the decision?

If your insurer denies your claim, you have the legal right to an internal appeal.¹⁶ This means you can ask your insurer to conduct a full and fair review of its decision. To appeal the denial, you should do the following:

Review the determination letter. Your insurer should have sent you a determination letter to tell you that it would not cover your claim. Review this document so you can understand why your insurer denied your claim and how you can appeal the denial.

Collect information. Collect the determination letter and all other documents the insurance company sent you. This includes your insurance policy and your insurer's medical necessity criteria. "Medical necessity criteria" refers to your insurer's policy for determining whether a treatment or service is necessary for your condition.¹⁷

Request documents. If you did not receive the determination letter or do not have your policy, the medical necessity criteria, or the instructions and forms for filing an appeal, call the insurer's customer service representative and ask for these documents. The company website will list the toll-free telephone number to call.

Call your health care provider's office. The health care professional's office or clinic has people on staff to help with the appeal process. They will tell you how to fill out the forms to request an appeal, write an appeal letter on your behalf, or handle the appeal request for you.

Submit the appeal request. It is important for you or your health care professional's office to submit the appeal request as soon as possible along with the letter from the health care professional and all additional information the insurer requested.

Once you file an appeal request, expect to wait up to 30 days to hear back from the insurance company regarding a treatment you hope to receive. It can take up to 60 days for a response if you received the treatment and are waiting for reimbursement.

Follow up. Follow up with your insurer regularly until you hear back. Be sure to keep a record of the name of any representative you speak with about the appeal, the date and time you spoke with that person, a confirmation number for the call, and a summary of your discussion.

What if my insurer denies my appeal?

Under law, you are entitled to take your appeal to an independent third party for an "external review," which means the insurance company no longer gets the final say over whether to approve a treatment or pay a claim. The situation applies if the insurer denies your appeal or if your medical situation is urgent and waiting would jeopardize your life or ability to function.

How do I request an external review?

To trigger an external review, file a written request with the independent organization within 60 days of the date your insurer sent you a final decision. The process should take no more than 60 days. However, in urgent situations requiring an expedited review, the process should take no longer than four business days. To find out whom to contact in your state to request an external review, please go to www.CoverageRights.org.

How do I file a complaint?

If your insurer denies your coverage after the external review process, you can file a complaint with the insurance commissioner or attorney general in your state. To determine whom to contact and how to submit the complaint, please go to www.CoverageRights.org.

Your complaint should include the following information:

- The name, address, email address, and telephone number of the person filing the complaint (“Complainant”);
- The name of the insured individual, if different from the Complainant;
- The names of any other parties involved in the claim (for example, the plan administrator);
- The name of insurance company and the type of insurance;
- The state where the insurance plan was purchased;
- Claim information, including the policy number, certificate number, claim number, dates of denial, and amount in dispute;
- The reason for and details of the complaint; and
- What you consider to be a fair resolution.

You should also submit the following documents as supporting information:

- A copy of your insurance card;
- Copies of coverage denials or adverse benefit determinations from your insurer;
- Copies of any determinations made by internal and external reviewers;
- Any materials submitted with prior appeals and complaints;
- Supporting documentation from your health care provider;
- A copy of your insurance policy; and
- All responses from your insurer.¹⁸

What happens after the insurance commissioner or attorney general receives my complaint?

The insurance commissioner or attorney general will assign someone to research, investigate, and resolve your complaint.¹⁹ That person will examine your account, records, documents, and transactions.²⁰ He or she may question witnesses, request additional documents from other parties, and hold a hearing.²¹ If the insurance commissioner or attorney general determines that the insurer violated laws or regulations, he or she may order the insurer to give you the requested coverage or compensate you.²²

Who should I call if I have any questions about filing a complaint?

To determine whom to call in your state, please go to www.CoverageRights.org.

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