

Chapter 14: Insurance Coverage for PKU Treatment



Insurance Overview

Medical foods (formula and foods modified to be low in protein) are a medical necessity for people with PKU. However, many adults and families face challenges in obtaining coverage from their health insurance.

Coverage for PKU-related medical foods varies from state to state, although 38 states have passed legislation that requires at least some coverage. Some states have passed legislation to mandate insurance coverage for medical foods, while others provide medical formula and some low protein foods directly to PKU patients through newborn screening or state health department programs.

To find information about legislation around insurance coverage of medical foods in your state, visit our state coverage resource tool at: <http://npkua.org/index.php/state-coverage-for-pku>⁹².

If you are facing insurance denials, the National PKU Alliance may be able to help with its newly launched insurance ombudsman project. To learn more, visit <http://npkua.org>. Here you find additional information on the insurance appeals rights, your rights under the recently passed Affordable Care Act, as well as how to request a volunteer advocate to assist you with your cover issues. The first step to understanding your coverage for medical foods is to have a basic understanding of your health insurance plan.

Questions to Consider When Choosing a Health Insurance Plan

Many employers change health insurance companies on a frequent basis. This typically happens with the start of the benefits year. If you are facing this situation, it is critical that you be pro-active and work with your employer to try to ensure coverage of medical foods for PKU.

Questions to ask when your company informs you that they will switch health insurance companies:

- Who is the first point of contact for questions?
 - o Your employer's HR Manager
 - o A Benefits Consultant/Advisor hired by your employer, if offered
 - o Toll free phone number for the insurance company
- Is the plan insured or self funded?
 - o Under an insured plan, the employer purchases commercial health care coverage from an insurance company, and the insurance company assumes the risk for payment of claims. Insured plans are regulated by the individual states. If the plan is self funded, (often times called a "self-insured" plan), the employer keeps the risk to pay the bills and usually hires a plan administrator to process the claims. This differentiation is important because self funded plans are not subject to state insurance laws or regulations – a state cannot require a self-funded employer to cover PKU medical foods (formula and foods modified to be low in protein).
 - o The best way to determine if the plan is self-funded is to ask the employer or call the plan. Generally, most very large employers and union plans self-funded.

⁹² National PKU Alliance. "State Coverage for PKU." <http://npkua.org/index.php/state-coverage-for-pku>

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- o Another way to determine if the plan is insured or self funded is to be aware of the documentation you receive. If your employer has an insurance policy, the plan is insured. If they have a plan document, the plan is self funded.
- o Be aware that many self-funded plans use insurance companies to process their claims and perform other administrative duties. To further the confusion, the insurance company may also “rent” their provider network to the plan, so a self-funded plan may look very much like an insured plan.
- o Sometimes self-funded plans are called “ERISA plans.” ERISA is a very broad federal law that also regulates employer health plans. Don’t be misled by this term - virtually ALL employer plans, whether they are insured or self-funded, are regulated by ERISA and technically are “ERISA plans.” But generally, if a plan is called an “ERISA plan” it is probably self-funded.
- o Another good way to determine if the plan is insured or self-funded is to read the documentation you receive. It may tell you directly if the plan is insured or self-funded.
- o In addition, all ERISA-regulated plans are required to provide certain information to plan participants, but many employers with insured plans do not fully comply with this rule. The plan sponsor (usually the employer) is responsible for this, not the insurance company. Thus, if the employer has an insured plan, you may not see federally required information in the plan documents – typically missing would be the name of the “plan administrator”, the designation of the plan’s fiduciary, the plan year and plan number (used for federal reporting), and the plan name. If this information is missing, it’s probably an insured plan.
 - Often your first point of contact at an insurance company will not know if there are state mandates. For example, when they first run a query, they will often get a message back stating that the formula is not covered because it is available over the counter. This can be disproven with just a few documents.
 - It may be necessary to submit your state’s insurance coverage laws to the insurance company’s appeals department in writing after your coverage begins. Current laws can be found on the NPKUA website at www.npkua.org under the legislation tab.
 - Be aware that private insurance companies may have different rules.
 - If your company opts for a self-insured plan, ask your company to work with you to ensure that formula is covered. Self- insured plans can design their own coverage spectrum and are not obligated to follow state mandates for coverage.
- o Understand what benefit category medical foods fall under. Typically medical foods are covered either as a pharmacy product or a medical product. Some insurers may provide coverage for the formula, but not the foods modified to be low in protein.
 - Pharmacy benefit – your medical foods will be covered like a prescription drug and you will need to pay a monthly co-pay.
 - Medical benefit – your medical foods will be covered like Durable Medical Equipment (DME). The cost may be \$0 per month or a percentage to be determined, after the deductible is met.
- In some instances the insured will pay out a percentage of the cost and be reimbursed.
- Some plans also establish annual benefit maximums.

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- What choices are available for plans? Does one meet your needs better than the others?
- o Three plans are often offered:
 - HMO – (Health Maintenance Organization) plans are often the most restricted and some may not cover medical foods.
 - POS - (Point of Service) plans usually provide good coverage but with limited choice of providers.
 - PPO - (Preferred Provider Organization) plans are sometimes the least restrictive in terms of both coverage and choices.

It's important that you do the math. Find out the contribution to the premium for each plan. This contribution is the amount of money you pay to an insurance company for insurance coverage. It is important to note that even if a certain plan has a lower contribution (meaning you will be paying less each month for your insurance coverage), it may mean you have to pay more out of pocket for medical services. So if you are going to be accessing health-care often, it may be worthwhile to pay a higher premium up front to get better coverage later when you need it most. Consider the following scenario:

- Standard Plan- Biweekly premium \$100 or \$200/mo. Benefits pay 50% of medical food costs. Medical formula is \$1200/mo. You would pay a total of \$800/mo (\$200 for insurance and \$600 for formula) under this plan.

- Premium Plan- Biweekly premium \$200 or \$400/mo. Benefits pay 80% of medical food costs. Medical formula is \$1200/mo. You would pay \$640/mo.(\$400 for insurance and \$240 for formula) under this plan.

- o If an itemized benefits package is not handed out, request one and read it over. Pay close attention to sections relating to the needs of PKU: pharmacy copays, Durable Medical Equipment coverage, and specialist doctors. If it is unclear you can ask your first point of contact for clarification or more details.
- o If none of the plans meet your needs, it doesn't hurt to ask for more options. It is not unheard of for an HR Manager in a small company to make changes to better meet the needs of the employees.
- o Find out if there is a Flexible Spending Account available. Your deductible and copays can be tax-free if planned out in advance. Keep in mind that these accounts do not roll over into the next year.
- o If your needs allow, you may find it beneficial to opt in to a Health Savings Account. These are similar to a Flexible spending Account in that they are not taxed, but may require you to choose a very high deductible plan. A benefit is that they do roll over at the end of the year. A Health Reimbursement Plan is similarly not taxed, but may not roll over year to year.
- o Know your expenses. Keep a record of how much you spend on PKU products per month and per year to help you determine which plan fits your needs best.
- Is your preferred PKU clinic in-network?
 - o If not, contact your clinic and ask if they can try to join the network, or if they already have a plan for such situations. You can also ask the plan for an "out of network" exception.

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Documentation to have available:

- Soft and hard copy of your state’s legislation regarding coverage for medical foods.
- Proof of prior coverage (will be sent by previous insurance company within 30 days of cancelation of coverage).
- Contact information for your previous insurance company, as well as your old group number, individual ID number, and toll free phone number (ID card or copy of both sides).
- Copy of your prescription for medical foods.
- Full name of your formula and manufacturer contact information.
- PKU quick facts sheet: description, diagnosis, symptoms, treatment, etc.
- Send your clinic your new health insurance information as soon as possible. Your new insurance company may require correspondence with your clinic to approve your formula coverage. It is much easier to get assistance from your clinic if they have had time to prepare for the near-inevitable request for Letters of Medical Necessity (see Appendix A).

Other Tips

- Your HR Manager or benefits consultant may request a list of your diagnoses and treatments, including all prescription products and procedures required. This helps them determine how to help you get the best coverage option. If they don’t ask for it you may offer it.
- The internet and search engines can be a valuable research tool to find information about health insurance companies, look up terminology, and reach out to your PKU communities for support.

Understanding Your Current Health Insurance Plan

In order to learn about your current coverage, or if you receive a denial for medical foods coverage, you need to get a copy of your master insurance policy (for insured plans) or the plan document (for self funded plans) and read it. If you have a self funded plan, ERISA requires that the plan administrator (generally the employer) provide this documentation within 30 days of a request. Many employers don’t know they are required to do this and will often tell employees that they don’t have anything. Sometimes people think they have 100% coverage for all prescriptions, services and medical foods, just because they have insurance. This is not true⁹³. It’s important to read your coverage document carefully.

- Find out if medical foods for PKU are a covered benefit and if you will be responsible for any co-payments, co-insurance and/or other deductibles⁹⁴.
- If medical foods are covered, you need to learn whether they are a medical benefit or a prescription benefit. This determines who will supply the formula. If your formula is covered under the prescription part of your benefits, then you can have your prescription filled at an approved pharmacy. If your medical food is covered under the medical part of your benefits then you will need to have a medical supply company provide the formula. To find an “In-Network” pharmacy or medical supply company, ask the insurance representative for a provider list or contact your metabolic team and/or the formula manufacturer⁹⁵.
- If you are a federal employee and have insurance through the Federal Health

⁹³Maltzman, S. : *My PKU Toolkit A Transition Guide to Adult PKU Management*. New Jersey: Applied Nutrition Corp. , p. 50.

⁹⁴Maltzman, S. : *My PKU Toolkit A Transition Guide to Adult PKU Management*. New Jersey: Applied Nutrition Corp. , p. 50.

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Employee Benefits (FEHB), medical formula is normally covered for children up to the age of 26. Foods modified to be low in protein are normally not covered. In addition, it's important to know that federal plans do not have to follow any state or most federal mandates for coverage.

- If you are on Medicaid, your formula should be covered and foods modified to be low in protein should be covered as part of the Early and Periodic Screening, Diagnostic and Treatment program as a health benefit under medical supplies.
- Contact your HR manager at work to learn if your health insurance plan is a self-insured plan. This will help you determine whether or not your plan has to follow any mandates that exist in your state regarding coverage for medical foods. ERISA prevents many adults and families from getting coverage for medical foods despite these state laws. Self-funded plans can design their own coverage spectrum. In many cases, these plans choose to exclude medical foods for the treatment of PKU from their coverage. Many companies provide a self-funded plan to their employees because it costs less to do so. If your employer moves from an insurance plan to a self-funded plan, they will often maintain the same benefits. They will often not remove the coverage until they find out they have large claims, but it is a violation of The Health Insurance Portability and Accountability Act (HIPAA) to remove benefits for a particular condition that a participant is being treated for.
- You still have a right to appeal a denial for medical foods coverage if you have a self-funded plan. See the section on Appeals Process for more information.

Letter of Medical Necessity

In order to obtain insurance coverage or appeal a denial, you will need a letter of medical necessity from your doctor. The letter should detail your specific needs for medical foods and laboratory coverage as treatment for your PKU condition. It should also clearly state why these treatments are necessary for managing your PKU. A sample letter of medical necessity can be found in the resources section.

Dealing with Your Insurance Company⁹⁶

To get the maximum coverage for medical foods to which you are entitled, you need to contact your insurance company. Call the member/customer service number on your insurance card and ask for the benefits department to find out if a prior approval is required. Always write down the name of the person with whom you spoke, the date and any information discussed. If the representative won't give out personal information, get his/her first name, ID number or direct phone extension, at the very least.

Inform the representative of your needs. Be sure to provide him/her with the product name, description, national drug code (NDC), HCPCS code, and manufacturer name and phone number. These codes can be located by calling the manufacturer of your medical food. Explain that you need this product for the dietary management of Phenylketonuria (ICD-9/ diagnosis code: 270.1), which is an inherited disorder of metabolism and that this product is medically necessary for your treatment. Specific information in commonly used codes can be found in Appendix B.

Your insurer should be able to tell you if medical foods are a covered benefit and whether

⁹⁶Maltzman, S. : *My PKU Toolkit A Transition Guide to Adult PKU Management*. New Jersey: Applied Nutrition Corp. , p. 51.

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or not you will need prior approval for coverage. If you do need prior approval, find out where to fax or mail the copy of your state law, prescription and letter of medical necessity to obtain a prior approval number. Keep records of any fax transmittals and return receipt via mail.

Sometimes the insurance representative may not be familiar with the policies regarding medical foods. If this is the case, ask to speak with a supervisor or case manager and begin again. At this point it may be helpful to mention that there is a state law that mandates coverage (if one exists in your state).

Keep an insurance file where all of the paper work, documentation and receipts can be kept for future reference. You can also request a case manager from the insurance company. Most insurance companies provide case management services for people with chronic health issues. A case manager can prove to be very helpful in navigating the insurance benefits.

Flexible Spending Accounts

A Flexible Spending Account (FSA) is an employer-provided benefit that allows employees to set aside income from their paychecks to pay for medical expenses. The major benefit to FSA account holders is that this income is not taxed, saving both money on income taxes as well as increasing the amount of money that can be spent on medical expenses (as it is actual income, rather than taxed income).⁹⁷

If you have medical food expenses that are not covered or partially-covered by your insurance company, an FSA can be a convenient way to save money over the course of the year from your paycheck. Usually you will determine how much money should be allocated from your paycheck into your FSA at the beginning of each year. Generally, only the cost of foods modified to be low in protein that exceed the cost of normal foods can be reimbursed.

Not every employer has an FSA benefit. Talk to your employer or benefits administrator about your employer's FSA plan and how it could work for you.

Insurance Resources

National PKU Alliance: The NPKUA works to improve the lives of individuals with PKU and pursue a cure. This tool-kit is part of our Insurance Ombudsman Initiative to provide information and support to adults and families struggling with insurance

What is ERISA?

The Employee Retirement Income Security Act of 1974 (ERISA) is a federal law which is primarily concerned with pension plans. However, it also sets minimum standards for many employee benefits, including employer provided health coverage.

ERISA governs approximately 2.5 million health benefit plans sponsored by private employers nationwide. It does not apply to government and church employee plans.

ERISA plans are not subject to state insurance laws or jurisdiction. Thus, even in your state has a law requiring some sort of coverage for medical foods, if your plan is self-funded, it does not have to follow the state law. This called an ERISA exemption.

⁹⁷FSAFeds. "What is a Flexible Spending Account?" <https://www.fsafeds.com/fsafeds/summaryofbenefits.asp#WhatIsFSA>

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coverage for medical foods. A central part of this new program will be to offer support and guidance through a network of lay advocates. www.npkua.org

The Patient Advocacy Foundation: This foundation provide pro bono case management and insurance mediation assistance for those with chronic, debilitating, or life threatening diseases. They may be able to provide assistance to PKU adult and families. www.patientadvocate.org. 1-800-532-5274.

Nutricia Product Coverage Navigator: Nutricia's program in Massachusetts, New York and Texas provides assistance to families using their metabolic products. They can provide assistance with prior authorizations, claims submissions, medical necessity letters, billing errors and the appeal process. 1-800-356-7354, ext. 1200.

Resources are available to support you in managing phenylketonuria (PKU) and its treatment. First, and most importantly, your PKU team is always available to support you as your primary support and source of information. Resources have also been developed and refined over the years to help you. Here we provide you with samples and direction to other resources that will continue to support you with managing PKU from infancy through to adulthood.