

# ACCESS TO MEDICAL FOODS AND FORMULA

Lifesaving Care for People with  
Heritable Metabolic Conditions

For people with metabolic disorders, **medical foods and formulas (aka, medical nutrition) is their medicine — not a dietary choice.**

## OVERVIEW

Individuals with inherited metabolic disorders—such as **phenylketonuria (PKU)**, **maple syrup urine disease (MSUD)**, and **homocystinuria**—cannot process certain nutrients found in regular food. For them, medical foods and formulas are not dietary preferences — they are essential therapy that prevents severe illness, organ damage, or death.

### WHAT ARE MEDICAL FOODS & FORMULAS?

Specially formulated nutritional products used to manage metabolic or genetic disorders, such as those without certain amino acids found in natural foods.

- Prescribed by a healthcare provider and used under medical supervision, including in home settings
- Provide nutrients that patients cannot obtain from normal food without harm.



### WHO RELIES ON **MEDICAL FOODS AND FORMULAS?**

- Patients with heritable metabolic disorders (e.g., PKU, MSUD, urea cycle disorders).
- Individuals who cannot metabolize certain amino acids, fats, or carbohydrates.
- People with certain other conditions, such as malabsorption conditions or food protein allergies.
- Many are children, for whom medical foods are the only safe option to grow and develop normally.



### COVERAGE **GAPS**

- Most insurance plans do not cover medical foods and formulas, as they are not classified as “drugs.” However, they typically cover more expensive treatments (e.g., enzyme replacement therapy) and costly hospitalizations that occur when a patient cannot access their medical nutrition.
- Families often pay \$5,000–\$20,000 annually out-of-pocket for medical foods and formulas.

### EXAMPLE OF A CONDITION REQUIRING MEDICAL NUTRITION

PKU is a heritable metabolic condition that makes it hard for the body to process phenylalanine (Phe), an amino acid found in protein-rich foods like meat, dairy, nuts, beans, and grains. If not carefully managed, **Phe can build up and cause irreversible brain damage. Specially made Phe-free medical foods and formulas are the only safe way for people with PKU to get the protein they need.**

### WHY IT MATTERS

- Without access to medical nutrition, patients risk hospitalization, disability, and even death.
- Coverage for medical foods and formulas would ensure access, thus reducing emergency care costs and supporting lifelong health and independence.
- **Medical nutrition is not a lifestyle – it is necessary medical care.**

