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# 5.80.001

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2024
<b>Subsection:</b>	Nutritional Products	<b>Original Policy Date:</b>	January 1, 2018
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**Last Review Date:** June 13, 2024

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## Medical Foods

### Description

#### Medical Foods

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#### Background

Medical foods are narrowly defined by the FDA under the Orphan Drug Act amendments as a food product specially formulated or processed to be used for the management of a disease or condition's specific nutritional needs or restrictions. The particular formulation and processing makes medical foods distinct from other foodstuffs consumed in their natural state. Medical foods are not simply those recommended by a physician for the management of a disease or condition. They are formulations developed specifically for the therapeutic or chronic management needs of a nutritional condition that could not be met through dietary modification alone, such as inborn errors of amino acid metabolism, food allergy, or an inability to meet nutritional needs orally.

Inborn errors of amino acid metabolism are, as implied by the name, metabolic disorders due to the inherited loss of an enzyme required for the metabolism of specific amino acids. For example, phenylketonuria (PKU) requires lifelong phenylalanine restriction and tyrosine supplementation in diet, while maple syrup urine disease requires only restriction of specific amino acids (leucine, valine, and isoleucine). As it would be nearly impossible to restrict specific components solely through naturally occurring foodstuffs alone, medical foods are often used to meet the nutritional needs of these patients.

Medical foods are also formulated to be hypoallergenic and can be used in the medical management of conditions where the specific allergen contributes to poor or worsening

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outcomes in the condition such as atopic dermatitis, gastrointestinal symptoms, IgE mediation, malabsorption disorder, seizure disorder, failure to thrive, or prematurity.

Specially formulated food may also be necessary to manage anatomic or structural issues, with or without a feeding tube, that inhibit food from reaching the small intestine, such as obstructing tumors, jaw fracture, or intestinal atresia. Functional inability to swallow foods or a significant risk of aspiration associated with chewing and swallowing food may also the use of medical food.

## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Medical foods may be considered **medically necessary** if the conditions indicated below are met.

Medical foods may be considered **investigational** for all other indications.

## Prior-Approval Requirements

### Diagnoses

Patient must have **ONE** of the following:

1. Tube feeding

**AND ALL** of the following:

- a. An inability to meet nutritional needs orally documented by **ONE** of the following:
  - i. An anatomic or structural problem that prevents food from reaching the small intestine (i.e., an obstructing tumor, reconstructive surgery, jaw fracture, gastrointestinal cancer, intestinal atresia (infants))
  - ii. An inability to functionally swallow foods orally with significant risk of aspiration (i.e., stroke, dysphagia, neurological/neuromuscular disease, CNS impairment)
  - iii. A disease that impairs the ability to absorb foods orally
- b. The presence of a feeding tube (i.e., NG tube, G tube, J tube, PEG tube) used for the administration of the medical food formula

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2. Inborn error of amino acid metabolism

**AND ONE** of the following diagnoses:

- a. Phenylketonuria (PKU)
- b. Tyrosinemia
- c. Homocystinuria
- d. Maple Syrup Urine Disease
- e. Propionic Acidemia
- f. Methylmalonic Acidemia
- g. Other Organic Acidemias
- h. Urea Cycle Disorders

3. Food allergy\*

- a. Product must be administered orally
- b. Product must provide sole source 100% of nutrition

**AND ONE** of the following:

- a. Atopic dermatitis (AD)
  - i. Documentation confirms role of commercial formulas in causing atopic dermatitis (e.g., an immediate reaction after ingestion, or a well-defined elimination diet)
- b. Bloody stools with or without weight loss or other GI symptoms
  - i. Guaiac card testing confirms the presence of bloody stools
- c. Eosinophilic esophagitis (EE) or eosinophilic gastroenteritis
  - i. Confirmed by elimination diet or supportive IgE-specific antibody testing
- d. Failure to thrive (FTT) disorder with **ONE** of the following:
  - i. Weight less than the 5<sup>th</sup> percentile for age
  - ii. BMI less than the 5<sup>th</sup> percentile
- e. Gastroesophageal reflux disease (GERD) or GI irritability
- f. IgE mediated food allergy
- g. Ketogenic formula for uncontrolled seizures
- h. Malabsorption disorder with **ONE** of the following:
  - i. Diagnosis of food protein-induced enteropathy or enterocolitis
  - ii. Clinical history and supportive testing confirming **ANY** of the following:
    - 1) Crohn's disease
    - 2) Ulcerative colitis
    - 3) Gastrointestinal motility disorders

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- 4) Chronic intestinal pseudo-obstruction
- 5) Cystic fibrosis
- i. Prematurity

**AND ALL** of the following for **ALL diagnoses**:

1. Product must be a medical food as defined by the FDA-drugs on the medical foods listing
2. Product must be intended for use solely under medical supervision in the dietary management of the condition
3. Patient must be receiving active, regular, and ongoing medical supervision and unable to manage the condition by modification of diet

\*Benefits for members with **food allergies** are limited to one year following the date of the initial prescription or physician order for the medical food.

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## Prior – Approval *Renewal* Requirements

Same as above

\*Benefits for members with **food allergies** are limited to one year following the date of the initial prescription or physician order for the medical food.

## Policy Guidelines

### Pre - PA Allowance

None

### Prior - Approval Limits

#### Tube feeding

**Duration** 12 months

#### Inborn error of amino acid metabolism

**Duration** 12 months

#### Food allergy

**Duration** 6 months (maximum of 1 year benefit per Lifetime )

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## Prior – Approval *Renewal* Limits

### Tube feeding

**Duration** 12 months

### Inborn error of amino acid metabolism

**Duration** 12 months

### Food allergy

**Duration** 6 months (maximum of 1 year benefit per Lifetime – **ONE** renewal only)

## Rationale

### Summary

Medical foods are specially processed and formulated products intended for use under the supervision of a healthcare provider for the management or treatment of a condition that could not be managed through diet modification alone. Conditions such as food allergies, anatomical or functional variation that inhibits food from reaching the small intestine, or inborn errors of amino acid metabolism.

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of medical food products while maintaining optimal therapeutic outcomes.

## Policy History

Date	Action
December 2017	Annual review. Addition to PA for January 1, 2018
February 2020	Changed tube feeding and inborn error of metabolism renewal duration from 6 months to 12 months and removed maximum 1 year of benefit per lifetime for inborn error of metabolism per FEP
March 2020	Annual review
May 2020	Removed age requirement for Food Allergy diagnosis and changed initial PA duration to 12 months for inborn error of metabolism and tube feeding per FEP/OPM
June 2020	Annual editorial review. Revised background section
June 2021	Annual review
December 2022	Annual review. Per FEP/OPM: removed age limit for inborn errors of amino acid metabolism. Changed policy number to 5.80.001

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June 2023	Annual review
June 2024	Annual review

## [Keywords](#)

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**This policy was approved by the FEP® Pharmacy Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.**