

5.80.01

Section:	Prescription Drugs	Effective Date:	July 1, 2022
Subsection:	Nutritional Products	Original Policy Date:	January 1, 2018
Subject:	Medical Foods	Page:	1 of 6

Last Review Date: June 16, 2022

Medical Foods

Description

Medical Foods

Background

Medical foods are defined by the FDA in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." These foods provide enteral nutritional for patients who find them medically necessary. Medically necessary products are those that are deemed effective as a specific treatment or are required to avoid chronic disability, mental retardation or death. The plan covers special medical formulas and enteral nutrition that are ordered by a licensed health care provider, and medically necessary to prevent clinical deterioration in members at nutritional risk:

1. An inability to meet their nutritional needs orally
2. Food allergy, GI irritability, seizure disorder, malabsorption disorder, failure to thrive, or prematurity
3. An inborn error of amino acid metabolism

Per the Service Benefit Plan Brochure, benefits are available for medical foods, when ordered by a healthcare provider for the clinical deterioration in members at nutritional risk. Coverage is provided as follows:

1. Inborn errors of amino acid metabolism in patients 22 years of age or younger
2. Food allergy with atopic dermatitis, gastrointestinal symptoms, malabsorption disorder, seizure disorder, failure to thrive, or prematurity, when administered orally and is the sole source (100%) of nutrition. This once per lifetime benefit is limited to one year

5.80.01

Section:	Prescription Drugs	Effective Date:	July 1, 2022
Subsection:	Nutritional Products	Original Policy Date:	January 1, 2018
Subject:	Medical Foods	Page:	2 of 6

following the date of the initial prescription or physician order for the medical food (e.g., Neocate, in a formula form or powders mixed to become formulas)

3. Medical foods and nutritional supplements when administered by catheter or nasogastric tubes

Coverage requirements:

- a. Nutritional formula must meet the definition of Medical Food;
- b. The Medical Food must be medically necessary;
- c. The Medical Food is not an excluded product (i.e., non-formula);
- d. Member must be receiving active, regular and ongoing medical supervision; and
- e. Member must be unable to manage their condition by modification of diet alone

Benefits are not available for Medical Foods in the following situations and are therefore not addressed in this policy:

1. Products and foods other than liquid formulas or powders mixed to become formulas such as:
 - a. Foods and formulas readily available in a retail environment and marketed for persons without medical conditions;
 - b. Low protein modified foods (i.e., pastas, breads, rice, sauces, baking mixes, etc.);
 - c. Nutritional supplements;
 - d. Energy products;
2. Special medical formulas and enteral nutrition used solely for food preference
3. Products administered orally for any condition not described in this policy
4. Medical foods administered orally for individuals age 22 and older

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 administered via a feeding tube may be considered **medically necessary** for members of any age that are unable to meet their nutritional requirements orally.

Medical Foods administered orally may be considered **medically necessary** in members with a diagnosis of inborn errors of Amino Acid Metabolism or food allergy; and if the conditions indicated below are met.

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

Section:	Prescription Drugs	Effective Date:	July 1, 2022
Subsection:	Nutritional Products	Original Policy Date:	January 1, 2018
Subject:	Medical Foods	Page:	3 of 6

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

2. Inborn Error of Amino Acid Metabolism

- a. 22 years of age or younger

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

5.80.01

Section:	Prescription Drugs	Effective Date:	July 1, 2022
Subsection:	Nutritional Products	Original Policy Date:	January 1, 2018
Subject:	Medical Foods	Page:	4 of 6

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 5th percentile for age
 - ii. BMI less than the 5th 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
 - 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

*NOTE: 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 (e.g., Neocate)

Section:	Prescription Drugs	Effective Date:	July 1, 2022
Subsection:	Nutritional Products	Original Policy Date:	January 1, 2018
Subject:	Medical Foods	Page:	5 of 6

Prior – Approval *Renewal* Requirements

Same as above

*NOTE: 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 (e.g., Neocate, in a formula form or powders mixed to become formulas)

[Policy Guidelines](#)

Pre - PA Allowance

None

Prior - Approval Limits

Tube Feeding

Duration 12 months

Inborn Error of Metabolism

Duration 12 months

Food Allergy

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

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)

[Rationale](#)

Summary

5.80.01

Section:	Prescription Drugs	Effective Date:	July 1, 2022
Subsection:	Nutritional Products	Original Policy Date:	January 1, 2018
Subject:	Medical Foods	Page:	6 of 6

Medical foods may be considered medically necessary if the nutritional product is being used for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. A patient is considered at nutritional risk when documentation confirms he/she is malnourished, or at risk for developing malnutrition, due to a medical condition, chronic disease, or increased metabolic requirements resulting from the inability to ingest or adequately absorb food.

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
June 2022	Annual review

Keywords

This policy was approved by the FEP® Pharmacy Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.