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 administered under the supervision of a physician:

1. For children through age 21 which are administered orally and provide the sole source (100%) of nutrition;
   a. This benefit is limited to one year following the date of the initial prescription or physician order for the medical food (e.g. Neocate, in formula form only); OR
2. For children through age 21 which are specialized nutritional formulas intended for use solely under medical supervision in the dietary management of an inborn errors of amino acid metabolism; OR
3. For any age member when medically necessary to be administered by a catheter or nasogastric tube

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 21 years of age or younger 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.

Prior-Approval Requirements

Tube Feeding
Age  None

Food Allergy & Inborn Error of Metabolism
Age  22 years of age or younger

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. Food Allergy*

   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:
       1. Product must be administered orally
       2. Product must provide sole source 100% of nutrition

3. 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

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 and Inborn Error of Amino Acid Metabolism are limited to one year following the date of the initial prescription or physician order for the medical food (e.g., Neocate)

Prior – Approval Renewal Requirements
Same as above

*NOTE: Benefits for members with Food Allergies and Inborn Error of Amino Acid Metabolism are limited to one year following the date of the initial prescription or physician order for the medical food (e.g., Neocate)

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Tube Feeding
Duration 6 months

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

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

Prior – Approval Renewal Limits

**Tube Feeding**

Duration 6 months

**Food Allergy**

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

**Inborn Error of Amino Acid Metabolism**

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

**Rationale**

**Summary**

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**

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<tr>
<td>December 2017</td>
<td>Annual review</td>
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<td>Addition to PA for January 1, 2018</td>
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**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2017 and is effective on January 1, 2018.