

## Home Enteral Nutrition

### Description

Enteral nutrition consists of nutritional support given via the alimentary canal directly or through any of a variety of tubes used in specific medical circumstances. This includes oral feeding, sip feeding, and tube feeding using nasogastric, gastrostomy, and jejunostomy or other tubes. While standard food is technically an enteral nutritional product, this document addresses "medical food" (please see the Definitions section for further information regarding "medical food") and commercially available processed enteral products, which are not standard food, when used in the home to meet basic metabolic needs in a variety of conditions affecting either the mechanical or metabolic process of digestion.

**Note:** Some benefit plans exclude products available without prescription, sometimes referred to as 'over the counter', even when prescribed by a physician or other healthcare provider. Enteral food products are often available without prescription. Please see the text in the footnote of this document regarding Federal and State mandates and contract language, as these documents often specifically address the topic of enteral nutrition.

### Clinical Indications

#### I. Oral Enteral Nutrition

#### Medically Necessary:

Oral enteral nutrition is considered medically necessary for individuals *who meet the following criteria:*

- A. The product must be a medical food for oral or tube feeding; and
- B. The product is the primary source of nutrition, i.e., more than half the intake for the individual; and
- C. The product must be labeled and used for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements to avert the development of serious physical or mental disabilities or to promote normal development or function as listed in below:

1. Conditions associated with an in-born error of metabolism that interfere with the metabolism of specific nutrients, including, but not limited to
    - a. Phenylketonuria (PKU), or
    - b. Homocystinuria, or
    - c. Methylmalonic acidemia, or
    - d. Propionic acidemia, or
    - e. Maple syrup urine disease, or
    - f. Propionic acidemiaor
  2. Conditions that interfere with nutrient absorption and assimilation, including, but not limited to:
    - a. Allergy or hypersensitivity to cow or soy milk diagnosed through a formal food challenge (standard basic/over the counter cow's milk and soy-based formulas are excluded)
    - b. Anaphylaxis to food
    - c. Allergic or eosinophilic enteritis (colitis/proctitis, esophagitis, gastroenteritis)
    - d. Cystic fibrosis with malabsorption
    - e. Diarrhea or vomiting resulting in clinically significant persistent dehydration requiring treatment by a medical provider
    - f. Malabsorption unresponsive to standard age-appropriate interventions when associated with failure to gain weight or meet established growth expectations
    - g. Failure to thrive unresponsive to standard age-appropriate interventions (e.g. Whole milk, Carnation Instant Breakfast™) when associated with weight loss, failure to gain weight or to meet established growth expectations, including but not limited to:
      - 1a. Premature infants who have not achieved the 25th percentile for weight based on their chronological age
      - 1b. individuals with end-stage renal disease and an albumin less than 4 gm/dl
- D. The product must be used under the supervision of a physician or nurse practitioner or ordered by a registered dietician upon referral by a health care provider authorized to prescribe dietary treatments.

3. Oral enteral nutrition is considered **medically necessary** when the diet consists of less than 50% enteral nutrition and more than 50% standard diet for age when:

- The enteral product is used as part of a defined and limited plan of care in transition from a diet of more than 50% enteral products to standard diet for age, or
- Medical records document a medical basis for the inability to maintain appropriate body weight and nutritional status prior to initiating or after discontinuing use of an enteral supplement as well as ongoing evidence of response to the enteral nutrition.

**Not Medically Necessary:**

Oral enteral nutrition is considered **not medically necessary** when the criteria above have not been met.

Oral enteral nutrition is considered **not medically necessary** when use of the enteral product is based on the convenience or preference of the individual or provider (i.e., when a diet consisting of typical processed foods where specific substances can be avoided, e.g., gluten free or food allergen free, would be appropriate).

**II. Enteral Nutrition Via Tube**

**Medically Necessary:**

Enteral nutrition via tube is considered **medically necessary** for individuals when the enteral nutrition comprises the majority of the diet, and the product is used under the supervision of a physician or nurse practitioner, or ordered by a registered dietician upon referral by a health care provider authorized to prescribe dietary treatments, and nutrients cannot be taken orally due to a medical condition which either, interferes with swallowing (e.g., dysphagia from a neurological condition, severe chronic anorexia nervosa unable to maintain weight and nutritional status with oral nutrition), or is associated with obstruction of the proximal gastrointestinal tract (e.g., tumor of the esophagus).

Enteral nutrition via tube is considered **medically necessary** when the diet consists of less than 50% enteral nutrition and more than 50% standard diet for age when the product is used under the supervision of a physician or nurse practitioner, or ordered by a registered dietician upon referral by a health care provider authorized to prescribe dietary treatments, and:

- A. The enteral product is used as part of a defined and limited plan of care in transition from a diet of more than 50% enteral products to standard diet for age, or
- B. Medical records document a medical basis for the inability to maintain appropriate body weight and nutritional status prior to initiating or after discontinuing use of an enteral supplement as well as ongoing evidence of response to the enteral nutrition.

#### **Not Medically Necessary:**

Enteral nutrition via tube is considered not medically necessary when used in individuals with normal swallowing and normal proximal gastrointestinal tract function, except as stated above. Enteral nutrition via tube is considered not medically necessary when used in individuals able to take most of their diet via the oral route except as indicated above.

### **III. Other Considerations**

#### **Not Medically Necessary:**

The use of formulas and other food products is considered not medically necessary when the criteria above have not been met, including but are not limited to:

- A. Used primarily for convenience or for features which exceed those which is medically necessary (e.g., pre-packaged, liquid vs. powder, etc.).
- B. When used for individuals with disorders of swallowing where non-medical food is tolerated.

#### **Definitions**

**Dysphagia:** Difficulty swallowing due to abnormal swallowing reflex

**Food allergy or hypersensitivity:** Clinically abnormal response believed to be caused by an immunologic reaction resulting from the ingestion of a food or food additive.

**Food anaphylaxis:** Classic allergic hypersensitivity reaction to food or food additives involving IgE antibody that occurs rapidly and may be life threatening.

**Food Challenge:** An evaluation technique that may be used to assist in diagnosis of food or eating-related disorders; after an adequate time with the exclusion of suspected foods (usually a week or two), the suspected food or foods are administered under close supervision in a dose escalation manner with proper observation periods between doses; food challenges may be done in an open

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manner with the patient aware of what they are being given, with the patient unaware, or with both the patient and physician unaware.

**Medical Food:** defined 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. \*

\* U.S. Food and Drug Administration. Regulatory information. Section 5 of Orphan Drug Act. Available at: 2023)

Proximal Gastrointestinal Tract: the section of the gastrointestinal tract from the mouth to the small bowel

Standard Food: regular grocery products including typical infant formulas such as Similac, Nutramigen and Enfamil

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