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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:*

1. The product must be a medical food for oral or tube feeding; and
2. The product is the primary source of nutrition, i.e., more than half the intake for the individual; and
3. 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 i. or ii. below:
 - i. 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
 - ii. 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), or
 - b. Anaphylaxis to food, or
 - c. Allergic or eosinophilic enteritis (colitis/proctitis, esophagitis, gastroenteritis); or
 - d. Cystic fibrosis with malabsorption; or
 - e. Diarrhea or vomiting resulting in clinically significant dehydration requiring treatment by a medical provider; or
 - f. Malabsorption unresponsive to standard age appropriate interventions when associated with failure to gain weight or meet established growth expectations; or
 - 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:
 - Premature infants who have not achieved the 25th percentile for weight based on their chronological age; or
 - individuals with end-stage renal disease and an albumin less than 4 gm/dl; and
4. 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.

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:

1. 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

2. 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, i) 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 ii) 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:

1. 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
2. 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 the majority 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 not limited to:

- Used primarily for convenience or for features which exceed that which is medically necessary (e.g., pre-packaged, liquid vs. powder, etc.).
- 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 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:

<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FCDAAct/ucm109555.htm> Accessed on December 9, 2010.

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

Discussion/General Information

Enteral nutrition is indicated in order to maintain optimal health status for individuals with diseases or structural defects of the alimentary tract that interfere with transport, digestion or absorption of nutrients. Such conditions may include anatomic obstructions due to cancer, motility disorders such as gastroparesis, or metabolic absorptive disorders such as Phenylketonuria (PKU).

When enteral nutrition is necessary, the optimal route is swallowing by mouth. In conditions where this is not possible, a tube is placed to facilitate transport of the enteral nutrition to the digestive/absorptive site in the GI tract. Tube placement and types are governed by the patient's needs. Easiest placement is the nasogastric approach through the nose. Proper location of the distal end of the tube is important, as there is the risk of migration and aspiration. Enteral tubes may also be placed percutaneously through an abdominal approach and secured for access. This approach is used for most long-term needs. The risk of aspiration and reflux is reduced since placement is lower in the GI tract (Simon, 2000; CMS NCD for Enteral Nutrition, 1984).

Total Enteral Nutrition (TEN) infers that the individual is receiving more than 50% of daily caloric intake via tube feedings. If fewer than 50% of daily calories are supplied daily by enteral nutrition products, they are considered supplemental.

Oral enteral formula is needed for individuals with inherited metabolic digestive disorders such as:

- Tyrosinemia
- Homocystinuria
- Maple syrup urine disease
- Propionic acidemia
- Methylmalonic acidemia
- (PKU)

These diseases are characterized by inborn errors of amino acid metabolism and have distinctive nutritional requirements. Special formulas are used for the dietary management of these diseases.

According to the FDA, medical foods are distinguished from the broader category of foods for special dietary use and from foods that make health claims by the requirement that medical foods be intended to meet distinctive nutritional requirements of a disease or condition, used under medical supervision and intended for the specific dietary management of a disease or condition. The term "medical foods" does not pertain to all foods fed to sick patients. Medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in a natural state) for the patient who is seriously ill or who requires the product as a major treatment modality. In general, to be considered a medical food, a product must, at a minimum, meet the following criteria:

1. The product must be a food for oral or tube feeding; and
2. The product must be labeled for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and
3. The product must be used under the supervision of a physician.

Medical foods are intended solely to meet routine dietary needs of individuals who have specific metabolic or physiological limitations that restrict their ability to digest regular food. The use of medical food by individuals who do not meet this definition is not medically necessary, including when used for reasons not associated with their medical properties, such being in liquid form, coming pre-mixed, having specific flavors, etc.

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Government Agency, Medical Society, and Other Authoritative Publications:

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Procedures

A. Attachments : None

B. History:

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