Anthem

Clinical UM Guideline

Subject: Home Enteral Nutrition
Guideline #: CG-MED-08
Status: Revised

Publish Date: 09/27/2023
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Description

This document addresses “medical food” or commercially available processed enteral products (please see the Definitions section for further information regarding medical 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. Enteral nutrition consists of nutritional support given via the gastrointestinal (GI) tract, either 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, jejunostomy, or other tubes. This document does not address standard food (not for medical purposes), although it is technically an enteral nutritional product.

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.

Note: For criteria related to Relizorb™, refer to applicable guidelines used by the plan.

Note: Please see the following related document for additional information:

- CG-MED-37 Intensive Programs for Pediatric Feeding Disorders

Clinical Indications

I. Oral Enteral Nutrition

Medically Necessary:

Oral enteral nutrition (oral feeding) is considered **medically necessary** when **all** of the following criteria are met:

A. The product must be a medical food for oral feeding;**and**
B. The product is the primary source of nutrition (that is, constitutes more than 50 percent of 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 1. or 2. 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**
    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;**or**
        b. Allergy to specific foods including food-induced anaphylaxis;**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 (for example, nutritionally complete liquid meal supplements) when associated with weight loss, failure to gain weight or to meet established growth expectations, including but not limited to:
            i. Premature infants who have not achieved the 25th percentile for weight based on their corrected age;**or**
            ii. Individuals with end-stage renal disease and an albumin less than 4 gm/dl;**and**
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.

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

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 percent 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:

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 a product is based on the convenience or preference of the individual or provider.

II. Enteral Nutrition Via Tube

Medically Necessary:

Enteral nutrition via tube feeding is considered**medically necessary** when **all** of the following criteria are met:

A. Enteral nutrition comprises the majority (greater than 50 percent) of the diet; **and**
    1. 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**
    2. Nutrients cannot be ingested orally due to a medical condition which either:
        a. Interferes with swallowing (for example, dysphagia from a neurological condition, severe chronic anorexia nervosa unable to maintain weight and nutritional status with oral nutrition); **or**
        b. Is associated with obstruction of the proximal GI tract (for example, tumor of the esophagus).

B. Enteral nutrition via tube is considered **medically necessary** when:
    1. The diet consists of less than 50 percent enteral nutrition and more than 50 percent standard diet for age; **and**
    2. When **all** of the following criteria are met:
        a. 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**
        b. The enteral product is used, as part of a defined and limited plan of care in transition from a diet of more than 50 percent enteral products to standard diet for age; **and**
        c. 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** the criteria above have not been met .

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:

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

Continuation of home enteral nutrition, regardless of route of administration, is considered **not medically necessary** when documentation demonstrates the applicable medical necessity criteria above are no longer met.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

HCPCS	
B4034	Enteral feeding supply kit; syringe fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape
B4035	Enteral feeding supply kit; pump fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape
B4036	Enteral feeding supply kit; gravity fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape
B4081-B4088	Nasogastric, stomach, gastrostomy/jejunostomy tubes [includes codes B4081, B4082, B4083, B4087, B4088]
B4100	Food thickener, administered orally, per ounce
B4102	Enteral formula, for adults, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
B4103	Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
B4104	Additive for enteral formula (e.g., fiber)
B4148	Enteral feeding supply kit; elastomeric control fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape
B4149-B4162	Enteral formula (administered through an enteral feeding tube) [includes codes B4149, B4150, B4152, B4153, B4154, B4155, B4157, B4158, B4159, B4160, B4161, B4162]
B9002	Enteral nutrition infusion pump, any type
S9340-S9343	Home therapy, enteral nutrition [includes codes S9340, S9341, S9342, S9343]
S9432	Medical foods for noninborn errors of metabolism
S9433	Medical food nutritionally complete, administered orally, providing 100% of nutritional intake
S9434	Modified solid food supplements for inborn errors of metabolism
S9435	Medical foods for inborn errors of metabolism

ICD-10 Diagnosis	
	All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met or for situations designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

Enteral nutrition is indicated in order to maintain optimal health status for individuals with diseases or structural defects of the GI 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 PKU.

The most optimal route of enteral intake is swallowing by mouth. In conditions where this is not possible, a tube may be placed to

facilitate transport of nutrition to the digestive/absorptive sites of the GI tract. Tube placement and types are governed by individual needs; the least invasive approach being placement of a nasogastric tube. Enteral tubes may also be placed percutaneously through an abdominal approach; this is most appropriate for long-term needs due to the reduced risk of aspiration and reflux (CMS NCD for Enteral Nutrition, 1984; Simon, 2000). The American Medical Dietary Association (2015), The American Academy of Hospice and Palliative Medicine (2013) and the American Geriatrics Society (2015) recommend against placement of percutaneous feeding tubes in individuals with advanced dementia; instead, oral assisted feedings should be offered. Advanced dementia, as described in the landmark CASCADE (Choices, Attitudes, and Strategies for Care of Advanced Dementia at the End-of-Life) study, is defined as the following: (1) Cognitive Performance Score (CPS) equal to 5 or 6, (2) cognitive impairment due to dementia (any type), (3) Global Deterioration Scale (GDS) equal to 7 (Mitchell, 2006).

The term Total Enteral Nutrition (TEN) infers that the individual is receiving more than 50% of their daily caloric intake via enteral nutrition products. If fewer than 50% of daily calories are supplied 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.

The term "medical foods" does not pertain to all foods fed to ill individuals. Medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in a natural state) for the individual who is seriously ill or who requires the product as a major treatment modality. Medical foods are intended solely to meet the dietary needs of individuals who have specific metabolic or physiological limitations that restrict their ability to digest regular food. According to the Food and Drug Administration (FDA), a product must meet all of the following minimum criteria to be considered a medical food:

1. The product must be a food for oral or tube feeding.
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.
3. The product must be used under the supervision of a physician.

The use of weight for a given age is a common metric used to determine if an individual meets criteria for failure to thrive (FTT). However, the threshold for weight for age is not standardized. Cole and colleagues (2011) use “weight less than 75 percent of median weight for age,” while the Agency for Healthcare Research and Quality (AHRQ) report states that the U.S. Social Security Administration (SSA) considers FTT to be present “when there is a fall in weight to below the 3rd percentile or to less than 75% of median weight-for-height or age in children under two years old” (Perrin, 2003). The current SSA language says growth retardation should be documented by 3 measurements over a 6 month period showing “less than the third percentile on the CDC’s [Center for Disease Control’s] most recent weight-for-length charts” for children under the age of 2, and “less than the 3rd percentile on the CDC’s most recent BMI for age growth charts” for children 2 years old and older (SSA, 105.08B1, 24598.002). Cole and colleagues (2011) further illustrate the lack of consensus on this issue by stating:

> Other definitions are used commonly in the professional literature such as height-for-weight <3rd percentile; weight-for-age less than 3rd or 5th percentile or less than 80 percent of median for age; weight-for-height <10th percentile; and weight-for-age more than 2 standard deviations below the mean for age.

Both the terms “corrected” age and “chronological” age appear frequently in the literature regarding the measurement of age in children diagnosed with FTT. The use of the term “corrected” allows for greater accuracy in the estimation of expected growth in children, specifically those born premature, who may have a significant discrepancy between their gestational and chronological ages. However, the use of this convention is not uniform in either the literature or guidelines addressing this issue. In accordance with Cole and colleagues (2011), this guideline uses the term “corrected” when referring to the measurement of premature infants.

Cessation of home enteral nutrition therapy may be warranted if the individual is no longer deriving benefit from therapy or in the opinion of the treating provider the risks of enteral treatment outweigh the benefits (Durfee, 2014). Such circumstances may be present when the condition for which the individual has been receiving therapy is no longer present, the individual has been transferred to the facility setting, the individual’s condition has changed such that other nutritional services are needed, and other such circumstances.

Definitions

Cognitive Performance Score (CPS): A validated score that uses 5 variables from the Minimum Data Set (MDS)20 to group individuals into the following 7 hierarchical cognitive performance categories; 0=intact, 1=borderline intact, 2=mild impairment, 3=moderate impairment, 4=moderately severe impairment, 5=severe impairment, and 6=very severe impairment.

Dysphagia: The term that describes difficulty swallowing due to abnormal swallowing reflex.

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

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

Food challenge: This is an evaluation technique that may be used to assist in the 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 subject aware of what they are being given, with the subject unaware, or with both the subject and physician unaware.

Global Deterioration Scale (GDS): Classifies dementia into 7 stages (1 to 7) based on broad descriptions of the cognitive and functional deficits that typify each stage. Stage 7 of the GDS is distinguished by the following features: very severe cognitive decline with minimal to no verbal communication, assistance needed to eat and toilet, incontinence of urine and stool, and loss of basic psychomotor skills (for example, may have lost ability to walk).

Medical food: As 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.*
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> * U.S. Food and Drug Administration. Regulatory Information. Section 5 of Orphan Drug Act. Available at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/default.htm. Accessed on May 4, 2023.

Proximal gastrointestinal tract: The section of the GI tract from the mouth to the small bowel.

Standard food: This is regular grocery products including typical (not specially formulated) infant formulas.

Supplemental nutrition: Fewer than 50% of daily calories are supplied by enteral nutrition products.

Total enteral nutrition (TEN): Individual is receiving more than 50% of their daily caloric intake via enteral nutrition products.

References

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Government Agency, Medical Society, and Other Authoritative Publications:

1. Centers for Medicare and Medicaid Services. National Coverage Determination: Enteral and Parenteral Nutritional Therapy. NCD #180.2. Effective July 11, 1987. Available at: https://www.cms.gov/medicare-coverage-database/search.aspx?redirect=Y&from=Overview&list_type=ncd. Accessed on May 4, 2023.
2. Cole SZ, Lanham JS. Failure to thrive: an update. Am Fam Physician. 2011; 83(7):829-834.
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21. Watson J, McGuire W. Transpyloric versus gastric tube feeding for preterm infants. Cochrane Database Syst Rev. 2013; (2):CD003487.

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History

Status	Date	Action
Revised	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised enteral nutrition via tube not medically necessary statement. Added treatment cessation criteria. Revised formatting of Clinical Indications section. Revised Discussion and References sections. Updated Coding section with 10/01/2023 HCPCS changes, added B4148.
Reviewed	08/11/2022	MPTAC review. Updated References section.
Reviewed	08/12/2021	MPTAC review. Added a “Note” related to review of Relizorb. Updated References section. Updated Coding section with 10/01/2021 HCPCS changes, added S9432; also removed code B4105 now addressed elsewhere.
Reviewed	08/13/2020	MPTAC review. Updated References section. Reformatted Coding section.
Reviewed	08/22/2019	MPTAC review. Updated Definitions and References section.
	12/27/2018	Updated Coding section with 01/01/2019 HCPCS changes; added B4105.
Reviewed	09/13/2018	MPTAC review. Updated Definitions and References section.
Reviewed	11/02/2017	MPTAC review. Updated header language from “Current Effective Date” to “Publish Date”. Updated References section.
Revised	11/03/2016	MPTAC review. Added advanced dementia to the NMN criteria. Updated Discussion/General Information, Definition and References sections. Updated Coding section with 01/01/2017 HCPCS changes.
Reviewed	11/05/2015	MPTAC review. Updated Discussion/General Information, Definitions, References and Website sections. Removed ICD-9 codes from Coding section.
Revised	11/13/2014	MPTAC review. Clarified Clinical Indications. Updated Description, Discussion/General Information, References and Websites sections.
Revised	11/14/2013	MPTAC review. Changed “chronological age” to “corrected age” in medically necessary criteria for oral enteral nutrition for children with failure to thrive unresponsive to standard age appropriate interventions. Updated Rationale and Reference sections.
Reviewed	02/14/2013	MPTAC review. No change to position statement.
Reviewed	02/16/2012	MPTAC review. No change to position statement.
Reviewed	02/17/2011	MPTAC review. No change to position statement. Updated Reference section.
	01/01/2011	Updated Coding section with 01/01/2011 HCPCS changes.
Reviewed	02/25/2010	MPTAC review. No change to position statement. Updated Reference section.
Revised	02/26/2009	MPTAC review. Modified note in description regarding benefit issues. Reorganized position statement section. Added requirement for documentation of food challenge to oral nutrition medically necessary statement regarding allergy or hypersensitivity to cow or soy milk. Added criteria to oral nutrition medically necessary statement for malabsorption conditions to include “when associated with failure to gain weight or meet established growth expectations.” Added Failure to Thrive as an oral nutrition medically necessary indication. Added statement for when oral or tube nutrition is medically necessary when it comprises less than 50% of intake. Added medically necessary criteria for tube nutrition requiring that individuals must have a condition that either interferes with swallowing or is associated with obstruction of the proximal gastrointestinal tract. Added not medically necessary statement for when used in individuals with normal swallowing and normal proximal gastrointestinal tract function. Updated Discussion, Definitions, and Reference sections.
	01/01/2009	Updated Coding section with 01/01/2009 HCPCS changes.

Revised	08/28/2008	MPTAC review. Added definition of “medical food.” Added the term “medical food” to all clinical indication statements. Added “conditions that interfere with the metabolism of specific nutrients” and other clarifying language to the medically necessary statement in section I. Added “The diagnosis is not failure to thrive” to medically necessary statement in Section II. Added “The diagnosis is not failure to thrive” and “the diagnosis is not allergy to mother’s milk”, and statement addressing continuation of therapy to medically necessary statement In section III. Added not medically necessary statement to section III addressing re-evaluation of therapy, and “The diagnosis is not failure to thrive” and “the diagnosis is not allergy to mother’s milk”. Added “The diagnosis is not failure to thrive” and “the diagnosis is not allergy to mother’s milk” to medically necessary section in Section IV. Added new not medically necessary statement to section IV for when medical food is used primarily for convenience or for individuals with disorders of swallowing where non-medical food is tolerated. Revised Discussion section. Updated Coding section with 10/01/2008 ICD-9 changes.
Revised	05/15/2008	MPTAC review. Revised age criteria for enteral feeding via tube. Reorganized position statement section. Clarified criteria regarding “inborn error of metabolism.”
Revised	11/29/2007	MPTAC review. Added “in all situations” to not medically necessary statement regarding over the counter and specialized pediatric formulas. Updated Reference section. Updated Coding section with 01/01/2008 HCPCS changes.
	10/01/2007	Updated coding section with 10/01/2007 ICD-9 changes.
Reviewed	12/07/2006	MPTAC review. No change to guideline position statement.
Revised	12/01/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem Virginia	07/29/2002	VA State Memo 1157	Medical Foods For Inborn Errors Of Metabolism And Severe Protein Or Soy Allergies
Anthem MidWest	02/11/2005	Anthem Midwest UM Guideline DME-019	Specialized Pediatric Nutrition
Anthem Connecticut	11/23/2004	CT State UM Guideline	Specialized Pediatric Nutrition Formula
WellPoint Health Networks, Inc.	12/04/2004	9.06.05	Home Enteral Nutrition

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