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Oral / Enteral Feeding - UM Clinical Coverage Guidance

PURPOSE

Provide Clinical Guidance for determining what medical services, procedures, devices, and drugs may be eligible for coverage and to evaluate whether a medical procedure or equipment is medically necessary. Providers are responsible for verifying eligibility and benefits before providing services to all Denver Health Medical Plan (DHMP) members.

Important Information - Please Read Before Using This Departmental Operating Procedure (DOP)

The following coverage policy applies to health benefit plans administered by DHMP and may not be covered by all DHMP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a Member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Coverage determinations for individual requests require consideration of:

· The terms of the applicable benefit document in effect on the date of service.

· Any applicable laws and regulations.

· Any relevant collateral source materials including coverage policies.

· The specific facts of the particular situation.

Contact DHMP Customer Service to discuss plan benefits more specifically.

SCOPE

This Clinical Coverage Guidance applies to DHMP Utilization Management Department and all lines of business.

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.*

* 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 August 17, 2018.

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.

PROCESS

CLINICAL COVERAGE GUIDELINE

This document addresses “medical food” or commercially available processed enteral products 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

Clinical Indications

I. Oral Enteral Nutrition

Medically Necessary:

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

1. The product must be a medical food for oral feeding; **and**
2. The product is the primary source of nutrition (that is, constitutes more than 50 percent of 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 a. or b. below:
    a. Conditions associated with an in-born error of metabolism that interfere with the metabolism of specific nutrients, including, but not limited to:
        i. Phenylketonuria (PKU); **or**
        ii. Homocystinuria; **or**
        iii. Methylmalonic acidemia; **or**
    b. Conditions that interfere with nutrient absorption and assimilation, including, but not limited to:
        i. Allergy or hypersensitivity to cow or soy milk diagnosed through a formal food challenge; **or**
        ii. Allergy to specific foods including food-induced anaphylaxis; **or**
        iii. Allergic or eosinophilic enteritis (colitis/proctitis, esophagitis, gastroenteritis); **or**
        iv. Cystic fibrosis with malabsorption; **or**
        v. Diarrhea or vomiting resulting in clinically significant dehydration requiring treatment by a medical provider; **or**
        vi. Malabsorption unresponsive to standard age appropriate interventions when associated with failure to gain weight or meet established growth expectations; **or**
        vii. 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:
        viii. Premature infants who have not achieved the 25th percentile for weight based on their corrected age; **or**
        ix. Individuals with end-stage renal disease and an albumin less than 4 gm/dl; and
        x. 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.

B. 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:

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

II. Enteral Nutrition via Tube

Medically Necessary:

A. Enteral nutrition via tube feeding is considered **medically necessary** when **all** of the following criteria are met:
   1. Enteral nutrition comprises the majority (greater than 50 percent) of the diet; **and**
   2. 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**
   3. 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 the diet consists of less than 50 percent enteral nutrition and more than 50 percent standard diet for age when **all** of the following criteria are met:
   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. 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**
   3. 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 GI 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.

Enteral nutrition via tube is considered **not medically necessary** when used in individuals with advanced dementia.

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:

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

2. When used for individuals with disorders of swallowing where non-medical food is tolerated.

Diagnosis

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:

A. The product must be a food for oral or tube feeding.

B. The product must be labeled for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements.

C. 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.

DOCUMENTATION/RECORDS

N/A

EXTERNAL REFERENCES

Peer Reviewed Publications:

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DHMP/DHHA RELATED DOCUMENTS

None

Attachments

No Attachments

Approval Signatures

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Applicability

Denver Health Medical Plan (DHMP)