ENTERAL AND ORAL NUTRITIONAL THERAPY

Policy Number: BIP108.G
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Covered benefits are listed in three (3) Sections - A, B and C. All services must be medically necessary. Each benefit plan contains its own specific provisions for coverage, limitations and exclusions as stated in the member’s Evidence of Coverage (EOC)/Schedule of Benefits (SOB). If there is a discrepancy between this policy and the member’s EOC/SOB, the member’s EOC/SOB provision will govern.

Essential Health Benefits for Individual and Small Group
For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the member specific benefit document to determine benefit coverage.

A. FEDERAL/STATE MANDATED REGULATIONS

California Health & Safety Code §1374.56: Testing and Treatment of phenylketonuria (PKU)

a. On or after July 1, 2000, every health care service plan contract, except a specialized health care service plan contract, issued, amended, delivered, or renewed in this state that provides coverage for hospital, medical, or surgical expenses shall provide coverage for the testing and treatment of phenylketonuria (PKU) under the terms and conditions of the plan contract.

b. Coverage for treatment of phenylketonuria (PKU) shall include those formulas and special food products that are part of a diet prescribed by a licensed physician and managed by a health care professional in consultation a physician who specializes in the treatment of metabolic disease and who participates in or is authorized by the plan, provided that the diet is deemed medically necessary to avert the development of serious physical or mental disabilities or to promote normal development or function as a consequence of phenylketonuria (PKU).

c. Coverage pursuant to this section is not required except to the extent that the cost of the necessary formulas and special food products exceeds the cost of a normal diet.
d. For purposes of this section, the following definitions shall apply:
   (1) "Formula" means an enteral product or enteral products for use at home that are
       prescribed by a physician or nurse practitioner, or ordered by a registered dietician upon
       referral by a health care provider authorized to prescribe dietary treatments, as medically
       necessary for the treatment of phenylketonuria (PKU).
   (2) "Special food product" means a food product that is both of the following:
       a) Prescribed by a physician or nurse practitioner for the treatment of phenylketonuria
          (PKU) and is consistent with the recommendations and best practices of qualified
          health professionals with expertise germane to, and experience in the treatment and
          care of, phenylketonuria (PKU). It does not include a food that is naturally low in
          protein, but may include a food product that is specially formulated to have less than
          one gram of protein per serving.
       b) Used in place of normal food products, such as grocery store foods, used by the
          general population

B. STATE MARKET PLAN ENHANCEMENTS

Enteral Nutrition-Amino acid-modified products used to treat congenital errors of amino acid
metabolism (such as Phenylketonuria) and elemental dietary enteral formula and additives when
used as a primary therapy for regional enteritis. Enteral nutrition formulas and additives are
covered for inherited diseases of metabolism.

C. COVERED BENEFITS

**IMPORTANT NOTE:** Covered benefits are listed in Sections A, B and C. Always refer to
Sections A and B for additional covered benefits not listed in this Section.

1. Enteral nutritional therapy, including formula, accessories and supplies, is covered under the
   medical benefit when all of the following criteria are met:
   • Enteral nutrition is covered for a member who has (a) permanent non-function or
disease of the structures that normally permit food to reach the small bowel or (b) disease of the small bowel which impairs digestion and absorption of an oral diet, either
   of which requires tube feedings to provide sufficient nutrients to maintain weight and
   strength commensurate with the member's overall health status.
   • The member must have a permanent impairment. Permanence does not require a
determination that there is no possibility that the member's condition may improve
   sometime in the future. If the judgment of the attending physician, substantiated in the
   medical record, is that the condition is of long and indefinite duration (ordinarily at least 3
   months), the test of Permanence is considered met. Enteral nutrition will be denied as
   non-covered in situations involving temporary impairments.
   • The member's condition could be either anatomic (e.g., obstruction due to head and neck
cancer or reconstructive surgery, etc.) or due to a motility disorder (e.g., severe
   Dysphagia following a stroke, etc.). Enteral nutrition is non-covered for members with a
   functioning gastrointestinal tract whose need for Enteral nutrition is due to reasons such
   as anorexia or nausea associated with mood disorder, end-stage disease, etc.
   • The member must require tube feedings to maintain weight and strength commensurate
   with the member's overall health status. Adequate nutrition must not be possible by
dietary adjustment and/or oral supplements. Coverage is possible for members with
partial impairments - e.g., a member with Dysphagia who can swallow small amounts of
food or a member with Crohn's disease who requires prolonged infusion of Enteral
nutrients to overcome a problem with absorption.
   • If the coverage requirements for Enteral nutrition are met, medically necessary nutrients,
   administration supplies, and equipment are covered.
   • The member is in a skilled nursing facility or receiving home health skilled nursing or
   skilled therapy visits under a plan of care prescribed by a physician. (Unless covered
   under Section A)

**Note:** When the member is no longer receiving home health or skilled nursing facility
services or skilled therapy visits, the pump and other accessories are covered as DME
and are subject to the applicable benefit maximum and the Enteral formula is not covered.

**Note: Associated supplies:** (Enteral feeding supply kits; Enteral nutrition infusion pump; Enteral tubing; gastrostomy/jejunostomy tube and tubing adaptor; nasogastric tubing; parenteral nutrition infusion pump; parenteral nutrition solutions; stomach tube, and supplies for self-administered injections.

2. State-mandated formula that requires Enteral feeding is covered as required by law. Refer to Section A.

3. **Phenylketonuria (PKU) Testing and Treatment** – Testing for Phenylketonuria (PKU) is covered to prevent the development of serious physical or mental disabilities or to promote normal development or function as a result of PKU enzyme deficiency. PKU includes those formulas and special food products that are part of a diet prescribed by a Network Physician and managed by a health care professional in consultation with a Physician who specializes in the treatment of metabolic disease and who takes part in or is authorized by UnitedHealthcare, provided that the diet is deemed Medically Necessary to prevent the development of serious physical or mental disabilities or to promote normal development or function as a consequence of PKU.

**D. NOT COVERED**

1. Non prescription oral formula, self blenderized formula, food, vitamins, herbs and dietary supplements unless covered under Section A (Examples include: food thickeners, other regular grocery products that can be blenderized, baby food, high and low protein foods, low carbohydrate foods, supplements, and electrolytes.

2. Enteral formula or medical food when the member is not receiving medically necessary skilled home health visits or skilled nursing facility services or skilled therapy visits unless covered under Section A **(Note: Home health or skilled nursing services are not considered medically necessary if the primary purpose is to monitor Enteral feedings.)**

**E. DEFINITIONS**

**Dysphagia:** A swallowing disorder that may be due to various neurological, structural, and cognitive deficits.

**Enteral Feeding:** The Provision of nutritional requirements through a tube into the stomach or bowel. It may be administered by syringe, gravity, or pump.

**Phenylketonuria (PKU) Treatment:** Diagnosis and treatment of PKU including formula and special food products necessary for the treatment that are part of a diet prescribed by the treating physician.

**Permanence:** For the purposes of this policy, Permanence does not require a determination that there is no possibility that the member’s condition may improve sometime in the future. If the physician’s opinion is that the condition is of long and indefinite duration (ordinarily at least 3 months), then the qualifier of permanent is met.

**F. REFERENCES**

National Coverage Determination (NCD) 180.2 Enteral and Parenteral Nutritional Therapy; Enteral and Parenteral Nutritional Therapy (180.2)

DME MAC LCD for Enteral Nutrition (L33783) and the DME MAC Local Coverage Articles (LCAs) for Enteral Nutrition - Policy Article (A52493). (Accessed September 5, 2019)
### G. POLICY HISTORY/REVISION INFORMATION

<table>
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<tr>
<th>Date</th>
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| 12/01/2019 | **Federal/State Mandated Regulations**  
- Revised language pertaining to *California Health & Safety Code §1374.56*  
  **Covered Benefits**  
- Revised list of covered benefits; added language pertaining to *Phenylketonuria (PKU) Testing and Treatment* to indicate:  
  - Testing for PKU is covered to prevent the development of serious physical or mental disabilities or to promote normal development or function as a result of PKU enzyme deficiency  
  - PKU includes those formulas and special food products that are part of a diet prescribed by a Network Physician and managed by a health care professional in consultation with a Physician who specializes in the treatment of metabolic disease and who takes part in or is authorized by UnitedHealthcare, provided that the diet is deemed medically necessary to prevent the development of serious physical or mental disabilities or to promote normal development or function as a consequence of PKU  
  **Not Covered**  
- Revised list of non-covered items to reflect/include:  
  - Non-prescription oral formula, self blenderized formula, food, vitamins, herbs, and dietary supplements unless covered under *Section A* of the policy; examples include food thickeners, other regular grocery products that can be blenderized, baby food, high and low protein foods, low carbohydrate foods, supplements, and electrolytes  
  - Enteral formula or medical food when the member is not receiving medically necessary skilled home health visits or skilled nursing facility services or skilled therapy visits unless covered under *Section A* of the policy; Home health or skilled nursing services are not considered medically necessary if the primary purpose is to monitor Enteral Feedings  
  **Definitions**  
- Updated definition of “Enteral Feeding”  
  **References**  
- Updated references to reflect the most current information  
  **Supporting information**  
- Archived previous policy version BIP108.F |