ENTERAL AND ORAL NUTRITIONAL THERAPY

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Related Benefit Interpretation Policy:

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).

FDA approved special low protein formulas specifically approved for PKU and food products that are specially formulated to have less than one gram of protein per serving.
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 patient 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 patient's overall health status.

   • The patient must have a permanent impairment. Permanence does not require a determination that there is no possibility that the patient'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 patient'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 patients 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 patient must require tube feedings to maintain weight and strength commensurate with the patient's overall health status. Adequate nutrition must not be possible by dietary adjustment and/or oral supplements. Coverage is possible for patients with partial impairments - e.g., a patient with Dysphagia who can swallow small amounts of food or a patient 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. See Section A.

### D. NOT COVERED

1. Non-prescription oral formula unless required by state law, refer to Section A above
2. Food products naturally low in protein unless covered under section A
3. Baby foods, groceries or blenderized foods
4. Formulas, food, vitamins, herbs and dietary supplements unless covered under Section A
5. Formula or food for the treatment of Phenylketonuria or other metabolic diseases unless covered under Section A
6. 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. 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

DME MAC LCDs for Enteral Nutrition and related key Articles (LCD L33783 and Article A52493); Accessed September 2018

CMS Medicare Benefit Policy Manual, Chapter; Chapter 8; § 60.5; Intradialytic Parenteral/Enteral Nutrition (IDPN); § 100.2.2-100.2.2.3; Evidence of Medical Necessity for Parenteral and Enteral Nutrition (PEN) Therapy; § 160-160.2

CMS National Coverage Determination 180.2 Enteral and Parenteral Nutritional Therapy; Enteral and Parenteral Nutritional Therapy (180.2)
### G. POLICY HISTORY/REVISION INFORMATION

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