Enteral and Oral Nutritional Therapy

Policy Number: BIP108.I
Effective Date: November 1, 2021

Instructions for Use

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Related Benefit Interpretation Policy

- Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/ Orthotics (Non-Foot Orthotics) and Medical Supplies Grid

Federal/State Mandated Regulations

California Health & Safety Code §1374.56

http://www.search-california-law.com/research/ca/HSC/1374.56./Cal-Health–Safety-Code-Section-1374.56/text.html

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.

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.

Covered Benefits

Important Note: Covered benefits are listed in *Federal/State Mandated Regulations*, *State Market Plan Enhancements*, and *Covered Benefits* sections. Always refer to the *Federal/State Mandated Regulations* and *State Market Plan Enhancements* sections for additional covered services/benefits not listed in this section.

- 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 the *Federal/State Mandated Regulations* section)
    Notes:
    - 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.
    - 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.
- State-mandated formula that requires Enteral feeding is covered as required by law. Refer to the *Federal/State Mandated Regulations* section.
- 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.

Not Covered

- Non prescription oral formula, self blenderized formula, food, vitamins, herbs and dietary supplements unless covered under the *Federal/State Mandated Regulations* section.
  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 the *Federal/State Mandated Regulations* section
  Note: Home health or skilled nursing services are not considered medically necessary if the primary purpose is to monitor Enteral feedings.

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.

References

National Coverage Determination (NCD) 180.2 Enteral and Parenteral Nutritional Therapy; Enteral and Parenteral Nutritional Therapy (180.2) (Accessed September 10, 2021)

Refer to the DME MAC LCD for Parenteral Nutrition (L38953) Refer to the DME MAC LCD for Enteral Nutrition (L38955) (Accessed September 10, 2021

(L and the DME MAC Local Coverage Articles (LCAs) for Enteral Nutrition - Policy Article (A52493). (Accessed September 10, 2021)

Policy History/Revision Information

Date	Summary of Changes
11/01/2021	• Routine review; no change to benefit coverage guidelines • Archived previous policy version BIP108.H

Instructions for Use

Covered benefits are listed in three (3) sections: *Federal/State Mandated Regulations*, *State Market Plan Enhancements*, and *Covered Benefits*. 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.