

UnitedHealthcare® West Benefit Interpretation Policy

Enteral and Oral Nutritional Therapy

Policy	Number:	BIP108.	.K
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Effective	Date:	December	1,	2023
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Instructions for Us

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Related Benefit Interpretation Policy

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

Federal/State Mandated Regulations

California Health & Safety Code §1374.56

 $\underline{https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=1374.56.\&lawCode=HSClaySectionNum=1374.56.&lawCode=HSClaySe$

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 Feeding

Enteral nutritional therapy, including administration supplies and equipment, is covered **under the medical benefit** when **all** of the following criteria are met:

- The member requires feeding via enteral access device to provide sufficient nutrients to maintain weight and strength commensurate with the member's overall health status and has a
 - Full or partial non-function or disease of the structures that normally permit food to reach the small bowel. Examples include (not an all-inclusive list):
 - Head and neck cancer with reconstructive surgery
 - Central nervous system disease leading to interference with the neuromuscular mechanisms of ingestion of such severity that the member cannot be maintained with oral feeding

or

- Disease that impairs digestion and/or absorption of an oral diet, directly or indirectly by the small bowel. Examples
 include (not an all-inclusive list):
 - Inflammatory bowel disease
 - Surgical resection of small bowel
 - Cystic fibrosis
 - Chronic pancreatitis
 - Advanced liver disease
- 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 substantiated in the medical record, including the
 judgment of the treating practitioner, is that the condition is of long and indefinite duration (ordinarily at least 3 months),
 the test of permanence is considered met.
- Adequate nutrition must not be possible by dietary adjustment and/or oral supplements.
- The member is receiving medically necessary authorized home health skilled visits, skilled nursing facility services skilled therapy visits under a plan of care prescribed by a physician. (Unless covered under the *Federal/State Mandated Regulations* section).

Notes:

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

Phenylketonuria (PKU) Testing and Treatment

Phenylketonuria (PKU) testing and Treatment 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 testing and Treatment 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.

Note: Special food products do not include food that is naturally low in protein, but may include a special low-protein formula specifically approved for PKU and special food products that are specially formulated to have less than one gram of protein per serving.

Not Covered

- Enteral nutrition in situations involving temporary impairments.
- Enteral nutrition 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
- Nonprescription oral formula, self blenderized formula, food, vitamins, herbs and dietary supplements unless covered under the *Federal/State Mandated Regulations* section.

Examples include:

- o Food thickeners,
- Other regular grocery products that can be blenderized,
- o Baby food,
- High and low protein foods,
- Low carbohydrate foods,
- o Supplements, and
- Electrolytes.
- Enteral formula or medical food when the member is not receiving medically necessary skilled home health visits, 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.
 - 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.

Definitions

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.

Dysphagia: Difficulty swallowing due to obstructive lesions and motor disorders. A more specific classification categorizes the cause of dysphagia according to location: preesophageal or oropharyngeal dysphagia, esophageal or transport dysphagia, postesophageal or esophagogastric dysphagia, and paraesophageal or extrinsic dysphagia.

Phenylketonuria (PKU) Treatment: Phenylketonuria (PKU) is a rare metabolic disorder (and orphan disease) that usually results from a deficiency of a liver enzyme known as phenylalanine hydroxylase (PAH). This enzyme deficiency leads to elevated levels of the amino acid phenylalanine (Phe) in the blood and other tissues. The untreated state is characterized by mental retardation, microcephaly, delayed speech, seizures, eczema, behavior abnormalities, and other symptoms. Treatment via medical nutrition therapy involves the use of medical foods including medical protein sources and modified low-protein products in addition to the provision of required amounts of Phe through small amounts of natural protein.

References

DME MAC LCD for Enteral Nutrition (L38955) and DME MAC Local Coverage Articles (LCAs) for Enteral Nutrition - Policy Article (A58833). (Accessed September 21, 2023).

National Coverage Determination (NCD) 180.2 Enteral and Parenteral Nutritional Therapy; <u>Enteral and Parenteral Nutritional Therapy</u> (180.2) (Accessed November 2, 2022)

NICHD. (2000, updated 2006). *Report of the NIH consensus development conference on phenylketonuria (PKU): Screening and management*. Retrieved May 15, 2012, from http://www.nichd.nih.gov/publications/pubs/pku/

Policy History/Revision Information

Date	Summary of Changes
12/01/2023	Covered Benefits
12/01/2020	Enteral Feeding
	Revised language to indicate:
	 Enteral nutritional therapy, including administration supplies and equipment, is covered under
	the medical benefit when all of the following criteria are met:
	 The member requires feeding via enteral access device to provide sufficient nutrients to
	maintain weight and strength commensurate with the member's overall health status and has:
	 A full or partial non-function or disease of the structures that normally permit food to
	reach the small bowel; examples include (not an all-inclusive list):
	Head and neck cancer with reconstructive surgery
	Central nervous system disease leading to interference with the neuromuscular machanisms of ingestion of such asyarity that the mambar cannot be maintained.
	mechanisms of ingestion of such severity that the member cannot be maintained with oral feeding
	or
	 A disease that impairs digestion and/or absorption of an oral diet, directly or indirectly
	by the small bowel; examples include (not an all-inclusive list):
	Inflammatory bowel disease
	Surgical resection of small bowel
	Cystic fibrosisChronic pancreatitis
	 Chronic pancreatitis Advanced liver disease
	The member must have a permanent impairment 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 judgement substantiated in the medical record, including the judgment of the
	treating practitioner, is that the condition is of long and indefinite duration (ordinarily at
	least 3 months), the test of permanence is considered met Adequate nutrition must not be possible by dietary adjustment and/or oral supplements
	The member is receiving medically necessary authorized home health skilled visits, skilled
	nursing facility services, or skilled therapy visits under a plan of care prescribed by a
	physician (unless covered under the Federal/State Mandated Regulations section of the
	policy)
	 State-mandated formula that requires enteral feeding is covered as required by law; refer to the
	 Federal/State Mandated Regulations section of the policy 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)
	Phenylketonuria (PKU) Testing and Treatment
	Added notation to indicate special food products do not include food that is naturally low in protein
	but may include a special low-protein formula specifically approved for PKU and special food
	products that are specially formulated to have less than one gram of protein per serving
	Not Covered
	Revised list of non-covered services; added (relocated from <i>Covered Benefits</i> section): The section of the section
	 Enteral nutrition in situations involving temporary impairments

Date	Summary of Changes	
	 Enteral nutrition 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. Added notation (relocated from <i>Covered Benefits</i> section) to indicate when the member is no longer receiving home health services, skilled nursing facility services, or skilled therapy visits: The enteral pump and other accessories are covered as durable medical equipment (DME) and are subject to the applicable benefit maximum The enteral formula is not covered 	
	Definitions	
	 Added definition of "Associated Supplies" (relocated from Covered Benefits section) Removed definition of: Enteral Feeding Permanence Updated definition of: Dysphagia Phenylketonuria (PKU) Treatment 	
	Supporting Information	
	Updated References section to reflect the most current information	
	Archived previous policy version BIP108.J	

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.