

UnitedHealthcare® West Benefit Interpretation Policy

Enteral and Oral Nutritional Therapy

Policy Number: BIP110	.K
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Effective Date: December 1, 2023

☐ 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

Texas Insurance Code, Section 1359.001 Definitions

https://statutes.capitol.texas.gov/Docs/IN/htm/IN.1359.htm

Section 1359.001 Definitions

In this chapter:

- (1) "Heritable disease" means an inherited disease that may result in mental or physical retardation or death.
- (2) "Phenylketonuria" means an inherited condition that, if not treated, may cause severe mental retardation.

Texas Insurance Code, Section 1359.003: Coverage Required

https://statutes.capitol.texas.gov/Docs/IN/htm/IN.1359.htm

- (a) A group health benefit plan must provide coverage for formulas necessary to treat phenylketonuria or a heritable disease.
- (b) The group health benefit plan must provide the coverage to the same extent that the plan provides coverage for drugs that are available only on the orders of a physician.

Texas 1377.051 Coverage for Certain Amino Acid-Based Elemental Formulas

https://statutes.capitol.texas.gov/Docs/IN/htm/IN.1377.htm

- a. A health benefit plan must provide coverage as provided by this chapter for amino acid-based elemental formulas, regardless of the formula delivery method, that are used for the diagnosis and treatment of:
 - 1) immunoglobulin E and non-immunoglobulin E mediated allergies to multiple food proteins;
 - 2) severe food protein-induced enterocolitis syndrome:
 - 3) eosinophilic disorders, as evidenced by the results of a biopsy; and
 - 4) impaired absorption of nutrients caused by disorders affecting the absorptive surface, functional length, and motility of the gastrointestinal tract
- Subject to Subsection (c), the coverage required under Subsection (a) is required if the treating physician has issued a written order stating that the amino acid-based elemental formula is medically necessary for the treatment of an enrollee who is diagnosed with a disease or disorder listed in Subsection (a). The coverage must include coverage of any medically necessary services associated with the administration of the formula.

c. A health benefit plan must provide the coverage described by Subsection (a) on a basis no less favorable than the basis on which prescription drugs and other medications and related services are covered by the plan, and to the same extent that the plan provides coverage for drugs that are available only on the orders of a physician.

State Market Plan Enhancements

None

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.

Amino Acid Based Elemental Formulas

Benefits are provided for amino acid-based elemental formulas, regardless of the formula delivery method, that are used for the diagnosis and treatment of:

- Immunoglobulin E and non-immunoglobulin E mediated allergies to multiple food proteins
- Severe food protein-induced enterocolitis syndrome
- Eosinophilic disorders, as evidenced by the results of a biopsy
- Impaired absorption of nutrients caused by disorders affecting the absorptive surface, functional length and motility of the gastrointestinal tract

Benefits will also be provided for any medically necessary services associated with the administration of the formula.

If an *Outpatient Prescription Drug Rider* is included under this contract, benefits for the amino acid based elemental formulas will be provided under the *Outpatient Prescription Drug Rider*. Otherwise, the benefits will be provided under this benefit category of the contract.

For benefits to be provided, the treating physician must issue a written order stating that the amino acid based elemental formula is medically necessary for the treatment of a covered person who is diagnosed with at least one of the diseases or disorders listed above.

Phenylketonuria (PKU) 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 consequence of PKU enzyme deficiency. PKU treatment includes those formulas and special food products that are part of a diet prescribed by a contracting physician and managed by a health care professional in consultation with a physician who specializes in the treatment of metabolic disease who participates in or is authorized by UnitedHealthcare, 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 PKU. Special food products do not include food that is naturally low in protein, but may include a special low-protein formulary specifically approved for PKU and special food products that are specially formulated to have less than one gram of protein per serving.

Not Covered

- Nonprescription oral formulas, self blenderized formula, food, vitamins, herbs and dietary supplements unless covered under the *Federal/State Mandated Regulations* section.
 Examples include:
 - o Food thickeners,
 - Baby food,

- o Food products,
- High and low protein foods,
- Low carbohydrate foods,
- o Supplements, and
- o 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

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. Reference section added

References

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
	Phenylketonuria (PKU) Treatment
	 Added language to indicate 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 consequence of PKU enzyme deficiency
	Definitions
	Removed definition of "Enteral Feeding"
	Updated definition of "Phenylketonuria (PKU) Treatment"
	Supporting Information
	Added References section
	Archived previous policy version BIP110.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.