

Enteral and Oral Nutritional Therapy

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[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

WAC 284-44-450: PKU Formula Coverage Requirements and Exceptions

<https://apps.leg.wa.gov/wac/default.aspx?cite=284-44-450>

- (1) The purpose of this section is to effectuate the provisions of section 3, chapter 173, Laws of 1988, by establishing the requirements and exceptions with respect to coverage for the formulas necessary for the treatment of phenylketonuria (PKU), applicable to **health care service contractors** registered pursuant to RCW 48.44.015
- (2) Each contract for health care services which is delivered or issued for delivery or renewed in this state on or after September 1, 1988, shall provide coverage for the formulas necessary for the treatment of phenylketonuria, subject to the following exceptions:
 - (a) A contract that is subject to chapter [48.66](#) RCW and provides medicare supplemental insurance need not provide the PKU formula coverage;
 - (b) A contract that is subject to chapter [48.84](#) RCW and provides long-term care insurance need not provide the PKU formula coverage;
 - (c) A contract that provides benefits for hospital services only or for custodial services only may limit the coverage for PKU formulas to a benefit that supplies the formula needed, or pays for the formula used, during time such services are provided.
 - (d) A contract which provides services or reimbursement exclusively for optometric or vision care services, dental or orthodontic services, podiatric services, ambulance services, mental health services, or chiropractic services need not provide coverage for PKU formula.
 - (e) A contract that is governed by 5 U.S.C. chapter 89 or 42 U.S.C. section 1395mm need not provide the PKU formula coverage.
 - (f) In response to the written request of a contractor, other contracts may exclude coverage for the PKU formula with the written consent of the commissioner upon a finding that such coverage would be inappropriate.
- (3) Coverage for the formulas necessary for the treatment of phenylketonuria may be limited to the usual and customary charge for such formulas, and may be made subject to deductibles, copayments, coinsurance or other reductions only to the extent that deductibles, copayments, coinsurance or other reductions are applied to general expenses incurred for common sicknesses or disorders under the provisions of the particular contract. (Relating the PKU formula to a special expense benefit, such as a prescription drug benefit, is not acceptable unless it results in the PKU formula benefit being paid at an amount no less than the amount that would be produced by application of the reimbursement formula for medically necessary treatment for common sicknesses or disorders.)

- (4) The amount charged by a health care service contractor shall be no greater to a family or individual receiving benefits under the PKU formula coverage, by reason thereof, than to a family or individual under the same contract form or group contract who is not receiving such benefits.
- (5) Preexisting condition provisions shall not be used with respect to PKU formula coverage, and no contractor shall cancel or decline to renew any contract, or restrict, modify, exclude, or reduce the amount of benefits payable or type of coverage provided in any contract, because an applicant or covered person has phenylketonuria.
- (6) For purposes of section 3, chapter 173, Laws of 1988, and this section, a contract is "renewed" when it is continued beyond the earliest date after September 1, 1988, upon which, at the contractor's sole option:
 - (a) The contract's termination could have been effectuated, for other than nonpayment of premium; or
 - (b) The contract could have been amended to add the PKU formula coverage, with, if justified, an appropriate rate increase for any increased cost in providing the PKU formula coverage under the contract.

The failure of the contractor to take any such steps does not prevent the contract from being "renewed." The intent of this subsection is to bring the PKU formula coverage under the maximum number of contracts possible at the earliest possible time, by permitting the contractor to exclude such coverage from only those contracts as to which there exists a right of renewal on the part of a contract holder without any change in any provision of the contract.

RCW 48.43.176 Eosinophilic Gastrointestinal Associated Disorder – Elemental Formula

<https://app.leg.wa.gov/rcw/default.aspx?cite=48.43.176>

- (1) Each health benefit plan issued or renewed after December 31, 2015, must offer benefits or coverage for medically necessary elemental formula, regardless of delivery method, when a licensed physician or other health care provider with prescriptive authority:
 - (a) Diagnoses a patient with an eosinophilic gastrointestinal associated disorder; and
 - (b) Orders and supervises the use of the elemental formula
- (2) Nothing in this section prohibits a health benefit plan from requiring prior authorization or imposing other appropriate utilization controls in approving coverage for medically necessary elemental formula.

WAC 284-46-100 PKU Formula Coverage Requirements

<https://apps.leg.wa.gov/wac/default.aspx?cite=284-46-100>

- (1) The purpose of this section is to effectuate the provisions of section 4, chapter 173, Laws of 1988, by establishing the requirements with respect to coverage for the formulas necessary for the treatment of phenylketonuria (PKU), **applicable to health maintenance organizations.**
- (2) Any agreement for health care services delivered or issued for delivery or renewed in this state on or after September 1, 1988, shall provide coverage for the formulas necessary for the treatment of phenylketonuria, subject to the following exceptions:
 - (a) A contract that is subject to chapter [48.66](#) RCW and provides medicare supplemental insurance need not provide the PKU formula coverage;
 - (b) A contract that is subject to chapter [48.84](#) RCW and provides long-term care insurance need not provide the PKU formula coverage;
 - (c) A contract that is governed by 5 U.S.C. chapter 89 or 42 U.S.C. section 1395mm need not provide the PKU formula coverage; and
 - (d) In response to the written request of a health maintenance organization, other contracts may exclude coverage for the PKU formula with the written consent of the commissioner upon a finding that such coverage would be inappropriate.
- (3) The amount charged by a health maintenance organization shall be no greater to a family or individual receiving benefits under the PKU formula coverage, by reason thereof, than to a family or individual under the same agreement form or group agreement who is not receiving such benefits.
- (4) Preexisting condition provisions shall not be used with respect to PKU formula coverage, and no health maintenance organization shall cancel or decline to renew any contract, or restrict, modify, exclude, or reduce the amount of benefits payable or type of coverage provided in any contract, because an applicant or covered person has phenylketonuria.
- (5) For purposes of section 4, chapter 173, Laws of 1988, and this section, an agreement is "renewed" when it is continued beyond the earliest date after September 1, 1988, upon which, at the health maintenance organization's sole option:
 - (a) The agreement's termination could have been effectuated, for other than nonpayment of premium; or
 - (b) The agreement could have been amended to add the PKU formula coverage, with, if justified, an appropriate rate increase for any increased cost in providing the PKU formula coverage under the contract.

The failure of the organization to take any such steps does not prevent the agreement from being "renewed." The intent of this subsection is to bring the PKU formula coverage under the maximum number of agreements possible at the earliest possible time, by permitting the health maintenance organization to exclude such coverage from only those agreements as to which there exists a right of renewal on the part of an enrollee without any change in any provision of the agreement.

- (6) Coverage for the formulas may be made subject to deductibles, copayments, coinsurance or other reductions only to the extent that such deductibles, copayments, coinsurance or other reductions do not exceed those applicable to common sicknesses or disorders in the particular contract.

WAC 284-50-260 PKU Formula Coverage Requirements and Exceptions

<https://app.leg.wa.gov/wac/default.aspx?cite=284-50-260>

- (1) The purpose of this section is to effectuate the provisions of sections 1 and 2, chapter 173, Laws of 1988, by establishing the requirements and exceptions with respect to coverage for the formulas necessary for the treatment of phenylketonuria (PKU).
- (2) Every **group disability insurance contract**, which is delivered or issued for delivery or renewed in this state on or after September 1, 1988, that insures for hospital or medical expenses shall provide coverage for the formulas necessary for the treatment of phenylketonuria, with the exception of the following contracts, which need not provide such coverage:
- (a) A contract of "blanket disability insurance" as defined in RCW [48.21.040](#);
 - (b) A group contract designed to provide benefits on an "accident only" or "specified disease only" basis;
 - (c) A group contract subject to chapter [48.66](#) RCW and providing medicare supplemental insurance;
 - (d) A group contract subject to chapter [48.84](#) RCW and providing long-term care insurance; and
 - (e) A group contract as to which the commissioner, in writing, consents to the exclusion of PKU formula coverage, upon a finding that such coverage would be inappropriate to the contract.
- (3) Every individual disability insurance contract, including a contract of "family expense disability insurance" as defined in RCW [48.20.340](#) and a contract on a "franchise plan" as defined in RCW [48.20.350](#), delivered or issued for delivery or renewed in this state on or after September 1, 1988, that insures for hospital or medical expenses, shall provide coverage for the formulas necessary for the treatment of phenylketonuria, subject to the following exceptions:
- (a) A contract providing only hospital confinement indemnity coverage, as such coverage is defined in WAC [284-50-345](#), need not provide the PKU formula coverage;
 - (b) A contract limited to providing accident only coverage, as such coverage is defined in WAC [284-50-360](#), need not provide the PKU formula coverage;
 - (c) A contract providing only specified disease or specified accident coverage, as such coverage is defined in WAC [284-50-365](#), need not provide the PKU formula coverage;
 - (d) A contract providing limited benefit health insurance coverage, as such coverage is defined in WAC [284-50-370](#), need not provide the PKU coverage to the extent that the commissioner allows an exception;
 - (e) A contract providing basic hospital expense coverage, as such coverage is defined in WAC [284-50-335](#), may limit the coverage for PKU formulas to a benefit that is based on the cost of formula consumed during a covered hospital stay;
 - (f) A contract that is subject to chapter [48.66](#) RCW and provides medicare supplemental insurance need not provide the PKU formula coverage;
 - (g) A contract that is subject to chapter [48.84](#) RCW and provides long-term care insurance need not provide the PKU formula coverage; and
 - (h) A contract as to which the commissioner, in writing, consents to the exclusion of PKU formula coverage, upon a finding that such coverage would be inappropriate to the contract.
- (4) Coverage for the formulas necessary for the treatment of phenylketonuria may be limited to the usual and customary charge for such formulas, and may be made subject to deductibles, copayments, coinsurance or other reductions only to the extent that deductibles, copayments, coinsurance or other reductions are applied to general expenses incurred for common sicknesses or disorders under the provisions of the particular contract. (Relating the PKU formula to a special expense benefit, such as a prescription drug benefit, is not acceptable unless it results in the PKU formula benefit being paid at an amount no less than the amount that would be produced by application of the reimbursement formula for medically necessary treatment for common sicknesses or disorders.)
- (5) Premiums for an insured receiving benefits under the PKU formula coverage shall be no greater, by reason thereof, than the premiums for anyone else who is covered under the same form and who is not receiving such benefits.
- (6) Preexisting condition provisions shall not be used with respect to PKU formula coverage, and no insurer shall cancel or decline to renew any contract, or restrict, modify, exclude or reduce the amount of benefits payable or type of coverage provided in any contract, because an applicant or insured has phenylketonuria.

- (7) For purposes of sections 1 and 2, chapter 173, Laws of 1988, and this section, a contract is "renewed" when it is continued beyond the earliest date, after September 1, 1988, upon which, at the insurer's sole option:
- (a) The contract's termination could have been effectuated, for other than nonpayment of premium; or
 - (b) The contract could have been amended to add the PKU formula coverage, with, if justified, an appropriate rate increase for any increased cost in providing the PKU formula coverage under the contract.
- The failure of the insurer to take any such steps does not prevent the contract from being "renewed." The intent of this subsection is to bring the PKU formula benefits under the maximum number of contracts possible at the earliest possible time, by permitting the insurer to exclude such coverage from only those contracts as to which there exists a right of renewal on the part of the insured without any change in any provision of the contract.

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 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
 - 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 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.

Note:

- 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.
- 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 consequence of PKU enzyme deficiency. PKU treatment includes those formulas and special food products that are part of a diet prescribed by a network provider and managed by a health care professional in consultation with a physician who specializes in the treatment of metabolic disease and 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 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 formulas, self blenderized formula, food, vitamins, herbs and dietary supplements unless covered under the *Federal/State Mandated Regulations* section.

Examples include:

- Food Thickeners
- Baby food
- High and low protein foods
- Low carbohydrate foods
- Supplements
- 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

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

References

DME MAC [LCD for Enteral Nutrition \(L38955\)](#) and the 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; [Enteral and Parenteral Nutritional Therapy \(180.2\)](#) (Accessed September 21, 2023)

Wolf DC. Dysphagia. In: Walker HK, Hall WD, Hurst JW, editors. Clinical Methods: The History, Physical, and Laboratory Examinations. 3rd edition. Boston: Butterworths; 1990. Chapter 82. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK408/>

Policy History/Revision Information

Date	Summary of Changes
12/01/2023	<p>Covered Benefits</p> <p>Enteral Feeding</p> <ul style="list-style-type: none"> ● Revised language to indicate: <ul style="list-style-type: none"> ○ Enteral nutritional therapy, including administration supplies and equipment, is covered under the medical benefit when all of the following criteria are met: <ul style="list-style-type: none"> ▪ 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: <ul style="list-style-type: none"> – 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): <ul style="list-style-type: none"> ● 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 – 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): <ul style="list-style-type: none"> ● Inflammatory bowel disease ● Surgical resection of small bowel ● Cystic fibrosis ● Chronic pancreatitis ● Advanced liver disease ▪ The member must have a permanent impairment <ul style="list-style-type: none"> – Permanence does not require a determination that there is no possibility that the member's condition may improve sometime in the future – If 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 ○ 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) ○ State-mandated formula that requires enteral feeding is covered as required by law; refer to the <i>Federal/State Mandated Regulations</i> section of the policy <p>Phenylketonuria (PKU) Testing and Treatment</p> <ul style="list-style-type: none"> ● Added language to indicate: <ul style="list-style-type: none"> ○ Testing for 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 network provider and managed by a health care professional in consultation with a physician who specializes in the treatment of metabolic disease and 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 formula specifically approved for PKU and special food products that are specially formulated to have less than one gram of protein per serving <p>Not Covered</p> <ul style="list-style-type: none"> ● Revised list of non-covered services; added (relocated from <i>Covered Benefits</i> section):

Date	Summary of Changes
	<ul style="list-style-type: none"> ○ 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. ● 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: <ul style="list-style-type: none"> ○ 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 <p>Definitions</p> <ul style="list-style-type: none"> ● Removed definition of: <ul style="list-style-type: none"> ○ Enteral Feeding ○ Phenylketonuria (PKU) Treatment ○ Permanence ● Updated definition of “Dysphagia” <p>Supporting Information</p> <ul style="list-style-type: none"> ● Updated <i>References</i> section to reflect the most current information ● Archived previous policy version BIP111.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.