



Nutritional Support and Supplies

LOB(s): <input checked="" type="checkbox"/> Commercial <input checked="" type="checkbox"/> Medicare <input checked="" type="checkbox"/> Medicaid	State(s): <input checked="" type="checkbox"/> Idaho <input checked="" type="checkbox"/> Montana <input checked="" type="checkbox"/> Oregon <input checked="" type="checkbox"/> Washington <input type="checkbox"/> Other: <input checked="" type="checkbox"/> Oregon <input type="checkbox"/> Washington
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Enterprise Policy

PacificSource is committed to assessing and applying current regulatory standards, widely-used treatment guidelines, and evidenced-based clinical literature when developing clinical criteria for coverage determination. Each policy contains a list of sources (references) that serves as the summary of evidence used in the development and adoption of the criteria. The evidence was considered to ensure the criteria provide clinical benefits that promote patient safety and/or access to appropriate care. Each clinical policy is reviewed, updated as needed, and readopted, at least annually, to reflect changes in regulation, new evidence, and advancements in healthcare.

Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determinations are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member's policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.

Background

Oral / Enteral nutrition is indicated to maintain optimal health status for individuals with diseases or structural defects of the GI tract that interfere with transport, digestion, or absorption of nutrients. The most optimal route of enteral intake is swallowing by mouth. In conditions where this is not possible, a tube may be placed to facilitate transport of nutrition to the digestive/absorptive sites of the GI tract. Tube placement and types are governed by individual needs; the least invasive approach being placement of a nasogastric tube. Enteral tubes may also be placed percutaneously through an abdominal approach; this is most appropriate for long-term needs due to the reduced risk of aspiration and reflux.

In addition, when human milk is not available, hospitalized infants may qualify to receive donor human breast milk or human-derived breast milk fortifiers. A milk bank must be used to ensure safety and have national accreditation proving they follow evidence-based guidelines for the screening, handling, and processing of donor milk, as well as record keeping.

Regulatory Information

The term **Medical Food**, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which

distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." Medical foods are foods specially formulated for the individual who is seriously ill or who requires the product as a major treatment modality.

Non-Medical Food

Regular grocery items, over-the-counter, prescription dietary products (including nutritional supplements or nutritional replacement products providing less than 60% of daily nutritional requirements), are Non-medical foods and are considered not medically necessary.

Nutritional support that is taken orally (e.g., by mouth), unless mandated by state law, is not considered a medical food.

Total Parenteral Nutrition (TPN) is the intravenous provision of a person’s complete nutritional requirements. TPN that is required for a short length of time is usually given through peripheral veins. Long-term TPN is often accomplished through a central venous catheter (e.g., Hickman, Broviac, PICC). TPN is usually required in patients with a disease process that causes a temporary or permanent loss of absorption through the surface of the small intestine. TPN should only be an option for patients who cannot receive adequate nutritional intake via oral or enteral nutrition.

TPN can be administered safely and effectively in the patient's home by persons with specialized training. TPN is covered under the home infusion/home health benefit.

Inborn Errors of Metabolism (IEM)

Inborn errors of metabolism (IEM) include inherited biochemical disorders in which a specific enzyme defect interferes with the normal metabolism of protein, fat, or carbohydrate. As a result of diminished or absent enzyme activity in these disorders, certain compounds accumulate in the body to toxic levels and the levels of others that the body normally makes may become deficient. If they are not treated, these metabolic disturbances can lead to a host of medical and developmental consequences ranging from intellectual disability to severe cognitive impairment and even death. Through early identification and initiation of treatment, many of the adverse outcomes of IEM can be mitigated or prevented. For many IEM, treatment strategies rely on the provision of specialized medical foods and dietary supplements.

Not all of the disorders identified through newborn screening or other diagnosed conditions require treatment with medical foods, dietary supplements, or both. This Table identifies IEMs or diagnoses with the principal management therapy is to treat with medical food and/or single amino acids, amino acid mixtures, vitamins, or other compounds that **may** require medical foods.

<p>Organic Acidurias</p> <ul style="list-style-type: none"> • Isovaleric acidemia • Glutaric acidemia type I • 3-Hydroxy 3 –methyl glutaric aciduria • Multiple carboxylase deficiency • Methylmalonic acidemia • 3-Methylcrotonyl-CoA carboxylase deficiency • Propionic acidemia • β-Ketothiolase 	<p>Fatty Acid Oxidation</p> <ul style="list-style-type: none"> • Medium-chain acyl- CoA dehydrogenase deficiency • Very long-chain acyl- CoA dehydrogenase deficiency • Long-chain L-3- hydroxyacyl-CoA dehydrogenase • Trifunctional protein deficiency Carnitine uptake defect
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<p>Amino Acids</p> <ul style="list-style-type: none"> • Phenylketonuria • Maple syrup (urine) disease • Homocystinuria • Citrullinemia • Argininosuccinic aciduria • Tyrosinemia type I • Ornithine transcarbamylase deficiency • Guanidinoacetate 	<p>Hematology</p> <ul style="list-style-type: none"> • Sickle cell anemia • Hb S/β thalassemia • Hb S/C disease
<p>Others</p> <ul style="list-style-type: none"> • Congenital hypothyroid • Biotinidase • Congenital adrenal hyperplasia • Classical galactosemia • Hearing loss • Cystic fibrosis • Severe combined immunodeficiency • Eosinophilic enteritis (colitis/proctitis, esophagitis, gastroenteritis); • Critical Congenital heart disease • Glycogen storage Disease • Type II (Pompe) • Mucopolysaccharidosis (type 1 and type 2) • X-Linked adrenoleukodystrophy • Spinal muscular atrophy due to homozygous deletion of exon 7 in SMN1 	

Criteria

Commercial

I. Oral Nutrition

Prior authorization is required

A. PacificSource considers oral nutrition medically necessary when **ALL** of the following is met:

1. Oral enteral nutrition is considered a **Medical Food**, which **DOES NOT** include coverage of Non-Medical Food, standard infant formulas, or blenderized foods given orally

Note: Definitions for Medical Food and Non-Medical Food are identified in the background section of this policy.

2. Oral nutrition comprises 60 percent or more of the daily nutritional intake
3. Diagnosis of an Inborn Error of Metabolism (including other diagnoses) identified in the IEM table in the background section above

Initial authorization approval period: Up to 6 months

Reauthorization approval period: Up to 12 months

II. Enteral Nutrition via Tube

Prior authorization is required

B. PacificSource considers enteral nutrition via tube (e.g., nasogastric, jejunostomy, peg tube) feeding to be medically necessary when **ALL** of the following criteria are met:

1. Enteral nutrition must be considered a Medical Food, which **DOES NOT** include coverage of Non-Medical Food, standard infant formulas, or blenderized foods

Note: Definitions for Medical Food and Non-Medical Food are identified in the background section of this policy.

2. Enteral nutrition comprises 60 percent or more of the daily nutritional intake
3. The product is used under the supervision of a physician or nurse practitioner, or ordered by a registered dietician upon referral by a health care provider authorized to prescribe dietary treatments
4. Nutrients cannot be ingested orally due to a medical condition which either:
 - a. Interferes with swallowing (e.g., anatomical abnormalities or dysphagia from a neurological condition)
 - b. Is associated with obstruction of the proximal GI tract (e.g., tumor of the esophagus)

C. PacificSource considers Digestive Enzyme that contains lipase (e.g., RELiZORB) to be medically necessary when **ALL** of the following criteria is met:

1. Member is 5 years old or older
2. Diagnosed with Cystic Fibrosis-Related Pancreatic Insufficiency

D. Behavioral health eating disorders- PacificSource considers enteral nutrition via tube feeding indicated for eating disorders to be medically necessary when member is unable to maintain an ideal body weight through oral feeding despite participating in an intensive eating disorder treatment program.

Initial authorization approval period: Up to 6 months

Reauthorization approval period: Up to 12 months

III. Donor Human Milk and Human Milk Fortifiers

- A. PacificSource considers donor human milk and/or human milk fortifiers (e.g., Prolacta) medically necessary when ordered by a licensed health care provider or board-certified lactation consultant when **ALL** of the following conditions are met:
1. For an inpatient infant who is medically or physically unable to receive maternal human milk or participate in breast feeding; **OR** for an inpatient infant whose parent is medically or physically unable to produce maternal human milk in sufficient quantity or caloric density, or parent is unable to participate in breast feeding
 2. Donor human milk must be obtained from an accredited milk bank
 3. The infant meets at least **ONE** of the following criteria:
 - a. An infant with birth weight less than 2,500 grams
 - b. An infant gestational age equal to or less than 34 weeks
 - c. Infant hypoglycemia
 - d. A high risk of development of necrotizing enterocolitis, bronchopulmonary dysplasia, or retinopathy of prematurity
 - e. A congenital or acquired gastrointestinal condition with long-term feeding or malabsorption complications
 - f. Congenital heart disease requiring surgery in the first year of life
 - g. An organ or bone marrow transplant
 - h. Sepsis
 - i. Congenital hypotonias associated with feeding difficulty or malabsorption
 - j. Renal disease requiring dialysis in the first year of life
 - k. Craniofacial anomalies
 - l. An immunologic deficiency
 - m. Neonatal abstinence syndrome
 - n. Any other serious congenital or acquired condition for which the use of pasteurized donor human milk and donor milk derived products
 - o. Any infant still inpatient within 72 hours of birth without sufficient human milk available

IV. Total Parenteral Nutrition (TPN)

Prior authorization is required

- A. PacificSource considers Total Parenteral Nutrition (TPN) in the home setting medically necessary when **ALL** of the following criteria are met:
1. Clear documentation of a clinically significant structural or functional gastrointestinal condition, which impairs intestinal absorption
 2. Nutritional status cannot be maintained by **ONE** of the following:
 - a. Modified nutrient composition of an oral or enteral diet (e.g., lactose-free diet) due to a clinically significant structural or functional gastrointestinal condition

- b. Pharmacological trial of dietary adjustment to treat the etiology of the malabsorption (e.g., pancreatic enzymes)
3. Failure of enteral nutrition as evidenced by **ONE** of the following:
- a. Patient unable to receive more than 50% of daily caloric needs from oral and/or enteral diet (e.g., tube feed)
 - b. Serum albumin less than 3.4 grams/dL
 - c. More than 10% weight loss over a three-month (or less) period

Approved service range may be no longer than 60 days per prior authorization, up to six month maximum. Requests for more than six months or requests for lifetime TPN require Medical Director review.

V. Oral / Enteral Infusion Pumps

Prior authorization is required

- A. PacificSource may consider an enteral nutrition infusion pump to be medically necessary when **ONE** of the following criteria are met:
1. The member has severe diarrhea, dumping syndrome, fluctuating blood glucose levels, or a condition that results in circulatory overload.
 2. The member's medical condition is such that gravity or syringe feeding is not clinically appropriate (e.g., there is a risk of aspiration or reflux); **or** the nutritional formula administration rate is such that a pump is required to titrate infusion for patient safety (e.g., less than 100 cc per hour).

Medicaid

PacificSource Community Solutions Physical Health follows Oregon Health Plan (OHP) per Oregon Administrative Rules (OAR) 410-148-0000 to 0320 for coverage of Nutritional Support and Supplies.

PacificSource Community Solutions Pharmacy reviews CPT codes B4150 thru B4161 B9002 and B4149

Medicare

PacificSource Medicare follows Local Coverage Determination L38953 for Parenteral Nutritional Therapy and Local Coverage Determination L38955 for Enteral Nutrition.

Experimental/Investigational/Unproven

PacificSource considers digestive enzyme cartridges that connect in-line with existing enteral feeding pump tubing sets and patient extension sets or enteral feeding tubes for any other diagnosis besides Cystic Fibrosis-Related Pancreatic Insufficiency to be experimental, investigational, or unproven.

Coding Information

The following list of codes are for informational purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

B4034 Enteral Feed Supply kit Syringe By Day

- B4035 Enteral Feed Supply Pump Per Day
- B4036 Enteral Feed Supply Kit Gravity By Day
- B4100 Food Thickener, Administered Orally, Per Ounce
- B4102 Enteral Formula adult fluids and electrolytes
- B4103 Enteral Formula ped fluid and electrolyte
- B4104 Additive for enteral formula
- B4105 In-line cartridge containing digestive enzyme(s) for enteral feeding, each-
- B4149 Enteral Formula blenderized foods
- B4150 Enteral Formula Category I
- B4152 Enteral Formula Category II
- B4153 Enteral Formula Category III
- B4154 Enteral Formula Category IV
- B4155 Enteral Formula Category V
- B4157 Enteral Formula special metabolic inherit
- B4158 Enteral Formula ped complete intact nutrition
- B4159 Enteral Formula ped complete soy based
- B4160 Enteral Formula ped caloric dense ≥ 0.7 kc
- B4161 Enteral Formula ped hydrolyzed/amino acid
- B4162 Enteral Formula ped spec metabolic inherit
- B4164 Parenteral nutrition solution: carbohydrates (dextrose), 50% or less (500 ml = 1 unit), home mix
- B4168 Parenteral nutrition solution; amino acid, 3.5%, (500 ml = 1 unit) - home mix
- B4172 Parenteral nutrition solution; amino acid, 5.5% through 7%, (500 ml = 1 unit) - home mix
- B4176 Parenteral nutrition solution; amino acid, 7% through 8.5%, (500 ml = 1 unit) - home mix
- B4178 Parenteral nutrition solution: amino acid, greater than 8.5% (500 ml = 1 unit) - home mix
- B4180 Parenteral nutrition solution: carbohydrates (dextrose), greater than 50% (500 ml = 1 unit), home mix
- B4185 Parenteral nutrition solution, not otherwise specified, 10 g lipids
- B4187 Omegaven, 10 g lipids
- B4189 Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 10-51 g of protein, premix
- B4193 Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 52-73 g of protein, premix
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- B4197 Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements and vitamins, including preparation, any strength, 74-100 g of protein premix

- B4199 Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements and vitamins, including preparation, any strength, over 100 g of protein, premix
- B4216 Parenteral nutrition; additives (vitamins, trace elements, Heparin, electrolytes), home mix, per day
- B4220 Parenteral nutrition supply kit; premix, per day
- B4222 Parenteral nutrition supply kit; home mix, per day
- B4224 Parenteral nutrition administration kit, per day
- B5000 Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, renal - Amirosyn RF, NephAmine, RenAmine – premix
- B5100 Parenteral nutrition solution compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, hepatic-HepatAmine-premix
- B5200 Parenteral nutrition solution compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, stress-branch chain amino acids-FreAmine-HBC-premix A
- B9002 Enteral nutrition infusion pump, any type
- B9004 Parenteral nutrition infusion pump, portable
- B9006 Parenteral nutrition infusion pump, stationary
- B9998 NOC for enteral supplies
- B9999 Not otherwise covered parenteral supplies
- S9364 Home infusion therapy, total parenteral nutrition (TPN); administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment including standard TPN formula (lipids, specialty amino acid formulas, drugs other than in standard formula and nursing visits coded separately), per diem (do not use with home infusion codes S9365-S9368 using daily volume scales)
- S9365 Home infusion therapy, total parenteral nutrition (TPN); one liter per day, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment including standard TPN formula (lipids, specialty amino acid formulas, drugs other than in standard formula and nursing visits coded separately), per diem
- S9366 Home infusion therapy, total parenteral nutrition (TPN); more than one liter but no more than two liters per day, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment including standard TPN formula (lipids, specialty amino acid formulas, drugs other than in standard formula and nursing visits coded separately), per diem
- S9367 Home infusion therapy, total parenteral nutrition (TPN); more than two liters but no more than three liters per day, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment including standard TPN formula (lipids, specialty amino acid formulas, drugs other than in standard formula and nursing visits coded separately), per diem
- S9368 Home infusion therapy, total parenteral nutrition (TPN); more than three liters per day, administrative services, professional pharmacy services, care coordination, and all necessary

supplies and equipment including standard TPN formula (lipids, specialty amino acid formulas, drugs other than in standard formula and nursing visits coded separately), per diem

S9432 Medical foods for non-inborn errors of metabolism

S9433 Medical food nutritionally complete, administered orally, providing 100% of nutritional intake

S9434 Modified solid food supplements for inborn errors of metabolism

S9435 Medical foods for inborn errors of metabolism

T2101 Human breast milk processing, storage, and distribution only-

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HCPCS® codes, descriptions and materials are copyrighted by Centers for Medicare and Medicaid Services (CMS).

Definitions

Donor Human Milk – human milk contributed to a milk bank by one or more donors.

Dysphagia - difficulty swallowing due to abnormal swallowing reflex.

Inborn Errors of Metabolism - a group of rare disorders that are caused by an inherited genetic defect and alter the body's ability to derive energy from nutrients.

Intellectual Disability - Intellectual disability (ID) is a neurodevelopmental disorder that is characterized by deficits in both intellectual functioning and adaptive functioning, whose onset is in the developmental period.

Medical food - A food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.

Milk Bank – an organization that engages in procurement, processing, storage, distribution, or use of human milk contributed by donors.

Related Policies

Neonatal Levels of Care and Inpatient Management

References

Advisory Committee on Heritable Disorders in Newborns and Children

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Appendix

Policy Number:

Effective: 10/1/2020

Next review: 4/1/2025

Policy type: Enterprise

Author(s):

Depts.: Health Services

Applicable regulation(s): Orphan Drug Act (21 U.S.C. 360ee (b) (3)), 42 CFR §156.111; ORS 743.188, RCW 41.05.017, RCW 48.21.300, RCW 48.43.715, MCA 33-22-131

Commercial Ops: 4/2024

Government Ops: 4/2024