



## Nutritional Support and Supplies

<b>LOB(s):</b> <input checked="" type="checkbox"/> Commercial  <input checked="" type="checkbox"/> Medicare  <input checked="" type="checkbox"/> Medicaid	<b>State(s):</b> <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
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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 nutritional 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 abdomen. Individual needs guide the type and placement of enteral tubes, such as a nasogastric (NG) or gastrostomy tube (G-tube).

Infants may qualify to receive donor human breast milk or human-derived breast milk fortifiers when human milk is not available.

To ensure the safety of donor milk, a nationally- accredited milk bank, (i.e., one using evidence-based guidelines for screening, handling, processing, and record keeping) must be used.

### Regulatory Information

**Medical Food** is defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) as "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.

**Food Additive**

A food additive does not become a component of food, but gives a different flavor, texture, or other characteristic in the food (e.g., food thickener).

**Total Parenteral Nutrition (TPN)**

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 given 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 may accumulate in the body to toxic levels and/or other levels may become deficient. Not all disorders identified through newborn screening or other diagnostic testing require treatment with medical foods and/or dietary supplements.

The table below identifies IEMs and other diagnoses where medical foods may be required as part of the primary treatment.

<p><b>Organic Acidurias</b></p> <ul style="list-style-type: none"> <li>• Isovaleric acidemia</li> <li>• Glutaric acidemia type I</li> <li>• 3-Hydroxy 3 –methyl glutaric aciduria</li> <li>• Multiple carboxylase deficiency</li> <li>• Methylmalonic acidemia</li> <li>• 3-Methylcrotonyl-CoA carboxylase deficiency</li> <li>• Propionic acidemia</li> <li>• β-Ketothiolase</li> </ul>	<p><b>Fatty Acid Oxidation</b></p> <ul style="list-style-type: none"> <li>• Medium-chain acyl- CoA dehydrogenase deficiency</li> <li>• Very long-chain acyl- CoA dehydrogenase deficiency</li> <li>• Long-chain L-3- hydroxyacyl-CoA dehydrogenase</li> <li>• Trifunctional protein deficiency</li> <li>• Carnitine uptake defect</li> </ul>
<p><b>Amino Acids</b></p>	<p><b>Hematology</b></p>

<ul style="list-style-type: none"> <li>• Phenylketonuria</li> <li>• Maple syrup (urine) disease</li> <li>• Homocystinuria</li> <li>• Citrullinemia</li> <li>• Argininosuccinic aciduria</li> <li>• Tyrosinemia type I</li> <li>• Ornithine transcarbamylase deficiency</li> </ul>	<ul style="list-style-type: none"> <li>• Sickle cell anemia</li> <li>• Hb S/β thalassemia</li> <li>• Hb S/C disease</li> </ul>
<p><b>Others</b></p> <ul style="list-style-type: none"> <li>• Biotinidase</li> <li>• Classical galactosemia</li> <li>• Congenital hypothyroid</li> <li>• Congenital adrenal hyperplasia</li> <li>• Critical Congenital heart disease</li> <li>• Cystic fibrosis</li> <li>• Glycogen storage Disease</li> <li>• Guanidinoacetate</li> <li>• Infantile Krabbe (Globoid Cell Leukodystrophy)</li> <li>• Mucopolysaccharidosis (type 1 and type 2)</li> <li>• Severe combined immunodeficiency</li> <li>• Spinal muscular atrophy due to homozygous deletion of exon 7 in SMN1</li> <li>• Type II (Pompe)</li> <li>• X-Linked adrenoleukodystrophy</li> </ul>	

## Criteria

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### Commercial

#### I. Oral Nutrition

**Prior authorization is required.**

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

1. The requested oral nutrition product is considered a **Medical Food**. Non-Medical Food, standard infant formulas, blenderized foods, or food thickener are **NOT** covered as medical food.

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

2. The requested Oral nutrition product comprises 60 percent or more of the daily nutritional intake
3. Member has one of the diagnoses identified in the above Inborn Error of Metabolism table.

**Initial authorization approval period:** Up to 6 months.

**Reauthorization approval period:** Up to 12 months.

## II. Enteral Nutrition via Tube

### Prior authorization is required.

- A. 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. The requested enteral nutrition product must be considered a Medical Food. Non-Medical Food, standard infant formulas, blenderized foods, food thickener are NOT covered as medical food.
- Note:** Definitions for Medical Food and Non-Medical Food are identified in the background section of this policy.
2. The requested enteral nutrition product comprises 60 percent or more of the daily nutritional intake
  3. The product is ordered by a physician, nurse practitioner, or registered dietician. Ordering registered dietician must work in conjunction with supervising physician or nurse practitioner.
  4. Nutrients cannot be ingested orally due to a medical condition which either:
    - a. Interference with swallowing (e.g., anatomical abnormalities, dysphagia from a neurological condition, or required gavage feeding)
    - b. Is associated with obstruction of the proximal GI tract (e.g., tumor of the esophagus)
- B. 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

### C. Behavioral health related eating disorders

PacificSource considers enteral nutrition via tube feeding indicated for eating disorders to be medically necessary when member has continued weight loss or inability to achieve prescribed caloric intake despite a structured 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 **ONE** of the following criteria:
    - a. Birth weight less than 2,500 grams

- b. Gestational age equal to or less than 34 weeks
- c. 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.

## Medicaid

PacificSource Community Solutions follows OAR 410-148-0000 through 410-148-0320 and the general coverage requirements, limitations, and exclusions outlined in OARs 410-141-3820, 410-141-3825, and 410-120-1200 to determine coverage of Nutritional support and supplies.

PacificSource Community Solutions (PCS) follows the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) coverage requirements in OAR 410-151-0000 through 410-151-0003 for EPSDT beneficiaries. Relevant coverage guidance, including but not limited to OAR 410-148-0000 through 410-148-0320, may be used to assist in informing a determination of medical necessity and medical appropriateness during the individual case review. A case-by-case review for EPSDT Medical Necessity and EPSDT Medical Appropriateness as defined in OAR 410-151-0001 is required prior to denying. Refer to the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) policy for details.

Enteral formula and oral nutritional supplements documented as the primary source of nutrition, for a client of any age, meets criteria for expedited prior authorization review.

PacificSource Community Solutions Pharmacy will review CPT codes B4150 thru B4161 B9002 and B4149 per Community Solutions Prior Authorization Criteria located at <https://pacificsource.com/medicaid/find-a-drug>

## Medicare

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

## Experimental/Investigational/Unproven

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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

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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.

- B4100 Food Thickener, Administered Orally, Per Ounce
- B4102 Enteral Formula adult fluids and electrolytes
- B4103 Enteral Formula ped fluid and electrolyte
- 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  $\geq 0.7$ 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 24
- 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-HepAmine-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
- B9998 NOC for enteral supplies
- B9999 Not otherwise covered parenteral supplies
- 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

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**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.

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

## References

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Advisory Committee on Heritable Disorders in Newborns and Children

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## Appendix

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**Depts.:** Health Services

**Applicable regulation(s):** Orphan Drug Act (21 U.S.C. 360ee (b) (3)), 42 CFR § 422.101(b-c); ORS 743A.188, ORS 743A.070; RCW 41.05.017, RCW 48.44.440, RCW 48.43.715, MCA 33-22-131, OARs 410-148-0000 through 410-148-0320, 410-120-1200, 410-141-3820, 410-141-3825, 410-151-0000 through 410-151-0003

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