Enteral Nutrition Support and Supplies

State(s):	LOB(s):
☒ *Idaho* ☒ *Montana* ☒ *Oregon* ☒ *Washington* ☐ *Other:*	☒ *Commercial* ☒ *Medicare* ☒ *Medicaid*

Enterprise Policy

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

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."

Regular grocery items are therefore, by definition, NOT medical food and are not covered items. FDA considers the requirement that a medical food be formulated to be consumed or administered enterally under the supervision of a physician to mean that the intended use of a medical food is for the

dietary management of a patient receiving active and ongoing medical supervision (e.g., in a health care facility or as an outpatient) by a physician who has determined that the medical food is necessary to the patient's overall medical care. Medical foods are foods specially formulated for the individual who is seriously ill or who requires the product as a major treatment modality. An example is processed enteral formula needed for individuals with a diagnosed inborn error of metabolism.

Inborn Errors of Metabolism

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.

According to the American Gastroenterological Association, there are five categories of IEM: Amino Acid Disorder, Fatty Acid Oxidation Disorder, Organic Academia, Urea Cycle Disorders and Other.

Amino Acid Disorder

- Classic phenylketonuria
- Homocystinuria
- Maple syrup urine disease
- Tyrosinemia, type I

Fatty Acid Oxidation Disorder

- Carnitine uptake defect/carnitine transport defect
- Long-chain L-3 hydroxyacyl-CoA dehydrogenase deficiency
- Medium-chain Acyl-CoA dehydrogenase deficiency
- Trifunctional protein deficiency
- Very long-chain Acyl-CoA dehydrogenase deficiency

Organic Academia

- 3-hydroxy-3-methylglutaric aciduria
- 3-methylcrotonyl-CoA carboxylase deficiency
- ß-ketothiolase deficiency
- Glutaric acidemia type I
- Holocarboxylase synthetase deficiency
- Isovaleric academia
- Methylmalonic acidemia (cobalamin disorders)

- Methylmalonic acidemia (methylmalonyl-CoA mutase)
- Propionic academia

Urea Cycle Disorders

- Argininosuccinic aciduria
- Citrullinemia type I

Other

- Biotinidase deficiency
- Classic galactosemia
- Glycogen storage disease type II (Pompe disease)
- Mucopolysaccharidosis I
- X-linked adrenoleukodystrophy

Criteria

Commercial

I. Donor Human Milk and Human Milk Fortifiers

A. PacificSource may consider donor human milk and/or human milk fortifiers (e.g., Prolacta) medically necessary when ordered by a licensed heath 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 chest 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 chest feeding;

2. Donor human milk must be obtained from an accredited milk bank; **AND**

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; **or**

o. Any infant still inpatient within 72 hours of birth without sufficient human milk available.

II. Oral Enteral Nutrition

Prior authorization is required.

A. PacificSource may consider oral enteral nutrition to be medically necessary when **ALL** of the following is met:

1. The product must be a medical food for oral feeding;

2. The product is the primary source of nutrition (that is, constitutes 60 percent or more of the intake for the individual);

3. The product must be labeled and used for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements to prevent the development of serious physical or mental disabilities or to promote normal development or function as listed in **a. or b.** below:

a. Diagnosis of inborn error of metabolism, refer to background section for specific examples; **or**

b. One of the following conditions:

i. Eosinophilic enteritis (colitis/proctitis, esophagitis, gastroenteritis); **or**

ii. Cystic fibrosis with malabsorption.

4. The product must be 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.

Initial authorization approval period: 6 months unless otherwise specified.

Reauthorization approval period: 12 months unless otherwise specified.

III. Enteral Nutrition via Tube

Prior authorization is required.

A. PacificSource may consider 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 comprises the majority (60 percent or more) of the diet;
2. 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;
3. 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); **or**
    b. Is associated with obstruction of the proximal GI tract (e.g., tumor of the esophagus).

B. PacificSource may consider enteral nutrition via tube feeding indicated for behavioral health eating disorders to be medically necessary when **ALL** of the following criteria are met:

1. Behavioral Health Medical Director approves the request and determines the authorization time period per current treatment plan;
2. Member is unable to maintain an ideal body weight through oral feeding despite participating in an intensive eating disorder treatment program;
3. Nutritional support must be administered through a feeding tube only (e.g., nasogastric, jejunostomy, peg tube). Enteral nutrition products and related supplies that are administered orally (i.e., by mouth) are not coverable.

Initial authorization approval period: 6 months unless otherwise specified.

Reauthorization approval period: 12 months unless otherwise specified.

IV. Enteral Infusion Pumps

Prior authorization is required.

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**

3. The individual's medical condition requires that 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).

NOTE: Supplies for gravity feedings do not require preauthorization if under $1000. Feeding tube supplies for medications and maintenance only do not require prior authorization if under $1,000.

Medicaid

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

PacificSource Community Solutions Pharmacy reviews CPT codes B4150 thru B4161.

HCPCS code B4149 Blenderized Foods is not a covered benefit under the OHP.

Medicare

PacificSource Medicare uses Local Coverage Determination L38955 for Enteral Nutrition and National Coverage Determination 180.2 for Enteral Nutritional Therapy.

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 are considered 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 >/= 0.7kc

B4161 Enteral Formula ped hydrolyzed/amino acid

B4162 Enteral Formula ped spec metabolic inherit

B9002 Enteral nutrition infusion pump, any type

S9432 Medical foods for noninborn 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

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

Total Parenteral Nutrition (TPN) in the Home Setting

References

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Appendix

Policy Number:

Effective: 10/1/2020 **Next review:** 4/1/2023

Policy type: Enterprise

Author(s):

Depts.: Health Services

Applicable regulation(s): 42 CFR Sec. 156.111; RCW 48.43.715, RCW 41.05.017

Commercial Ops: 7/2022

Government Ops: 8/2022