Home Enteral Nutrition

Introduction

Enteral nutrition is a term that means any method of feeding which uses the digestive tract. The nutrition product can be taken in through the mouth (oral) or may be sent to the stomach or intestines by a tube. In the normal eating process, a person eats and the body breaks down the food in the stomach and bowel and distributes the nutrients throughout the body. Sometimes, however, a person isn’t able to eat or swallow because of an illness. In other situations, the body can’t break down or absorb the nutrients in a regular diet. This policy discusses the conditions when enteral nutrition is considered medically necessary and the situations when it is not covered.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Service</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enteral nutrition given</td>
<td>Enteral nutrition or supplements given orally may be</td>
</tr>
<tr>
<td>Service</td>
<td>Medical Necessity</td>
</tr>
<tr>
<td>------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>orally</td>
<td>considered medically necessary when used for the treatment of inborn errors of metabolism, such as (not an all-inclusive list):</td>
</tr>
<tr>
<td></td>
<td>• Histidinemia</td>
</tr>
<tr>
<td></td>
<td>• Homocystinuria</td>
</tr>
<tr>
<td></td>
<td>• Maple syrup urine disease (MSUD)</td>
</tr>
<tr>
<td></td>
<td>• Phenylketonuria (PKU)</td>
</tr>
<tr>
<td></td>
<td>• Tyrosinemia</td>
</tr>
</tbody>
</table>

For Washington Fully-insured Members only: In addition to the above diagnoses, elemental enteral formula given orally or via feeding tube may be considered medically necessary when ALL of the following criteria are met:

- There is a diagnosis of eosinophilic gastrointestinal associated disorders (eosinophilic esophagitis, eosinophilic gastroenteritis, or eosinophilic colitis)
- There is a prescription
- The provider supervises the use of the elemental formula.

In addition to those inborn errors of metabolism listed above, there may rarely be other inborn errors of metabolism for which supplements are requested. There are hundreds of types of inborn errors of metabolism; therefore, not all could be listed within the policy. Not all inborn errors of metabolism require special foods for treatment. These requests must be reviewed and approved by a medical director on a case-by-case basis. Please refer to the table in the Coding section below.

<table>
<thead>
<tr>
<th>Enteral nutrition via a feeding tube</th>
<th>Enteral nutritional support received by a feeding tube may be considered medically necessary for patients who are unable to take adequate nutrition by mouth and have:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adequate intestinal absorption despite:</td>
</tr>
<tr>
<td></td>
<td>• Disorders of the gastrointestinal tract (eg, head and neck cancer, an obstructing tumor or stricture of the esophagus or stomach, or Crohn disease)</td>
</tr>
<tr>
<td>Service</td>
<td>Medical Necessity</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td><strong>OR</strong></td>
</tr>
<tr>
<td></td>
<td>o Central nervous system disease or injury resulting in interference with neuro-muscular coordination of chewing and swallowing that presents a risk of aspiration</td>
</tr>
<tr>
<td></td>
<td>• Anorexia or bulimia, when the patient meets the following:</td>
</tr>
<tr>
<td></td>
<td>o Enteral nutrition (EN) should be temporary until such time as the patient is able to orally take in and retain adequate amounts of food in order to correct the specific physical abnormalities and maintain the corrected state. Within one week of beginning EN, attempts at oral feedings should be made. An additional week may be required to wean off EN. Concomitant psychotherapy to address the underlying psychological reasons for pathologically restricting intake and/or purging is mandatory.</td>
</tr>
<tr>
<td></td>
<td>• Failure to thrive</td>
</tr>
<tr>
<td></td>
<td><strong>The following criteria must be met before the start of enteral nutrition services.</strong></td>
</tr>
<tr>
<td></td>
<td>• The patient receives no more than 30% of his/her caloric intake orally</td>
</tr>
<tr>
<td></td>
<td><strong>OR</strong></td>
</tr>
<tr>
<td></td>
<td>• The patient is unable to maintain estimated nutritional needs even though he may be receiving &gt;30% orally (eg, cysticfibrosis or failure to thrive)</td>
</tr>
<tr>
<td></td>
<td><strong>Note:</strong> A physician must specifically order nutrients and the manner of administration for EN, medical food, and for oral nutrition supplies for the treatment of inborn errors of metabolism. However, a physician order for the nutritional support does not, in itself, qualify the service or supply for coverage.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relizorb™ immobilized lipase cartridge</td>
<td>Digestive enzymes added to enteral formula via a cartridge device attached to the tubing used for enteral feeding is considered investigational (eg, Relizorb™ immobilized lipase cartridge).</td>
</tr>
</tbody>
</table>
The medical records submitted for review should document that medical necessity criteria are met.

For enteral nutrition given orally:

- Provide clinical documentation that the patient’s condition is associated with an inborn error of metabolism that interferes with how the body uses food. These are conditions such as:
  - Histidinemia (elevated blood levels of the amino acid histidine)
  - Homocystinuria (the body is not able to process certain amino acids)
  - Maple syrup urine disease or MSUD (the body is not able to process certain amino acids and is characterized by sweet odor of the urine)
  - Phenylketonuria or PKU (an increase in the blood levels of the amino acid phenylalanine)
  - Tyrosinemia (problems in breaking down the amino acid tyrosine)

- **Washington Fully-insured members only:** For elemental enteral formula given orally or via feeding tube, in addition to any of the above conditions ALL of the following must be clinically documented:
  - Diagnosis of eosinophilic gastrointestinal associated disorders such as eosinophilic esophagitis, eosinophilic gastroenteritis, or eosinophilic colitis (EGID occurs when the body creates too many white blood cells known as eosinophils)
  - There is prescription
  - The product is used under the supervision of a healthcare provider

For enteral nutrition via a feeding tube:

- Provide clinical documentation that the patient is unable to take adequate nutrition by mouth but is able to absorb nutrients. One of the following conditions also must be present:
  - Disorders of the gastrointestinal tract (eg, head and neck cancer, an obstructing tumor or stricture of the esophagus or stomach, or Crohn disease)
  - Central nervous system disease or injury resulting in interference with neuromuscular coordination of chewing and swallowing which presents a risk of aspiration
  - Anorexia or bulimia with documentation of concomitant psychotherapy to address the underlying psychological reasons for pathologically restricting intake and/or purging
  - Failure to thrive

- In addition to the above, provide clinical documentation of the following before starting the enteral nutrition services:
### Documentation Requirements

- If patient is able to swallow, the patient gets less than one-third of nutrients by eating
  - OR
- The patient is able to swallow more than one-third of needed nutrients but the nutritional needs still can’t be met

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CPT</strong></td>
<td></td>
</tr>
<tr>
<td>44015</td>
<td>Tube or needle jejunostomy for enteral alimentation, intraoperative, any method (List separately in addition to primary procedure)</td>
</tr>
<tr>
<td><strong>HCPCS</strong></td>
<td></td>
</tr>
<tr>
<td>B4100</td>
<td>Food thickener, administered orally, per oz</td>
</tr>
<tr>
<td>B4102</td>
<td>Enteral formula, for adults, used to replace fluids and electrolytes (eg, clear liquids), 500 ml = 1 unit</td>
</tr>
<tr>
<td>B4103</td>
<td>Enteral formula, for pediatrics, used to replace fluids and electrolytes (eg, clear liquids), 500 ml = 1 unit</td>
</tr>
<tr>
<td>B4104</td>
<td>Additive for enteral formula (eg, fiber)</td>
</tr>
<tr>
<td>B4105</td>
<td>In-line cartridge containing digestive enzyme(s) for enteral feeding, each (new code effective 1/1/19)</td>
</tr>
<tr>
<td>B4149</td>
<td>Enteral formula, manufactured blenderized natural foods with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4150</td>
<td>Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4152</td>
<td>Enteral formula, nutritionally complete, calorically dense (equal to or greater than 1.5 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4153</td>
<td>Enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4154</td>
<td>Enteral formula, nutritionally complete, for special metabolic needs, excludes inherited</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>B4155</td>
<td>Enteral formula, nutritionally incomplete/modular nutrients, includes specific nutrients, carbohydrates (eg, glucose polymers), proteins/amino acids (eg, glutamine, arginine), fat (eg, medium chain triglycerides) or combination, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4157</td>
<td>Enteral formula, nutritionally complete, for special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4158</td>
<td>Enteral formula, for pediatrics, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4159</td>
<td>Enteral formula, for pediatrics, nutritionally complete soy-based with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4160</td>
<td>Enteral formula, for pediatrics, nutritionally complete calorically dense (equal to or greater than 0.7 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4161</td>
<td>Enteral formula, for pediatrics, hydrolyzed/amino acids and peptide chain proteins, includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4162</td>
<td>Enteral formula, for pediatrics, special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B9002</td>
<td>Enteral nutrition infusion pump – with alarm</td>
</tr>
<tr>
<td>B9004</td>
<td>Parenteral nutrition infusion pump, portable</td>
</tr>
<tr>
<td>B9006</td>
<td>Parenteral nutrition infusion pump, Stationary</td>
</tr>
<tr>
<td>B9998</td>
<td>NOC for enteral supplies</td>
</tr>
<tr>
<td>B9999</td>
<td>NOC for parenteral supplies</td>
</tr>
<tr>
<td>Q9994</td>
<td>In-line cartridge containing digestive enzyme(s) for enteral feeding, each (code terminated 1/1/19)</td>
</tr>
<tr>
<td>S9340</td>
<td>Home therapy; enteral nutrition; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>-------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>S9341</td>
<td>Home therapy; enteral nutrition via gravity; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem</td>
</tr>
<tr>
<td>S9342</td>
<td>Home therapy; enteral nutrition via pump; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem</td>
</tr>
<tr>
<td>S9343</td>
<td>Home therapy; enteral nutrition via bolus; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem</td>
</tr>
<tr>
<td>S9433</td>
<td>Medical food nutritionally complete, administered orally, providing 100% of nutritional intake</td>
</tr>
<tr>
<td>S9434</td>
<td>Modified solid food supplements for inborn errors of metabolism</td>
</tr>
<tr>
<td>S9435</td>
<td>Medical foods for inborn errors of metabolism</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Code</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>D81.810</td>
<td>Biotinidase deficiency</td>
</tr>
<tr>
<td>D81.818</td>
<td>Multiple carboxylase deficiency</td>
</tr>
<tr>
<td>E71.19</td>
<td>Beta-ketothiolase deficiency</td>
</tr>
<tr>
<td>E71.41</td>
<td>Carnitine deficiency</td>
</tr>
<tr>
<td>E71.110</td>
<td>Isovaleric academia</td>
</tr>
<tr>
<td>E71.118</td>
<td>3-OH 3-CH3 glutaric aciduria</td>
</tr>
<tr>
<td>E71.120</td>
<td>Methylmalonic academia</td>
</tr>
<tr>
<td>E71.121</td>
<td>Propionic academia</td>
</tr>
<tr>
<td>E71.310</td>
<td>Long chain/very long chain acyl CoA dehydrogenase deficiency</td>
</tr>
<tr>
<td>E71.311</td>
<td>Medium chain acyl CoA dehydrogenase deficiency</td>
</tr>
<tr>
<td>E71.318</td>
<td>Other disorders of fatty-acid oxidation</td>
</tr>
<tr>
<td>E72.3</td>
<td>Glutaric aciduria (type I)</td>
</tr>
<tr>
<td>E72.21</td>
<td>Argininemia</td>
</tr>
<tr>
<td>E72.23</td>
<td>Citrullinemia</td>
</tr>
</tbody>
</table>
### Table 1. Examples of Inborn Errors of Metabolism

<table>
<thead>
<tr>
<th>Brief Description</th>
<th>ICD-10 code</th>
</tr>
</thead>
<tbody>
<tr>
<td>histidinemia</td>
<td>E70.41</td>
</tr>
<tr>
<td>homocystinuria</td>
<td>E72.11</td>
</tr>
<tr>
<td>maple syrup urine disease (MSUS)</td>
<td>E71.0</td>
</tr>
<tr>
<td>tyrosinemia type 1</td>
<td>E70.21</td>
</tr>
<tr>
<td>phenylketonuria (PKU)</td>
<td>E70.0</td>
</tr>
</tbody>
</table>

### Related Information

**Benefit Application**

Regular food products, nutritional supplements and formula are considered **contract exclusions**, including but not limited to:

- Baby food
- Banked breast milk
- Food thickeners
- Food supplements for a deficient diet
- Food supplements to provide alternative nutrition in the presence of conditions such as hypoglycemia, allergies, obesity, and gastrointestinal disorders
- Gluten-free food products
- High protein powders and mixes
- Lactose-free products; products to aid in lactose digestion
- Low carbohydrate diets
- Normal grocery items
- Nutritional supplement puddings
- Oral vitamins and minerals
- Standardized or specialized infant formula for conditions other than those for inborn errors of metabolism
- Weight-loss foods and formula (products to aid weight loss)

Physician supervision is defined as periodic assessment of nutritional status by a provider with prescriptive authority. A physician must specifically order nutrients and the manner of administration for EN, medical food, and for oral nutrition supplies for the treatment of inborn errors of metabolism. However, a physician order for the nutritional support does not, in itself, qualify the service or supply for coverage.

Eligible nutritional support expenses could be reimbursed using the member’s Medical benefits, under Infusion, Medical Supply, Home Health or Medical Equipment and Supply benefits depending on the design of the individual member’s contract.

Nutritional support for complications of non-covered services such as bariatric surgery may be excluded by the member contract.

**Oregon**

Oregon state statute 743A.070 mandates benefit coverage for a nonprescription elemental enteral formula for home use, if the formula is medically necessary for the treatment of severe intestinal malabsorption and a physician has issued a written order for the formula and the formula comprises the sole source, or an essential source, of nutrition. More information can be found at the following link: [http://www.oregonlaws.org/ors/743A.070](http://www.oregonlaws.org/ors/743A.070) Accessed March 2019.
**Note:** This state statute is applicable to fully-insured members. Self-funded groups may or may not elect to provide similar provisions to their contract. Please check the member contract for benefits and administer accordingly.

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**Washington**

Effective for health benefit plans that are issued or renewed after December 31, 2015, Washington state statute (HB 2153) requires plans to cover medically necessary elemental formula, regardless of delivery method, when a provider diagnoses a patient with eosinophilic gastrointestinal associated disorders and subsequently orders and supervises the use of the elemental formula. More information can be found at the following link: [http://apps.leg.wa.gov/documents/billdocs/2013-14/Pdf/Bill%20Reports/House/2153%20HBA%20HCW%2014.pdf](http://apps.leg.wa.gov/documents/billdocs/2013-14/Pdf/Bill%20Reports/House/2153%20HBA%20HCW%2014.pdf) Accessed March 2019.

**Note:** This state statute is applicable to fully-insured members. Self-funded groups may or may not elect to provide similar provisions to their contract. Please check the member contract for benefits and administer accordingly.

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**Evidence Review**

**Description**

Enteral nutrition is nutritional support given via the gastrointestinal tract. This includes oral feeding, sip feeding, and feeding using a tube. The tube may enter the body through the nose (nasogastric), through an opening made in the skin of the abdomen into the stomach (gastrostomy), or through an opening made in the skin of the abdomen into the small intestine (jejunostomy).\(^1\)

**Background**

Most enteral formulas used for nutritional support (feeds) are ready-to-use fluids, in microbial-free containers that provide macronutrients, micronutrients, fluids and, in some cases, soluble or insoluble fiber. They are usually nutritionally complete within a specific volume, providing the necessary nutrients to support the dietary needs of the patient.\(^2\)
Table 2. Classification of enteral feed/formulas

<table>
<thead>
<tr>
<th>Type of Feed/formula</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease-specific enteral formula</td>
<td>Designed for specific clinical conditions and metabolic disorders (ie, chronic renal failure, respiratory disease, diabetes, cancer).</td>
</tr>
<tr>
<td>General feeds (polymeric)</td>
<td>For patients with normal digestion and absorption. They contain whole proteins. Usual osmolarity: 300-500 mOsm/kg, 1-1.2 kcal/ml, 30-40 g protein/l.</td>
</tr>
<tr>
<td>Hydrolysed/elemental</td>
<td>For patients with limited GI function. They contain free amino acids, low in fat and low residue. Hyperosmotic, 1 kcal/ml, 40 g protein/L.</td>
</tr>
<tr>
<td>Semi-elemental/partially hydrolyzed/peptide feeds</td>
<td>For patients with disturbed GI function, who need partially hydrolysed nutrients for better digestion and absorption. Osmolarity: depends on the level of hydrolysis, 1-1.2 kcal/ml, 30-45 g protein/l.</td>
</tr>
</tbody>
</table>

Elemental and semi-elemental feeds facilitate digestion and absorption in patients with abnormal GI function. They are indicated for patients with inflammatory bowel disease, pancreatic insufficiency, malabsorption, short bowel syndrome, radiation enteritis, early enteral feeding or intolerance to the normal nutritional molecules found in food.2

Treatment for most metabolic disorders includes exclusion of specific nutritional elements present in common diets. Special formulas are required for infants and children with these disorders to prevent or restrict physical and/or neurological injury that results from faulty metabolism. Life-long dietary restrictions may be required.

Malabsorption of ingested food has many causes. For example, surgical shortening of the small bowel, mucosal damage, impaired motility of the digestive tract and other problems can all cause malabsorption of ingested food.3 Gastrointestinal eosinophilia is a broad term for an abnormal accumulation of eosinophils in the gastrointestinal tract. It is a very rare condition, and may be related to many different diseases.4-5 Adults receiving enteral tube feedings who cannot break down and absorb fats may opt to use an immobilized lipase delivery system called Relizorb™. Relizorb mimics the normal action of pancreatic lipase and is proposed to improve fat absorption and increase the amount of absorbable calories from enteral formula.6 The system is a single-use, point-of-care digestive enzyme cartridge that connects in-line with existing enteral pump feed sets, and pump extension sets. The device received FDA approval in 2015. Not all enteral tube feed formulas are compatible with Relizorb. Large scale studies in human subjects are still lacking. At this time, Relizorb lacks sufficient evidence in the peer reviewed literature to support its use.7
Regulatory Status

Enteral formulas are considered food supplements by the Food and Drug Administration (FDA) and are therefore not under the same regulatory control as medications. As a result, enteral formula labels may make “structure and function” claims without prior FDA review or approval. Furthermore, there is a lack of prospective, randomized, controlled clinical trials supporting the intended usefulness of the majority of the specialized formulas currently on the market.

Medical Food: defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b)) 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. Available at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/ucm054048.htm Accessed March 2019.

References


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>08/04/98</td>
<td>Add to Therapy Section - New Policy</td>
</tr>
<tr>
<td>03/02/99</td>
<td>Replace Policy - Policy and Policy Guidelines sections changed.</td>
</tr>
<tr>
<td>05/08/01</td>
<td>Replace Policy - Revised and updated.</td>
</tr>
<tr>
<td>05/14/02</td>
<td>Policy Deleted - Services will not be reviewed.</td>
</tr>
<tr>
<td>04/15/03</td>
<td>Policy Re-instated - Policy reviewed and updated. No change to the policy statement.</td>
</tr>
<tr>
<td>08/12/03</td>
<td>Replace Policy - Policy language clean-up only; no change to policy statement.</td>
</tr>
<tr>
<td>01/01/04</td>
<td>Replace Policy - CPT code updates only.</td>
</tr>
<tr>
<td>05/11/04</td>
<td>Replace Policy - Scheduled review, no changes to policy statement.</td>
</tr>
<tr>
<td>09/01/04</td>
<td>Replace Policy - Policy renumbered from PR.8.01.102. No changes to dates.</td>
</tr>
<tr>
<td>05/10/05</td>
<td>Replace Policy - Scheduled review; no changes to policy statement.</td>
</tr>
<tr>
<td>04/11/06</td>
<td>Replace Policy - Scheduled review; no changes to policy statement.</td>
</tr>
<tr>
<td>06/02/06</td>
<td>Disclaimer and Scope update - No other changes.</td>
</tr>
<tr>
<td>04/10/07</td>
<td>Replace Policy - Policy updated with literature review; reference added and codes updated. No change in policy statement.</td>
</tr>
<tr>
<td>07/08/08</td>
<td>Replace Policy - Policy updated with literature search; no change to the policy statement.</td>
</tr>
<tr>
<td>06/09/09</td>
<td>Replace Policy - Policy updated with literature search; no change to the policy statement.</td>
</tr>
<tr>
<td>08/11/09</td>
<td>Replace Policy - Allergic disorders addressed in the Policy Guidelines and Benefit Application as an OTC food source.</td>
</tr>
<tr>
<td>05/11/10</td>
<td>Replace Policy - Policy statement revised to restrict oral nutrition only for treatment of errors of inborn metabolism. TPN and EN policy statements reworded but intent is unchanged. Guidelines, Benefit Application and References updated. Title updated.</td>
</tr>
<tr>
<td>06/13/11</td>
<td>Replace Policy - Policy updated and reviewed by practicing pediatrician. No change to policy statement.</td>
</tr>
<tr>
<td>05/22/12</td>
<td>Replace policy. Policy updated and reviewed by practicing pediatrician. Minor edits for</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>-----------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>05/28/13</td>
<td>Replace policy. Policy updated and reviewed by practicing pediatrician. No change to policy statement.</td>
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<tr>
<td>12/18/13</td>
<td>Update Related Policies. Modify title to 7.01.516.</td>
</tr>
<tr>
<td>05/02/14</td>
<td>Annual Review. Added two policy statements for WA and OR mandates. Removed policy statements, description, rationale and codes on TPN. References 1-5 added. Clarification added in Benefit application section. Policy title changed to “Home Enteral Nutrition”.</td>
</tr>
<tr>
<td>02/25/15</td>
<td>Coding update. ICD-9 diagnosis and procedure codes removed; these were inadvertently reflected on the policy.</td>
</tr>
<tr>
<td>04/14/15</td>
<td>Annual Review. Clarification added in Policy Guidelines. Added table with IEM diagnosis, ICD-9 and ICD-10 codes.</td>
</tr>
<tr>
<td>05/27/15</td>
<td>Coding update. HCPCS codes S9434 and S9435 added.</td>
</tr>
<tr>
<td>11/20/15</td>
<td>Update Related Policies. Remove 7.01.516.</td>
</tr>
<tr>
<td>02/09/16</td>
<td>Annual Review. Policy reviewed. Policy statements unchanged.</td>
</tr>
<tr>
<td>01/01/17</td>
<td>Interim review, approved December 13, 2016. Policy statement added that digestive enzymes added to enteral formula via a cartridge device (Relizorb) are investigational. Policy updated with literature search through September 2016. References added.</td>
</tr>
<tr>
<td>04/14/17</td>
<td>Coding update; added HCPCS code S9433.</td>
</tr>
<tr>
<td>07/01/17</td>
<td>Annual Review, approved June 22, 2017. Policy moved into new format. Minor clarification updates to policy. No change to policy statements.</td>
</tr>
<tr>
<td>09/07/18</td>
<td>Coding update, added HCPCS code Q9994.</td>
</tr>
<tr>
<td>01/01/19</td>
<td>Coding update, added new HCPCS code B4105 (new code effective 1/1/19).</td>
</tr>
<tr>
<td>02/01/19</td>
<td>Coding update, removed HCPCS code B9000.</td>
</tr>
<tr>
<td>03/19/19</td>
<td>Coding update, added table to outline covered diagnosis codes.</td>
</tr>
<tr>
<td>04/01/19</td>
<td>Annual Review, approved March 19, 2019. Minor edits for clarity. OR state statute policy statement deleted as it only applies to fully-insured plans in OR which no longer applies to this line of business at this time.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply.
Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
- Civil Rights Coordinator - Complaints and Appeals
  PO Box 91102, Seattle, WA 98111
  Toll free 855-332-4535, Fax 425-918-5592. TTY 800-842-5357
  Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
- U.S. Department of Health and Human Services
  200 Independence Avenue SW, Room 509F, HHH Building
  Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.

Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Arabic):

中文 (Chinese):

本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保障的重要訊息。本通知可能有關於重要日期。您可能需要在截止日期之前採取行動。以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

Oromo (Cushite):


Deutsche (German):


Deutsch (German):


Italiano (Italian):

To og kluczowe daty, które mogą być ważne w przypadku utrzymania polisy ubezpieczeniowej lub przerwania jej. Zadbaj, aby nie jednakże oznaczać, jeśli potrzebujesz listy ważnych terminów w przypadku utrzymania polisy ubezpieczeniowej lub przerwania jej, połącz z 800-722-1471 (TTY: 800-842-5357) w celu uzyskania dodatkowych informacji.


Русский (Russian): Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами.

您有权在我的语言中获取这些信息，并在需要时获得帮助。请拨打800-722-1471 (TTY: 800-842-5357)。

Español (Spanish): Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas claves en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

泰语 (Tagalog): Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon. Ang paunawa na ito ay maaaring naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagaksak sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring maaari upang may mga mahalagang petsa dito sa paunawa. Maaring maaari upang may mga mahalagang petsa dito sa paunawa. Maaring maaari upang may mga mahalagang petsa dito sa paunawa. Maaring maaari upang may mga mahalagang petsa dito sa paunawa.