GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

DESCRIPTION
Enteral Nutrition is commonly defined as the provision of nutritional requirements through a tube in the stomach or small intestine such as a nasogastric (NG) tube or a percutaneous gastrostomy (PEG) tube. Enteral feedings are delivered by syringe, gravity, or via an electric infusion pump. Feedings can be delivered on an intermittent or continuous basis. Individuals may require enteral nutritional therapy to provide sufficient nutrients to maintain weight and strength commensurate with their overall health status if their nutritional needs cannot be met through dietary adjustments and/or oral supplements.

Relizorb is a single-use, point-of-care digestive enzyme cartridge that connects in-line with existing enteral pump feed sets and pump extension sets. Relizorb is designed to hydrolyze fats contained in the enteral formulas, mimicking the function of the digestive enzyme lipase that is normally secreted by the pancreas. There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management for the use of the Relizorb device.

Parenteral Nutrition, also known as total parental nutrition (TPN), is typically reserved for situations when there is inadequate or insufficient absorption of nutrients through the gastrointestinal tract. This method of nutrition contains nutrients such as glucose, amino acids, lipids and added vitamins and dietary minerals delivered intravenously through a peripheral or central vein.

POLICY
Enteral nutrition requires prior authorization for items B4102-B4104, B4149-B4155, B4158-B4161 for all product lines.

Items B4157 & B4162 do not require a prior authorization for members diagnosed with inborn errors of metabolism for all product lines.

Food thickener (B4100, B4100-U1) does not require prior authorization for Advantage. (Limits may apply.)

Food thickener (B4100, B4100-U1) is non-covered for HMO, PPO, Individual Marketplace, & Elite.

Digestive enzyme cartridge (e.g. Relizorb) (B4105, Q9994) with tube fed enteral nutrition therapy is non-covered.

Items B4172 & B5200 are non-covered for Advantage.

Parenteral Nutrition does not require a prior authorization for all product lines.

(See terms of coverage below.)

Unlisted (Requires NDC and/or invoice review to determine the products reported for these codes.)
B9998, B9999
B9998 and B9999 are unlisted products and will always require invoice review to determine the products reported for these codes. B9998 is denied when used to report feeding supplies such as extension tubing and gravity sets because these are considered included in the supply of the standard feeding sets.

Exception include,

- The MIC-KEY® Gastrostomy Tube Extension Set for this is a specific attachment and the basic feeding set will not attach to the MIC-KEY® Gastrostomy button without this specific extension.
- The Farrell valve is a vented, closed, disposable system used for gastric pressure relief with some enterally fed beneficiaries. It is used to eliminate the buildup of gastric reflux and gas in the stomach and around the outside of a feeding tube. The Farrell valve is not indicated or required for all enterally fed beneficiaries.
  o a. the beneficiary is receiving continuous enteral feedings via gravity or pump;
  o b. there is documented evidence of disorders or complications with enteral feedings, including gastric dysmotility, abdominal distention, aspiration pneumonia, anti-reflux surgery, gastric pseudo-obstruction, tracheoesophageal fistula, or atresia repair; and
  o c. other attempted gastric decompression measures have failed.
  o The Farrell valve is not covered when clinical documentation demonstrates that the beneficiary is tolerating continuous enteral feedings without difficulty or complications.
  o Coverage maximum of one valve per day per beneficiary for a maximum period of six months. For additional approvals, medical necessity must be re-established for each successive six months.
  o The health record must contain documentation by the physician, physician assistant, or nurse practitioner substantiating the medical necessity requirement. A starting date and expected duration for the use of the Farrell valve must also be included. The medical necessity must specifically address the beneficiary’s complicating factors, such as gastric dysmotility, distention, reflux, aspiration risk, excessive gastric residuals, pain, neurological impairments, and dates of any anti-reflux procedures. The inability of the beneficiary to tolerate enteral feedings without the Farrell valve must be documented. Note: Only one Farrell valve per day is allowed. The valve is not provided and billed under routine enteral feeding supply kits.

Prior Authorization

1. Prior authorization requests for members who cannot maintain weight must include a current weight history.
2. Initial prior authorization requests for enteral nutrition products may be approved for a maximum of twelve months. Subsequent PAs for the same member for the same disease state may be approved for a maximum of twelve months.
3. Members having a change in their treatment plan that requires the use of an enteral product that is different than a previously authorized enteral product will require a new certificate of medical necessity before a new enteral product will be authorized.
4. Enteral nutrition requires prior authorization for items B4102-B4155, B4158-B4161. Items B4157 & B4162 do not require a prior authorization for members diagnosed with inborn errors of metabolism.

Dispensing

1. Enteral nutrition products shall be dispensed in no greater quantity than one month's supply.
2. Providers may dispense enteral nutrition products' generic equivalents (e.g., vendor branded or private label equivalent) if available, as long as the substituted product is correctly formulated to meet the needs of the member and the member's prescriber is notified in advance of dispensing.
3. Providers may not provide a re-supply of enteral nutrition products sooner than one week before a member's next scheduled supply dispense date.
4. No dispensing, mailing, or delivery fees are separately reimbursable.
5. The member will be supplied with the ordered enteral product that is in the most cost effective formulation that the member can tolerate.

Non-Covered Products

1. Enteral nutrition products that are designed to provide meal replacements, or snack alternatives to be eaten within the context of a member's individualized meal plan, are not covered. These products include, but are not limited to:
   a. Shakes
   b. Meal bars
   c. Snack bars
   d. Supplement thickeners
   e. Cereals
   f. Puddings
   g. Vitamins/ minerals
   h. Blenderized or pureed foods
2. Enteral nutrition products that are designed as meal replacements, or to be eaten within the context of a member's prescribed reduced calorie diet for members with diabetes, obesity issues, pre- or post-gastric bypass, or bariatric surgery, are not covered.

3. Enteral nutrition products that are administered in an outpatient provider setting (i.e., a dialysis outpatient clinic or a facility receiving per diem payments from the department) are not separately reimbursable.

4. Adult and pediatric electrolyte replacement is covered under the pharmacy benefit.

5. Digestive enzyme cartridges (e.g., Relizorb) (B4105, Q9994) with tube fed enteral nutrition therapy are considered experimental and investigational and are therefore non-covered.

Advantage
According to the Ohio Department of Medicaid 5160-10-26 Enteral Nutritional Products:

"Enteral nutrition" is defined as oral or tube-delivered caloric sustenance products for those Medicaid consumers demonstrating a disability or life-threatening disease with significant nutritional problems that cannot be managed by ordinary or blenderized foods.

Coverage Determination

1. For an enteral nutritional product to be considered for coverage, one of the following criteria must be met:
   a. The member is unable to swallow food due to a damaged or diseased (non-functioning) oral pathway and must be tube-fed, as determined and documented by a licensed prescriber.
   b. The member has the ability to swallow, but is unable to meet caloric and nutritional requirements from ordinary foods, including pureed or blenderized foods, to maintain life-sustaining functions, as determined and documented by a licensed prescriber.

2. Members with infants and children age five or younger whose children require enteral nutrition products, breast-feeding members with an infant one year of age or younger, or post-partum mothers with a child six months of age or younger, must apply to their county women, infant and children (WIC) program for an eligibility evaluation before coverage will be considered.

HMO, PPO, Individual Marketplace, Elite
According to the Centers for Medicare & Medicaid Services Local Coverage Determination Enteral Nutrition:

Enteral nutrition is the provision of nutritional requirements through a tube into the stomach or small intestine.

Coverage Determination
Enteral nutrition is covered for a member who has:

1. Permanent non-function or disease of the structures that normally permit food to reach the small bowel
   a. The member must have a permanent impairment. Permanence does not require a determination that there is no possibility that the member’s condition may improve sometime in the future. If the judgment of the attending physician, substantiated in the medical record, is that the condition is of long and indefinite duration (ordinarily at least 3 months), the test of permanence is considered met. Enteral nutrition will be denied as non-covered in situations involving temporary impairments.

2. Disease of the small bowel which impairs digestion and absorption of an oral diet, either of which requires tube feedings to provide sufficient nutrients to maintain weight and strength commensurate with the member’s overall health status.
   a. The member’s condition could be either:
      • Anatomic (e.g., obstruction due to head and neck cancer or reconstructive surgery, etc.)
      • Due to a motility disorder (e.g., severe dysphagia following a stroke, etc.)

Enteral nutrition is non-covered for members with a functioning gastrointestinal tract whose need for enteral nutrition is due to reasons such as anorexia or nausea associated with mood disorder, end-stage disease, etc.

The member must require tube feedings to maintain weight and strength commensurate with the member’s overall health status. Adequate nutrition must not be possible by dietary adjustment and/or oral supplements. Coverage is possible for members with partial impairments - e.g., a member with dysphagia who can swallow small amounts of food or a member with Crohn's disease who requires prolonged infusion of enteral nutrients to overcome a problem with absorption.

Enteral nutrition products that are administered orally and related supplies are non-covered, no benefit.

If the coverage requirements for enteral nutrition are met, medically necessary nutrients, administration supplies, and equipment are covered.
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

### HCPCS CODES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>B4034</td>
<td>Enteral feeding supply kit; syringe fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape</td>
</tr>
<tr>
<td>B4034-U1</td>
<td>Enteral feeding supply kit; syringe, per day-used with inline lipase cartridge</td>
</tr>
<tr>
<td>B4035</td>
<td>Enteral feeding supply kit; pump fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape</td>
</tr>
<tr>
<td>B4035-U1</td>
<td>Enteral feeding supply kit; pump fed, per day-used with inline lipase cartridge</td>
</tr>
<tr>
<td>B4036</td>
<td>Enteral feeding supply kit; gravity fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape</td>
</tr>
<tr>
<td>B4036-U1</td>
<td>Enteral feeding supply kit; gravity fed, (per day, includes bags/containers)-used with inline lipase cartridge</td>
</tr>
<tr>
<td>B4081</td>
<td>Nasogastric tubing with stylet</td>
</tr>
<tr>
<td>B4082</td>
<td>Nasogastric tubing without stylet</td>
</tr>
<tr>
<td>B4083</td>
<td>Stomach tube - levine type</td>
</tr>
<tr>
<td>B4087</td>
<td>Gastrostomy/jejunostomy tube, standard, any material, any type, each</td>
</tr>
<tr>
<td>B4088</td>
<td>Gastrostomy/jejunostomy tube, low-profile, any material, any type, each</td>
</tr>
<tr>
<td>B4100</td>
<td>Food thickener, administered orally, per ounce</td>
</tr>
<tr>
<td>B4100-U1</td>
<td>Food thickener, oral, concentrated formula, per ounce</td>
</tr>
<tr>
<td>B4102</td>
<td>Enteral formula, for adults, used to replace fluids and electrolytes (e.g. clear liquids), 500 ml = 1 unit</td>
</tr>
<tr>
<td>B4103</td>
<td>Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g. clear liquids), 500 ml = 1 unit</td>
</tr>
<tr>
<td>B4104</td>
<td>Additive for enteral formula (e.g. fiber)</td>
</tr>
<tr>
<td>B4105</td>
<td>In-line cartridge containing digestive enzyme(s) for enteral feeding, each (New code effective 01/01/2019)</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 disease of metabolism, includes altered composition of proteins, fats, carbohydrates, vitamins and/or minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4155</td>
<td>Enteral formula, nutritionally incomplete/modular nutrients, includes specific nutrients, carbohydrates (e.g. glucose polymers), proteins/amino acids (e.g. glutamine, arginine), fat (e.g. 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>B4164</td>
<td>Parenteral nutrition solution: carbohydrates (dextrose), 50% or less (500 ml = 1 unit) - homemix</td>
</tr>
<tr>
<td>B4168</td>
<td>Parenteral nutrition solution: amino acid, 3.5%, (500 ml = 1 unit) - homemix</td>
</tr>
<tr>
<td>B4172</td>
<td>Parenteral nutrition solution: amino acid, 5.5% through 7%, (500 ml = 1 unit) - homemix</td>
</tr>
<tr>
<td>B4176</td>
<td>Parenteral nutrition solution: amino acid, 7% through 8.5%, (500 ml = 1 unit) - homemix</td>
</tr>
<tr>
<td>B4178</td>
<td>Parenteral nutrition solution: amino acid, greater than 8.5% (500 ml = 1 unit) - homemix</td>
</tr>
<tr>
<td>B4180</td>
<td>Parenteral nutrition solution: carbohydrates (dextrose), greater than 50% (500 ml=1 unit) - homemix</td>
</tr>
<tr>
<td>B4185</td>
<td>Parenteral nutrition solution, per 10 grams lipids</td>
</tr>
<tr>
<td>B4189</td>
<td>Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 10 to 51 grams of protein - premix</td>
</tr>
</tbody>
</table>
B4193 Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 52 to 73 grams of protein - premix

B4197 Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements and vitamins, including preparation, any strength, 74 to 100 grams of protein - premix

B4199 Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements and vitamins, including preparation, any strength, over 100 grams of protein - premix

B4216 Parenteral nutrition; additives (vitamins, trace elements, heparin, electrolytes) homemix per day

B4220 Parenteral nutrition supply kit; premix, per day

B4222 Parent Nutrition Supply Kit, Home Mix, Complete

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, nephramine, renamine - premix

B5100 Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, hepatic - freamine hbc, 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 - premix

B9000 Enteral nutrition infusion pump - without alarm

B9002 Enteral nutrition infusion pump - with alarm

B9004 Parenteral nutrition infusion pump, portable

B9006 Parenteral Nutrition Infusion Pump-Stationary

B9998 Enteral Supplies, Not Otherwise Specified

B9999 Parenteral Supplies, Not Otherwise Specified

Q9994 In-line cartridge containing digestive enzyme(s) for enteral feeding, each (Deleted code effective 12/31/18)

**TAWG REVIEW DATES:** 05/26/2017

**REVISION HISTORY EXPLANATION**

02/01/08: No Change
01/15/09: Added exceptions
01/14/14: Added HCPCS Codes B4222 & B9006. Policy reviewed and updated to reflect most current clinical evidence. Policy approved per Medical Policy Steering Committee as revised.
07/08/14: Items B4157 & B4162 do not require a prior authorization for members diagnosed with inborn errors of metabolism as mandated by The Ohio Department of Medicaid. B4100 is covered for Advantage only per The Ohio Department of Medicaid. Policy approved by Medical Policy Steering Committee as revised.
05/26/17: Digestive enzyme cartridges (e.g. Relizorb) with tube fed enteral nutrition therapy are non-covered. Policy reviewed and updated to reflect most current clinical evidence per the Technology Assessment Working Group (TAWG).
07/10/18: Added effective 7/1/18 new code Q9994. Added modifier U1 for codes B4034, B4035, B4036, & B4100 per ODM guidelines. Food thickener (B4100, B4100-U1) is covered without prior authorization for Advantage. Food thickener (B4100, B4100-U1) is non-covered for HMO, PPO, Individual Marketplace, & Elite. Item B5200 is now covered for HMO, PPO, Individual Marketplace, Elite per CMS guidelines. Item B5200 remains non-covered for Advantage per ODM guidelines. Policy reviewed and updated to reflect most current clinical evidence per the Medical Policy Steering Committee.
08/14/18: Added CMS criteria from L33783 & A52493 for the HMO, PPO, Individual Marketplace, Elite product lines. Policy reviewed and updated to reflect most current clinical evidence per the Medical Policy Steering Committee.
01/08/19: Effective 12/31/18 code Q9994 is deleted. Added effective 01/01/19 new code B4105. Policy reviewed and updated to reflect most current clinical evidence per the Medical Policy Steering Committee.
09/23/19: Added unlisted exception coverage and criteria for the Farrell valve.

**REFERENCES/RESOURCES**

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid [http://ifs.ohio.gov/](http://ifs.ohio.gov/)
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review