

FORMULAS AND OTHER ENTERAL NUTRITION

Policy # 95

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Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Enteral nutritional support is used for members with medical conditions that result in nutritional risk. Nutritional risk is considered having a potential for developing malnutrition as shown by clinical indicators. Enteral nutrition is providing sufficient nutrients to maintain weight, strength, and overall health status. Enteral nutrition involves the use of special formulas or medical foods that are administered orally or through a tube placed in the gastrointestinal tract. Enteral nutrition is used when a person cannot maintain sufficient nutrition to support health. Some definitions of enteral nutrition are as follows:

Medical foods: 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."

Low-protein modified food products have a low amount of protein per serving. Low-protein modified food products are intended for use under the direction of a physician for the dietary treatment of hereditary metabolic diseases.

Enteral nutrition is defined as, nutrition, involving or passing through the small intestine, either naturally via the mouth and esophagus, or through an artificial opening. Formulas consisting of semi-synthetic intact proteins or protein isolates can be used for enteral feeding in most patients who meet criteria for enteral feeding.

Standard infant formulas are foods that purport to be for special dietary use, solely as a food for infants, by reason of their simulation of human milk or their suitability as a complete or partial substitute for human milk.

Elemental/amino acid formulas are a type of exempt infant formula which is regulated by the U.S. Food and Drug Administration (FDA) and is prescribed for infants with specific medical or dietary problems. An amino acid-based formula contains proteins which are broken down into their simplest and purest form making it easier for the body to process and digest. An infant or child may be placed on an amino acid-based formula if he/she is unable to digest or tolerate whole proteins found in other formulas, due to certain allergies or gastrointestinal conditions. Examples of amino acid-based elemental formulas are Neocate, EleCare, and PurAmino.

Hydrolyzed formulas are formulas with partial (not fully broken down) proteins. Hydrolyzed formulas can be labeled as hypoallergenic because the proteins in those formulas have been broken down (or hydrolyzed) so that the body's immune system may not detect the proteins as being an allergen. Although many babies with food allergies and food intolerances tolerate extensively hydrolyzed formulas, there is a subset that do not, often having symptoms including diarrhea, vomiting, rashes, and poor growth. This is where amino acid-based formulas can be helpful as they are sometimes considered the least allergenic option in comparison with extensively hydrolyzed formulas.

Short-chain fatty acid formulas are a sub-group of fatty acids with aliphatic tails of two to six carbons. They include formic acid, acetic acid (vinegar), propionic acid, isobutyric acid (2-methylpropanoic acid), butyric acid, isovaleric acid (3-methylbutanoic acid), and valeric acid (pentanoic acid). Short-chain fatty acids and medium-chain fatty acids are primarily absorbed through the portal vein during lipid digestion, while long-chain fatty acids are packed into chylomicrons and enter lymphatic capillaries—and enter the blood first at the subclavian vein. Short-chain fatty acids are produced in small amounts when dietary fiber is fermented in the colon.

IEM (Inborn errors of metabolism) disorders are genetic disorders that affect the ability of an individual to digest foods and metabolize nutrients. IEMs are caused by genetic defects that usually result in the absence of an enzyme; the enzyme is necessary to convert chemical substances called substrates into other substances in the body. A common IEM is phenylketonuria (PKU). An individual with PKU cannot process the substrate phenylalanine, an essential amino acid commonly present in foods. Consumption of a typical diet for an individual with PKU would cause toxic build-up of phenylalanine within the body. Thus, treatment of PKU requires a diet with very low, to absent, phenylalanine.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

A. Select Health covers oral/enteral formula when at least ONE of the following criteria are met (1–6):

1. Oral/enteral feeding comprises more than 50% total estimated daily caloric need, and A or B AND C of the following are met:

- A. There is a severe neurological, gastrointestinal, or psychiatric condition; or diagnosis of failure to thrive that:
 - i. Prevents safe or adequate consumption of food; and
 - ii. Could result in physical disability, intellectual disability, or death if nutritional therapy is not instituted; **OR**
- B. There is a diagnosis of active malnutrition, defined by any one of the following:
 - i. For ages 0 to 2 years old: Weight for Length (WFL) \leq 5th percentile -or- WFL Z-score less than 1.5
 - ii. For ages 0 to 20 years old: Weight for Age (WFA) \leq 5th percentile -or- WFA Z-score less than 1.5
 - iii. For ages > 2-20 years old: BMI \leq 5th percentile or BMI Z-score less than 1.5
 - iv. For ages >20 years old: BMI < 18.5
 - v. Unintentional weight loss of 5% in one month, 7.5% in three months, or 10% in six months; **AND**
- C. Conservative therapy to increase caloric intake has been attempted but did not result in adequate rate of growth and/or adequate weight gain; and

For continued coverage of oral/enteral formula after 24 months, there must be documented failure to maintain weight for adults; or weight-for-length/height, or weight for age or BMI percentile in children, after attempts are made to reduce or taper supplemental formula. If taper or reduction is contraindicated, or failed in the past, supporting medical documentation is required.

-OR-

2. A diagnosis of an inborn error of metabolism and:

- a. The formula is specifically formulated and used for the treatment of errors of amino acid or urea cycle metabolism; **and**
- b. The product is used under the direction of a physician, and its use remains under the supervision of the physician.

-OR-

3. A diagnosis of cystic fibrosis (CF) and:

- a. Documented malabsorption, nutritional compromise, or caloric deficiencies related to the CF, **and**
 - i. Nutritional compromise is demonstrated by a documented weight loss/lack of weight gain. A weight for length/height or BMI < 50th percentile is considered sufficient to meet the weight loss parameter; **OR**
 - ii. Inability to maintain weight-for-length/height or BMI at least 50th percentile when supplemental formula is discontinued.
- b. If applicable, supplementation with commercially available foods/nutritional supplements has been attempted (e.g., Carnation Instant Breakfast, food thickeners, butter/cream added to prepared foods), **and**
- c. The member is being followed by a gastroenterology or CF specialist and a registered dietitian.

-OR-

4. A congenital cardiac condition in a child under age 18 and:

- a. Documented poor growth as manifested by:
 - i. Growth charts demonstrating weight is < 10th percentile for height and age; **or**
 - ii. Member with weight \leq 25th percentile for height and weight who have demonstrated 3 months of flat or declining weight; **and**
- b. Documentation is submitted demonstrating a reasonable attempt at supplementation with other commercially available foods and nutritional supplemental foods (e.g., Carnation Instant Breakfast, butter or cream added to prepared foods, etc.); **and**
- c. Member being actively followed by a cardiovascular specialist for the underlying congenital heart condition

-OR-

5. Oral/enteral fat emulsion formulas are covered when the following criteria are met:

- a. Member has at least ONE of the following:
 - i. For children under age 8, documentation of decline in weight percentile despite a reasonable trial of standard approved formulas. Decline is measured on standardized growth charts.
 - ii. Documented need for fluid restriction and is unable to meet daily nutritional needs with standard enteral formulas.
 - iii. A specific gastrointestinal or metabolic condition being met by fat emulsion formulas (e.g., lactose intolerance, or celiac disease).

- iv. For refeeding in adult members with anorexia nervosa who are unable to take adequate oral nutrition and have a BMI < 18; or for refeeding in children/adolescent members with anorexia nervosa who are unable to take adequate oral nutrition and have a BMI < 5%.

-OR-

6. Oral/enteral formula comprises at least 20% of the member's daily caloric needs AND documentation demonstrates at least ONE of the following:

- a. Member is on total parenteral nutrition (TPN) and formula is being used to supplement the TPN or to taper the member off TPN.
 - i. Enteral formula coverage is based on the caloric needs not met via oral intake/TPN (e.g., if the member is receiving 70% of caloric needs via TPN, Select Health will cover enough formula to meet the remaining 30%).
- b. Member is tapering off long-term enteral formula use and is transitioning to oral foods.
 - i. Enteral formula coverage is based on caloric needs not met via oral intake (e.g., if member is receiving 80% of caloric needs orally, Select Health will cover enough formula to meet the remaining 20%).
- c. Coverage of formula for members tapering off TPN or enteral formula is reviewed every 90 days.

B. In addition to meeting ONE of the criteria above (1-6), the member must meet ALL the following criteria, regardless of condition or diagnosis:

- a. Annual assessment by registered dietitian.
- b. The requested formula can only be obtained through a pharmacy with a provider prescription.
 - i. Select Health may make exceptions to this criterion on a case-by-case basis, most often when the retail-only formula is replacing a prescription-only formula **AND** there is a documented medical need for specialized formula.
- c. Written documentation demonstrates medical necessity, including the following information:
 - i. The attending physician's order or prescription (updated at least annually).
 - ii. Diagnosis and description of functional impairment that relates to the need for enteral nutrition.
 - iii. Annual statement from member's attending physician attesting to appropriateness of therapy and that they have personally assessed the individual.

COVERAGE LIMITATIONS

- 1. After initial certification period, renewed certifications will usually be 6 months unless clinical documentation supports chronic long-term need. In these instances, renewal will be annually. Shorter renewal certifications may occur depending on clinical circumstances.

COVERAGE OF SPECIALIZED ENTERAL FORMULAS

Select Health covers specialized enteral formulas for members who meet criteria A and B above, when the following criteria are met:

1. **Hydrolyzed/amino acid/elemental formulas**, when the member has at least ONE of the following:
 - a. Weight loss or stall in weight gain with standard formula
 - b. Excessive irritability with no other cause identified
 - c. Poor or difficult feeding
 - d. Failure of 2 weeks of ALL the following:
 - i. Addition of probiotics; and
 - ii. Change in maternal diet (if breast milk is used)
 - e. Presence of GI bleeding with no other cause found
 - f. Documentation supports presence of a formula allergy

2. **Ketogenic diet for the treatment of seizure disorders: Select Health does not cover any food supplements for the ketogenic diet.** Formula is covered for members on a ketogenic diet if other formula coverage criteria are met.

COVERAGE EXCLUSIONS

1. Medical foods (except as mandated by state law).
2. Regular food products such as baby food, or other regular grocery products that can be mixed in blenders and used with an enteral system, regardless of whether these regular food products are taken orally or through a feeding tube.
 1. Weight-loss foods and formula (e.g., Slim Fast)
 2. Mega-vitamin therapy
 3. Gluten-free food products
 4. Lactose-free food products
 5. Products to aid in lactose digestion
 6. Over-the-counter high protein powders and mixes
 7. Nutritional supplement puddings
 8. Oral rehydration therapy (ORT) (e.g., Pedialyte, Infalyte, Naturalyte, and Rehydralyte) which is intended for very short-term use primarily with infants or children to replace water and electrolytes lost during severe bouts of vomiting and diarrhea. An ORT fluid does not serve the same purpose as a food; therefore, it is not an eligible formula.
 9. Food thickeners

Enzyme packed cartridges (e.g., Relizorb (Alcresta Pharmaceuticals)) for enzyme replacement in members receiving enteral tube feedings

Select Health Advantage (Medicare/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

Select Health Community Care (Medicaid)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit

their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

Through peer review literature and guideline recommendations, when enteral nutrition is necessary, the optimal route is by mouth. In conditions where this is not possible, a tube is placed to facilitate transport of the enteral nutrition to the digestive/absorptive site in the GI tract.

The American Academy of Pediatrics Committee issued recommendations on reimbursement for medical foods for metabolism disorders. Metabolism disorders are rare disorders that lack the natural enzymes required to digest certain foods. These disorders are treated with dietary restrictions. Examples of these disorders are phenylketonuria (PKU), maple syrup urine disease, citrullinemia, cystinosis, homocystinuria, methylmalonic academia, and propionic academia. Special formulas and medical foods have been developed which eliminate the amino acid that cannot be metabolized.

American Gastroenterological Association Medical Position Statement: Guidelines for the Use of Enteral Nutrition, although one or two enteral formulations can meet most patients' needs, specialty products may be useful in certain disease states. These include blenderized, lactose-containing and lactose-free, fiber-containing, elemental, and modular products and specialized feedings such as pulmonary formulas. Although some formulations have clear clinical indications (e.g., lactose-free mixtures for patients with lactase deficiency), the advantages of others are less clear.

Relizorb is considered a first of its kind digestive enzyme cartridge designed to mimic the normal function of the pancreas by breaking down fats in enteral tube feeding formula into their absorbable forms (fatty acids and monoglycerides). Relizorb is designed for use by adults on enteral tube feeding who have trouble breaking down and absorbing fats. It was approved by the FDA for this indication. However, large scale studies in human subjects are still lacking. Therefore, there is insufficient evidence to support its use.

Billing/Coding Information

CPT CODES

- | | |
|--------------|--|
| 99507 | Home visit for care and maintenance of catheter(s) (e.g., urinary, drainage, and enteral) |
| 99601 | Home infusion/specialty drug administration, per visit (up to 2 hours); |
| 99602 | Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour (List separately in addition to code for primary procedure) |

HCPCS CODES

- | | |
|--------------|--|
| B4034 | Enteral feeding supply kit; syringe fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape |
| B4035 | Enteral feeding supply kit; pump fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape |
| B4036 | Enteral feeding supply kit; gravity fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape |
| B4081 | Nasogastric tubing with stylet |
| B4082 | Nasogastric tubing without stylet |
| B4083 | Stomach tube-Levine type |
| B4087 | Gastrostomy/jejunostomy tube, standard, any material, any type, each |
| B4088 | Gastrostomy/jejunostomy tube, low-profile, any material, any type, each |

- B4100** Food thickener, administered orally, per oz.
- B4102** Enteral formula, for adults, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml= 1 unit
- B4103** Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
- B4104** Additive for enteral formula (e.g., fiber)
- B4149** 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
- B4150** Enteral formula, nutritionally complete with intact nutrients, include proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories= 1 unit
- B4152** 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, administrated through an enteral feeding tube, 100 calories= 1 unit
- B4153** 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
- B4154** 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
- B4155** Enteral formula, nutritionally complete/modular nutrients, includes specific nutrients, carbohydrates (e.g., glucose polymers), proteins/amino acids 9e, glutamine, arginine), fat (e.g., medium chain triglycerides) or combination, administered through an enteral feeding tube, 100 calories = 1 unit
- B4157** 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.
- B4158** 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.
- B4159** 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
- B4160** 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.
- B4161** 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
- B4162** 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
- B9002** Enteral nutrition infusion pump, any type
- B9998** NOC for enteral supplies

- S5497** Home infusion therapy, catheter care/ maintenance, not otherwise classified; includes administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
- S5498** Home infusion therapy, catheter care/ maintenance, simple (single lumen), includes administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
- S5501** Home infusion therapy, catheter care/ maintenance, complex (more than one lumen), includes administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
- S5502** Home infusion therapy, catheter care/ maintenance, implanted access device, includes administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem (use this code for interim maintenance of vascular access not currently in use)
- S5517** Home infusion therapy, all supplies necessary for restoration of catheter patency or declotting
- S5518** Home infusion therapy, all supplies necessary for catheter repair
- S5520** Home infusion therapy, all supplies (including catheter) necessary for a peripherally inserted central venous catheter (PICC) line insertion
- S5521** Home infusion therapy, all supplies (including catheter) necessary for a midline catheter insertion
- S5522** Home infusion therapy, insertion of peripherally inserted central venous catheter (PICC), nursing services only (no supplies or catheter included)
- S5523** Home infusion therapy, insertion of midline central catheter, nursing services only (no supplies or catheter included)

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