

Formulas and Other Enteral Nutrition

Policy MP-012

Origination Date: 07/30/2018

Reviewed/Revised Date: 09/15/2021

Next Review Date: 09/15/2022

Current Effective Date: 09/15/2021

Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial, and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.

Description:

Enteral nutritional support is used for members with medical conditions that impair the gastrointestinal absorption which results 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 the body cannot properly process foods to maintain their nutrition the body needs. Some definitions of enteral nutrition are as followed:

Medical foods The term medical food, as defined by the Food and Drug Administration (FDA) in section (b) (3) of the Orphan Drug Act (21 USC 360ee) 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 the provision of liquid food feedings through a tube into the stomach or small intestine (e.g., nasogastric, nasojejunal, gastrostomy or jejunostomy tubes). Formulas consisting of semi-synthetic intact proteins or protein isolates can be used for enteral feeding in the majority of patients who meet criteria for enteral feeding. Examples of these products include but are not limited to: Ensure, Ensure HN, Ensure Powder, Isocal, Lonalac Powder, Meritene, Meritene Powder, Osmolite, Osmolite HN, Portagen Powder, Sustacal, Sustagen Powder, and Travasorb.

Nutritional formulas are products formulated to replace normal food products and are used for individuals with hereditary metabolic diseases or with a disorder of gross anatomy. Nutritional product formulas are specialized and/or nonspecialized infant formulas used for a specific medical condition. Over-the-counter products such as Ensure, Sustacal, Osmolite, and Boost are examples of formulas used for these conditions.

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 Nutramigen AA LIPIL.

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), 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 example of an 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.

Policy Statement and Criteria

1. Commercial Plans

GENERAL COVERAGE REQUIREMENTS

U of U Health Plans covers enteral nutrition only in the following limited circumstances as follows:

- A. For **hereditary metabolic** disorders when:

- i. The Member has an error of amino acid or urea cycle metabolism; and
 - ii. The product is specifically formulated and used for the treatment of errors of amino acid or urea cycle metabolism; and
 - iii. The product is used under the direction of a Physician, and its use remains under the supervision of the Physician.
- B. Certain enteral formulas according to U of U Health Plans policy – See the “Specific Coverage Requirements” section below.**

MEDICAL NECESSITY CRITERIA for ENTERAL FORMULAS

A. Indications for oral/tube enteral feedings BOTH must be met

- i. Enteral feeding must be the patients sole source of nutrition (defined as obtaining >70% of members total caloric intake daily); and
- ii. Have one of the following medical conditions:
 - a. Non-function or disease of the structures that normally permit food to reach the small bowel including dysphagia or disease of the small bowel that 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; or
 - b. Severe neurologic disease such that the patient is not able to consume food safely or adequately to provide at least 70% of estimated nutritional needs.

MEDICAL NECESSITY FOR ENTERAL FEEDING PUMPS

In some circumstances the patient/member may be receiving a noncovered enteral feeding such as pureed ‘natural’ food or noncovered “OTC” enteral formula not otherwise covered. In these instances, the patient/member may still qualify for the enteral supplies.

Enteral supplies may be allowed coverage if the request meets **ALL** other criteria except the specific “The requested enteral formula can only be obtained through a pharmacy/DME vendor/medical supplier with a provider prescription”.

SPECIFIC COVERAGE REQUIREMENTS (Must meet ALL [A – D])

- A. Patient assessment by registered nutritional specialist required annually; and
- B. The requested enteral formula can only be obtained through a pharmacy/DME vendor/medical supplier with a provider prescription; and

- C. Product defined and labeled as a medical food; and
- D. Written documentation from the medical record specifying the medical necessity, including the following information, may be required:
 - i. The attending physician's order or prescription (updated at least annually); and
 - ii. Diagnosis and description of functional impairment that relates to the need for enteral nutrition; and
 - iii. Estimated duration of therapy with indication of next review by the attending physician; and
 - iv. When applicable, the rationale for use of formula containing manufactured blenderized natural foods with intact nutrients; and
 - v. Documented efforts to facilitate progression to oral feeding. Including but not limited to: behavioral health, speech therapy, occupational therapy, dietary consult, time frame, PCP involvement or an annual statement from patients attending physician attesting to appropriateness of therapy and that they have personally assessed the individual.

COVERAGE LIMITATIONS

- A. Initial certification is typically 3 months; this may vary given the clinical circumstance to as little as 2 weeks.
- B. 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.

SPECIAL COVERAGE CONSIDERATIONS

- A. **Amino Acid/Elemental Formulas** – Coverage is provided for formulas consisting of natural intact protein/protein isolates when the member has an allergy or intolerance to semi-synthetic formulas.

100% hydrolyzed amino acids infant formulas- are a covered benefit when **ALL** of the following apply (i – v):

- i. Documented allergy to cow's milk; and
- ii. Documented soy formula intolerance; and
- iii. Documented multiple protein intolerance; and
- iv. The 100% hydrolyzed amino acids nutritional formula being administered is the primary source of nutrition; and

- v. Must be recommended by a Pediatric Allergist, Pediatric Pulmonologist or Pediatric Gastroenterologist.

- B. Short-chain Fatty Acid Formulas** – Some studies have demonstrated short-chain fatty acids to assist in the absorption of water and sodium from the colon but no measurable nutritional benefit from these compounds have been identified from medium or long-chain fatty acids.

U of U Health Plans does not cover short-chain fatty acid formulas as no direct health benefits have been identified in the published medical literature related to these products. Use of these products is considered unproven and investigational.

- C. Fat Emulsion Formulas** – Specific formulas (e.g. Microlipid™ or MCT oil) have been developed which are calorically dense and primarily composed of various oils such as sunflower oil, safflower or coconut oil. These formulas allow for the delivery of higher caloric content in a smaller volume of fluid. They are typically absorbed in the portal system and thus their use needs to be monitored as excess absorption may result in deposition of lipid in developing structures such as the brain. Potential indications for these formulas would be circumstances in which the patient has a high caloric need (e.g. severely burned patient) or has not been able to meet their metabolic needs due fluid restrictions.

Fat emulsion solutions are available as 10% or 20% preparations, with osmolalities of 280 mosmol/kg and 330 mosmol/kg, respectively. They are derived from soybean, safflower, or cotton-seed oil, with the fat mainly present as triglyceride. The ultimate total daily dose of parenteral lipid emulsion should not exceed 4 g/kg and the infusion rate should be less than 0.25 g/kg/h. During the first week of life for low-birth-weight infants, the amount of lipids should not exceed 0.5-1 g/kg/day. The 20% emulsion provides approximately 2 kcal/ml (8.4 MJ/l) and is more rapidly cleared than the 10% emulsion.

Fat emulsion formulas are covered in the following circumstances:

- i. Patient has met general medical necessity and coverage requirements and has demonstrated **ONE** of the following (a, b, c, d, or e) :
 - a. For children under age 8, documentation of further fall off in their weight percentile based upon standardized growth charts documents despite a reasonable trial of standard approved formulas.
 - b. Patient has the documented need for fluid restriction and is unable to meet daily nutritional needs with standard enteral formulas.

- c. Patient has a specific gastrointestinal or metabolic condition being met by fat emulsion formulas (e.g. lactose intolerance, or celiac disease).
 - d. For re-feeding in patients with anorexia nervosa who are unable to take adequate oral nutrition and have a BMI <18.
 - e. Verified lactose intolerance.
- ii. Patient does not have one of the following:
 - a. Serum bilirubin >100 µmol/l (6 mg/dl)
 - b. Serum pH <7.25
 - c. Serum triglycerides >7.8 mmol/l (300 mg/dl)

D. Glycogen Storage Diseases -Glycogen Storage Diseases (GSD) occurs as the genetic lack of specific enzymes used to cleave the glycogen molecule in energy metabolism. Glycogen subsequently builds up in the liver resulting in eventual liver failure and associated conditions. There are at least 10 different types of GSDs. The types are put into groups based on the enzyme that is missing.

Treatment depends on the type of GSD. Some GSD types cannot be treated; others are fairly easy to control by treating the symptoms. For the types of GSD that can be treated, patients must carefully follow a special diet. For some patients **frequent high carbohydrate meals during the day** provides adequate treatment. For some children, eating several small meals rich in sugars and starches every day helps prevent blood sugar levels from dropping.

Another treatment involves the use of **cornstarch**. For some young children, giving uncooked cornstarch every four to six hours – including during overnight hours – also can help keep blood sugar levels from getting low.

Continuous nighttime feeding are sometimes necessary to maintain the blood glucose level, a special feeding tube can be placed into the child's stomach. The feeding tube is then used to give formula with a high concentration of glucose. This helps control the blood sugar level. Younger children will have to use this tube each evening, but doctors feel that this may not be necessary once children get older. In the daytime the feeding tube is not used, but the patient must eat foods rich in sugars and starches about every three hours. This treatment can be successful in reversing most symptoms.

U of U Health Plans covers enteral formulas in patients with Glycogen Storage Disease in the following circumstances:

- i. Genetic Testing has verified patient has a glycogen storage disease; and

- ii. Submitted documentation from nutritional specialist and patient's specialist clinician demonstrate that patient's clinical condition requires prescribed therapy to optimize the patient's medical condition.

E. **Cystic Fibrosis** –Two separate circumstances may arise in which patients with cystic fibrosis (CF) may require enteral nutrition. The first instance are those circumstances in which the patient has significant malabsorption due to pancreatic insufficiency related to the CF and is unable to take adequate nutrition from standard formulas or regular nutritional sources. The other potential sources for enteral formulas/ supplementation are circumstances in which the high metabolic rate associated with the patient's CF cannot be adequately met with standard formulas or regular nutritional sources. In this circumstance additional enteral nutrition may be necessary to avoid the patient becoming malnourished or developing respiratory acidosis which may result in respiratory decompensation. For patients with cystic fibrosis, enteral nutrition are covered in the following circumstances:

- i. For **malabsorption with nutritional compromise in children and adults associated with cystic fibrosis**, U of U Health Plans covers enteral nutrition when the general medical necessity and coverage requirements are met, and **ALL** of the following:
 - a. Nutritional compromise is documented by weight loss/lack of weight gain or other nutritional deficiencies; and
 - b. The diagnosis is confirmed by testing; and
 - c. For formula fed infants and children, both cow-milk-based and soy-based formula trials have failed; and
 - d. If applicable, the member must have documented attempted supplementation with other commercially available foods and nutritional supplemental foods (e.g. Carnation Breakfast Essentials, food thickeners, butter or cream added to prepared foods, etc.); and
 - e. The member is being closely followed by gastroenterology or a CF specialist and a nutritionist.
- ii. For patients who **manifest caloric deficiencies related to their CF** and the request is to augment their other caloric intake, U of U Health Plans covers enteral nutrition when the general medical necessity and coverage requirements are met, and **ALL** of the following (a and b):
 - a. A weight for length/height or BMI < 50th percentile is considered sufficient to meet the weight loss parameter; and
 - b. There must be documentation of the following:
 - 1) Patient has verified CF; and

- 2) For formula fed infants and children, a failure of both cow-milk-based and soy-based formula trials; and
- 3) If a supplement to formula is being requested or for members over one year of age, a detailed dietary/feeding history with calorie counts and referral to a nutritionist; and
- 4) The member must have first attempted supplementation with other commercially available foods and nutritional supplemental foods (e.g. Carnation Breakfast Essentials, butter or cream added to prepared foods, etc.); and
- 5) For member's over one year of age, documentation/results from a relevant specialist.

F. **Congenital Cardiac Conditions in Children** – Infants and children with CHD exhibit a range of delays in weight gain and growth. In some instances the delay can be relatively mild, whereas in other cases, the failure to thrive can result in permanent physical or developmental impairment. While the cause of abnormal growth and development is multifactorial, reduced energy consumption and increased energy expenditure, or both, may be the most important players. Despite the most aggressive feeding programs, some children are still unable to ingest enough calories in order to achieve or maintain a normal body weight.

Enteral formula-based nutrition may be used for **congenital cardiac conditions in children** if the following criteria are met:

- i. The patient meets general medical necessity and coverage requirements and **ALL** of the following are met:
 - a. Patient has documented failure to thrive as manifested by:
 - 1) Growth charts demonstrating weight is <10%ile for height and age or;
and
 - 2) Patient with weight <25%ile for height and weight who have demonstrated 3 months of flat or declining weight; and
 - b. Documentation is submitted demonstrating a reasonable first attempted supplementation with other commercially available foods and nutritional supplemental foods (e.g. Carnation Breakfast Essentials, butter or cream added to prepared foods, etc.); and
 - c. Patient being actively followed by a cardiovascular specialist for the underlying congenital heart condition.

- G. **Ketogenic Diet for the Treatment of Seizure Disorders** – As most benefit plan descriptions exclude coverage of over-the-counter dietary supplements or regularly purchased food items typically used in the ketogenic diet, U of U Health Plans does **NOT** cover any food supplements for **the ketogenic diet**.

Hospitalization for initiation of a ketogenic diet is considered medically necessary when for children (older than 12 months and younger than 8 years old) with seizures, refractory to or intolerant of multiple conventional anti-epileptic drugs. The inpatient setting is needed not only to monitor the patient during the initial fasting period to induce marked ketosis and weight loss, but also to provide the intense education required to maintain a ketogenic diet once discharged. The length of hospital stay will depend on the proposed initial starvation period, and generally should not exceed 3 days.

COVERAGE EXCLUSIONS

- A. Dietary or oral supplements that are not covered including, but not limited to: Ensure, Boost, and Carnation Breakfast Essentials, even if prescribed by a physician. Exceptions will be considered for these products if intended to replace a prescription nutritional supplement which otherwise meets coverage criteria
- B. Medical foods (except as mandated by state law)
- C. Regular food products are not considered medical items. Regular food products include baby food, infant formula, 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
- D. Weight-loss foods and formulas (e.g. Slim Fast)
- E. Mega-vitamin therapy
- F. Baby food
- G. Breast milk and breast milk substitutes
- H. Standard infant formulas
- I. Gluten-free food products
- J. Lactose-free products; products to aid in lactose digestion
- K. High protein powders and mixes
- L. Nutritional supplement puddings
- M. Oral rehydration therapy (ORT) (e.g., Pedialyte, Enfalyte, 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

N. Food Thickeners

O. Enzyme packed cartridges (e.g. RELiZORB™ [Alcresta Pharmaceuticals]) for enzyme replacement in patients receiving enteral tube feedings

2. Medicaid Plans

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 U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at

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

In addition, WIC Supplementation: Medicaid covers above what allowable amount for WIC ~ 0-5 years, any ONE of the following:

- A. Children who live at home and are in the WIC program, for quantities which exceed the WIC program allowed amounts.
- B. The target weight of a child cannot be attained with oral feedings.
- C. The oral food intake is inadequate due to weakness, illness, or disease.
- D. The child is concurrently using a ventilator or oxygen, or has a tracheostomy and is unable to reach or maintain age appropriate weight.

If the condition of a child requires total nutrition through a tube, Medicaid will cover the nutrition and not require WIC program participation.

- Nutritional products must be a medical food.
- Prescribed by a physician for the specific diagnosis (es) of the member's condition.

Clinical Rationale

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, propionic academia, tyrosinemia, histidinemia, organic acidemias, and urea cycle disorders. 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 at this time.

Applicable Coding

CPT Codes

- 99507** Home visit for care and maintenance of catheter(s) (eg, urinary, drainage, and enteral)
- 99601** Home infusion/specialty drug administration, per visit (up to 2 hours);
- 99602** ; 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)
- B4105** In-line cartridge containing digestive enzyme(s) for enteral feeding, each

- 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, includes 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, administered 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 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
- 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
- S9340** 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
- S9341** 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
- S9342** 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
- S9343** 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

References:

1. American Academy of Pediatrics Committee on Nutrition. Reimbursement for medical foods for inborn errors of metabolism. *Pediatrics*. 1994;93(5):860.
2. Centers for Medicare & Medicaid Services (CMS). Enteral and parenteral nutrition therapy covered as prosthetic device. Medicare Coverage Issues Manual Section 65-10. Baltimore, MD: CMS
3. Koretz RL, Lipman TO, Klein S; American Gastroenterological Association. AGA Technical review on parenteral nutrition. *Gastroenterol*. 2001 Oct;121(4):970-1001. Accessed Jun 20, 2006. Available at URL address: <http://www.gastro.org/clinicalRes/medicalStatements.html>.
4. NHIC. Specialty Enteral Formulas (article) - effective February 2011 (A50613). [CMS Website].
5. U.S. Food and Drug Administration. Center for Food Safety and Applied Nutrition. Office of Nutritional Sampson EL, Candy B, Jones L. Enteral tube feeding for older people with advanced dementia. *Cochrane Database of Systematic Reviews* 2009, Issue 2. Art. No.: CD007209.
6. North American Society for Pediatric Gastroenterology, Hepatology and Nutrition website accessed 9/1/13, <http://www.naspghan.org/wmspage.cfm?parm1=127>.
7. Smith P. Primary care in children with congenital heart disease. *J Pediatr Nurs*. 2001 Oct;16(5):308-19.
8. Leitch CA. Growth, nutrition and energy expenditure in pediatric heart failure. *Prog Pediatr Cardiol*.. 2000 Sep 1;11(3):195-202.
9. Hofner G; Behrens R; Koch A; Singer H; Hofbeck M. Enteral nutritional support by percutaneous endoscopic gastrostomy in children with congenital heart disease. *Pediatr Cardiol*. 2000 Jul-Aug;21(4):341-6.
10. Roy, Claude C. , Kien, C. Lawrence, Bouthillier Lise, Levy, Emile. Short-Chain Fatty Acids: Ready for Prime Time? *Nutr Clin Pract* August 2006 vol. 21 no. 4 351-366.
11. Yen, E. H., et al. (2013). "Better nutritional status in early childhood is associated with improved clinical outcomes and survival in patients with cystic fibrosis." *J Pediatr* **162**(3): 530-535 e531.
12. Medscape, LLC. FDA clears Relizorb for use with enteral tube feedings. Medscape, LLC. New York, NY. December 03, 2015. Available at:<http://www.medscape.com/viewarticle/855434>. Accessed March 23, 2016.
13. Food and Drug Administration (FDA). Medical Foods Guidance Documents & Regulatory Information [Last updated Dec 6, 2017]. Available at: <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/>

14. American Gastroenterological Association (AGA). American Gastroenterological Association Medical Position Statement: "Guidelines for the Use of Enteral Nutrition" *Gastroenterology*, 108 (1995), pp. 1280-1301 Available at: [https://doi.org/10.1016/0016-5085\(95\)90230-9](https://doi.org/10.1016/0016-5085(95)90230-9)

Disclaimer:

This document is for informational purposes only and should not be relied on in the diagnosis and care of individual patients. Medical and Coding/Reimbursement policies do not constitute medical advice, plan preauthorization, certification, an explanation of benefits, or a contract. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the member's individual benefit plan that is in effect at the time services are rendered.

The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

U of U Health Plans makes no representations and accepts no liability with respect to the content of any external information cited or relied upon in this policy. U of U Health Plans updates its Coverage Policies regularly, and reserves the right to amend these policies and give notice in accordance with State and Federal requirements.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from U of U Health Plans.

"University of Utah Health Plans" and its accompanying logo, and its accompanying marks are protected and registered trademarks of the provider of this Service and or University of Utah Health. Also, the content of this Service is proprietary and is protected by copyright. You may access the copyrighted content of this Service only for purposes set forth in these Conditions of Use.

© CPT Only – American Medical Association