Medical Policy

Enteral Nutrition (Tube Feeding) Products Supplied and Billed by Home Infusion Providers and Digestive Enzyme Cartridges

Policy Number: OCA 3.37
Version Number: 28
Version Effective Date: 08/01/22

Impacted Products

- ☒ **All Products**
- ☒ NH Medicaid
- ☒ NH Medicare Advantage
- ☒ MA MassHealth ACO
- ☒ MA MassHealth MCO
- ☒ MA Qualified Health Plans/Employer Choice Direct
- ☒ MA Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Policy Summary

The Plan considers tube fed enteral nutrition products dispensed and billed by home infusion providers to be **medically necessary** for a member who is at nutritional risk due to a specific medical condition when Plan criteria are met for an adult or pediatric member (or are required EPSDT services for a member age 20 or younger on the date of service, when applicable), with coverage in compliance with regulatory guidelines. The use of RELiZORB® is considered medically necessary when clinical review criteria are met. Prior authorization is required, as stated below:

1. **Enteral Tube Feedings:** This policy applies to **home infusion providers** dispensing and billing tube fed enteral nutrition products. Tube fed enteral products from durable medical equipment (DME) providers require prior authorization from Northwood, Inc. Review the *Prior Authorization Matrix* on the Plan's website for contact information. Northwood does NOT manage any requests for RELiZORB®.

2. **Digestive Enzyme Cartridges for Enteral Tube Feedings:** This policy applies to any provider type requesting Plan authorization for the use of a digestive enzyme cartridge (e.g., RELiZORB®, an FDA-cleared digestive enzyme cartridge) with enteral tube feedings.

3. **Oral Enteral Products:** Enteral products administered orally are managed by Northwood when dispensed and billed by any provider type. Prior authorization from Northwood is required.

Clinical Criteria

Criteria must be met for the use of tube fed enteral nutrition formulas (item I), RELiZORB® (item II), or services that require Medical Director review (item II):

I. **Criteria for Tube Fed Enteral Nutrition or Tube Fed Special Medical Formulas**

ALL criteria must be met in items A through D:

A. Tube fed enteral nutrition formula (including a prescription or non-prescription product) is ordered by a treating physician or a licensed practitioner (e.g., APRN or PA) working within the scope of the practitioner's license; AND

B. Evidence that the member's nutritional needs cannot be met with regular food; standard, commercial formula and food products; and/or supplementation with commercially available products and one of the following criteria is met:

C. Member is diagnosed with a condition that precludes the full use of regular food/formula; AND

D. Tube fed enteral nutrition formula will be used for ANY indication listed in items 1 through 8:

1. **Treatment for Premature Infants**:

   Specialized tube fed enteral nutrition products are medically necessary for premature infants who are born under 34 weeks of gestational age (i.e., prescription products and/or non-prescription products ordered by a treating physician or licensed practitioner); OR

2. **Impaired Digestion with Formula Use for Infants and Children** - All criteria must be met in items a through c (regardless of member's weight):

   a. Trial of commercial formulas meets criteria in either item (1) or item (2):

      (1) At least 2 different commercial tube fed infant formulas have been attempted, cow milk-based and soy milk-based products with generally a 4 to 5-day trial for each product (or for the timeframe recommended by the treating provider) with an unfavorable outcome (e.g., documented impaired digestion of formula, lack of weight gain, or weight loss) for each trial. ; OR

      (2) Treating provider has determined that trial of commercial formula is contraindicated; AND

b. Before using an amino acid-based tube fed enteral nutrition product, the member has attempted an extensively hydrolyzed or partially hydrolyzed formula with an unfavorable outcome unless the treating provider has determined that it is contraindicated; AND

c. Member meets criteria in either item (1) or item (2):

(1) Member has colic, enterocolitis, eosinophilic esophagitis, esophagitis, or malabsorption syndrome or short-bowel syndrome and one of the following criteria is met in item (a) or item (b):

(a) Extensively hydrolyzed and/or partially hydrolyzed tube fed enteral nutrition product(s) used until the member's 3rd birthday; OR

(b) Amino acid-based tube fed enteral nutrition products used until the member's 1st birthday; AND

(2) Member has uncomplicated gastrointestinal reflux with symptoms of persistent spitting, regurgitation, or vomiting and meets applicable criteria for trial and then continued use in item (a) or item (b):

(a) Trial: 2 to 4-week trial of hydrolyzed formula is attempted with an unfavorable outcome before a 2 to 4-week trial of an amino acid-based formula; OR

(b) Continued Use: Documentation of improved symptoms must be submitted for continued requests for hydrolyzed formula or amino acid-based formula If the formula is effective, the hydrolyzed formula may be used until the member's 3rd birthday and an amino acid-based formula may be used until the member's 1st birthday; OR

3. **Atopic Disease Associated with Formula Use for Infants and Children** - Both criteria are met in items (a) and (b):

a. One criteria is met for formula use in item (1) or item (2):

(1) Extensively hydrolyzed tube fed enteral nutrition product(s) used until the member's 3rd birthday unless unable to tolerate cow's milk or soy milk formula; OR

(2) Amino acid-based tube fed enteral nutrition products used until the member's 1st birthday; AND

b. Member has ANY symptom listed in items (1) through (11):

(1) Allergic enteropathy and/or eosinophilic gastritis as evidenced by persistent blood and/or mucus in the stools; OR

(2) Anaphylaxis; OR

(3) Angioedema; OR

(4) Persistent blood and/or mucus in stools; OR

(5) Pulmonary hemosiderosis; OR

(6) Rash, pruritus or eczema (localized or generalized); OR

(7) Rhinitis; OR

(8) Significant diarrhea, vomiting, or abdominal pain; OR

(9) Stridor or wheezing; OR

(10) Urticaria; OR

(11) Weight loss or lack of weight gain; OR

4. **Inborn Errors of Metabolism for Adult and Pediatric Members** - Both criteria are met in items a and b:

   a. ANY criteria is met in item (1) or item (2) for use of tube fed enteral nutrition:

      (1) Used to treat a member's condition resulting from inborn errors of metabolism; OR

      (2) Used to prevent the effects of inherited metabolic disease in the unborn fetus of a pregnant member; AND

   b. Member has ANY condition in items (1) through (12):

      (1) Cystinosis; OR

      (2) Glutaric acidemia; OR

      (3) Hartnup disease; OR

      (4) Histidinemia; OR

      (5) Homocystinuria; ⌂ OR

(6) Maple syrup urine disease; ⌂ OR

(7) Methylamalonic acidemia; ⌂ OR

(8) Phenylketonuria (PKU); ⌂ OR

(9) Propionic aciduria; OR

(10) Tyrosinemia; OR

(11) Urea cycle disorder; OR

(12) Other organic and/or amino acidemias ⌂ ◊

Notes:
⌂ The General Laws of Massachusetts mandate coverage for non-prescription enteral formulas for home use when a physician has issued a written order and are medically necessary for the treatment of malabsorption/malnutrition caused by Crohn's disease, ulcerative colitis, gastroesophageal reflux, gastrointestinal motility, chronic intestinal pseudo-obstruction, and inherited diseases of amino acids and organic acids. Coverage for inherited diseases of amino acids and organic acid shall include food products modified to be low protein (low protein food products). Coverage is also mandated for those special medical formulas which are approved by the Commissioner of the Department of Public Health, prescribed by a physician, and are medically necessary for treatment of phenylketonuria (PKU), tyrosinemia, homocystinuria, maple syrup disease, propionic acidemia, or methylmalonic acidemia in infants and children or medically necessary to protect the unborn fetuses of pregnant individuals with phenylketonuria. Tube fed enteral nutrition is covered to treat these conditions for members when Plan criteria are met.
◊ According to New Hampshire Medicaid coverage guidelines, enteral formulas are covered to treat inherited diseases of amino acids organic acids and conditions of impaired absorption of nutrients caused by disorders affecting the absorptive surface, functional length, or motility of the gastrointestinal tract when prescribed by a physician who has issued a written order; tube fed enteral nutrition is covered to treat the conditions specified in this section for members when Plan criteria are met.

5. **Impaired Digestion, Malabsorption‡, or Nutritional Risk for Adult and Pediatric Members** - Criteria must be met in either item a or item b:

   a. Member is a nutritional risk from acute pancreatitis requiring tube fed enteral nutrition for up to 8 weeks; OR

   b. BOTH criteria are met in items (1) and (2) for a **chronic** condition:

(1) Member is at nutritional risk from ANY chronic condition in items (a) through (j):

(a) Chronic intestinal pseudo-obstruction; ∞OR

(b) Crohn's disease; ∞OR

(c) Failure to thrive (with or without feeding aversion); OR

(d) Gastroesophageal reflux disease; ∞OR

(e) Gastrointestinal motility disorder; ∞OR

(f) Inherited diseases of amino acids and/or organic acids; ∞‡ OR

(g) Ulcerative colitis; ∞OR

(h) Prolonged nutrient losses due ANY condition in items i through ix:

i. Cancer; OR

ii. Celiac disease; OR

iii. Chronic pancreatitis; OR

iv. Congenital or acquired heart disease; OR

v. Diabetes; OR

vi. Draining abscess or wound; OR

vii. Malabsorption syndrome; OR

viii. Renal disease or dialysis; OR

ix. Short-bowel syndrome; OR

(i) Anatomic structure of the gastrointestinal tract that impairs digestion and absorption; OR

(j) Neurological disorder that impairs swallowing or chewing; AND

(2) Member presents with clinical signs and symptoms of impaired digestion and/or malabsorption and age-specific criterion is met in item (a) or item (b):

(a) Member age 21 or older has ANY condition listed below:

i. Member has involuntary or acute weight loss of greater than or equal to 10% of the member's usual body weight during a 3 to 6-month period; OR

ii. Member's body mass index (BMI) is below 18.5 kg/m2, with consideration for measurement of BMI in members with chronic immobility for whom height is difficult to measure by using another anthropometric method such as height associated with arm span or ration of upper body to lower extremity length; OR

(b) Member age 20 or younger has ANY condition listed in items i through vi:

i. Very low birth weight (VLBW < 1500 g) within the first 3 months of life corrected for prematurity even in the absence of a gastrointestinal, pulmonary, and/or cardiac disorder; OR

ii. Member's weight-for-height child growth standard or BMI-for-age child growth standard is < 10th percentile; OR

iii. Deceleration of growth velocity and the member has crossed downward at least 2 percentile lines (i.e., below 2 standard deviations) of weight for age on the standard growth chart; OR

iv. A lack of weight gain, or weight gain less than 2 standard deviations below the age-appropriate mean (i.e., below the 2nd percentile), and not growing at a rate parallel to the growth curve in a 3-month period for children under 6 months of age, or 4-month period for children aged 6-12 months, and that does not reverse with instruction in appropriate diet for age; OR

v. No weight gain or abnormally slow rate of gain for 6 months for children older than 1 year, or documented weight loss that does not reverse with instruction in appropriate diet for age; OR

vi. Weight or weight-for-height less than 2 standard deviations below the mean for age and gender (i.e., below the 2nd percentile) and not growing at a rate parallel to the growth curve; OR

Notes:
∞ According to Massachusetts state law, non-prescription enteral formulas are covered for specific conditions (indicated above with ∞) for fully insured members when a written order

has been issued by a physician; tube fed enteral nutrition is covered to treat these conditions for all members when Plan criteria are met.

‡ According to New Hampshire Medicaid coverage guidelines, non-prescription enteral formulas are covered to treat inherited diseases of amino acids, organic acids and conditions of impaired absorption of nutrients caused by disorders affecting the absorptive surface, functional length, or motility of the gastrointestinal tract when prescribed by a physician who has issued a written order; tube fed enteral nutrition is covered to treat the conditions specified in this section for all members when Plan criteria are met.

6. **Disorders Requiring Permanent or Long-Term Use of Tube Fed Enteral Nutrition for Adult and Pediatric Members** - Member has ANY condition listed in items a though c and it is expected to be a permanent impairment:¤

   a. Disease of the small bowel that impairs absorption of an oral diet; OR

   b. Dysmotility or anatomical obstruction of the gastrointestinal tract which prevents food from reaching the stomach or intestine; OR

   c. Neuromuscular or central nervous system disorders that impair the ability to ingest oral nutrition; OR

¤ Note: Permanent impairment is defined as an impairment expected to exceed 90 days, as determined by the treating physician or a licensed practitioner (e.g., advanced practitioner registered nurse or physician assistant) working within the scope of the practitioner's license and substantiated in the member's medical record (which is consistent with CMS guidelines for review).

7. **Tube Fed Ketogenic Formula for Adult and Pediatric Members with Seizure Disorders** - BOTH criteria must be met in items a and b:

   a. Member has a seizure disorder that is refractory to antiepileptic drugs; AND

   b. Member requires tube fed enteral nutrition to maintain ketogenic diet that cannot be maintained otherwise; OR

8. **Formulas Covered by the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC):**

   The Plan will cover the regular formulas that the WIC Nutrition Program covers, **when intended for tube feeding**, if the member does not meet WIC eligibility criteria or does not receive adequate amounts above the monthly allotment by the WIC program for medical needs. ALL of the following information must be submitted to the Plan:

a. Evidence that WIC is providing the maximum allowed amount or evidence that the member is not WIC eligible; AND

b. Provider statement that additional calories are required to provide adequate nutrition; AND

c. Growth chart demonstrating inadequate growth on the maximum calories allowed by WIC; OR

II. **Criteria for RELiZORB®** - ALL criteria in items A through E must be met:

A. Member is diagnosed with cystic fibrosis and is ≥ 5 years of age on the date of service; AND

B. RELiZORB® is prescribed for the member by a treating physician or a licensed practitioner (e.g., APRN or PA) working within the scope of the practitioner's license; AND

C. Member has a confirmed history of exocrine pancreatic insufficiency and documented failure of pancreatic enzyme replacement therapy (PERT); AND

D. Member requires tube fed enteral nutrition for continuous durations of 6 hours or more; AND

E. RELiZORB® will be used according to FDA-cleared guidelines and manufacturer's instructions, including but not limited to the following: single-use cartridge, no greater than 2 cartridges will be used in a 24-hour period per member, and utilized only with compatible enteral formulas, pump systems, and tubing sets within established thresholds for maximum feeding volumes; OR

III. Plan Medical Director review is required when continued tube fed enteral nutrition is requested for a member discharged from an inpatient facility to a home setting.

Limitations and Exclusions

1. Tube fed enteral nutrition therapy is NOT medically necessary for members with stable nutritional status and short-term parenteral nutrition therapy might be required for less than 2 weeks.

2. Tube fed enteral nutrition therapy is NOT medically necessary for routine preoperative care and/or routine postoperative care.

3. The use of digestive enzyme cartridges other than RELiZORB® is considered experimental and investigational or NOT medically necessary with tube enteral feedings to assist with fat hydrolysis, fat absorption, and/or for any other indication due to insufficient evidence documenting the clinical utility and clinical validity of digestive enzyme cartridges other than RELiZORB®.

4. When medically necessary, the initial Plan authorization for RELiZORB® will NOT exceed **90 calendar days**. Reauthorizations are required every **3 months** with documentation of weight gain and/or reduction of gastrointestinal symptoms.

5. Plan prior authorization for tube fed enteral nutrition products will be for no more than a **12-month supply**, unless otherwise specified by the Plan. Plan authorization for a supply of tube fed enteral nutrition requires relevant clinical documentation (e.g., findings of nutritionist evaluation, calorie counts, gastroenterologist and/or allergist evaluation).

Variations

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for the Plan's Senior Care Options (SCO) members and New Hampshire Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, NCD 180.2 includes guidelines for enteral and parenteral nutritional therapy. Verify CMS guidelines in effect on the date of the prior authorization request. When there is no guidance from CMS for the requested service, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

Applicable Coding for the Plan's Massachusetts Products

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. Since these codes may be updated at different intervals than the medical policy review cycle, the list of applicable codes included in a policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization for the services specified in the Clinical Criteria section and Limitations and Exclusions section of a medical policy, even if an applicable code appropriately describing the service is not included in the policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

HCPCS Codes	**Description: Codes Covered When Medically Necessary**
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

	Plan note: Code used for a digestive enzyme cartridge (e.g., RELiZORB®).
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 protein, fats, carbohydrates, vitamins and mineral, 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 protein, 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

Applicable Coding for the Plan's New Hampshire Products

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. Since these codes may be updated at different intervals than the medical policy review cycle, the list of applicable codes included in a policy is informational only and may not be all

inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization for the services specified in the Clinical Criteria section and Limitations and Exclusions section of a medical policy, even if an applicable code appropriately describing the service is not included in the policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

HCPCS Codes	**Description: Codes Covered When Medically Necessary**
B4104	Additive for enteral formula (e.g., fiber)
B4105	In-line cartridge containing digestive enzyme(s) for enteral feeding, each Plan note: Code used for a digestive enzyme cartridge (e.g., RELiZORB®).
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 protein, fats, carbohydrates, vitamins and mineral, 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 protein, 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

References

Academy of Nutrition and Dietetics, American Society for Parenteral and Enteral Nutrition (ASPEN). Becker P, Carney LN, Corkins MR, Monczka J, Smith E, Smith SE, Spear BA, White JV; Academy of Nutrition and Dietetics; ASPEN. Consensus Statement of the Academy of Nutrition and Dietetics/ASPEN: Indicators Recommended for the Identification and Documentation of Pediatric Malnutrition (Undernutrition). Nutr Clin Pract. 2015 Feb;30(1):147-61. doi: 10.1177/0884533614557642. Epub 2014 Nov 24. PMID: 25422273.

Academy of Nutrition and Dietetics. Clinical Malnutrition.

Academy of Nutrition and Dietetics. Roehl K, Sewak SL. Practice Paper of the Academy of Nutrition and Dietetics: Classic and Modified Ketogenic Diets for Treatment of Epilepsy. J Acad Nutr Diet. 2017 Aug;117(8):1279-92. doi: 10.1016/j.jand.2017.06.006. PMID: 28754198.

Alcresta Therapeutics, Inc. RELiZORB® (iMMOBILIZED LIPASE) Cartridge.

Alcresta Therapeutics, Inc. RELiZORB® (iMMOBILIZED LIPASE) Cartridge. Instruction for Use.

Al-Omran M, Albalawi ZH, Tashkandi MF, Al-Ansary LA. Enteral versus parenteral nutrition for acute pancreatitis. Cochrane Database Syst Rev. 2010 Jan 20;(1):CD002837. doi: 10.1002/14651858. CD002837.pub2. PMID: 20091534.

American Academy of Neurology (AAN). Guidelines.

American Academy of Pediatrics (AAP). Greer FR, Sicherer SH, Burks AW; AAP Committee on Nutrition; AAP Section on Allergy and Immunology. The Effects of Early Nutritional Interventions on the Development of Atopic Disease in Infants and Children: The Role of Maternal Dietary Restriction, Breastfeeding, Hydrolyzed Formulas, and Timing of Introduction of Allergenic Complementary Foods. Pediatrics. 2019 Apr;143(4):e20190281. doi: 10.1542/peds.2019-0281. Epub 2019 Mar 18. PMID: 30886111.

American College of Gastroenterology (ACG). Gardner TB, Adler DG, Forsmark CE, Sauer BG, Taylor JR, Whitcomb DC. ACG Clinical Guideline: Chronic Pancreatitis. Am J Gastroenterol. 2020 Mar;115(3):322-39. doi: 10.14309/ajg.0000000000000535. PMID: 32022720.

American Diabetes Association (ADA). Statistics About Diabetes.

American Diabetes Association (ADA). Summary of Revisions: Standards of Medical Care in Diabetes-2022. Diabetes Care. 2022;45(Supplement_1):S4–S7.

American Gastroenterological Association (AGA). AGA Medical Position Statement: Guidelines for the Use of Enteral Nutrition. Gastroenterology. 1995 Apr;108(4):1280-1. PMID: 7698595.

American Gastroenterological Association (AGA). AGA Medical Position Statement: Parenteral Nutrition. Gastroenterol. 2001 Oct;121(4):966-9. PMID: 11606511.

American Gastroenterological Association (AGA). AGA Medical Position Statement: Short Bowel Syndrome and Intestinal Transplantation. Gastroenterology. 2003 Apr;124(4):1105-10. doi: 10.1053/gast.2003.50139. PMID: 12671903.

American Gastroenterological Association (AGA). Clinical Guidelines.

American Gastroenterological Association (AGA). Kirby DF, Delegge MH, Fleming CR. American Gastroenterological Association technical review on tube feeding for enteral nutrition. Gastroenterology. 1995 Apr;108(4):1282-301. PMID: 7698596.

American Geriatrics Society (AGS). AGS Ethics Committee and Clinical Practice and Models of Care Committee. American Geriatrics Society feeding tubes in advanced dementia position statement. J Am Geriatr Soc. 2014 Aug;62(8):1590-3. doi: 10.1111/jgs.12924. Epub 2014 Jul 17. PMID: 25039796.

American Society for Parenteral and Enteral Nutrition (ASPEN). Boullata JL, Gilbert K, Sacks G, Labossiere RJ, Crill C, Goday P, Kumpf VJ, Todd W. Mattox TW, Plogsted S, Holcombe B; ASPEN. ASPEN clinical guidelines: parenteral nutrition ordering, order review, compounding, labeling, and dispensing. JPEN J Parenter Enteral Nutr. 2014 Mar-Apr;38(3):334-77. doi: 10.1177/0148607114521833. PMID: 24531708.

American Society for Parenteral and Enteral Nutrition (ASPEN). Clinical Guidelines.

American Society for Parenteral and Enteral Nutrition (ASPEN). Druyan ME, Compher C, Boullata JI, Braunschweig CL, George DE, Simpser E, Worthington PA; ASPEN Board of Directors. Clinical Guidelines for the Use of Parenteral and Enteral Nutrition in Adult and Pediatric Patients: applying the GRADE system to development of ASPEN clinical guidelines. JPEN J Parenter Enteral Nutr. 2012 Jan;36(1):77-80. doi: 10.1177/0148607111420157. Epub 2011 Dec 16. PMID: 22179521.

American Society for Parenteral and Enteral Nutrition (ASPEN), the Federación Latino Americana de Terapia Nutricional, Nutrición Clínica y Metabolismo (FELANPE). Kumpf VJ, de Aguilar-Nascimento JE, Diaz-Pizarro Graf JI, Hall AM, McKeever L, Steiger E, Winkler MF, Compher CW; FELANPE; ASPEN. ASPEN-FELANPE Clinical Guidelines. JPEN J Parenter Enteral Nutr. 2017 Jan;41(1):104-112. doi: 10.1177/0148607116680792. Epub 2016 Dec 5. PMID: 27913762.

American Society for Parenteral and Enteral Nutrition (ASPEN). Kovacevich DS, Corrigan M, Ross VM, McKeever L, Hall AM, Braunschweig C. ASPEN Guidelines for the Selection and Care of Central Venous Access Devices for Adult Home Parenteral Nutrition Administration. JPEN J Parenter Enteral Nutr. 2019 Jan;43(1):15-31. doi: 10.1002/jpen.1455. Epub 2018 Oct 19. PMID: 30339287.

American Society for Parenteral and Enteral Nutrition (ASPEN). Mehta NM, Corkins MR, Lyman B, Malone A, Goday PS, Carney LN, Monczka JL, Plogsted SW, Schwenk WF; ASPEN Board of Directors. Defining pediatric malnutrition: a paradigm shift toward etiology-related definitions. JPEN J Parenter Enteral Nutr. 2013 Jul;37(4):460-81. doi: 10.1177/0148607113479972. Epub 2013 Mar 25. PMID: 23528324.

American Society for Parenteral and Enteral Nutrition (ASPEN). Wales PW, Allen N, Worthington P, George D, Compher C, Teitelbaum D; ASPEN. ASPEN Clinical Guidelines: Support of Pediatric Patients with Intestinal Failure at Risk of Parenteral Nutrition-Associated Liver Disease. JPEN J Parenter Enteral Nutr. 2014 Jul;38(5):538-57. doi: 10.1177/0148607114527772. Epub 2014 Apr 2. PMID: 24696095.

Berry AJ. Pancreatic enzyme replacement therapy during pancreatic insufficiency. Nutr Clin Pract. 2014 Jun;29(3):312-21. doi: 10.1177/0884533614527773. Epub 2014 Mar 31. PMID: 24687867.

Berry SA, Kenney MK, Harris KB, Singh RH, Cameron CA, Kraszewski JN, Levy-Fisch J, Shuger JF, Greene CL, Lloyd-Puryear MA, Boyle CA. Insurance coverage of medical foods for treatment of inherited metabolic disorders. Genet Med. 2013 Dec;15(12):978-82. doi: 10.1038/gim.2013.46. Epub 2013 Apr 18. PMID: 23598714.

Bodamer OA. Overview of Phenylketonuria. UptoDate. 2020 Jul 17.

Camp KM, Parisi MA, Acosta PB, Berry GT, Bilder DA, Blau N, Bodamer OA, Brosco JP, Brown CS, Burlina AB, Burton BK, Chang CS, Coates PM, Cunningham AC, Dobrowolski SF, Ferguson JH, Franklin TD, Frazier DM, Grange DK, Greene CL, Groft SC, Harding CO, Howell RR, Huntington KL, Hyatt-Knorr HD, Jevaji IP, Levy HL, Lichter-Konecki U, Lindegren ML, Lloyd-Puryear MA, Matalon K, MacDonald A, McPheeters ML, Mitchell JJ, Mofidi S, Moseley KD, Mueller CM, Mulberg AE, Nerurkar LS, Ogata BN, Pariser AR, Prasad S, Pridjian G, Rasmussen SA, Reddy UM, Rohr FJ, Singh RH, Sirrs SM, Streamer DE, Tagle DA, Thompson SM, Urv TK, Utz JR, van Spronsen F, Vockley J, Waisbren SE, Weglicki LS, White DA, Whitley CB, Wilfond BS, Yannicelli S, Young JM. Phenylketonuria Scientific Review Conference: state of the science and future research needs. Mol Genet Metab. 2014 Jun;112(2):87-122. doi: 10.1016/j.ymgme.2014.02.013. Epub 2014 Mar 6. PMID: 24667081.

Capurso G, Traini M, Piciucchi M, Signoretti M, Arcidiacono PG. Exocrine pancreatic insufficiency: prevalence, diagnosis, and management. Clin Exp Gastroenterol. 2019 Mar 21;12:129-39. doi: 10.2147/CEG.S168266. eCollection 2019. PMID: 30962702.

Capurso G, Zerboni G, Signoretti M, Valente R, Stigliano S, Piciucchi M, Delle Fave G. Role of the gut barrier in acute pancreatitis. J Clin Gastroenterol. 2012 Oct;46 Suppl:S46-51. doi: 10.1097/MCG.0b013e3182652096. PMID: 22955357.

Cawsey SI, Soo J, Gramlich LM. Home enteral nutrition: outcomes relative to indication. Nutr Clin Pract. 2010 Jun;25(3):296-300. doi: 10.1177/0884533610368702. PMID: 20581325.

Centers for Disease Control and Prevention (CDC). Mazurek GH, Villarino ME; Division of Tuberculosis Elimination; National Center for HIV, STD, and TB Prevention. Guidelines for Using the QuantiFERON®-TB Test for Diagnosing Latent Mycobacterium tuberculosis Infection. MMWR Recomm Rep. 2003 Jan 31;52(RR02):15-8.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-02. Medicare Benefit Policy Manual. Chapter 15 – Covered Medical and Other Health Services.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-03. Medicare National Coverage Determinations (NCD) Manual.

Centers for Medicare & Medicaid Services (CMS). Medicare Claims Processing Manual. Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).

Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Durable Medical Equipment Reference List 280.1. Version 2. 2005 May 5.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Enteral and Parenteral Nutritional Therapy 180.2. Version 2. 2022 Jan 1.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Medical Nutrition Therapy 180.1. Version 2. 2022 Jan 1.

Centers for Medicare & Medicaid Services (CMS). Stage 2 Critical Elements for Tube Feeding Status. Form CMS–20093. 2015 Jul.

Centers for Medicare & Medicaid Services (CMS). Transmittals.

Charlie Foundation for Ketogenic Therapies, Mathew's Friends, Child Neurological Society (CNS). Kossoff EH, Zupec-Kania BA, Auvin S, Ballaban-Gil KR, Bergqvist AGC, Blackford R, Buchhalter JR, Caraballo RH, Cross JH, Dahlin MG, Donner EJ, Guzel O, Jehle RS, Klepper J, Kang HC, Lambrechts DA, Liu YMC, Nathan JK, Nordli Jr DR, Pfeifer HH, Rho JM, Scheffer IE, Sharma S, Stafstrom CE, Thiele EA, Turner Z, Vaccarezza MM, van der Louw EJTM, Veggiotti P, Wheless JW, Wirrell EC; The Charlie Foundation, Matthew's Friends, and Practice Committee of the CNS. Optimal clinical management of children receiving the ketogenic diet: Updated recommendations of the International

Ketogenic Diet Study Group. Epilepsia Open. 2018 May 21;3(2):175-92. doi: 10.1002/epi4.12225. eCollection 2018 Jun. PMID: 29881797.

Commonwealth of Massachusetts. Division of Insurance (DOI) Bulletins.

Commonwealth of Massachusetts. Early Intervention Policies.

Commonwealth of Massachusetts. MassHealth Guidelines for Medical Necessity Determination for Enteral Nutrition and Special Medical Formulas. 2019 Oct.

Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Manuals.

Commonwealth of Massachusetts. MassHealth Transmittal Letters.

Cystic Fibrosis Foundation. Schwarzenberg SJ, Hempstead SE, McDonald CM, Powers SW, Wooldridge J, Blair S, Freedman S, Harrington E, Murphy PJ, Palmer L, Schroeder AE, Shiel K, Sullivan J, Wallentine M, Marshall BC, Leonard AR. Enteral Tube Feeding Clinical Care Guidelines. J Cyst Fibros. 2016. Nov;15(6):724-35. Epub 2016 Sep 3. PMID: 27599607.

DeMauro SB, Abbasi S, Lorch S. The impact of feeding interval on feeding outcomes in very low birth-weight infants J Perinatol. 2011 Jul;31(7):481-6. doi: 10.1038/jp.2010.153. Epub 2011 Jan 20. PMID: 21252961.

Dominguez-Muñoz JE. Diagnosis and treatment of pancreatic exocrine insufficiency. Curr Opin Gastroenterol. 2018 Sep;34(5):349-54. doi: 10.1097/MOG.0000000000000459. PMID: 29889111.

Elke G, van Zanten ARH, Lemieux M, McCall M, Jeejeebhoy KN, Kott M, Jiang X, Day AG, Heyland DK. Enteral versus parenteral nutrition in critically ill patients: an updated systematic review and meta-analysis of randomized controlled trials. Critical Care. 2016 Apr 29;20(1):117. doi: 10.1186/s13054-016-1298-1. PMID: 27129307.

European Crohn's and Colitis Organisation (ECCO) and European Society of Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN). Ruemmele FM, Veres G, Kolho KL, Griffiths A, Levine A, Escher JC, Amil Dias J, Barabino A, Braegger CP, Bronsky J, Buderus S, Martín-de-Carpi J, De Ridder L, Fagerberg UL, Hugot JP, Kierkus J, Kolacek S, Koletzko S, Lionetti P, Miele E, Navas López VM, Paerregaard A, Russell RK, Serban DE, Shaoul R, Van Rheenen P, Veereman G, Weiss B, Wilson D, Dignass A, Eliakim A, Winter H, Turner D; ECCO; ESPGHAN. Consensus guidelines of ECCO/ESPGHAN on the medical management of pediatric Crohn's disease. J Crohns Colitis. 2014 Oct;8(10):1179-207. doi: 10.1016/j.crohns.2014.04.005. Epub 2014 Jun 6. PMID: 24909831.

European Society for Clinical Nutrition and Metabolism (ESPEN), European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN), European Cystic Fibrosis Society (ECFS).

Turck D, Braegger CP , Colombo C, Declercq D, Morton A, Pancheva R, Robberecht E, Stern M, Strandvik B , Wolfe S, Schneider SM, Wilschanski M. ESPEN-ESPGHAN-ECFS Guidelines on Nutrition Care for Infants, Children, and Adults with Cystic Fibrosis. Clin Nutr. 2016 Jun;35(3):557-77. doi: 10.1016/j.clnu.2016.03.004. Epub 2016 Mar 15. PMID: 27068495.

Freedman S, Orenstein D, Black P, Brown P, McCoy K, Stevens J, Grujic D, Clayton R. Increased Fat Absorption From Enteral Formula Through an In-line Digestive Cartridge in Patients With Cystic Fibrosis. J Pediatr Gastroenterol Nutr. 2017 Jul;65(1):97-101. doi: 10.1097/MPG.0000000000001617. PMID: 28471913.

Fujisawa D, Nakamura K, Mitsubuchi H, Ohura T, Shigematsu Y, Yorifuji T, Kasahara M, Horikawa R, Endo F. Clinical features and management of organic acidemias in Japan. J Hum Genet. 2013 Dec;58(12):769-74. doi: 10.1038/jhg.2013.97. Epub 2013 Sep 26. PMID: 24067294.

Grant JP. Nutritional support in acute and chronic pancreatitis. Surg Clin North Am. 2011 Aug;91(4):805-20, viii. doi: 10.1016/j.suc.2011.04.005. PMID: 21787969.

Greer FR, Sicherer SH, Burks AW. Effects of Early Nutritional Interventions on the Development of Atopic Disease in Infants and Children: The role of maternal dietary restriction, breastfeeding, timing of introduction of complementary foods, and hydrolyzed formulas. Pediatrics. 2008 Jan;121(1):183-91. doi: 10.1542/peds.2007-3022. PMID: 18166574.

Hauser NS, Manoli I, Graf JC, Sloan J, Venditti CP. Variable dietary management of methylmalonic acidemia: metabolic and energetic correlations. Am J Clin Nutr. 2011 Jan;93(1):47-56. doi: 10.3945/ajcn.110.004341. Epub 2010 Nov 3. PMID: 21048060.

Janisch NH, Gardner TB. Advances in Management of Acute Pancreatitis. Gastroenterol Clin North Am. 2016 Mar;45(1):1-8. doi: 10.1016/j.gtc.2015.10.004. Epub 2015 Dec 19. PMID: 26895677.

Kelley SA, Kossoff EH. How effective is the ketogenic diet for electrical status epilepticus of sleep? Epilepsy Res. 2016 Nov;127:339-343. doi: 10.1016/j.eplepsyres.2016.09.018. Epub 2016 Sep 23. PMID: 27710878.

Kessler SK, Gallagher PR, Shellhaas RA, Clancy RR, Bergqvist AG. Early EEG improvement after ketogenic diet initiation. Epilepsy Res. 2011 Mar;94(1-2):94-101. doi: 10.1016/j.eplepsyres.2011.01.012. Epub 2011 Feb 23. PMID: 21345653.

Klein P, Janousek J, Barber A, Weissberger R. Ketogenic diet treatment in adults with refractory epilepsy. Epilepsy Behav. 2010 Dec;19(4):575-9. doi: 10.1016/j.yebeh.2010.09.016. PMID: 20937568.

Klein P, Tyrlikova I, Mathews GC. Dietary Treatments in Adults with Refractory Epilepsy: A Review. Neurology. 2014 Nov 18;83(21):1978-85. doi: 10.1212/WNL.0000000000001004. Epub 2014 Oct 29. PMID: 25355830.

Leonard SA, Nowak-Wegrzyn A. Food protein-induced enterocolitis syndrome: an update on natural history and review of management. Ann Allergy Asthma Immunol. 2011 Aug;107(2):95-101;quiz 101, 162. doi: 10.1016/j.anai.2011.06.004. PMID: 21802016.

Levy RG, Cooper PN, Giri P. Ketogenic diet and other dietary treatments for epilepsy. Cochrane Database Syst Rev. 2012 Mar 14;(3):CD001903. doi: 10.1002/14651858.CD001903.pub2. PMID: 22419282.

Lowe AL, Dharmage SC, Allen KJ, Tang MLK, Hill DJ. The role of partially hydrolyzed whey formula for the prevention of allergic disease: evidence and gaps. Expert Rev Clin Immunol. 2013 Jan;9(1):31-41. doi: 10.1586/eci.12.80. PMID: 23256762.

Macleod EL, Ney DM. Nutritional Management of Phenylketonuria. Ann Nestle Eng. 2010 Jun;68(2):58-69. doi: 10.1159/000312813. PMID: 22475869.

Martin K, Jackson CF, Levy RG, Cooper PN. Ketogenic diet and other dietary treatments for epilepsy. Cochrane Database Syst Rev. 2016 Feb 9;2:CD001903. doi: 10.1002/14651858.CD001903.pub3. PMID: 26859528.

Martorell A, Plaza AM, Boné J, Nevot S, García Ara MC, Echeverria L, Alonso E, Garde J, Vila B, Alvaro M, Tauler E, Hernando V, Fernández M. Cow's milk protein allergy. A multi-center study: clinical and epidemiological aspects. Allergol Immunopathol (Madr). 2006 Mar-Apr;34(2):46-53. doi: 10.1157/13086746. PMID: 16606545.

Massachusetts Department of Public Health. Early Intervention Operational Standards. 2013 Jul.

McDonald TJW, Cervenka MC. Ketogenic Diets for Adults With Highly Refractory Epilepsy. Epilepsy Curr. 2017 Nov-Dec;17(6):346-530. doi: 10.5698/1535-7597.17.6.346. PMID: 29217974.

Mei L, Song P, Kokudo N, Xu L, Tang W. Current situation and prospects of newborn screening and treatment for Phenylketonuria in China compared with the current situation in the United States, UK and Japan. Intractable Rare Dis Res. 2013 Nov;2(4):106-14. doi: 10.5582/irdr.2013.v2.4.106. PMID: 25343113.

Min M, Patel B, Han S, Bocelli L, Kheder J, Vaze A, Wassef W. Exocrine Pancreatic Insufficiency and Malnutrition in Chronic Pancreatitis: Identification, Treatment, and Consequences. Pancreas. 2018 Sep;47(8):1015-8. doi: 10.1097/MPA.0000000000001137. PMID: 30074926.

Morgan J, Young L, McGuire W. Delayed introduction of progressive enteral feeds to prevent necrotizing enterocolitis in very low birth weight infants. Cochrane Database Syst Rev. 2013 May 31;(5):CD001970. doi: 10.1002/14651858.CD001970.pub4. PMID: 23728636.

National Institute for Health and Care Excellence (NICE). Cystic fibrosis: diagnosis and management. NICE guideline NG78. 2017 Oct 25.

National Institute for Health and Care Excellence (NICE). Nutrition support in adults: Oral nutrition support, enteral tube feeding and parenteral nutrition. Clinical Guideline CG32. 2006 Feb 22. Updated 2017 Aug 4.

Neal EG, Chaffe H, Schwartz RH, Lawson MS, Edwards N, Fitzsimmons G, Whitney A, Cross JH. The ketogenic diet for the treatment of childhood epilepsy: A randomized controlled trial. Lancet Neurol. 2008 Jun;7(6):500-6. doi: 10.1016/S1474-4422(08)70092-9. Epub 2008 May 2. PMID: 18456557.

Nesvaderani M, Eslick GD, Cox MR. Acute pancreatitis: update on management. Med J Aust. 2015 May 4;202(8):420-3. PMID: 25929504.

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. Provider Notices.

Ney DM, Blank RD, Hansen KE. Advances in the nutritional and pharmacological management of phenylketonuria. Curr Opin Clin Nutr Metab Care. 2014 Jan;17(1):61-8. doi: 10.1097/MCO.0000000000000002. PMID: 24136088.

North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN). Clinical Guidelines/Position Statements.

North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN). Critch J, Day AS, Otley A, King-Moore C, Teitelbaum JE, Shashidhar H; NASPGHAN IBD Committee. Use of enteral nutrition for the control of intestinal inflammation in pediatric Crohn disease. J Pediatr Gastroenterol Nutr. 2012 Feb;54(2):298-305. doi: 10.1097/MPG.0b013e318235b397. Erratum in J Pediatr Gastroenterol Nutr. 2012 Apr;54(4):573. PMID: 22002478.

North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN). Eosinophilic Esophagitis.

North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) and European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN). Rosen R, Vandenplas Y, Singendonk M, Cabana M, DiLorenzo C, Gottrand F, Gupta S, Langendam M, Staiano A, Thapar N, Tipnis N, Tabbers M. Pediatric Gastroesophageal Reflux Clinical Practice Guidelines: Joint Recommendations of the NASPGHAN and ESPGHAN. J Pediatr Gastroenterol Nutr. 2018 Mar;66(3):516-544. doi: 10.1097/MPG.0000000000001889. PMID: 29470322.

Oláh A, Romics L Jr. Enteral nutrition in acute pancreatitis: A review of the current evidence. World J Gastroenterol. 2014 Nov 21;20(43):16123–31. doi: 10.3748/wjg.v20.i43.16123. PMID: 25473164.

Pinto A, Almeida MF, Cunha A, Carmona C, Rocha S, Guimas A, Ribeiro R, Mota CR, Martins E, MacDonald A, Rocha JC. Dietary management of maternal phenylketonuria with glycomacropeptide and amino acids supplements: A case report. Mol Genet Metab Rep. 2017 Oct 18;13:105-110. doi: 10.1016/j.ymgmr.2017.10.004. eCollection 2017 Dec. PMID: 29085781.

Rapkin RH. Formula Intolerance. Pediatrics in Review. 1997 Jun;18(6):191. doi:10.1542/pir.18-6-191.

The Renal Association. Guidelines and Commentaries.

Rossen LM, Simon AE, Herrick KA. Types of Infant Formulas Consumed in the United States. Clin Pediatr (Phila). 2016 Mar;55(3):278-85. doi: 10.1177/0009922815591881. Epub 2015 Jul 6. PMID: 26149849.

Sathe MN, Patel D, Stone A, First E. Evaluation of the Effectiveness of In-line Immobilized Lipase Cartridge in Enterally Fed Patients With Cystic Fibrosis. J Pediatr Gastroenterol Nutr. 2021 Jan 1;72(1):18-23. doi: 10.1097/MPG.0000000000002984. PMID: 33165085.

Schoeler NE, Wood S, Aldridge V, Sander JW, Cross JH, Sisodiya SM. Ketogenic dietary therapies for adults with epilepsy: Feasibility and classification of response. Epilepsy Behav. 2014 Aug;37:77-81. doi: 10.1016/j.yebeh.2014.06.007. Epub 2014 Jul 8. PMID: 25010319.

Sharma S and Jain P. The ketogenic diet and other dietary treatments for refractory epilepsy in children. Ann Indian Acad Neurol. 2014 Jul-Sep;17(3):253-8. doi: 10.4103/0972-2327.138471. PMID: 25221391.

Shek LP, Soderstrom L, Ahlstedt S, Beyer K, Sampson HA. Determination of food specific IgE levels over time can predict the development of tolerance in cow's milk and hen's egg allergy. J Allergy Clin Immunol. 2004 Aug;114(2):387-91. doi: 10.1016/j.jaci.2004.04.032. PMID: 15316521.

Society of Critical Care Medicine (SCCM), American Society for Parenteral and Enteral Nutrition (ASPEN). McClave SA, Taylor BE, Martindale RG, Warren MM, Johnson DR, Braunschweig C, McCarthy MS, Davanos E, Rice TW, Cresci GA, Gervasio JM, Sacks GS, Roberts PR, Compher C; SCCM; ASPEN. Guidelines for the Provision and Assessment of Nutrition Support Therapy in the Adult Critically Ill Patient: SCCM and ASPEN. JPEN J Parenter Enteral Nutr. 2016 Feb;40(2):159-211. doi: 10.1177/0148607115621863. Erratum in: JPEN J Parenter Enteral Nutr. 2016 Nov;40(8):1200. PMID: 26773077.

Society of Critical Care Medicine (SCCM), American Society for Parenteral and Enteral Nutrition (ASPEN). Mehta NM, Skillman HE, Irving SY, Coss-Bu JA, Vermilyea S, Farrington EA, McKeever L, Hall AM, Goday PS, Braunschweig C. Guidelines for the Provision and Assessment of Nutrition Support Therapy in the Pediatric Critically Ill Patient: SCCM and ASPEN. JPEN J Parenter Enteral Nutr. 2017 Jul;41(5):706-42. doi: 10.1177/0148607117711387. Epub 2017 Jun 2. PMID: 28686844.

Stevens J, Wyatt C, Brown P, Patel D, Grujic D, Freedman SD. Absorption and Safety With Sustained Use of RELiZORB Evaluation (ASSURE) Study in Patients With Cystic Fibrosis Receiving Enteral Feeding. J Pediatr Gastroenterol Nutr. 2018 Oct;67(4):527-32. doi: 10.1097/MPG.0000000000002110. PMID: 30074573.

Taub KS, Kessler SK, Bergqvist AG. Risk of seizure recurrence after achieving initial seizure freedom on the ketogenic diet. Epilepsia. 2014 Apr;55(4):579-83. doi: 10.1111/epi.12583. Epub 2014 Mar 27. PMID: 24673650.

Taylor RR, Sladkevicius E, Panca M, Lack G, Guest JF. Cost-effectiveness of using an extensively hydrolyzed formula compared to an amino acid formula as first-line treatment for cow milk allergy in the UK. Pediatr Allergy Immunol. 2012 May;23(3):240-9. doi: 10.1111/j.1399-3038.2011.01262.x. Epub 2012 Feb 23. PMID: 22360663.

Titre-Johnson S, Schoeler N, Eltze C, Williams R, Vezyroglou K, McCullagh H, Freemantle N, Heales S, Kneen R, Marston L, Martland T, Nazareth I, Neal E, Lux A, Parker A, Agrawal S, Fallon P, Cross JH. Ketogenic diet in the treatment of epilepsy in children under the age of 2 years: study protocol for a randomized controlled trial. Trials. 2017 Apr 26;18(1):195. doi: 10.1186/s13063-017-1918-3. PMID: 28446244.

U. S. Food and Drug Administration (FDA). Device Classification under Section 513(f)(2)(de novo). Device Name RELiZORB. De Novo Number DEN150001.

U. S. Food and Drug Administration (FDA). Medical Foods Guidance Documents & Regulatory Information. 2017 Dec 6.

Waisbren SE, Rohr F, Anastasoaie V, Brown M, Harris D, Ozonoff A, Petrides S, Wessel A, Levy HL. Maternal Phenylketonuria: Long-term Outcomes in Offspring and Post-pregnancy Maternal Characteristics. JIMD Rep. 2015;21:23-33. doi: 10.1007/8904_2014_365. Epub 2015 Feb 25. PMID: 25712380.

Watson J, McGuire W. Transpyloric versus gastric tube feeding for preterm infants. Cochrane Database Syst Rev. 2013 Feb 28;(2):CD003487. doi: 10.1002/14651858.CD003487.pub3. PMID: 23450542.

Wilmshurst JM, Gaillard WD, Vinayan KP, Tsuchida TN, Plouin P, Van Bogaert P, Carrizosa J, Elia M, Craiu D, Jovic NJ, Nordli D, Hirtz D, Wong V, Glauser T, Mizrahi EM, Cross JH. Summary of recommendations for the management of infantile seizures: Task Force Report for the ILAE Commission of Pediatrics. Epilepsia. 2015 Aug;56(8):1185-97. doi: 10.1111/epi.13057. Epub 2015 Jun 30. PMID: 26122601.

Zhu D, Wang M, Wang J, Yuan J, Niu G, Zhang G, Sun L, Xiong H, Xie M, Zhao Y. Ketogenic diet effects on neurobehavioral development of children with intractable epilepsy: A prospective study. Epilepsy Behav. 2016 Feb;55:87-91. doi: 10.1016/j.yebeh.2015.12.011. Epub 2016 Jan 13. PMID: 26773676.

Zupec-Kania B, Zupanc ML. Long-term management of the ketogenic diet: seizure monitoring, nutrition, and supplementation. Epilepsia. 2008 Nov;49(Suppl 8):23-6. doi: 10.1111/j.1528-1167.2008.01827.x. PMID: 19049580.

Next Review Date

07/01/23

Authorizing Entity

MPCTAC

Appendix

Appendix: Policy History

Disclaimer Information:

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

Appendix: Policy History

Original Approval Date	Original Effective Date* and Version Number	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A Internal Approval: 03/25/03	05/25/03 Version 1	Director of Medical Policy as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC)	Quality and Clinical Management Committee (Q&CMC)

*Effective Date for QHP Commercial Product: 01/01/12
*Effective Date for New Hampshire Medicaid Product: 01/01/13
*Effective Date for Senior Care Options Product: 01/01/16
*Effective Date for New Hampshire Medicare Advantage HMO Product: 01/01/22

Policy title from 05/25/03 to 03/31/17 was *Tube Fed Enteral Nutrition (Supplied and Billed by Home Infusion Providers)*.
Policy title from 04/01/17 to 07/31/20 was changed to *Tube Fed Enteral Nutrition (Supplied and Billed by Home Infusion Providers) and Digestive Enzyme Cartridges*.
Policy title as of 08/01/20 is *Enteral Nutrition (Tube Feeding) Products Supplied and Billed by Home Infusion Providers and Digestive Enzyme Cartridges*.

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date and Version Number**	**Approved by**
09/06/05	Updated clinical coverage criteria.	Version 2	09/06/05: Q&CMC
11/07/06	Removed procedure section as preauthorization requirement does not apply.	Version 3	11/07/06: Q&CMC
11/13/07	No changes.	Version 4	11/13/07: MPCTAC
05/13/08	Review for effective date 09/01/08. Updated clinical criteria and added preauthorization requirements for certain categories of formulas.	09/01/08 Version 5	05/13/08: MPCTAC 06/24/08: Utilization Management Committee (UMC) 06/26/08: Quality Improvement Committee (QIC)
06/23/09	Review for effective date 10/01/09. Added additional criteria for hydrolyzed and specialized formulas, updated the names of the standard regular formulas that WIC covers. (Good Start Supreme DHA/ARA, Good Start Supreme Soy DHA/ARA, Good Start Supreme, Enfamil Lipil with Iron, Enfamil Lipil Low Iron, ProSobee Lipil were all removed and replaced with Good Start	10/01/09 Version 6	06/23/09: MPCTAC 06/23/09: UMC 07/22/09: QIC

Policy Revisions History			
	Gentle, Good Start Soy Plus and Good Start Nourish Plus Powder.)		
10/27/09	Revised WIC information.	Version 7	10/27/09: MPCTAC 11/19/09: QIC
10/01/10	Revised the criteria for hydrolyzed formulas, updated references and definitions.	Version 8	10/20/10: MPCTAC 11/22/10: QIC
04/01/11	Revised this policy to be applicable for enteral nutritional tube fed products dispensed and billed by home infusion providers only.	Version 9	10/19/11: MPCTAC 11/29/11: QIC
10/01/11	Added Commercial mandated language that tube fed prescription enteral nutrition products are medically necessary in infants and children or to protect the unborn fetuses of pregnant individuals for inborn errors of metabolism and inherited metabolic disease. Added language that non-prescription tube fed enteral formulas ordered by a physician for home use are medically necessary for the treatment of: malabsorption caused by Crohn's disease, ulcerative colitis, gastroesophageal reflux, gastrointestinal motility, chronic intestinal pseudo-obstruction and inherited diseases of amino acids and organic acids.	Version 10	10/19/11: MPCTAC 11/29/11: QIC
08/20/12	Off cycle review for New Hampshire Medicaid product, reformatted Medical Policy Statement, revised code list to include all enteral products, updated references. Review of entire policy conducted.	Version 11	08/30/12: MPCTAC 09/06/12: QIC
10/01/12 and 11/01/12	Review for effective date 03/01/13. Revised Summary section, moved text from Note section to Summary section, revised and reformatted clinical criteria for enteral nutrition, added limitations, updated language in Applicable Coding section and revised applicable code list, and updated references.	03/01/13 Version 12	10/17/12: MPCTAC 11/24/12: MPCTAC 12/20/12: QIC
08/14/13 and 08/15/13	Off cycle review for New Hampshire Medicaid product and merged policy format. Incorporate policy revisions dated 10/01/12 and 11/01/12 (as specified above) for the New Hampshire Medicaid product; these policy revisions were approved by MPCTAC (on 10/17/12 and 11/24/12) and QIC on 12/20/13 for applicable Plan products. Review of entire policy conducted.	Version 13	08/14/13: MPCTAC (via electronic vote) 08/15/13: QIC

Policy Revisions History			
08/21/13	Review for effective date 10/01/13. Revised Medical Policy Statement section without changing criteria. Updated references.	10/01/13 Version 14	08/21/13: MPCTAC 09/19/13: QIC
09/01/14	Review for effective date 01/01/15. Updated Summary, Description of Item or Service, Definitions, and References sections. Updated criteria in the Medical Policy Statement section and Limitations section. Added indication for tube fed enteral nutrition products (i.e., ketogenic diet for recurrent, uncontrolled seizures with severe epilepsy for pediatric members). Increased the maximum timeframe for authorizations from 6 months to 12 months. Listed applicable coding for Massachusetts Plan products and New Hampshire Medicaid product into two separate sections and updated the introductory paragraph in both of the Applicable Coding sections. No change made to the applicable code list for Massachusetts products. Removed HCPCS codes B4102 and B4103 from the applicable code list for NH Medicaid product.	01/01/15 Version 15	09/24/14: MPCTAC (electronic vote) 10/08/14: QIC
09/01/15	Review for effective date 01/01/16. Updated list of applicable products, including removing Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available. Updated criteria in the Medical Policy Statement section. Revised Definitions and References sections.	01/01/16 Version 16	09/16/15: MPCTAC 10/14/15: QIC
11/25/15	Review for effective date 01/14/16. Revised language in the Applicable Coding sections.	01/14/16 Version 17	11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
09/01/16 and 09/28/16	Review for effective date 11/01/16. Updated Definitions, Clinical Background Information, References, and References to Applicable Laws and Regulations sections. Revised Plan notes in the Applicable Coding section for Massachuetts products without changing the applicable code list. Administrative changes made to clarify language related to gender.	11/01/16 Version 18	09/21/16: MPCTAC 09/30/16: MPCTAC (electronic vote) 10/12/16: QIC
12/01/16	Review for effective date 04/01/17. Revised policy title to include digestive enzyme cartridges. Updated Summary, Description of Item or Service, Clinical Background Information, and References sections. Revised criteria in the Medical Policy Statement and Limitations	04/01/17 Version 19	12/21/16: MPCTAC 01/11/17: QIC

Policy Revisions History			
	sections. Added experimental and investigational code in the Applicable Coding section.		
09/01/17	Review for effective date 10/01/17. Administrative changes made to the Policy Summary, Medical Policy Statement, Limitations, and References sections.	10/01/17 Version 20	09/20/17: MPCTAC
06/01/18	Review for effective date 07/01/18. Updated the Policy Summary, References, and Other Applicable Policies sections. Added new HCPCS code Q9994 for a digestive enzyme cartridge (e.g., RELiZORB), an industry-wide code addition, and revised Plan notes in the Applicable Coding for Massachusetts Products and Applicable Coding for NH Products sections.	07/01/18 Version 21	06/20/18: MPCTAC
09/01/18	Review for effective date 12/01/18. Administrative changes made to the Applicable Coding for MA Products, Applicable Coding for NH Products, References, and Other Applicable Polices sections. Updated criteria in the Limitations section.	12/0/18 Version 22	09/19/18: MPCTAC
12/01/18	Review for effective date 01/01/19. Administrative changes made to the Policy Summary, Medical Policy Statement, Limitations, and References sections. Industry-wide code updates, revisions to applicable coding, and revisions to Plan notes made to the Applicable Coding for MA Products section and the Applicable Coding for NH Products section.	01/01/19 Version 23	12/19/18: MPCTAC
07/01/19	Review for effective date 08/01/19. Administrative changes made to the References and Reference to Applicable Laws and Regulations sections.	08/01/19 Version 24	07/17/19: MPCTAC
07/01/20	Review for effective date 10/01/20. Revised policy title. Updated the References section. Revised criteria in the Medical Policy Statement and Limitations sections.	10/01/20 Version 25	07/15/20: MPCTAC
08/01/21	Review for effective date 11/01/21. Administrative changes made to the Policy Summary, Description of Item or Service, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections. Revised criteria in the Medical Policy Statement and Limitations sections. Added medically necessary indications for RELiZORB®	11/01/21 Version 26	08/27/21: MPCTAC (electronic vote)

Policy Revisions History			
	and updated Applicable Coding for MA Products and Applicable Coding for NH Products sections.		
11/01/21	Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections, Medical Policy Statement section renamed Clinical Criteria, the Limitations section renamed Limitations and Exclusions section. Added NH Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, Applicable Coding for MA Products, Applicable Coding for NH Products, and References sections.	12/01/21 Version 27	11/17/21: MPCTAC
07/01/22	Review for effective date 08/01/22. Administrative changes made to the Policy Summary, Clinical Criteria and References section. Non-material changes made to criteria.	08/01/22 Version 28	07/25/22: MPCTAC (electronic vote)