Regence

Medical Policy Manual Allied Health, Policy No. 05

Enteral and Oral Nutrition Therapy in the Home Setting

Effective: November 1, 2023

Next Review: June 2024
Last Review: September 2023

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Enteral nutrition is the administration of nutritional formulas directly into the gastrointestinal tract through nasogastric, gastrostomy, or jejunostomy tubes. Feedings may be either intermittent (i.e., overnight or bolus) or continuous (infused 24 hours a day). Feedings are delivered by syringe, gravity drip or by use of an infusion pump. In-born errors of metabolism (IEM) are a group of rare metabolic disorders that result from a missing or abnormally functioning enzyme, leading to either accumulation or deficiency of a specific metabolite. Treatment of IEMs include providing specialty medical foods, orally or through a feeding tube.

MEDICAL POLICY CRITERIA

Notes:

- This policy only applies to certain member contracts. Please check the preauthorization website for the member contract to confirm requirements.
- This policy addresses enteral and oral nutrition therapy in the home setting only and does not apply to nutrition provided during a hospital or facility stay.
- Enteral nutrition and supplies in the home setting are approved for six months for initial authorization and re-authorization for continuation.
- Re-authorization is not required for:

- Specialized nutrition formula (including specialty infant formula) for supplementation or dietary replacement for the treatment of inborn errors of metabolism (including, but not limited to Phenylketonuria).
- Permanent nonfunction or disease.

I. Enteral nutrition formula (administered via gastrostomy, jejunostomy or nasogastric tube) and the necessary supplies (syringe or gravity system and tubing) in the home setting may be considered **medically necessary** when one of the following criteria is met:
   A. There is severe intestinal malabsorption (e.g., Crohn's disease, short bowel syndrome or intestinal failure), and the formula is the sole source or an essential source of nutrition; or
   B. There is permanent (see Policy Guidelines) nonfunction or disease of the structures that normally permit food to reach the small bowel (e.g., head and neck cancer or an obstructing tumor or stricture of the esophagus or stomach) such that tube feedings are required to provide sufficient nutrients to maintain weight and strength commensurate with the patient's overall health status; or
   C. When both of the following criteria are met (1. and 2.):
      1. A neuromuscular or central nervous system disorder is present, or the patient is a premature infant; and
      2. There is sufficient interference with the coordination of chewing and swallowing such that a risk of aspiration exists (e.g., dysphagia secondary to Cerebral Vascular Accident); or
   D. There is a diagnosis of failure to thrive.

II. An infusion pump (and supplies) may be considered **medically necessary** when one of the following conditions is met:
   A. Gravity feeding is not satisfactory due to reflux and/or aspiration; or
   B. Administration rate is less than 100 ml per hour; or
   C. Patient has severe diarrhea; or
   D. Patient has dumping syndrome; or
   E. Patient has blood glucose fluctuations; or
   F. Patient has circulatory overload.

III. Enteral in-line digestive enzyme cartridges (e.g. RELiZORB®) may be considered **medically necessary** for patients 5 years or older with Exocrine Pancreatic Insufficiency (EPI) due to Cystic Fibrosis who are on enteral feeding.

IV. Specialized nutrition formula (including specialty infant formula) for supplementation or dietary replacement may be considered **medically necessary** for the treatment of inborn errors of metabolism (including, but not limited to Phenylketonuria).

V. Enteral nutrition formula and the necessary supplies (syringe or gravity system and tubing) is considered **not medically necessary** when Criterion I. is not met.

VI. An infusion pump (and supplies) is considered **not medically necessary** when Criterion II. is not met.

VII. Enteral in-line digestive enzyme cartridges (e.g. RELiZORB®) are considered **not medically necessary** when Criterion III. is not met.

VIII. Specialized nutrition formula (including specialty infant formula) for supplementation or dietary replacement is considered **not medically necessary** when Criterion V. is not met.

IX. Non-medical foods are considered **not medically necessary** including (but not limited to):

- A. Food thickeners; or
- B. Baby food or formula (other than specialized for inborn errors of metabolism); or
- C. Non-medical foods that can be blenderized for enteral feeding; or
- D. Fluid and electrolyte replacements; or
- E. Fiber additives; or
- F. Oral supplements (e.g., vitamins, minerals, electrolytes, gluten free products, high protein, supplements for weight loss or weight gain, supplements to treat mild or moderate food allergies or intolerances).

X. Continuation of enteral nutrition (including supplies) may be considered **medically necessary** if both A. and B. are met:

- A. Member continues to meet indication for initial therapy per Criterion I. or II. or III.; and
- B. Documentation of current nutrition status including regular interval monitoring and nutritional reassessments are submitted with continuation requests, including the following:
  1. Assessments for tolerance and adequacy of nutrition support; and
  2. Continued requirement of enteral nutrition to maintain weight and strength commensurate with the patient's overall health status.

XI. Continuation of enteral nutrition formal and supplies is considered **not medically necessary** when Criterion X. is not met.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

POLICY GUIDELINES

Permanence does not require a determination that there is no possibility that the member's condition may improve sometime in the future. If the judgment of the doctor, substantiated in the medical record, is that the impairment can reasonably be expected to exceed three months (90 days), the test of permanence is considered met. This is consistent with Center for Medicare and Medicaid Services (CMS) guidelines.[1]

LIST OF INFORMATION NEEDED FOR REVIEW

REQUIRED DOCUMENTATION:

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and physical/chart notes
- Documentation of the need of enteral feeding as identified in Criteria I.
- Documentation of the necessity of specialized enteral formulas (e.g., semi-synthetic intact proteins or protein isolates, natural intact proteins or protein isolates, hydrolyzed proteins, calorically dense formulas)
- If inborn error of metabolism disorder, include diagnosis and documentation of need of specialty oral or enteral foods or formulas (including for specialty infant formulas)
- If Exocrine Pancreatic Insufficiency (EPI) (e.g. Cystic Fibrosis), include diagnosis and need for use of in-line digestive enzymes
- If requiring an infusion pump for administration of enteral nutrition include documentation for rational identified in Criterion II.
- Provide documentation of estimated length of need of nutritional support

CROSS REFERENCES

None

BACKGROUND

Enteral tube feeding is indicated in patients who cannot main adequate oral intake of food or nutrition to meet their metabolic demands.[2] Home enteral nutrition is used for the treatment of patients who cannot meet their nutritional needs orally and who are at risk of severe malnutrition. Enteral nutrition involves administering nutritional formulas directly into the gastrointestinal tract through nasogastric, gastrostomy, or jejunostomy tubes. The daily amount of enteral nutrition formula required is specific to the needs of the patient. Feedings may be either intermittent (i.e., overnight or bolus) or continuous (infused 24 hours a day). Feedings are delivered by syringe, gravity drip or by use of an infusion pump.

Oral nutritional support is medical food or formula taken orally to replace or supplement dietary intake in patients at risk of or experiencing malnutrition.

In-born errors of metabolism (IEM) are a group of rare metabolic disorders that result from a missing or abnormally functioning enzyme, leading to either accumulation or deficiency of a specific metabolite. Clinical manifestations of these disorders generally include central nervous system dysfunction, developmental delay, seizures, liver dysfunction, gastrointestinal distress (including vomiting and feeding issues) and, in severe cases, death. The clinical manifestations in many of these disorders can be reduced and or prevented if diagnosis is achieved early and appropriate treatment is instituted immediately.

Examples of IEMs include but are not limited to:

- Amino acid disorders (i.e. Phenylketonuria [PKU] citrullinemia, cystinosis, homocystinuria, methylmalonic acidemia)
- Lysosomal storage diseases

- Organic acidemias
- Peroxisomal disorders
- Mitochondrial diseases
- Glycogen storage diseases
- Urea cycle diseases

For some of the inborn errors of metabolism, special formulas and medical foods have been developed, which eliminate the nutrient (i.e., amino acid) that cannot be metabolized. Nutrition treatment is considered standard of medical care for inborn errors of metabolism. For example;

> Glycogen storage diseases occur in children who do not produce an enzyme responsible for releasing glucose from glycogen during fasting states. Because glucose cannot be produced endogenously, hypoglycemia occurs. The aim of treatment is to prevent hypoglycemia. This may include frequent high carbohydrate meals during the day combined with oral supplements such as cornstarch or and continuous enteral infusion of a nutritional supplement (e.g.,Vivonex®) overnight to sustain blood glucose.
>
> Phenylketonuria (PKU) is an autosomal recessive disorder in which the patient is missing an enzyme that breaks down the amino acid phenylalanine. Women diagnosed with classic PKU desiring pregnancy alter their diet by using a special maternal dietary supplement low in phenylalanine. The use of this supplement reduces the risk of severe intellectual disability in the infant of a mother with PKU. The baby will be tested for PKU at birth and, if diagnosed, will require special formulas/supplements that are low in phenylalanine.

Exocrine pancreatic insufficiency (EPI) is the decreased production of pancreatic digestive enzymes. The two most common causes of EPI are chronic pancreatitis and Cystic Fibrosis (CF)[3] Other causes include Gastric, pancreatic, or small bowel resection, pancreatic duct obstruction, Shwachman-Diamond syndrome, hereditary hemochromatosis, gastrinoma (Zollinger-Ellison syndrome) may develop exocrine pancreatic insufficiency due to inactivation of pancreatic enzymes by gastric acid. Small bowel mucosal disease (e.g., celiac disease) can result in decreased cholecystokinin release, which in turn can result in reduced pancreatic secretion. Treatment for EPI include pancreatic enzyme replacement (PERT). For enteral nutrition enzyme replacements can be provided in the form of a cartridge that is used in-line with the enteral feeding (e.g., RELiZORB®).

REGULATORY STATUS

Medical Foods

According to the U.S. Food and Drug Administration, the term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is ‘a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Medical foods do not have to undergo premarket review or approval by FDA and individual medical food products do not have to be registered with FDA.[4] This guidance indicates that medical foods are specially formulated and processed for partial or exclusive feeding orally or by tube; are designed for patients with limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foods or nutrients, whereby dietary management cannot

be achieved by modification of the normal diet alone; and are to be used to manage the unique nutrient needs of a specific disease or condition determined by medical evaluation.[5]

RELiZORB®

RELiZORB® is indicated for use in pediatric patients (ages 5 years and above) and adult patients to hydrolyze fats in enteral formula.[6]

- June 2016: 510(k) Class II clearance for RELiZORB® for the use in adult patients to hydrolyze fats in enteral formula (K163057).[7]
- July 2017: use expanded to include pediatric patient's ages five years and above.[8]
- December 2019: RELiZORB® revised with no changes to target population or intended use.[9]

Infant Formulas

The FDA regulates infant formulas developed for Inborn Errors of Metabolism (IEM) and categorizes these formulas as "exempt." An exempt infant formula is an infant formula intended for commercial or charitable distribution that is represented and labeled for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems (21 CFR 107.3). Prior to any company or person manufacturing and marketing a new exempt infant formula or any infant formula, certain practices, procedures and processes must be followed (Section 412 of the Federal Food, Drug, and Cosmetic Act).[10]

EVIDENCE SUMMARY

HOME ENTERAL NUTRITION (HEN)

Systematic reviews (SRs) have evaluated the accumulated evidence for home enteral nutrition feeding addressed in this policy. Therefore, this evidence review primarily focuses on the most recent systematic reviews and randomized controlled trials (RCT).

Systematic Reviews

Elgersma (2023) published a SR to evaluate the risk factors for tube feeding at discharge in infants undergoing neonatal surgery for Coronary Heart Disease (CHD).[11] Included studies (N=18) were primarily retrospective cohort designs and results were often inconsistent. The authors conclude that infants who struggle with feeding preoperatively, experience increased nothing by mouth duration and/or low oral feeding volume postoperatively, experience increased duration of mechanical ventilation, or have vocal cord dysfunction may be at risk for tube feeding at hospital discharge. The authors also note factors warranting further examination include cardiac physiology (e.g., aortic arch obstruction) and the relationship between neurodevelopment and oral feeding. The authors recommend that clinicians prioritize early implementation of interventions that facilitate oral feeding development. The authors report that the included studies, as a group, exhibited substantial risk for bias.

Marsh (2022) published a SR comparing clinical outcomes of different methods of dietary management of active ulcerative colitis, including enteral nutrition (EN), total parenteral nutrition (TPN), elimination diets and standard oral diets.[12] Ten studies of low quality were included in the analysis. No difference was found between EN, TPN and bowel rest in terms of disease activity measures when compared to a standard oral diet. The authors note that there

is lack of clinical guidelines and further high-quality studies are need for nutrition care in ulcerative colitis.

Keane (2022) evaluated the effects of oral nutrition supplements (ONS), (EN) and parenteral nutrition (PN) on both clinical and nutritional outcomes of scleroderma patients.[13] A total of nine studies (ONS: 2, EN: 1 and PN: 6) were included. All patients had scleroderma and were malnourished or at risk of malnutrition. Artificial nutrition support was shown to be an effective therapy for preventing nutritional decline and reversing malnutrition but had no impact on disease progression. Mean BMI increased with home parenteral nutrition (HPN) and HEN, from 15kg/m2 to 21.0kg/m2. Weight was maintained with ONS, and sarcopenia decreased. Only HPN positively impacted quality of life and GI symptoms, with complication rates similar to patients with other indications. The authors concluded that Scleroderma patients should be routinely screened for malnutrition. Malnutrition is treated in a stepwise manner, starting with ONS, then EN and finally PN, based on GI sufficiency and tolerance of the patient. They also indicate that larger, long-term, prospective studies for each nutritional therapy are required to make firm conclusions.

Xueting (2021) published a SR evaluating the impact of HEN nutritional status, complications, and quality of life (QOL) after upper gastrointestinal (GI) resection.[14] Including 15 RCTs (1059 patients) they compared a normal oral diet with oral nutrition supplements (ONS) and HEN Compared with normal oral diet, HEN significantly prevented weight loss (-3.95 vs -5.82kg; SMD: 1.98kg; 95% CI: 1.24-2.73); improved added level of albumin (3.48 vs 2.41g/L; SMD: 1.36g/L; 95% CI: 0.81-1.91), hemoglobin (6.54 vs -1.29g/L; WMD: 7.45g/L; 95% CI: 5.05-9.86), pre-albumin (37.59 vs 7.35mg/L; WMD: 21.6mg/L; 95% CI: 5.96-37.24), and transferrin (63.08 vs 50.45mg/L; WMD: 16.44mg/L; 95% CI: 13.51-19.38); and reduced the incidence of malnutrition or latent malnutrition (RR = 0.54; P<0.01). Weight loss in the HEN subgroup was significantly less than that of the control group (WMD = 2.69, P<0.01), while there was no significant difference between the ONS subgroup and the control group (P = 0.1). The same results were found in albumin. Physical function (WMD: 5.29; 95% CI: 1.86-8.73) and fatigue (WMD: -8.59; 95% CI: -12.61, -4.58) dimensions in quality of life (QOL) were significantly better in the HEN group. No significant differences in gastrointestinal and tube-related complications. The authors concluded that enteral nutrition improved nutritional status and some dimensions of QOL in upper GI malignancy patients after surgery, without increasing complications.

Liu (2020) reported the impacts of HEN after esophagectomy in esophageal cancer patients.[15] Nine randomized controlled trials (757 patients) were included in the SR. Compared with oral diet, HEN was associated with significantly increased body weight (WMD 3kg, 95% CI 2.36-3.63, P<.001), body mass index (WMD 0.97kg/m, 95% CI 0.74-1.21, P<.001), albumin (WMD 3.43g/L, 95% CI 2.35-4.52, P<.001), hemoglobin (WMD 7.23g/L, 95% CI 5.87-8.59, P<.001), and total protein (WMD 5.13g/L, 95% CI 3.7-6.56, P<.001). No significant differences were observed in prealbumin and gastrointestinal adverse reactions. Physical (WMD 8.82, 95% CI 6.69-10.95, P<.001) and role function (WMD 12.23, 95% CI 2.72-21.74, P=.01) were also significantly better in the HEN group. Symptoms such as nausea/vomiting (WMD -5.43, 95% CI -8.29 to -2.57, P=.002), Fatigue (WMD -11.76, 95% CI -16.21 to -7.32, P<.001), Appetite loss (WMD -8.48, 95% CI -14.27 to -4.88, P=.001), diarrhea (WMD -3.9, 95% CI -7.37 to -0.43, P=.03), and sleep disturbance (WMD -7.64, 95% CI -12.79 to -2.5, P=.004) were significantly less in the HEN The authors concluded that HEN improved nutrition status, physical and role function, and reduced nausea/vomiting, fatigue, appetite loss, diarrhea, and sleep disturbance

compared with an oral diet in esophageal cancer patients postsurgery. Additionally, HEN did not increase adverse reactions.

Ojo (2020) published a systematic review comparing the nutritional value, physical properties, and clinical outcomes of blended enteral nutrition formula (ENF) with commercial ENF.[16] The results of the meta-analysis demonstrated that there were no significant differences ($p > 0.05$) between the blenderized ENF and the commercial ENF in relation to the fat and protein contents of the diets. However, the blenderized ENF was significantly lower ($p < 0.05$) than the commercial ENF regarding the energy content of the diets, with an overall mean difference of -29.17 Kcal/100 mL (95% CI, -51.12, -7.22) and carbohydrate content with an overall mean difference of -5.32 g/100 mL (95% CI, -7.64, -3.00). In terms of sodium, potassium, and vitamin A, there were no significant differences ($p > 0.05$) between the blenderized and commercial ENF, although significant differences ($p < 0.05$) were observed between the two diets with respect to calcium, phosphorus, magnesium, zinc, iron, and vitamin C contents. Furthermore, the blenderized ENF showed significantly higher levels ($p < 0.05$) of viscosity and osmolality than the commercial ENF. The authors conclude that there is significant variability in the nutritional value of blenderized ENF compared with commercial ENF. The nutritional values of the blenderized ENF do not meet the expected nutrient recommended levels compared with commercial ENF. Further studies are needed to elucidate the nutritional value of blenderized ENF on patients' clinical outcomes.

Randomized Trials

Amaratunga (2023) compared tube feeding with oral nutrition in patients with advanced head and neck cancer during intensive outpatient radiation therapy.[17] Patients (N = 26) with Stage III and IV head and neck cancers were stratified by site (nasopharynx vs. all other tumors, including recurrent nasopharynx) and randomized to receive oral or tube feeding during radiation therapy. Patients were counseled to maintain similar caloric and protein intake (40 kcal/kg and 1g protein per kg body weight, respectively). The tube-fed group maintained higher caloric and protein intakes (35 to 42 kcal/kg, 1.2 to 1.6 gm protein per kilogram) than the oral fed group (15 to 34 kcal/kg, 0.3 to 1.3 gm protein per kilogram). No differences in body weights were observed between the tube-fed (means = 3.8%) and the oral-fed (means = 3.3%) patients with nasopharyngeal carcinoma. Patients with oropharyngeal and recurrent nasopharyngeal carcinoma had significantly less weight loss with tube feeding (means = 0.2%) than with oral feeding (means = -7.3%; $p = .005$); The authors conclude that tube feeding is recommended during radiation therapy in patients with head and neck cancers.

Grooten (2017) reported the results of a multicenter, open-label RCT called the Maternal and Offspring outcomes after Treatment of HyperEmesis by Refeeding (MOTHER) trial to evaluate if early enteral tube feeding in addition to standard care improved birth weight.[18] Patients (N=116) hospitalized for hyperemesis gravidarum (HG) between 5 and 20 wk of gestation were randomly allocated to enteral tube feeding for ≥7 d in addition to standard care with intravenous rehydration and antiemetic treatment (N = 59) or to standard care alone (N=57). Women were encouraged to continue tube feeding at home. The mean ± SD birth weight was 3160 ± 770 g in the enteral tube feeding group compared with 3200 ± 680 g in the standard care group (mean difference: -40 g, 95% CI: -230, 310 g). Secondary outcomes, including maternal weight gain, duration of hospital stay, readmission rate, nausea, and vomiting symptoms, decrease in quality of life, psychological distress, prematurity, and small-for-gestational-age, also were comparable. Of the women allocated to enteral tube feeding, 28 (47%) were treated according to protocol. Enteral tube feeding was discontinued within 7 d of

placement in the remaining women, primarily because of its adverse effects (34%). The authors concluded that in women with HG, early enteral tube feeding does not improve birth weight or secondary outcomes. Additionally, many women discontinued tube feeding because of discomfort, suggesting that it is poorly tolerated as an early routine treatment of HG. This trial (www.trialregister.nl as NTR4197).

Section Summary

There is sufficient evidence and evidence-based guidelines supporting the benefits of home enteral nutrition support in certain individuals with malabsorption syndromes, failure to thrive, who are malnourished or high risk of malnutrition, permanent non function of the gastro-intestinal tract, or those with neuromuscular interference with gastrointestinal function such as inability to swallow or high risk of aspiration.

EXOCRINE PANCREATIC INSUFFICIENY (EPI)

Stevens (2018) published a prospective, single-arm, multicenter, open-label study (ASSURE) trial to evaluate the safety, tolerability and improvement of fatty acids (FA) in red blood cells (RBC) membranes with an in-line digestive cartridge (RELiZORB®) during enteral nutrition (EN) feedings in patients (n=36) with cystic fibrosis (CF).[19] The primary outcome measured the change in the omega-3 index, which is a measure of the percentage of total DHA (docosahexaenoic acid) plus EPA (eicosapentaenoic acid) relative to the total fatty acid (FA) composition present in RBC membranes. Secondary efficacy outcomes included changes in plasma and erythrocyte membrane composition (%) of total EPA, total DHA, and omega-6 to omega-3 as well as plasma concentrations of total DHA+EPA. Changes in weight gain and standardized body weight and body mass index (BMI) were also examined. There were not any adverse events related to RELiZORB® use. Fat absorption increased significantly from a baseline value of 4.4%, to 8.4% at 60 days and 9.4% at 90 days ($p<0.001$ for each increase from baseline to 60 and 90 days). The secondary efficacy outcomes changed significantly from baseline to each post-baseline visit. Body mass index (BMI) did not change significantly over the course of the study period. The author concluded that RELiZORB® use was found to be safe, well tolerated, and resulted in increased levels of Fas in RBCs and plasma. Limitations included small sample size, lack of long-term followup and open label study design.

Freedman (2017) conducted a multicenter, randomized, double-blind, crossover trial to evaluate the safety, tolerability, and fat absorption of an in-line digestive cartridge (RELiZORB) that hydrolyzes fat in enteral formula provided to patients with cystic fibrosis (CF).[20] Subjects (N = 33) had a diagnosis of CF with a history of exocrine pancreatic insufficiency (EPI) and received enteral nutrition at least four times a week through a feeding tube, used pancreatic enzyme replacement therapy (PERT), and a stable health status. All subjects received standard enteral formula (Peptamen 1.5) for seven days. Subjects were then randomized into a group receiving digestive cartridges and the second group had placebo/sham cartridges with cross over after seven-day washout. For the third part of the study, all subjects received impact peptide formula (high fat), overnight with RELiZORB® digestive cartridge for seven days. The outcomes measured changes in plasma fatty acid concentrations of docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) for 24 hours along with the safety and tolerability of the cartridge. The total and peak concentration of DHA+EPA were significantly higher with digestive cartridge use ($p<0.001$). Adverse effects such as such as abdominal pain, bloating, constipation, and diarrhea were lower with digestive cartridge use. Limitations of the include small sample size methodology associated with measurement of fat absorption and lack of

long-term data for safety. Larger RCTs with long-term follow-up are needed to further support the use of RELiZORB® cartridges in patients with CF on enteral feeding.

Section Summary

There is evidence that supports the use of digestive enzyme cartridges (eg., RELiZORB®) in patients with CF for the treatment of EPI when use of oral enzymes (PERT) fails. RELiZORB® has been approved by the FDA for use in patients (≥ 5 years old). There is insufficient evidence to support the use of RELiZORB® in patients with EPI from other causes (e.g., chronic pancreatitis, pancreatic cancer, pancreatic duct obstruction, gastrectomy, small bowel resection, short bowel syndrome, celiac disease, Crohn's disease, Shwachman-Diamond syndrome and Zollinger-Ellison syndrome) who are on enteral nutrition.

PRACTICE GUIDELINE SUMMARY

American Society for Parenteral and Enteral Nutrition (ASPEN)[21, 22]

The 2009 and 2002 ASPEN Guidelines for the Use of Parenteral and Enteral

Nutrition in Adult and Pediatric Patients include the following recommendations:

- Specialized Nutrition Support (SNS) should be used in patients who cannot meet their nutrient requirements by oral intake. (Level of Evidence B)
- When SNS is required, EN should generally be used in preference to PN. (Level of Evidence B)
- When SNS is indicated, PN should be used when the gastrointestinal tract is not functional or cannot be accessed and in patients who cannot be adequately nourished by oral diets or EN.
- SNS should be initiated in patients with inadequate oral intake for 7 to 14 days, or in those patients in whom inadequate oral intake is expected over a 7- to 14-day period.
- SNS should be used in patients who cannot meet their nutrient requirements by oral intake and who are able to receive therapy outside of an acute care setting. (B)
- When Home SNS is required, HEN is the preferred route of administration when feasible. (B)

National Institute for Health and Care Excellence (NICE) guidelines: Nutrition support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition[23]

Section 1.3: Indications for nutrition support in hospital and the community

1.3.1 Nutrition support should be considered in people who are malnourished, as defined by any of the following:

- a BMI of less than 18.5 kg/m2
- unintentional weight loss greater than 10% within the last 3 to 6 months
- a BMI of less than 20 kg/m2 and unintentional weight loss greater than 5% within the last 3 to 6 months.

1.3.2 Nutrition support should be considered in people at risk of malnutrition who, as defined by any of the following:

- have eaten little or nothing for more than 5 days and/or are likely to eat little or nothing for the next 5 days or longer.
- have a poor absorptive capacity, and/or have high nutrient losses and/or have increased nutritional needs from causes such as catabolism.

Section 1.7:

1.7.1: Healthcare professionals should consider enteral tube feeding in people who are malnourished or at risk of malnutrition, as defined in recommendations 1.3.1 and 1.3.2, respectively, and have: inadequate or unsafe oral intake and a functional, accessible gastrointestinal tract.

The Cystic Fibrosis Foundation

Enteral tube feeding for individuals with cystic fibrosis: Cystic Fibrosis Foundation evidence-informed guidelines include the following: [24]

- The CF Foundation recommends enteral tube feeding as a means to improve age-dependent anthropometrics in individuals with CF that are unable to consume adequate calories and protein to meet growth/weight maintenance goals, despite appropriate evaluation and intervention by a multidisciplinary team.
- The CF Foundation recommends naso-enteral tube feeding in individuals with CF who require short-term (less than 3 months) nutritional repletion.
- The CF Foundation recommends that individuals with CF who are intolerant of gastric feeding receive jejunal feeding.
- The CF Foundation recommends the use of supplemental enteral nutrition for pregnant or lactating women with CF who are unable to consume adequate calories and protein to meet nutritional goals despite appropriate evaluation and intervention by a multidisciplinary team.
- The CF Foundation does not recommend for or against the use of a specific type of formula (polymeric, semi-elemental, elemental) for enteral tube feeding in individuals with CF.
- The CF Foundation does not recommend for or against a specific method of providing pancreatic enzyme therapy during enteral tube feeding in individuals with CF.

American College of Medical Genetics and Genomics (ACMG) and Genetic Metabolic Dietician's International (GMDI)

The Medical and Dietary Guidelines for the Treatment of PKU state:

- Medical foods should be consumed throughout the day and divided into at least three servings because more frequent consumption is associated with better phenylalanine (PHE) tolerance and improved plasma PHE concentrations.
- Any combination of therapies (medical foods, sapropterin, large amino acids, etc) that improve a patient's blood PHE levels is appropriate and should be individualized.
- Large amino acids may be used in adults who are not in good metabolic control and do not adhere to other treatment options.

SUMMARY

There is enough evidence to show that home enteral nutrition therapy can provide sufficient nutrients to maintain weight and strength relative to the patients overall health status; and when the patient has full or partial non-function or disease of the structures that normally permit food to reach the small bowel; or a disease that impairs digestion and/or absorption of an oral diet, directly or indirectly, by the small bowel; or are at risk of malnutrition such as in failure to thrive. Therefore, enteral nutrition and supplies (syringe or gravity system and tubing) to deliver enteral nutrition in the home setting maybe considered medically necessary when policy criteria are met.

Enteral nutrition and the supplies (syringe or gravity system and tubing) have not been shown to improve health outcomes when used for conditions other than those in Criterion I. Therefore, enteral nutrition and the supplies (syringe or gravity system and tubing) required to deliver enteral nutrition are considered not medically necessary when policy criteria are not met.

In some patients, a pump is required to deliver enteral nutrition due to side effects (i.e. blood glucose fluctuations, dumping syndrome, circulatory overload) or the patient requires a continuous infusion at a rate less than 100 ml/hour. Therefore, an infusion pump to deliver enteral nutrition in the home setting may be considered medically necessary when policy criteria are met.

An infusion pump to deliver enteral nutrition is not necessary if the patient can tolerate syringe or gravity enteral feeding or the infusion rate is higher than 100ml/hour. Therefore, an infusion pump is considered not medically necessary when policy criteria are not met.

Patients with Exocrine Pancreatic Insufficiency (EPI) due to cystic fibrosis require enzyme additives to be able to digest the enteral formula. Therefore, enteral in-line digestive enzyme cartridges (e.g., RELiZORB®) may be considered medically necessary for patients ≥ 5 years old with EPI due to cystic fibrosis who are on enteral feeding in the home setting.

Enteral in-line digestive enzyme cartridges for treating Exocrine Pancreatic Insufficiency (EPI) have not been shown to be necessary other than in patients with cystic fibrosis. Therefore, enteral in-line digestive enzyme cartridges are considered not medically necessary for patients on enteral feeding who do not have EPI due to cystic fibrosis.

Enteral nutrition therapy in the home setting may be necessary for longer than six months in some cases. Continuation of enteral nutrition and supplies may be considered medically necessary when policy criteria are met.

Continuation of enteral nutrition and supplies in the home setting has not been shown to improve health outcomes when policy criteria are not met and therefore is not medically necessary.

Specialized nutrition formula (including specialty infant formula) for supplementation or dietary replacement is standard of medical care for inborn errors of metabolism. Therefore, specialized medical foods are considered medically necessary for patients diagnosed with inborn errors of metabolism (e.g., PKU or glycogen storage diseases).

Specialized nutrition formula (including specialty infant formula) for supplementation or dietary replacement has not been shown to improve health outcomes when inborn errors of metabolism are not present. Therefore, specialized nutrition formula is considered not medically necessary when policy criteria are not met.

Food products that are considered non-medical (e.g., vitamins, minerals, electrolytes, gluten free products, high protein, supplements for weight loss or weight gain, supplements to treat mild or moderate food allergies or intolerances) are considered not medically necessary.

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CODES

Codes	Number	Description
CPT	None	
HCPCS	A9152	Single vitamin/mineral/trace element, oral, per dose, not otherwise specified
	A9153	Multiple vitamins, with or without minerals and trace elements, oral, per dose, not otherwise specified
	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

Codes	Number	Description
	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
	B9002	Enteral nutrition infusion pump, any type
	B9998	NOC for enteral supplies
	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
	B4148	Enteral feeding supply kit; elastomeric control fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape
	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

Codes	Number	Description
	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
	S9432	Medical foods for non-inborn errors of metabolism
	S9433	Medical food nutritionally complete, administered orally, providing 100% of nutritional intake
	S9434	Modified solid food supplements for inborn errors of metabolism
	S9435	Medical foods for inborn errors of metabolism

Date of Origin: *June 2023*