Enteral Nutrition Therapy and Oral Formula

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NOTICE: This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations, or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and be updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

DESCRIPTION

Enteral nutrition is indicated in order to maintain optimal health status for individuals with diseases or structural defects of the gastrointestinal (GI) tract that interfere with transport, digestion, or absorption of nutrients. Such conditions may include anatomic obstructions due to cancer, motility disorders such as gastroparesis, or metabolic absorptive disorders such as phenylketonuria (PKU).

The most optimal route of enteral intake is swallowing by mouth. In conditions where this is not possible, a tube may be placed to facilitate transport of nutrition to the digestive/absorptive sites of the GI tract. Tube placement and types are governed by individual needs; the least invasive approach being placement of a nasogastric (NG) tube. Enteral tubes may also be placed percutaneously through an abdominal approach

(gastrostomy, or jejunostomy tubes); this is most appropriate for long-term needs due to the reduced risk of aspiration and reflux.

The term Total Enteral Nutrition (TEN) infers that the individual is receiving more than 50% of their daily caloric intake via enteral nutrition products. If fewer than 50% of daily calories are supplied by enteral nutrition products, they are considered supplemental.

Note: *For the purposes of this policy, the term "enteral nutrition therapy" will refer to nutrients administered into the alimentary canal through a tube, such as percutaneous endoscopic gastrostomy (PEG) tube, jejunostomy (J-tube) tube, percutaneous endoscopic jejunostomy (PEJ) tube, nasogastric (NG) tube*. R*efer to the member's benefit document to determine coverage.*

Specialized Formula
"Specialized formula" means a nutritional formula for children up to age eight that is **exempt** from the general requirements for nutritional labeling under the statutory and regulatory guidelines of the Federal Food and Drug Administration (FDA) and is intended for use solely under medical supervision in the dietary management of specific diseases. The use of enteral nutrition preparations and specialized formula is frequently given orally for conditions that include allergies, malnutrition, gastrointestinal reflux, eating disorders, and weight loss. Wellmark contracts (r*efer to the member's benefit document to determine coverage)* exclude the use of enteral nutrition preparations when given orally including specialized and over the counter formula when given orally (for permanent in-born errors of metabolism, see medical policy 10.01.15 Medical Foods and Specialized Formula for Inborn Errors of Metabolism).

Digestive Enzyme Cartilage for Enteral Feeding Via Tube with Cystic Fibrosis-Related Pancreatic Insufficiency
Pancreatic insufficiency is characterized by the inability of the pancreas to produce or deliver sufficient enzymes required to break down and absorb nutrients. The most common cause of pancreatic insufficiency is cystic fibrosis (CF). Individuals with pancreatic insufficiency experience an insufficient release of amylase, protease, and lipase into the duodenum of the small intestine. This results in inadequate digestion of carbohydrates, proteins, and fats. Up to 20% of children and adolescents with cystic fibrosis (CF) use tube feeding and the overall prevalence of cystic fibrosis is estimated to be 30,000 in the United States and > 70,000 worldwide.

Individuals with pancreatic insufficiency most commonly present with gastrointestinal symptoms that include gas, bloating, dyspepsia (indigestion), abdominal pain, diarrhea, nausea, weight loss, steatorrhea (abnormally high fat content in feces), and other biochemical changes related to lipid malabsorption and maldigestion. This can lead to an impaired quality of life, changes in bone density, increased risk of mortality, and other sequalae of nutritional deficiencies.

The primary pharmacologic treatment for pancreatic insufficiency that cannot be controlled by dietary and lifestyle interventions alone is pancreatic enzyme replacement therapy (PERT). PERT generally contains a mixture of enzymes, including amylase, lipase, and protease, and is most commonly administered orally in conjunction with food. However, some patients with pancreatic insufficiency may also receive enteral nutrition. Enteral nutrition is provided for a variety of indications in patients who are unable to obtain sufficient nutrition through conventional feeding. It involves administration of a specialized formula containing a mixture of carbohydrates, lipids, proteins, vitamins, and minerals to the stomach or small intestine via a feeding tube. Delivery can be via a nasogastric tube or a surgically implanted tube (e.g., gastrostomy or jejunostomy tube). Individuals with pancreatic insufficiency who receive enteral nutrition typically receive PERT orally, although some may mix PERT with enteral formula or utilize novel in-line enzyme cartridges (i.e., Relizorb).

Currently, Relizorb is the only in-line immobilized lipase-coated cartridge marketed for hydrolysis of lipase in individuals receiving enteral nutrition. Relizorb was developed to address challenges of timing and route of lipase delivery associated with pancreatic enzyme replacement therapy (PERT) by providing continuous in-line enzyme replacement therapy, particularly for individuals receiving longer-duration or continuous feeds.

Review of Evidence

In 2021 Sathe et. al. evaluated the effectiveness of in-line immobilized lipase cartridge (RELiZORB) in enterally fed patients with cystic fibrosis (CF). Baseline anthropometric data were obtained, and subsequent measurements of height, weight, and body mass index (BMI) were collected at 6 and 12 months. Inclusion criteria were met by 100 patients (age = 0--45 years). Over 12 months of use in patients >2 years of age (n = 93), there were significant improvements seen in height and weight *z*-scores with improvement trend seen in BMI. The frequency of achieving the 50th percentile increased steadily for weight and BMI from baseline to 12 months but not for height. The authors concluded, the evaluation of this program to assist patient access to immobilized lipase cartridge (ILC) (RELiZORB) demonstrated that better growth is possible over standard of care. The association of ILC use with significantly improved anthropometric parameters over a 12-month period in people with CF demonstrating the effectiveness of ILC as rationale enzyme therapy during enteral feedings.

In 2018, Stevens et. al. conducted the Absorption and Safety with Sustained use of RELiZORB Evaluation (ASSURE) Study in patients with cystic fibrosis (CF) and exocrine pancreatic insufficiency (EPI) receiving enteral feeding which was designed to evaluate safety, tolerability, and efficacy of sustained use of RELiZORB over a 90-day using enteral nutrition (EN) as part of their regular nutrition regimen. The ASSURE trial was a prospective, single-arm, multicenter, open-label study (ClinicalTrials.gov Identifier: NCT02750501). The study was conducted between July 20, 2016, and March 30, 2017. Patients were eligible for the study if they were ≥4 years of age, had a confirmed diagnosis of CF, a documented history of EPI, were taking enteral formula a

minimum of 4 times per week, were using PERT, and were consuming an unrestricted fat diet. The primary endpoint was change over time in RBC uptake of docosahexaenoic acid (DHA)+ eicosapentaenoic acid (EPA). Gastrointestinal symptoms were collected to evaluate safety and tolerability. Several clinical and anthropometric parameters were also assessed throughout the study. A total of 36 subjects completed the study with a mean age of 13.8 years, body mass index of 17.7 and 6.2 years mean use of overnight EN. Fat absorption significantly improved as shown by increased RBC levels of DHA+EPA, improved ω-6/ω-3 ratio, and increased plasma levels of DHA+EPA. RELiZORB use was not associated with any unanticipated adverse events. The authors concluded that RELiZORB use was found to be safe, well tolerated, and resulted in increased levels of fatty acids (FAs) in red blood cells and plasma. This is the first prospective study to show enteral nutrition (EN) can improve fatty acid abnormalities in cystic fibrosis (CF). Because improvements in omega-3 levels have been shown to help pulmonary and inflammatory status as well as anthropometric parameters in CF, RELiZORB may have important long-term therapeutic benefits in patients with CF.

In a published randomized study (2017 Freedman et.al.) involving 33 patients with cystic fibrosis (CF) and exocrine pancreatic insufficiency (EPI) receiving enteral nutrition (EN), the short-term use of RELiZORB was safe, well-tolerated, and significantly increased plasma omega-3 FA levels, systemic markers of fat absorption. Because this study involved only a single treatment with RELiZORB, a study to evaluate its longer-term use was needed (2018 Stevens above).

Summary of Evidence
Based on review of the peer reviewed medical literature results from the ASSURE trial a prospective, single-arm, multicenter, open-label study (ClinicalTrials.gov Identifier: NCT02750501) showed that Relizorb can improve the absorption of omega-3 fatty acids in tube-fed cystic fibrosis (CF) patients receiving enteral nutrition (EN) with exocrine pancreatic insufficiency (EPI) and failure of pancreatic enzyme replacement therapy (PERT). Other studies have shown the therapy can ease digestion-related symptoms. Results from a year-long observational study showed that using Relizorb led to significant improvements in weight and height among cystic fibrosis patients with exocrine pancreatic insufficiency (EPI) who require tube feedings. Based on the evidence Relizorb is indicated for use in individuals ages 5 years and older with cystic fibrosis (CF) for the treatment of pancreatic insufficiency when there is documented failure of pancreatic enzyme replacement therapy (PERT), as the evidence has demonstrated effectiveness in this complex population of patients who do not have viable alternatives. The evidence is sufficient to determine the technology results in improve net health outcomes.

Digestive Enzyme Cartridge for Enteral Feeding Via Tube for Other Conditions
Based on the review of the peer reviewed medical literature the evidence is currently limited regarding the use of Relizorb for the treatment of pancreatic insufficiency in individuals with complex disorders including but not limited to the following: chronic pancreatitis, pancreatic cancer, gastric/pancreatic surgery, and short bowel syndrome who

require enteral tube feedings with documented failure of pancreatic enzyme replacement therapy (PERT). Further randomized controlled trials are needed to determine how Relizorb is best administered and optimized in these individuals compared to other methods of administration of PERT. The evidence is insufficient to determine the technology results in improved net health outcomes.

Regulatory Status

Relizorb™ (Alcresta Therapeutics Inc.) received De Novo device classification on November 20, 2015 (DEN150001). It was cleared for marketing through the Food and Drug Administration (FDA) 510(k) Premarket Notification process on June 30, 2016 (K161247) with no changes in indications, warnings or instructions for use, device design, device technology, or device functionality. A subsequent 510(k) clearance was issued on July 12, 2017 (K163057), expanding the indications to include pediatric patients. On December 4, 2019, a clearance was issued for a Relizorb device with minor device and functional differences (K191379). The indications for use were unchanged.

Device	510(k) Number or PMA Number	Notice Date	Indication
Relizorb (Alcresta Therapeutics Inc.)	K163057	July 12, 2017	Relizorb is indicated for use in pediatric patients (age ≥5 years) and adult patients to hydrolyze fats in enteral formula.
Relizorb (Alcresta Therapeutics Inc.)	K161247	June 30, 2016	Relizorb is indicated for use in adults to hydrolyze fats in enteral formula.
Relizorb (Alcresta Therapeutics Inc.)	DEN150001	November 20, 2015	Relizorb is indicated for use in adults to hydrolyze fats in enteral formula.

Relizorb consists of a clear cylindrical plastic cartridge with an inlet port and outlet port that connects in-line with enteral feeding pump tubing sets. The internal surface of the cartridge is coated with small beads that are covalently bonded to lipase. The lipase-coupled beads are retained within the cartridge, and the enteral formula containing hydrolyzed fats passes out of the cartridge and into the body. A single Relizorb cartridge is designed for up to 500 milliliters (mL) of enteral formula, and 2 Relizorb cartridges can be connected in tandem for feedings of up to 1000 mL. Cartridges are single use.

PRIOR APPROVAL

Not applicable.

POLICY

See Related Medical Policy:

- ***10.01.15 Medical Foods and Specialized Formula for Inborn Errors of Metabolism***

Refer to the member's benefit document to determine coverage.

Enteral Nutrition Therapy Via Tube
Benefits are available for enteral nutrition therapy **ONLY** when the prescribed feeding solution is issued or authorized by a licensed healthcare practitioner and is administered through a feeding tube (e.g., nasogastric, gastrostomy, jejunostomy).

Note: *Blenderized baby food, food additives, and over the counter food administered with an enteral nutrition feeding system is considered a* ***non-covered benefit and NOT eligible for coverage****, see also medical policy 10.01.15 Medical Foods and Specialized Formula for Inborn Errors of Metabolism.*

Digestive Enzyme Cartridge
A digestive enzyme cartridge (e.g., Relizorb^{TM}) for use in conjunction with enteral nutritional therapy through a feeding tube (e.g., nasogastric, gastrostomy, jejunostomy) may be considered **medically necessary** for the treatment of pancreatic insufficiency due to cystic fibrosis (CF) for individuals $\geq$ 5 years of age when there is documented failure of pancreatic enzyme replacement therapy. (PERT). *(See Policy Guidelines below)*

A digestive enzyme cartridge (e.g., Relizorb^{TM}) not meeting the above criteria and for **ALL** other indications is considered **investigational,** because the evidence is insufficient in determining the technology improves net health outcomes**.**

Oral Enteral Formula Nutrition Therapy
Oral enteral formula nutrition therapy is considered a **non-covered benefit**, **except** for permanent inborn errors of metabolism that interfere with the metabolism of specific nutrients when the product is a medical food for oral feeding, *see medical policy 10.01.15 Medical Foods and Specialized Formula for Inborn Errors of Metabolism.*
Specialized formulas to include regular store-bought formula, including but not limited to the following below, and banked human breast milk regardless of whether these are prescribed by or authorized by a licensed healthcare practitioner when given orally for

enteral nutrition therapy given to replace intolerable foods, lactose intolerance, to supplement a deficient diet or to provide alternative nutrition in the presence of the following conditions allergies, gastrointestinal disorders, hypoglycemia and obesity are considered a **non-covered benefit and not eligible for coverage**:

- Alimentum®
- Elecare®
- Mongen®
- Neocate®
- Neosure®
- Nutramigen®
- Portagen®
- Progestimil®

Policy Guidelines

Pancreatic Insufficiency:
Pancreatic insufficiency is characterized by the inability of the pancreas to produce or deliver sufficient enzymes required to break down and absorb nutrients. The most common causes of pancreatic insufficiency are cystic fibrosis and chronic pancreatitis. Some patients with pancreatic insufficiency may also receive enteral nutrition through feeding tube to supplement dietary needs.

Patients with pancreatic insufficiency most commonly present with gastrointestinal symptoms that may include the following:

- Gas
- Bloating
- Dyspepsia (indigestion)
- Abdominal pain
- Diarrhea
- Nausea
- Weight loss
- Steatorrhea (abnormally high fat content in feces)
- Other biochemical changes related to malabsorption and maldigestion.

Pancreatic Enzyme Replacement Therapy (PERT)
Pancreatic enzyme replacement therapy (PERT) generally contains a mixture of enzyme, including amylase, lipase, and protease.

When the individual is receiving enteral nutrition through feeding tube (nasogastric, gastrostomy or jejunostomy) and the individual has pancreatic insufficiency PERT may be mixed with the enteral tube feeding formula.

FDA Approved Oral Pancreatic Enzyme Preparations

- Creon (oral delayed release capsule)

- Zenpep (oral delayed release capsule)
- Pancreaze (oral delayed release capsule)
- Ultresa (oral delayed release capsule)
- Viokace (non-enteric coated immediate release tablet)
- Pertyze (oral delayed release capsule with bicarbonate-buffered enteric-coated microspheres)

Pancreatic Enzyme Replacement Therapy (PERT) Response or Failure
Several factors determine the response to treatment including degree of residual pancreatic function, anatomy, and the size and fat content of meals. Differences in the remaining pancreatic secretion and gastric production of lipase therapy tailored to the individual patient, based on severity of symptoms and response to treatment. The response to pancreatic enzyme replacement therapy (PERT) should be gauged by improvement in symptoms including the following:

- Stool consistency
- Loss of visible fat or oily droplets in the stool
- Weight gain

Repeating fecal fat measurement can help gauge response. Of note, fecal elastase-1 measures will not be affected by PERT and should not be used to guide dose adjustments. Fat soluble vitamins should be periodically checked to ensure adequate supplementation.

The most common reason for failure is inadequate dose. Either the patient requires more enzyme, or the timing of delivery is off, resulting in inadequate mixing of enzymes with chyme in the duodenum. In patients taking the PERT correctly, the first step would be to double the dose of enzyme. The addition of acid suppression with proton pump inhibitors (PPI) or histamine 2 blockers (H2B) is a reasonable next step in patients with suboptimal response. On occasion, changing formulations may improve symptoms if dosage increases and acid suppression fails to improve symptoms.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- B4100 Food thickener, administered orally, per oz
- B4102 Enteral formula, for adults, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
- B4103 Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
- B4104 Additive for enteral formula (e.g., fiber)
- B4105 In-line cartridge containing digestive enzyme (s) for enteral feeding, each

- B4149 Enteral formula, manufactured blenderized natural foods with intact nutrients, includes proteins, fats, carbohydrates, vitamins, and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- B4150 Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins, and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- B4152 Enteral formula, nutritionally complete, calorically dense (equal to or greater than 1.5 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins, and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- B4153 Enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), includes fats, carbohydrates, vitamins, and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- B4154 Enteral formula, nutritionally complete, for special metabolic needs, excludes inherited disease of metabolism, includes altered composition of proteins, fats, carbohydrates, vitamins and/or minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- B4155 Enteral formula, nutritionally incomplete/modular nutrients, includes specific nutrients, carbohydrates (e.g., glucose polymers), proteins/amino acids (e.g., glutamine, arginine), fat (e.g., medium chain triglycerides) or combination, administered through an enteral feeding tube, 100 calories = 1 unit
- B4157 Enteral formula, nutritionally complete, for special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins, and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- B4158 Enteral formula, for pediatrics, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins, and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit
- B4159 Enteral formula, for pediatrics, nutritionally complete soy based with intact nutrients, includes proteins, fats, carbohydrates, vitamins, and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit
- B4160 Enteral formula, for pediatrics, nutritionally complete calorically dense (equal to or greater than 0.7 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins, and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- B4161 Enteral formula, for pediatrics, hydrolyzed/amino acids, and peptide chain proteins, includes fats, carbohydrates, vitamins, and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- B4162 Enteral formula, for pediatrics, special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins, and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit

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POLICY HISTORY

Date	Reason	Action
April 2022	Annual Review	Policy Revised
April 2021	Annual Review	Policy Revised
April 2020	Annual Review	Policy Revised
April 2019	Annual Review	Policy Revised
June 2018	Interim Review	Policy Revised
April 2018	Annual Review	Policy Renewed
April 2017	Annual Review	Policy Renewed
April 2016	Annual Review	Policy Resurrected
August 2013	Annual Review	Policy Retired
September 2012	Annual Review	Policy Renewed
September 2011	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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