Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCNUT001B.0425	**NUTRITIONAL PRODUCTS MEDICAL NUTRITION**
Effective Date: 6/1/2025	**Review/Revised Date**: 08/99, 08/0, 09/01, 05/02, 12/03, 12/04, 12/05, 06/07, 10/08, 10/09, 10/10, 12/11, 04/12, 08/12 , 08/13 , 10/13, 08/14, 08/15, 07/16, 07/17, 08/18, 07/19, 07/20, 10/20, 03/21, 03/22, 02/23, 03/24, 01/25, 03/25 (TVNT)
Original Effective Date: 09/98	**P&T Committee Meeting Date**: 08/00, 08/00, 09/01, 05/02, 08/02, 12/03, 12/04, 12/05, 06/07, 10/08, 10/09, 10/10, 12/11, 04/12, 08/12, 08/13, 08/14, 08/15, 08/16, 08/17, 08/18, 08/19, 08/20, 12/20, 04/21, 04/22, 04/23, 04/24, 02/25, 04/25
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:
Medicare Part B – Local Coverage Determination L38955

POLICY CRITERIA:

COVERED USES:
All Medically-Accepted Indications

REQUIRED MEDICAL INFORMATION:

For coverage of enteral nutrition, member must have a diagnosis listed in Table 1, or must meet the following criteria:

1. Documentation of a medical condition that prevents food from reaching the digestive tract (such as head and neck cancer with reconstructive surgery, central nervous system disease that interferes with neuromuscular mechanisms of ingestion) or disease of the small bowel that impairs digestion and/or absorption of an oral diet (such as inflammatory bowel disease, surgical resection of small bowel, cystic fibrosis, chronic pancreatitis, advanced liver disease)
   AND
2. Documentation that the condition is of long and indefinite duration as deemed by the judgment of the attending provider or substantiated in the medical records
   AND
3. Adequate nutrition must not be possible by dietary adjustment and/or oral supplements
   AND
4. For in-line digestive enzyme cartridge requests, must have a diagnosis of exocrine pancreatic insufficiency (EPI)

Reauthorization:

The assessment and treatment plan must demonstrate that adequate nutrition (at least 75% of required intake) is not possible by dietary adjustment and/or oral supplementation.

EXCLUSION CRITERIA:
- Food thickeners, baby food, and other regular grocery products that can be blenderized and used with the enteral system
- Electrolyte-containing fluids
- Self-blenderized formulas
- Oral administration of enteral nutrition products

AGE RESTRICTIONS: N/A

PRESCRIBER RESTRICTIONS: N/A

COVERAGE DURATION:
Initial authorization and reauthorization will be approved for up to one year.

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:
Enteral nutrition therapy is the provision of nutrition directly into either the stomach or small intestine through a feeding tube. The enteral nutrition benefit will include all related supplies, equipment and nutrients. Skilled assessment of nutritional status will be done at a frequency consistent with the member's diagnosis and general nutritional condition.

POSITION STATEMENT:
- Enteral nutrition therapy is a covered benefit when it is determined to be medically necessary to prevent or treat malnutrition and nutritional needs which cannot be met by oral intake alone. Enteral nutrition will be covered under the

member's medical benefit (for Medicare members, this is their Part B benefit). Medicare considers enteral nutrition as a prosthetic device, which requires that a member must have a permanently inoperative internal body organ or function thereof. Therefore, enteral therapy is not normally covered under Part B in situations involving temporary impairments. The medical policy and criteria are developed based on Medicare and ASPEN guidelines.

- Medicare requires that a beneficiary has a permanent impairment for coverage of enteral nutrition under the prosthetic device benefit, as outlined in the Medicare Benefit Policy Manual. However, this does not require a determination that there is no possibility that the beneficiary's condition may improve sometime in the future. If the medical record, including the judgment of the treating practitioner, indicates that the impairment will be of long and indefinite duration, the test of permanence is considered met.
- For Medicare members, enteral and parenteral nutritional therapies are not covered under Part B in situations involving temporary impairments. Orally administered enteral nutrition products, related supplies and equipment will be denied non-covered, no benefit.
- Some patients require supplementation of their daily protein and caloric intake. Nutritional supplements are often given as a medicine between meals to boost protein-caloric intake or the mainstay of a daily nutritional plan. Nutritional supplementation is not covered under Medicare Part B.
- As mandated by Medicare, dispensing of nutritional therapy is limited to a one-month supply at any one time.

Relizorb™

- Exocrine pancreatic insufficiency (EPI) occurs in 85-95% of patients with cystic fibrosis. This leads to fat malabsorption and negatively impacts growth in children and BMI in adults, both of which are important in maintenance of pulmonary function. In 2008, The Cystic Fibrosis Foundation Subcommittee on Growth and Nutrition made a recommendation for using pancreatic enzyme replacement therapy (PERT) for the treatment of cystic fibrosis-related pancreatic insufficiency in both children and adults18. Approximately 44% of patients with cystic fibrosis are unable to meet their nutritional requirements orally and require enteral nutrition19, and while PERT is the standard of care in patients with pancreatic insufficiency, there is a lack of clinical trial data on its use in patients using enteral nutrition. Additionally, no standardized recommendations have been published regarding the use of pancreatic enzyme therapy with enteral feeding. The Cystic Fibrosis Foundation does not recommend for or against a specific method of providing pancreatic enzyme therapy during enteral tube feeding in individuals with cystic fibrosis20. Due to the relatively short duration of action of PERT (45 to 60 minutes), individuals typically take it orally before and after enteral feeding, and during if possible, which can be challenging for continuous

overnight enteral feeding. Others crush or dissolve pancreatic enzymes in the enteral formula, however there is no evidence of efficacy with this, and it is against most manufacturer guidelines19.

- Relizorb™ is a single-use digestive enzyme (i.e., lipase) cartridge to be used in conjunction with enteral feeding sets. Approved by the FDA in 2016, it is designed to mimic digestive enzymes normally secreted by the pancreas to break down fats in enteral formula for absorption. Relizorb™ is indicated for use in pediatric patients (ages five years and older) and adult patients to hydrolyze fats in enteral formula. In a clinical trial by Freeman, et al (N=34), patients were given either 11 days of placebo cartridges or Relizorb™ and found a significant change in omega-3 fat levels in the blood. However, this study was small in scale, did not measure clinical outcomes, and was short in duration. In 2021 a retrospective analysis evaluating the effectiveness of Relizorb™ in enterally fed patients with cystic fibrosis was published. Baseline anthropometric data were obtained, and subsequent measurements of height, weight, and body mass index (BMI) were collected at six and 12 months. Inclusion criteria were met by 100 patients (ages 0-45 years old). The data showed significant improvements in height and weight z-scores (in patients >2 years of age [n = 93]) at six months, which increased or was sustained through 12 months, and improvement trend seen in BMI21. The frequency of achieving the 50th percentile increased steadily for weight and BMI from baseline to 12 months but not for height. Although additional literature is needed to determine safety, efficacy, and place in therapy, current evidence shows that Relizorb™ may be beneficial in some patients with cystic fibrosis and exocrine pancreatic insufficiency who are unable to manage their pancreatic insufficiency with the use of pancreatic enzyme replacement therapy.

HCPCS CODES

The following table includes codes that may be eligible for coverage under this policy. This list may not be all inclusive and does not guarantee coverage. This information is for reference purposes only.

Prior Authorization Required	
HCPCS Code	**Description**
B4034	Enteral feeding supply kit; syringe fed, per day, includes but not limited to feeding/flushing syringe, administrative set tubing, dressings, tape
B4035	Enteral feeding supply kit; pump fed, per day, includes but not limited to feeding/flushing syringe, administrative set tubing, dressings, tape
B4036	Enteral feeding supply kit; gravity fed, per day, includes but not limited to feeding/flushing syringe, administrative set tubing, dressings, tape
B4104	Additive for enteral formula (e.g., fiber) – not separately payable
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 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
No Prior Authorization Required	

A5200	Percutaneous catheter/tube anchoring device, adhesive skin attachment
A9270	Non-covered item or service
B4081	Nasogastric tubing with stylet
B4082	Nasogastric tubing without stylet
B4083	Stomach tube-levine type
B4087	Gastronomy/Jejunostomy tube, standard, any material, any type, each
B4088	Gastronomy/Jejunostomy tube, low profile, any material, any type, each
B4148	Administration set
B9002	Enteral nutrition infusion pump, any type
B9998	NOC for enteral supplies
E0776	IV Pole
Not Covered	
B4100	Food thickener, administered orally, per ounce
B4102	Enteral formula, for adults, used to replace fluids and electrolytes (e.g., clear liquids) 500ml = 1 unit
B4103	Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g., clear liquids) 500ml = 1 unit
HCPCS Modifiers	
BA	Item furnished in conjunction with parenteral enteral nutrition (PEN) services
BO	Orally administered nutrition, not by feeding tube
EY	No physician or other licensed health care provider order for this item or service
GA	Waiver of liability statement issued as required by payer policy, individual case
GY	Item or service statutorily excluded or does not meet the definition of any Medicare benefit
GZ	Item or service expected to be denied as not reasonable and necessary
KX	Requirements specified in the medical policy have been met

TABLE 1

Nutrition HCPCS codes will not require Prior Authorization when billed with any of the following diagnosis codes:

ICD-10 Code	Description
C01	Malignant neoplasm of base of tongue
C02	Malignant neoplasm of other and unspecific parts of tongue
C03	Malignant neoplasm of gums
C04	Malignant neoplasms of floor of mouth
C05	Malignant neoplasm of palate
C06	Malignant neoplasm of cheek mucosa
C07	Malignant neoplasm of parotid gland
C08	Malignant neoplasm of submandibular gland

C09	Malignant neoplasm of tonsil
C10	Malignant neoplasm of oropharynx
C11	Malignant neoplasm of nasopharynx
C12	Malignant neoplasm of pyriform sinus
C13	Malignant neoplasm of hypopharynx
C14	Malignant neoplasm of pharynx
C15	Malignant neoplasm of esophagus
C16	Malignant neoplasm of stomach
C76.0	Malignant neoplasm of head, face, and neck
E70.0, E70.1	Phenylketonuria
E70.21	Tyrosinemia
E70.41	Histidinemia
E71.0	Maple syrup disease
E72.11	Homocystinuria
E72.23	Citrullinemia
E84.0-E84.9	Cystic fibrosis
G80.0-G80.9	Cerebral palsy
G12.21	Amyotrophic lateral sclerosis

REFERENCE/RESOURCES:

1. Bankhead R, Boullata J, Brantley S et al. Enteral Nutrition Practice Recommendations. JPEN J Parenter Enteral Nutr. 2009 Mar-Apr;33(2):122-67.
2. FDA 510(k) approval letter. July 12, 2017. RELiZORB. Alcresta Therapeutics, Inc. FDA website. https://www.accessdata.fda.gov/cdrh_docs/pdf16/K163057.pdf. Accessed November 3, 2020.
3. FDA Device Classification under Section 513(f)(2)(de novo) database. FDA website. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm?ID=DEN150001. Accessed November 3, 2020.
4. Freeman S, Orenstein D, Black P. et al. Increased Fat Absorption for Enteral Formula Through an In-line Digestive Cartridge in Patients with Cystic Fibrosis. J Pediatr Gastroenterol Nutr. 2017 Jul:65 (1):97-101.
5. Pancreatic Enzymes Clinical Care Guidelines. Last updated 2016. CFF website. https://www.cff.org/Care/Clinical-Care-Guidelines/Nutrition-and-GI-Clinical-Care-Guidelines/Pancreatic-Enzymes-Clinical-Care-Guidelines/. Accessed July 18, 2018.
6. Schwarzenberg SJ, Hempstead SE, McDonald CM, et al. Enteral tube feeding for individuals with cystic fibrosis: Cystic Fibrosis Foundation

evidence-informed guidelines. J Cyst Fibros. 2016; 15(6): 724 – 735. DOI: 10.1016/j.jcf.2016.08.004.

7. *Enteral nutrition L38955*. CMS.gov Centers for Medicare & Medicaid Services. (n.d.). Retrieved March 7, 2022, from https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38955
8. Enteral Nutrition – Policy Article. CMS.gov Centers for Medicare & Medicaid Services. (n.d.). Retrieved February 16, 2023, from https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=58833&ver=11&keyword=nutrition&keywordType=starts&areaId=s44&docType=NCA,NCD,MCD,6,3,5,1,F&contractOption=name&contractorName=5&sortBy=relevance&bc=1
9. Stallings VA, Stark LJ, Robinson KA, et al. Evidence-Based Practice Recommendations for Nutrition-Related Management of Children and Adults with Cystic Fibrosis and Pancreatic Insufficiency: Results of a Systematic Review, Journal of the American Dietetic Association. 2008;108(5):832-839. https://doi.org/10.1016/j.jada.2008.02.020.
10. Freedman SD. Options for Addressing Exocrine Pancreatic Insufficiency in Patients Receiving Enteral Nutrition Supplementation. Am J Manag Care. 2017;23:-S0. https://www.ajmc.com/view/options-for-addressing-exocrine-pancreatic-insufficiency-in-patients-receiving-enteral-nutrition-supplementation-article
11. Schwarzenberg SJ, Hempstead SE, McDonald CM, et. al. Enteral Tube Feeding for Individuals With Cystic Fibrosis: Cystic Fibrosis Foundation Evidence-Informed Guidelines. J Cyst Fibros. 2016. Nov;15(6):724-735.PMID: 27599607.
12. Sathe, Meghana N.∗; Patel, Dhiren†; Stone, Archie‡; First, Eric‡. Evaluation of the Effectiveness of In-line Immobilized Lipase Cartridge in Enterally Fed Patients With Cystic Fibrosis. Journal of Pediatric Gastroenterology and Nutrition 72(1):p 18-23, January 2021. | DOI: 10.1097/MPG.0000000000002984