Medical Coverage Policy | Digestive Enzyme Cartridges

EFFECTIVE DATE: 08|01|2023
POLICY LAST UPDATED: 07|31|2023

OVERVIEW

This policy describes the reimbursement for digestive enzyme cartridges (e.g. Relizorb).

RELiZORB™ (Alcresta Pharmaceuticals) is a single use digestive enzyme cartridge indicated for use in individuals to break down enteral formula. It is designed to hydrolyze fat present in the enteral formula from triglycerides into fatty acids and monoglycerides to allow for their absorption by the body. This breakdown of fats is intended to mimic the function of the enzyme lipase in individuals who do not excrete sufficient levels of pancreatic lipase.

MEDICAL CRITERIA

Medicare Advantage Plans

Digestive enzymes added to enteral formula via a cartridge device attached to the tubing used for enteral feeding (eg, Relizorb™ immobilized lipase cartridge) is considered medically necessary for chronic medical conditions. These conditions include, but are not limited to, individuals with Cystic Fibrosis, Crohn's Disease or Ulcerative Colitis with complications, and Pancreatic disorders. Refer to Coding section for details.

Commercial Products

Initial requests for digestive enzymes added to enteral formula via a cartridge device attached to the tubing used for enteral feeding (eg, Relizorb™ immobilized lipase cartridge) may be approved if the following criteria are met:

1. Individual has a diagnosis of cystic fibrosis; AND individual has a confirmed history of exocrine pancreatic insufficiency; AND
2. Individual requires enteral tube nutrition for continuous durations of 6 hours or more, and using Relizorb to hydrolyze fats in enteral formula; AND
3. Individual has continued malabsorption of fats (as evidenced by insufficient weight gain or weight loss) from enteral formula, despite optimizing therapy with pancreatic enzyme replacement therapy (PERT) tablets or capsules administered orally or via feeding tube (capsules only).

Continuation requests for digestive enzymes added to enteral formula via a cartridge device attached to the tubing used for enteral feeding (eg, Relizorb™ immobilized lipase cartridge) may be approved if the following criteria are met:

1. Individual has evidence of stable or increased weight from use of Relizorb; AND
2. Individual continues to require enteral tube nutrition for continuous durations of 6 hours or more.

PRIOR AUTHORIZATION

Prior authorization is not required for Medicare Advantage Plans and is recommended for Commercial Products via the online tool for participating providers. See the Related Policies section.

POLICY STATEMENT

Medicare Advantage Plans

Digestive enzymes added to enteral formula via a cartridge device attached to the tubing used for enteral feeding (eg, Relizorb™ immobilized lipase cartridge) is considered medically necessary when the criteria above is met. Refer to Coding section for details.

Commercial Products
Digestive enzymes added to enteral formula via a cartridge device attached to the tubing used for enteral feeding (eg, Relizorb™ immobilized lipase cartridge) is considered medically necessary when the criteria above is met.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, Subscriber agreement for the applicable "Medical Equipment, Medical Supplies and Prosthetic Devices" coverage.

BACKGROUND

Commercial Products
The Absorption and Safety with Sustained use of Relizorb Evaluation (ASSURE) study evaluated 36 individuals with cystic fibrosis and a mean age of 13.8 years receiving overnight enteral nutrition with an in-line digestive cartridge (Relizorb™). The results showed that fat absorption improved significantly as shown by increased red blood cell and plasma levels of docosahexaenoic acid (DHA)+ eicosapentaenoic acid (EPA). The authors stated that Relizorb was found to be safe and well tolerated and resulted in increased levels of fatty acids in red blood cells and plasma. Improvement in omega-3 plasma levels (a measure of fat absorption) has been shown to aid the pulmonary and inflammatory status in individuals with cystic fibrosis. The authors concluded that Relizorb™ may have therapeutic benefits in individuals with cystic fibrosis.

Freedman (2017) stated that patients with Exocrine Pancreatic Insufficiency (EPI) have suboptimal secretion of pancreatic digestive enzymes and experience a range of clinical symptoms related to the malabsorption of fat. In patients with EPI unable to meet their nutritional requirements, EN support is used to augment nutritional status. In addition to protein and carbohydrate, EN formulas contain fats as a calorie source, as well as vitamins and minerals to help prevent nutritional deficiencies related to malabsorption. Semi-elemental EN formulas are advantageous as they contain hydrolyzed protein, shorter chain carbohydrates, and may contain medium chain triglycerides as a fat source. However, severely pancreatic insufficient patients may be unable to absorb complex long-chain triglycerides provided by EN formulas due to insufficient pancreatic lipase; replacement pancreatic enzyme products are recommended for these patients. The author stated that currently, none of the FDA-approved pancreatic enzyme replacement therapy (PERT) products are indicated for use in patients receiving EN and administration of enzymes by mixing into EN formula is not supported by guidelines as this route is associated with risks. Relizorb is a novel in-line digestive cartridge that has been designed to address the unmet need for PERT in patients receiving EN. Relizorb efficacy and compatibility with a range of commercially available polymeric and semi-elemental formulas with varying nutrient, caloric content, and triglyceride chain lengths have been demonstrated. In most formulas, Relizorb efficiently hydrolyzed greater than 90 % of fats within the formula into absorbable FAs and monoglycerides.

CODING

Medicare Advantage Plans
The following code is covered when filed with a covered ICD-10 code below:
B4105 In-line cartridge containing digestive enzyme(s) for enteral feeding, each

Covered DX for HCPCS Code B4105 for Medicare Advantage Plans

Commercial Products
The following code is covered when the medical criteria above is met:
B4105 In-line cartridge containing digestive enzyme(s) for enteral feeding, each

RELATED POLICIES

Coding and Payment Guideline
Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations

PUBLISHED

Provider Update, April 2023, June 2023
Provider Update, April 2022

Provider Update, May 2021
Provider Update, September 2019
Provider Update, February 2019

REFERENCES

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2. Centers for Medicare and Medicaid Services, Local Coverage Determination Article, Noridian Healthcare Solutions, LLC, A58833, Enteral Nutrition.
3. Alcresta Therapeutics at http://relizorb.com/ Accessed January 10, 2023.
4. Department of Health and Human Services, Section 510k Premarket Summary Approval for Alcresta Therapeutics, Inc. for Relizorb, http://www.accessdata.fda.gov/cdrh_docs/pdf16/K163057.pdf. Accessed January 9, 2023.
5. FDA De Novo classification: RELiZORB™™. Available at: https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN150001.pdf >. accessed September 10, 2020.
6. Freedman S, Orenstein D, Black P, et al. 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. PMID: 28471913. https://pubmed.ncbi.nlm.nih.gov/28471913/.
7. Stevens, J, Wyatt C, Brown P, et al. Absorption and safety with sustained use of Relizorb evaluation (Assure) study in patients with cystic fibrosis receiving enteral feeding. J Pediatr Gastroenterol Nutr 2018; 67 (4): 527-532. PMID: 30074573.
8. Freedman SD. Options for addressing exocrine pancreatic insufficiency in patients receiving enteral nutrition supplementation. Am J Manag Care. 2017;23(12 Suppl):S220-S228.