

Medical Policy

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| Policy: | CMP202017 | Initial Effective Date: | 10/01/2020 |
| SUBJECT: | Digestive Enzyme Cartridge (Relizorb) | Annual Review Date: | 10/22/2024 |
| | | Last Revised Date: | 10/22/2024 |

Some or all procedure codes listed in this Corporate Medical Policy may be considered experimental/investigational.

Definition: Digestive enzyme cartridges (e.g., Relizorb, Alcresta Therapeutics, Inc.) are used in conjunction with enteral tube feeding. They contain a lipase enzyme that helps to break down fats in enteral formulas to allow for their absorption and utilization by the body. This allows the delivery of more absorbable calories to the patient and helps maintain or increase weight gain, leading to increased patient growth and development.

Medical Necessity: The Company considers digestive enzyme cartridges **medically necessary** and eligible for reimbursement providing that **all of** the following medical criteria are met:

- Ages 2 years and older
- Enteral feedings are necessary
- Diagnosis of exocrine pancreatic insufficiency (due to complications of cystic fibrosis, pancreatitis, diabetes etc).

Use of digestive enzyme cartridges for any other indication may be considered experimental/investigational.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member, and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results, and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply, and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

NOTE: After reviewing the relevant documentation, the Company reserves the right to apply this policy to the service, or procedure, supply, product, or accommodation performed or furnished regardless of how the service, or procedure, supply, product, or accommodation was coded by the Provider.

Approval or clearance by the U.S. Food and Drug Administration alone is not a basis for coverage.

Medical Policy

Coverage may differ for Medicare Advantage plan members; please see any applicable national and/or local coverage determinations for details. This information may be available at the Centers for Medicare & Medicaid Services (CMS) website.

Sources of Information:

- Alcresta Therapeutics. Relizorb: (Immobilized Lipase) Cartridge Patient Guide. 2024. Available at <https://www.relizorb.com/pdf/RELiZORB-Patient-Guide.pdf>.
- Freedman S, Orenstein D, Black P, Brown P, McCoy K, Stevens J, 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
- Hendrix SJ, Flume PA, First ER, Improvements in anthropometric measures and gastrointestinal tolerance in patients with cystic fibrosis by using a digestive enzyme cartridge with overnight enteral nutrition. *Nutr Clin Pract.* 2022 Apr;37(2):344-350.
- Journal of Pediatric Gastroenterology and Nutrition. October 2018, available at: <https://journals.lww.com/jpgn/toc/2018/10000>
- Katkin, JP, Baker, RD, Baker, SS. Cystic fibrosis: Assessment and management of pancreatic insufficiency. In: UpToDate, Whitcome DC, Grover S (Eds). August 2020. UpToDate, Waltham, MA. Accessed October 1, 2020.
- Katkin, JP, Baker, RD, Baker, SS. Cystic fibrosis: Assessment and management of pancreatic insufficiency. In: UpToDate, Whitcome DC, Grover S (Eds). August 2020. UpToDate, Waltham, MA. Accessed November 21, 2023.
- Schwarzenberg SJ, Hempstead SE, McDonald CM, Powers SW, Wooldridge J, Blair S, 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.
- Stevens J, Wyatt C, Brown P, Patel D, Grujic D, Freedman SD. Absorption and Safety With Sustained Use of Relizorb Evaluation (ASSURE) Study in Patients With Cystic Fibrosis Receiving Enteral Feeding. *J Pediatr Gastroenterol Nutr.* 2018 Oct; 67(4): 527-532.
- Tsikis ST, Fligor SC, Mitchell PD, Hirsch TI, Carbeau S, First E, Loring G, Rudie C, Freedman SD, Martin CR, Gura KM, Puder M. Fat digestion using RELiZORB in children with short bowel syndrome who are dependent on parenteral nutrition: Protocol for a 90-day, phase 3, open labeled study. *PLoS One.* 2023 Mar 1;18(3):e0282248.

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| Applicable Code(s): | |
| CPT: | B4105 |
| HCPCS: | |
| ICD10 Procedure Codes: | |

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