Neighborhood Health Plan OF RHODE ISLAND™

Clinical Medical Policy

Relizorb Enzyme Cartridge (RELiZORB™) - # 074

Last reviewed: 10/14/26

Application

Application of this Medical Policy applies to:
RIte Care (MED), Rhody Health Partners (RHP), Rhody Health Expansion (RHE), Children with Special Health Care Needs (CSN), Substitute Care (SUB), Commercial (HBE)
Application Excluded for:
Extended Family Planning (EFP), INTEGRITY for Duals (FIDE) Duals CONNECT (CO-DSNP)

Medicare Distinction

For INTEGRITY for Duals (FIDE) and Duals CONNECT (CO-DSNP) members: Neighborhood Health Plan of Rhode Island (Neighborhood) uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations, including medical necessity. Coverage determinations are based on applicable payment policies, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and other available CMS published guidance.

In the absence of an applicable or incomplete NCD, LCD, or other Medicare guidelines, then Neighborhood will apply coverage guidance from other widely used treatment guidelines with peer-reviewed scientific evidence, such as InterQual® and/or internal Clinical Medical Policies.

Overview

RELiZORB is a single- use point-of-care digestive enzyme cartridge that connects in-line with existing enteral feeding supplies. RELiZORB is indicated for use in pediatric (including neonates and infants) and adult patients to hydrolyze fats during enteral feeding. RELiZORB is designed to hydrolyze (digest) fats contained in enteral nutrition, mimicking the function of the digestive enzyme lipase that is normally secreted by the pancreas. By hydrolyzing fats from enteral nutrition, RELiZORB allows for the delivery of absorbable fatty acids and monoglycerides.

Coverage Determination Criteria:

RELiZORB™ Digestive Enzyme Cartridge may be covered when enteral nutrition is medically necessary, and when the following criteria are met:

1. A recent (within the past 90 days) comprehensive medical history and physical examination has been documented.

2. Documentation of a written plan of care including monitoring for signs and symptoms of improvement in the member's condition, particularly nutritional status.
3. Member has a diagnosis of Cystic Fibrosis (CF).
4. The prescribing provider is a specialist in CF care (Physician or Nurse Practitioner)
5. Member has a confirmed history of exocrine pancreatic insufficiency supported by laboratory evidence (fecal elastase or elevated fecal fat).
6. Member requires enteral tube nutrition for continuous durations of 6 hours or more;
7. Documentation that the member has failed a 6-month trial of standard therapy with Pre and Post feed pancreatic enzyme replacement therapy (PERT) (as evidenced by insufficient weight gain or weight loss)
8. In adults and post-pubertal adolescents, documentation is submitted showing involuntary or acute weight loss of greater than or equal to 10 percent of usual body weight during a three-to-six- month period, or body mass index (BMI) below 18.5 kg/m^2, and for pediatric members < 18 years old, the member's BMI is less than the 50th percentile AND the Height and Weight data show a reduction of these metrics by growth chart.

Approval will be made for the first 6 months, and then reauthorization will be required every 6 months.

Criteria for Reauthorizations:

A new or updated prior authorization request for enteral nutrition products and RELiZORB™ digestive enzyme cartridge therapy must be submitted to continue use of enteral nutrition products before the expiration of the current prior authorization.

1. Member continues to require enteral tube nutrition for continuous durations of 6 hours or more.
2. Documentation member has evidence of stable or increased weight from use of RELiZORB

Exclusions and Limitations

1. The member is underweight but has the ability to meet nutritional needs through the use of regular formula or food consumption.
2. Enteral nutrition products are used as supplements to a normal or regular diet in a member showing no clinical indicators of nutritional risk.
3. The member has food allergies, lactose intolerance, or dental problems, but has the ability to meet his or her nutritional requirements through an alternative food source comparable in effect and available to the member.
4. Enteral nutrition products used for dieting or a weight loss program.
5. The member has failed a previous trial of RELiZORB™

References:

- Alkaade S, Vareedayah AA. A primer on exocrine pancreatic insufficiency, fat malabsorption, and fatty acid abnormalities. Am J Manag Care. 2017 Jul;23(12 Suppl):S203-S209. PMID: 28727474.
- Executive Office of Human Health and Services, State of Rhode Island. Coverage Guidelines For Durable Medical Equipment and Clinical Guidelines for Enteral Nutrition. Available at eohhs.ri.gov/ProvidersPartners/ProviderManualsGuidelines/MedicaidProviderManual/DME/CoverageGuidelinesforDurableMedicalEquipment.aspx. Last accessed August 30, 2021.
- Freedman S, Orenstein D, Black P, Brown P, McCoy K, Stevens J, Grujic D, Clayton R. 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. doi: 10.1097/MPG.0000000000001617. PMID: 28471913.
- Freedman SD. Options for addressing exocrine pancreatic insufficiency in patients receiving enteral nutrition supplementation. Am J Manag Care. 2017 Jul;23(12 Suppl):S220-S228. PMID: 28727476.
- 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.
- 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. doi: 10.1097/MPG.0000000000002110. PMID: 30074573; PMCID: PMC6155360.

Authorization Request Forms

Access prior authorization request forms by visiting Neighborhood's website at www.nhpri.org.

1. Click on Providers
2. Click on Provider Resources
3. Click on Forms
4. Click on "Click here for a list of prior authorization request forms" – forms are listed alphabetically.

A phone messaging system is in place for requests/inquiries both during and outside of business hours. Providers can call 1-800-963-1001 for assistance.

Covered Codes: For information on coding, please reference the Authorization Quick Reference Guide.

Created	12/01/21
Review Month	April
Review Dates:	3/16/22, 3/8/23, 4/10/24, 4/9/25, 4/8/26, 10/14/26
Revision Dates:	4/9/25, 4/8/26, 10/14/26
CMC Review Dates:	3/16/22, 3/8/23, 4/10/24, 4/9/25, 4/8/26, 10/14/26
Medical Director Approval Dates:	3/16/22, 3/8/23, 4/10/24, 4/9/25, 4/8/26, 10/14/26
Effective Date:	12/1/21, 3/16/22, 3/8/23, 4/10/24, 4/9/25, 4/8/26, 10/14/26

Disclaimer:

Neighborhood has developed medical policies to assist us in administering health benefits. This medical policy is made available to you for informational purposes only and does not constitute medical advice. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Members should always consult their physician before making any decisions about medical care. Treating providers are solely responsible for medical advice and treatment of members. Benefits and eligibility are determined by the member's coverage plan; a member's coverage plan will supersede the provisions of this medical policy. For information on member-specific benefits, call member services. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. Neighborhood reserves the right to review and revise this policy for any reason and at any time, with or without notice.