

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), Extended Family Planning (EFP), Commercial (HBE), INTEGRITY for Duals (FIDE), Duals CONNECT (CO-DSNP)
Application Excluded for:
None

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 National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and other Medicare guidelines.

For FIDE Members: In the absence of an applicable or incomplete NCD, LCD, or other Medicare guidelines OR if available Medicare coverage guidance is not met, then Neighborhood will apply coverage guidance from the Rhode Island Executive Office of Health & Human Services (EOHHS), or other widely used treatment guidelines with peer-reviewed scientific evidence, such as InterQual® and/or internal Clinical Medical Policies as a means of secondary coverage through the member's Medicaid benefit.

For CO-DSNP Members: 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 digestive enzyme cartridge containing the enzyme lipase. It aims to mimic the action of pancreatic lipase for use in adults and children (ages 5 years and above) who receive enteral tube feedings. RELIZORB™ hydrolyzes (breaks up) fat molecules in enteral formulas, allowing for absorption of fatty acids and monoglycerides, and improvement in nutritional status in patients with cystic fibrosis who require enteral feeds.

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. A written plan of care including monitoring for signs and symptoms of improvement in the member's condition, particularly nutritional status.
3. Enteral nutrition is indicated as the primary source of nutritional support essential for the management of risk factors that impair digestion and has a functioning feeding tube with tube feeds being received on a daily basis.
4. The member is over the age of 5 years old.
5. The member has a diagnosis of Cystic Fibrosis. The prescribing provider is a specialist in CF care. Physician or NP.
6. The member has failed a 6-month trial of standard therapy with Pre and Post feed pancreatic enzyme replacement therapy (PERT).
7. In adults and post-pubertal adolescents, 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/m², with consideration for measurement of BMI in members with chronic immobility for whom height is difficult to measure by using another anthropometric method such as height associated with arm span or ratio of upper body to lower extremity length.
8. 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 is continuing on enteral tube feedings.
2. Documentation of no decrease in BMI, while maintained on enteral feedings and RELiZORB™ digestive enzyme cartridge therapy.

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/DM E/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
Revision Dates:	4/9/25
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Medical Director Approval Dates:	3/16/22, 3/8/23, 4/10/24, 4/9/25
Effective Date:	12/1/21, 3/16/22, 3/8/23, 4/10/24, 4/9/25

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.