Clinical Policy: RELiZORB®

Reference Number: MI.CP.MP.504
Last Review Date: 04/24

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

RELiZORB	A digestive enzyme cartridge that is used in adults to helps break down (digest) the fats in enteral tube feeding formula into an absorbable form the body can use.

Relizorb is a single-use, point-of-care digestive enzyme cartridge that connects in-line with existing enteral pump feed sets and pump extension sets. It is designed to mimic the action of pancreatic lipase for use in adults and pediatric patients age 5 years and above receiving enteral tube feedings .It was approved by the FDA for this indication. However, large scale studies in human subjects are still lacking.

Relizorb is designed for use by patients on enteral tube feeding who have trouble breaking down and absorbing fats. Enteral feeding is used as part of standard of care in a subset of people, typically nocturnally to maintain or gain weight, reduce fatty acid and deficiencies and improve GI symptoms. It quickly and easily connects to the enteral tube feeding system. When fats are not broken down, this can result in getting fewer calories or not enough calories, not being able to gain or maintain weight, losing weight, having lower levels of some vitamins, and not getting enough of certain kinds of fats (such as omega-3 fats, which are important for normal growth and development). In preclinical studies: Relizorb has been shown to break down fats in enteral tube feeding formulas -- including omega-3 fats. The clinical significance of these observations has not been determined. Higher levels of Vitamins D and E were observed with the use of Relizorb.

As the enteral tube feeding formula passes through Relizorb, it makes contact with the iLipase and the fat in the formula is broken down to its absorbable form (fatty acids and monoglycerides) prior to ingestion. The iLipase remains in the cartridge and does not become part of what is ingested. Relizorb has been shown to break down 90% of fats in most enteral feeding tube formulas, including the most difficult to breakdown long-chain polyunsaturated fatty acids, such as docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA) and arachidonic acid (AA), which are critical for growth and development.

In December 03, 2015, the US Food and Drug Administration (FDA) ~~has~~ approved a first-of-its-kind digestive enzyme cartridge designed to mimic the normal function of pancreatic lipase for use in ADULTS on enteral tube feeding who have trouble breaking down and absorbing fats. In July 2017, The U.S. Food and Drug Administration (FDA) approved the use of RELiZORB® for children ages 5 to 18 who use a feeding tube.

Policy/Criteria

CLINICAL POLICY
RELiZORB®

I. It is the policy of MeridianHealth that all requests for Relizorb will be reviewed by a Meridian Medical Director and on a case-by-case basis.
   A. Required Documentation:
      i. Recent clinical notes (within the last 12 mo) that include alternative treatment(s) that were trialed and failed
   B. There is no evidence in peer-reviewed, randomized, placebo controlled medical/scientific literature supporting the therapeutic efficacy and/or safety of Relizorb over current therapy and
   C. There is insufficient published evidence about the use of Relizorb in patients receiving enteral nutrition with conditions affecting breakdown and absorption of dietary fats.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2019, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT®* Codes	Description
N/A	

HCPCS ®* Codes	Description
N/A	

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

+ Indicates a code(s) requiring an additional character

ICD-10-CM Code	Description
N/A	

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Original approval date		12/20/16
Annual Review Relizorb background information removed. Removed information that Relizorb is investigation and experimental. Additional to policy: Cases to be reviewed by Medical Directors on a case by case basis. There is insufficient published evidence about the use of Relizorb in patients receiving enteral nutrition with conditions affecting breakdown and	06/25/21	06/25/21

Reviews, Revisions, and Approvals	Revision Date	Approval Date
absorption of dietary fats. Formatting updates to align with Centene corporate policy template.		
References were updated, Grammatical changes were made.	05/22	01/23
Annual Review with no changes	04/23	
Annual Review with no changes	4/24	6/24

Line of Business Applicability:
This policy applies to Michigan Medicaid

Coverage is based on medical necessity criteria being met and the codes being submitted and considered for review being included on the Michigan Medicaid Fee Schedule (located at: https://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_42542_42543_42546_42551-159815--,00.html)
If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual (located at: https://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_5100-87572--,00.html), the applicable Medicaid Provider Manual will govern.

References

1. Relizorb (Alcresta Therapeutics Inc.) for Enteral Feeding in Patients with Cystic Fibrosis-Related Pancreatic Insufficiency: September 10, 2021 https://evidence.hayesinc.com/report/eer.relizorb3607
2. ClinicalTrials.gov, Safety, Tolerability and Fat Absorption Using Enteral Feeding In-line Enzyme Cartridge (Relizorb) : https://clinicaltrials.gov/ct2/show/NCT02598128 Last updated Jan 2017
3. U.S. Food & Drug Administration (FDA), 513(f)(2)(De Novo), DEN150001, RELIZORB, 04/10/2023: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm?ID=DEN150001

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health

plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.