

Medical Policy: Relizorb (immobilized lipase) Cartridge

| POLICY NUMBER | LAST REVIEW | ORIGIN DATE |
|---------------|------------------|-----------------|
| MG.MM.PH.57 | January 10, 2024 | January 1, 2019 |

Medical Guideline Disclaimer Property of EmblemHealth. All rights reserved.

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

RELIZORB (immobilized lipase) cartridge is a first-of-its-kind cartridge designed to hydrolyze fats prior to ingestion of enteral formula. The cartridge contains immobilized digestive enzyme lipase covalently bound to small polymer beads. When enteral formula flows through the cartridge, the lipase hydrolyzes fats from triglyceride form, which in turn allows delivery of fatty acids and monoglycerides to patient for absorption.

Despite RELIZORB’s de novo FDA approval in 2015, the number of large scale studies in human subjects is inadequate to support the device’s safety, effectiveness, and impact on health outcomes. At this time, RELIZORB lacks sufficient evidence in published peer-reviewed literature to support the use of this device. Therefore, the use of RELIZORB is considered experimental and investigational.

Guideline

RELIZORB is not considered medically necessary due to insufficient evidence of therapeutic value.

Limitations/Exclusions

RELIZORB is considered experimental and investigational for all indications, and is therefore not covered.

Applicable Procedure Codes

| Code | Description |
|-------|---|
| B4105 | Relizorb Cartridge B4105 In-line cartridge containing digestive enzyme(s) for enteral feeding, each |

ICD-10 Diagnoses

| Code | Description |
|--------|--|
| E16.4 | Increased secretion of gastrin |
| E84.1 | Cystic fibrosis with intestinal manifestations |
| K86.1 | Other chronic pancreatitis |
| K86.81 | Exocrine pancreatic insufficiency |
| K50.00 | Crohn's disease of small intestine without complications |
| K90.0 | Celiac disease |
| Q45.3 | Other congenital malformations of pancreas and pancreatic duct |

Revision History

| Company(ies) | DATE | REVISION |
|-----------------------------|-----------|---------------------------|
| EmblemHealth & ConnectiCare | 1/10/2024 | Annual Review: No changes |
| EmblemHealth & ConnectiCare | 1/11/2023 | Transfer to New Template |
| EmblemHealth & ConnectiCare | 1/1/2019 | New Policy |

References

1. Alcresta Therapeutics. RELIZORB: (Immobilized Lipase) Cartridge, 2017. Accessed on December 6, 2019 and available at: <http://relizorb.com/>.
2. Alcresta Therapeutics. Absorption and Safety With Sustained Use of RELIZORB Evaluation (ASSURE) Study in Patients With Cystic Fibrosis Receiving Enteral Feeding. Accessed on July 10, 2018
3. ClinicalTrials.gov. Safety, Tolerability and Fat Absorption Using Enteral Feeding In-line Enzyme Cartridge (RELIZORB), ClinicalTrials.gov Identifier: NCT02598128. Last updated: June 2016. Accessed on July 10, 2018 and available at: <https://clinicaltrials.gov/ct2/show/NCT02598128>.
4. FDA Clears RELIZORB for Use With Enteral Tube Feeding, December 03, 2015. Accessed on July 10, 2018
5. Freedman S., Orenstein D et al. Increased fat absorption from enteral formula through an in-line digestive cartridge in patients with Cystic Fibrosis. Accessed on July 10, 2018 and available at: <https://www.ncbi.nlm.nih.gov/pubmed/?term=relizorb>.