



RELIZORB™ (immobilized lipase) Cartridge

Last Review Date: January 1, 2019

Number: MG.MM.PH.57v2

Medical Guideline Disclaimer

Property of EmblemHealth. All rights reserved. The treating physician or primary care provider must submit to EmblemHealth the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request for prior authorization. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. 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. 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 Services Company LLC, ("EmblemHealth") has adopted the herein policy in providing management, administrative and other services to HIP Health Plan of New York, HIP Insurance Company of New York, Group Health Incorporated and GHI HMO Select, related to health benefit plans offered by these entities. 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.

Revision History

1/1/2019

Added new code B4105 – effective January 1, 2019. Removed Q9994 – D/C as of 1/1/2019

Applicable Procedure Codes

B4105	In-line cartridge containing digestive enzyme(s) for enteral feeding
-------	--

Applicable Diagnosis Codes

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

References

1. Alcresta Therapeutics. Relizorb: (Immobilized Lipase) Cartridge, 2017. Accessed on July 10, 2018 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 and available at: <https://cff.org/Trials/Finder/details/470/ASSURE-Study-of-Relizorb-in-people-with-CF-who-receive-enteral-tube-feeding>.
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 and available at: https://Medscape.com/view_article/855434.
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>.