Medical Policy:
Relizorb (immobilized lipase) Cartridge

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

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.