Medical Drug Clinical Criteria

Subject:	Relizorb (immobilized lipase) cartridge		
Document #:	CC-0198	**Publish Date:**	02/03/2025
Status:	Revised	**Last Review Date:**	12/09/2024

Table of Contents

Overview

This document addresses the use of Relizorb (immobilized lipase) cartridge for individuals for hydrolyzation of fats when used with enteral nutrition via feeding tube.

Relizorb cartridge is an FDA-approved device that delivers lipase immobilized onto polymeric carrier beads to existing enteral feeding pump tube systems to help individuals digest fats contained in enteral formulas, similar to the function of tablet and capsule formulations of available pancreatic enzyme replacement therapies (PERT). However, unlike other PERT agents, Relizorb does not provide protease or amylase.

Relizorb was studied specifically in individuals with cystic fibrosis, where supplementation with continuous enteral nutrition may be necessary if oral nutrition alone yields suboptimal growth and weight gain.

While the Cystic Fibrosis Foundation included mention of Relizorb in its guidelines for Enteral Tube Feeding for Individuals with Cystic Fibrosis (2016), it does not make any recommendations for or against any specific method of providing PERT. It does, however, state that evaluation of Relizorb's benefits and limits should be considered before use.

Instructions for use of Relizorb warns against use in enteral formulas containing insoluble fiber as it may clog the Relizorb cartridge. The document also recommends monitoring for fibrosing colonopathy, a rare and serious adverse effect associated with use of high-dose PERT in the treatment of those with cystic fibrosis.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Relizorb (immobilized lipase) cartridge

Initial requests for Relizorb (immobilized lipase) cartridge may be approved if the following criteria are met:

I. Individual has a diagnosis of cystic fibrosis; **AND**
II. Individual has a confirmed history of exocrine pancreatic insufficiency; **AND**
III. Individual requires enteral tube nutrition for continuous durations of 6 hours or more, and using Relizorb to hydrolyze fats in enteral formula; **AND**
IV. Individual has continued malabsorption of fats (as evidenced by insufficient weight gain or weight loss) from enteral formula, despite optimizing therapy with pancreatic enzyme replacement therapy (PERT) *tablets* or *capsules* administered orally or via feeding tube (capsules only) (Pertzye 2020, Ferrie 2011, Shileout 2011).

Continuation requests for Relizorb (immobilized lipase) cartridge may be approved if the following criteria are met:

I. Individual has evidence of stable or increased weight from use of Relizorb; **AND**
II. Individual continues to require enteral tube nutrition for continuous durations of 6 hours or more.

Approval Duration:
Initial request: 6 months
Continuation request: 6 months

Relizorb (immobilized lipase) cartridge may not be approved when the above criteria are not met and for all other indications.

Quantity Limits

Relizorb (immobilized lipase) cartridge Quantity Limits

Drug	Limit
Relizorb (immobilized lipase) cartridge	6 cartridges per day

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

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

ICD-10 Diagnosis

E84.0-E84.9	Cystic Fibrosis
K86.81	Exocrine pancreatic insufficiency
K86.89	Other specified diseases of pancreas
K90.89	Other intestinal malabsorption

Document History

Revised: 12/09/2024
Document History:

- 12/09/2024 – Annual Review: Update quantity limits per label. Coding Reviewed: Added ICD-10-CM K86.81.
- 12/11/2023 – Annual Review: Updated references. Coding Reviewed: No changes.
- 12/12/2022 – Annual Review: Updated references. Coding Reviewed: Added ICD-10-CM K86.89, K90.89.
- 12/13/2021 – Annual Review: No changes. Coding Reviewed: No changes.
- 05/21/2021 – Selected Review: Add new clinical criteria document for Relizorb (immobilized lipase) cartridge. Coding Reviewed: Added HCPCS B4105, Added E84.0-E84.9, K86.8, K90.8.

References

1. Ferrie S, Graham C, Hoyle M, et. al. Pancreatic Enzyme Supplementation for patients receiving enteral feeds. Nutr Clin Pract 2011;26:349-51.
2. NCT02750501. Absorption and Safety With Sustained Use of Relizorb Evaluation (ASSURE) Study (ASSURE) ClinicalTrials.gov. U.S. National Library of Medicine. U.S. National Institutes of Health. Available at https://clinicaltrials.gov/ct2/show/NCT02750501?term=relizorb&rank=2.
3. NCT02598128. Safety, Tolerability and Fat Absorption Using Enteral Feeding In-line Enzyme Cartridge (Relizorb). ClinicalTrials.gov. U.S. National Library of Medicine. U.S. National Institutes of Health. Available at https://clinicaltrials.gov/ct2/show/NCT02598128.
4. Pertzye Packet Inserts. Pertzye. U.S. Food and Drug Administration. Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process. Accessed on December 6, 2024.
5. Relizorb Package inserts. Relizorb (immobilized lipase) cartridge. Available at: https://www.relizorb.com/docs/pdfs/Relizorb-Instructions-for-Use.pdf. Accessed: December 6, 2024.
6. 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. Nov;15(6):724-735.PMID: 27599607. Accessed December 6, 2024.
7. Shileout G, Koerner A, Maffert M, et. al. Administration of Creon pancrelipase pellets via gastrostomy tube is feasible with no loss of gastric resistance or lipase activity. Clin Drug Investig. 2011;31:e1-e7.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.