STATE OF IOWA DEPARTMENT OF
Health AND Human
SERVICES

RELiZORB
DME-020

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	1/21/2022
Revision Number:	3	**Last Rev Date:**	1/19/2024
Reviewed By:	Medicaid Medical Director	**Next Rev Date:**	1/17/2025
Approved By:	Medicaid Clinical Advisory Committee	**Approved Date:**	1/21/2022

Descriptive Narrative

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 5 years of age and older receiving enteral tube feedings. It was approved by the FDA for this indication. RELiZORB® is designed for use by patients on enteral tube feeding who have trouble breaking down and absorbing fats despite optimal therapy with pancreatic enzyme replacement therapy (PERT), which remains the recommended first line treatment.

Enteral feeding is used as part of standard of care in a subset of people, typically administered nocturnally to maintain or gain weight, reduce fatty acid deficiencies, and improve gastrointestinal symptoms. Failure to break down fats results in insufficient caloric intake, not being able to gain or maintain weight, weight loss, 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.

As the enteral tube feeding formula passes through RELiZORB®, contact is made 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 percent of fats in most enteral feeding tube formulas, including the most difficult to break down long-chain polyunsaturated fatty acids, such as docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA), and arachidonic acid (AA), which are critical for growth and development.

Criteria

Prior authorization is required.

RELiZORB® is considered medically necessary when **ALL** the following are met:

1. Member has a diagnosis of cystic fibrosis; **AND**
2. Member has a confirmed history of exocrine pancreatic insufficiency; **AND**
3. Member requires enteral tube nutrition for continuous durations of 6 hours or more; **AND**
4. Member has continued malabsorption of fats (as evidenced by insufficient weight gain or weight loss) from enteral formula, despite optimizing therapy with PERT in the form of oral tablets or capsules administered via feeding tube.

RELiZORB® is considered medically necessary for continuation of therapy when **ALL** the following are met:

1. Member has evidence of stable or increased weight from use of RELiZORB®; **AND**
2. Reduction of symptoms including diarrhea or morning bloating; **AND**
3. Member continues to require enteral tube nutrition for continuous durations of 6 hours or more.

Approval Duration/Quantity Limits

Initial requests for RELiZORB® will be approved for 6 months.

Continuation of RELiZORB® will be approved for 12 months.

Quantity limit of 2 cartridges per day.

Coding

The following list(s) of codes are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS/CPT code is inappropriate.

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

ICD-10	Description
E84.0-E84.9	Cystic fibrosis.

Compliance

1. Should conflict exist between this policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual and as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

EncoderPro Optum 360.

Baker RD. Baker SS. Bojczuk G. Cystic Fibrosis: Nutritional Issues. UpToDate. Last updated Sep 16, 2021.

RELiZorb for Enteral Feeding in Patients with Cystic Fibrosis Related Pancreatic Insufficiency. Evolving Evidence Review. Hayes. Sep 10, 2021.

RELiZorb (Immobilized Lipase) Cartridge. Patient Instructions. Alcresta Therapeutics, Inc. 2020.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version

Signature

Change Date	Changed By	Description of Change	Version

Signature

Change Date	Changed By	Description of Change	Version
1/19/2024	CAC	Annual review.	3

Signature
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Change Date	Changed By	Description of Change	Version
1/20/2023	CAC	Annual review.	2

Signature
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Change Date	Changed By	Description of Change	Version
1/21/2022	CAC	Criteria implementation.	1

Signature
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