Clinical Policy: Immobilized Lipase Cartridges (RELiZORB®)

Reference Number: CP.MP.252
Date of Last Revision: 02/26

Revision Log
Coding Implications

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

This policy describes the medical necessity criteria for immobilized lipase cartridges (RELiZORB®) for use with enteral feeding.

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation® that requests for immobilized lipase cartridges (RELiZORB®) are **medically necessary** when meeting all the following:

A. Member/enrollee requires enteral feeding and one of the following:
   1. Documented failure to achieve or maintain enteral nutrition goals despite optimization of oral pancreatic enzyme replacement therapy (PERT) and nutritional support;
   2. Documented contraindication to or intolerance of oral PERT during enteral feeding;

B. Member/enrollee has an established diagnosis of exocrine pancreatic insufficiency (EPI) confirmed by fecal elastase;

C. Request is for one of the following:
   1. Up to two cartridges per day for member/enrollees ≤ six months of age;
   2. Up to six cartridges per day for members/enrollees > six months of age.

Background

RELiZORB® Immobilized Lipase Cartridge

RELiZORB is the only U.S. Food and Drug Administration (FDA)–cleared, digestive enzyme cartridge indicated for use with enteral feeding systems to hydrolyze fats. The single-use, point-of-care device contains immobilized lipase which hydrolyzes triglycerides present in enteral formulas into absorbable fatty acids and monoglycerides before entering the gastrointestinal tract. It is designed to mimic the normal pancreatic function of lipase release to enhance fat absorption and utilization, supporting improved nutritional outcomes in individuals that do not secrete sufficient levels of lipase due to pancreatic insufficiency or related conditions.[1]

Exocrine pancreatic insufficiency (EPI) is a disorder caused by the failure of the pancreas to deliver a minimum threshold level of specific pancreatic digestive enzymes to the intestine, leading to the maldigestion and malabsorption of nutrients, including macronutrients, resulting in variable nutritional deficiencies. This condition is common in individuals with cystic fibrosis, chronic pancreatitis, and other disorders that impair pancreatic function.

Once EPI is diagnosed, pancreatic enzyme replacement therapy (PERT) is considered standard of care. Despite appropriate PERT administration, some individuals, particularly those receiving enteral nutrition, may continue to experience fat malabsorption, which can lead to decreased caloric absorption, impaired utilization of essential fatty acids (including omega-3 fatty acids), deficiencies of fat-soluble vitamins (A, D, E, and K), and increased gastrointestinal symptoms. These effects may adversely impact nutritional status and quality of life.[5]

Clinical evidence has demonstrated RELiZORB's ability to increase absorption of essential fatty acids

and improve tolerance of enteral nutrition in individuals with EPI who have not achieved adequate results with oral PERT alone.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2025, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed. Reviewed by internal and external specialist.	02/26	02/26

References

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible

for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCD's and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.