

Corporate Medical Policy

Enteral Nutrition

File Name: enteral_nutrition
Origination: 2/1996
Last Review: 5/2024

Description of Procedure or Service

Enteral Nutrition (EN) is defined as nutrition provided through the gastrointestinal tract via a tube, catheter, or stoma that delivers nutrients distal to the oral cavity. Enteral formulas, including adult and pediatric formulas, are classified by the U.S. Food and Drug Administration (FDA) under the heading of medical foods. Currently, the FDA defines medical foods as “a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.”

Some patients who receive enteral feedings experience difficulty breaking down fats found in enteral formula. This malabsorption of fats can lead to issues with maintaining or gaining weight which can cause respiratory exacerbations, as well as, decreased bone health, chronic infections, and deficiency of fatty acids in plasma and tissue. Chronic gastrointestinal symptoms can also be a major concern with regards to fat malabsorption including diarrhea, fatty stools, abdominal pain, bloating, constipation, flatulence, nausea, and vomiting.

Relizorb™, (Alcresta Pharmaceuticals) is a digestive enzyme cartridge that received de novo approval by the FDA (Nov. 2015) for use in adults to hydrolyze (breakdown) fats in enteral formula. In July 2017, the FDA expanded use of Relizorb to include pediatric patients 5 years of age and older. In August 2023, Relizorb was cleared by the FDA for expanded use in pediatric patients ages 2 years and above. The cartridge connects in-line with existing enteral pump feeding sets and pump extension sets. This breakdown of fats from triglycerides into fatty acids and monoglycerides that are present in enteral formulas, allows for better absorption and utilization by the body.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC does not provide coverage for most Enteral Nutrition. They are considered non-covered and are ineligible as benefits, except when the medical criteria and guidelines noted below are met.

BCBSNC will provide coverage for Relizorb™ for the treatment of hydrolyzing fats in enteral formula when it is determined to be medically necessary because the medical criteria and guidelines below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein.

Please refer to the Member's Benefit Booklet for availability of benefits.

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Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Enteral Nutrition is covered

Enteral Nutrients that **require a prescription** are eligible for coverage when prescribed for individuals with one of the following conditions:

- Malabsorption syndrome
- Certain short bowel syndromes
- Crohn's disease
- Severe pancreatitis

Relizorb™ is considered medical necessary for the treatment of hydrolyzing fats in enteral formula when the following criteria are met:

- Individual has a diagnosis of cystic fibrosis
- Individual has failed to achieve enteral feeding goals with pancreatic enzyme replacement therapy (PERT) in conjunction with enteral feedings
- Individual exhibits symptoms of fat malabsorption including but not limiting to:
 - Diarrhea
 - Fatty stools
 - Abdominal pain
 - Bloating
 - Nausea
 - Constipation
 - Flatulence
 - Vomiting
- Individual demonstrates failure to achieve or maintain target BMI
- Individual requires overnight enteral feeding to meet caloric and nutritional demands with need for sustained lipase delivery throughout feeding

When Enteral Nutrition is not covered

Most enteral food products are available without a prescription or over the counter, and thus not eligible for coverage.

Relizorb is considered investigational for use with enteral tube feeding when the above criteria are not met and for all other indications.

Policy Guidelines

If a patient requires enteral nutrition, the supplies (e.g., tubing, syringes) are covered as supplies.

Recent published literature with both short and long-term data demonstrate statistically significant increases in height and weight growth scores, increases in BMI scores, and improved plasma concentrations of fatty acids in patients with cystic fibrosis. The 2019 Journal of Cystic Fibrosis published support of Relizorb™, concluding that use of the immobilized lipase cartridge (ILC) “can produce measurable clinically relevant benefits” The evidence in published, peer-reviewed scientific literature is sufficient to determine the benefits of Relizorb as an adjunct therapy in individuals who require both enteral nutrition and pancreatic enzyme supplementation.

Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: B4102, B4103, B4104, B4105, B4149, B4150, B4152, B4153, B4154, B4155, B4157, B4158, B4159, B4160, B4161, B4162, S9433.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual

Medical Policy Advisory Group Review 3/99

Specialty Matched Consultant Advisory Panel - 9/2000

Medical Policy Advisory Group - 12/2000

Specialty Matched Consultant Advisory Panel - 6/2002

JPEN J Parenter Enteral Nutr 2009; 33; 122 originally published online Jan 26, 2009. Accessed February 2, 2015.

American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.). Enteral Nutrition Practice Recommendations. JPEN J Parenter Enteral Nutr. 2009; 33(3):122-167. Available at:<http://pen.sagepub.com/cgi/reprint/33/2/122>. Accessed April 30, 2015.

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFood/default.htm>. Accessed April 30, 2015.

Specialty Matched Consultant Advisory Panel 5 /2015

Medical Director review 5/2015

Specialty Matched Consultant Advisory Panel 5 /2016

Medical Director review 5/2016

Specialty Matched Consultant Advisory Panel 5/2017

Medical Director review 5/2017

Specialty Matched Consultant Advisory Panel 5/2018

Medical Director review 5/2018

Alcresta Therapeutics at <http://relizorb.com/> Accessed May 16, 2018

http://www.accessdata.fda.gov/cdrh_docs/pdf16/K163057.pdf Section 510k premarket summary approval. Accessed May 16, 2018.

Freedman S, Orenstein D, Black P, et al. Increased fat absorption from enteral formula through an in-line digestive cartridge in patients with cystic fibrosis. J Pediatr Gastroenterol Nutr. 2017 Jul;65(1):97-101.

Specialty Matched Consultant Advisory Panel 5/2019

Medical Director review 5/2019

Specialty Matched Consultant Advisory Panel 5/2020

Medical Director review 5/2020

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Specialty Matched Consultant Advisory Panel 5/2021

Medical Director review 6/2021

Sathe M, Patel D, Stone A, First E, Evaluation of the Effectiveness of In-line Immobilized Lipase Cartridge in Enterally Fed Patients With Cystic Fibrosis. J Pediatr Gastroenterol Nutr. 2021 Jan; 72: 324-340.

Challenging barrier to an option for improved provision of enteral nutrition. Journal of Cystic Fibrosis. 2019; 18:447-449.

Specialty Matched Consultant Advisory Panel 5/2022

Medical Director review 5/2022

Specialty Matched Consultant Advisory Panel 5/2023

Medical Director review 5/2023

Specialty Matched Consultant Advisory Panel 5/2024

Medical Director review 5/2024

Policy Implementation/Update Information

2/96	Original Policy issued
2/97	Reaffirmed
3/99	Reviewed by MPAG. Reaffirmed.
8/99	Reformatted, Medical Term Definitions added.
10/00	System coding changes.
12/00	Specialty Matched Consultant Advisory Panel. Statements added to say, "Certificates do not provide benefits for dietary supplements. When they are administered in the hospital, skilled nursing facility, or nursing home they are considered an integral part of the room and board charge and are not eligible for separate reimbursement." and "If a patient requires enteral nutrients, the supplies (e.g., tubing and syringes) are covered as supplies." Policy name changed from Dietary Supplements (Enteral Nutrients) to Enteral Nutrition. Criteria reworded in "When Enteral Nutrition is covered" and "When Enteral Nutrition is not Covered" sections for clarity. Medical Policy Advisory Group review. Table of noncovered enteral feedings removed from policy. Approve.
6/02	Specialty Matched Consultant Advisory Panel. No changes. Approve.
7/03	Policy status changed to: "Active policy, no longer scheduled for routine literature review."
3/04	Benefits Application and Billing/Coding sections updated for consistency. Individual CPT codes listed for CPT code ranges B4150-B4156 under Billing/Coding section.
1/6/05	First Quarter 2005 HCPCS codes B4102, B4103, B4104, B4149, B4157, B4158, B4159, B4160, B4161, B4162 added to the Billing/Coding section of policy.
1/5/09	Added new HCPCS code S9433 to "Billing/Coding" section. (btw)
6/22/10	Policy Number(s) removed (amw)
2/10/15	References updated. Policy Statement remains unchanged. (td)
7/1/15	Description section revised. When Covered section revised. References updated. Specialty Matched Consultant Advisory Panel review 5/27/2015. Medical Director review 5/2015. Policy Statements remain unchanged. (td)

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- 7/1/16 Specialty Matched Consultant Advisory Panel review 5/25/2016. Medical Director review 5/2016. (jd)
- 6/30/17 Specialty Matched Consultant Advisory Panel 5/2017. Medical Director review 5/2017. (jd)
- 6/8/18 Policy statement added that Relizorb for use with enteral tube feedings is considered investigational. Investigational language for Relizorb added to When Enteral Nutrition is not covered section of policy. Policy guideline and references updated. HCPCS code Q9994 effective July 1, 2018 added to Billing/Coding section. References updated. Specialty Matched Consultant Advisory Panel 5/2018. Medical Director review 5/2018. (jd)
- 12/31/18 Billing/Coding section updated; added B4105 and deleting Q9994 effective 1/1/19. (jd)
- 5/28/19 Specialty Matched Consultant Advisory Panel 5/2019. Medical Director review 5/2019. (jd)
- 6/9/20 Specialty Matched Consultant Advisory Panel 5/2020. Medical Director review 5/2020. (jd)
- 7/13/21 Policy updated to support coverage of Relizorb when the criteria indicated in the When Covered section are met. Description section, Policy statement, When Covered, When Not Covered, and policy guidelines revised in support of positive coverage of Relizorb. **CPT code B4105 noticed for PPA 7/13/21, effective 10/1/21.** References updated. Specialty Matched Consultant Advisory Panel 5/2021. Medical Director review 7/2021. (jd)
- 6/30/22 Policy title updated. Policy formatting updated to align with the new utilization management tool. No changes to policy statement or intent. Specialty Matched Consultant Advisory Panel 5/2022. Medical Director review 5/2022. (jd)
- 5/30/23 When Covered section edited for clarity, no change to policy statement. References updated. Specialty Matched Consultant Advisory Panel 5/2023. Medical Director review 5/2023. (tm)
- 5/29/24 Removed codes B4151 and B4156 from Billing/Coding section. Description and References sections updated. Specialty Matched Consultant Advisory Panel 5/2024. Medical Director review 5/2024. (tm)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.