

Policy Name: Outpatient Enteral Therapy MP9069

Effective Date: May 1, 2024

This policy was developed with input from specialists in gastroenterology, general surgery, internal medicine and pediatrics and endorsed by the Medical Policy Committee.

#### IMPORTANT INFORMATION - PLEASE READ BEFORE USING THIS POLICY

These services may or may not be covered by Prevea360 Health Plan. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Prevea360 Health Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. https://www.prevea360.com/Providers/Provider-communications-library

Prevea360 Health Plan medical policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

#### **PURPOSE**

To promote consistency between utilization management reviewers by providing the criteria that determines the medical necessity.

#### BACKGROUND

#### **Definitions**

A. **Enteral nutritional therapy** delivers nutrient solution to the gastro-intestinal tract by nasogastric, jejunostomy, or gastrostomy tube via bolus, gravity or pump-controlled infusion. Enteral nutritional therapy is typically required for patients who have permanent non-function or disease of the structures that



- normally permit food to reach the small bowel or disease of the small bowel which impairs digestion and absorption of an oral diet. Enteral formulas may consist of semi-synthetic or natural ingredients.
- B. **Sole source of nutrition**: Enteral nutrition feedings are intended to provide sufficient nutrients to maintain weight and strength appropriate enough to maintain the patient's overall health status, and to achieve growth in children. Some patients are required, as a part of the physician-prescribed treatment plan, to ingest a small amount of oral feeding. However, when oral intake of these patients is not considered by their physician to be sufficient to maintain weight, or to maintain growth and development, enteral nutritional support may be indicated. When the enteral feeding formula comprises 60% or more of caloric nutritional intake, the primary source of nutrition (the enteral feeding) is considered to be the sole source of nutrition.

### BENEFIT CONSIDERATIONS

- 1. Prior authorization **is required** for enteral nutritional therapy. Please see the prior authorization list for prior authorization requirements.
- 2. Coverage may vary according to the terms of the member's plan document.
  - a. Most member plan documents exclude coverage of enteral feedings unless they are the sole source of nutrition; however, enteral feedings of standard infant formulas, standard baby food and regular grocery products used in blenderized formulas are excluded regardless of whether they are the sole source of nutrition.
- 3. Grocery products which are liquefied in a food blender to allow administration through an enteral system are not covered.
- 4. Digestive enzyme cartridges (e.g., Relizorb® [HCPCS code: B4105]) therapy is **investigative** and therefore not covered.
- 5. Refer to the member's plan document for additional coverage information; e.g., coverage of medical dietary treatment of phenylketonuria (PKU) or other metabolic disorders.
- 6. Enteral nutrition formulas that are administered orally and related supplies are not covered unless specifically included in the member's plan document or addressed in a separate coverage policy. Amino acid-based elemental formulas are covered for specific diagnoses or disorders. Please refer to Coverage Policy: <u>Amino Acid-Based Elemental Oral Formula MP9355</u> or the member's plan document for coverage indications.
- 7. Supplies and equipment necessary to accomplish enteral formula administration are covered according to the terms of the member plan document.
- 8. If the Medical Necessity Criteria and Benefit Considerations are met, Prevea360 Health Plan will authorize benefits within the limits in the member's plan document.
- 9. If it appears that the Medical Necessity Criteria and Benefit Considerations are not met, the case will be reviewed by the medical director or an external reviewer.



Practitioners are advised of the appeal process in their Provider Administrative Manual.

#### MEDICAL NECESSITY CRITERIA

- Indications for enteral feedings
  - Enteral feedings (synthetic or semi-synthetic) are considered medically necessary when documentation in the medical record indicates that **all of the following** criteria are met:
  - A. The enteral feedings must be the individual's sole source of nutrition\* (dietary adjustment or oral supplements are contraindicated or are not possible). Some patients are required, as a part of the physician-prescribed treatment plan, to ingest a small amount of oral feeding. However, when the oral intake of these patients is not considered by their physician to be sufficient to achieve or maintain an acceptable body weight or to achieve growth in children, enteral nutritional support may be indicated. Therefore, in such patients, when the enteral feeding formula comprises 60% or more of caloric nutritional intake, the primary source of nutrition (the enteral feeding) is considered to be the sole source.
  - B. The patient has a functional intestinal tract, and has **one of the following** conditions:
    - 1. Non-function or disease of the pharynx, esophagus, or stomach that prevents nutrients from reaching the small intestine
    - Central nervous system disease leading to sufficient interference with the neuromuscular coordination of chewing and swallowing such that a risk of aspiration exists.
  - \*Most member plan documents exclude coverage of enteral feedings unless they are the sole source of nutrition.
- II. Enteral formula consisting of manufactured blenderized natural foods with intact nutrients, includes proteins, fats, carbohydrates, vitamins, minerals and may include fiber, administered through an enteral feeding tube (HCPCS code: B4149), are eligible for coverage when the individual meets **all of the following**:
  - A. Criteria for enteral nutritional therapy, in section I above
  - B. Documentation indicating that patient has **one of the following**:
    - 1. Intolerance to a semi-synthetic enteral product
    - 2. Severe allergic reaction to a semi-synthetic enteral product.



## CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

 For Medicare members, refer to the following, as applicable at: <a href="https://www.cms.gov/medicare-coverage-database/new-search/search.aspx">https://www.cms.gov/medicare-coverage-database/new-search/search.aspx</a>

### WISCONSIN BADGERCARE PLUS

 For members with State of Wisconsin BadgerCare Plus review Forward Health website for coverage and prior authorization requirements. (<u>Forward Health WI Portal</u>)

#### **DOCUMENT HISTORY**

Original Effective Date	Created 01/10/1990
MPC Endorsement Date(s)	02/09/1998, 02/12/1999, 03/20/2000, 04/11/2001, 03/13/2002, 03/12/2003. 03/10/2004. 03/09/2005, 03/08/2006, 11/08/2006, 12/13/2006, 02/14/2007, 03/14/2007, 03/12/2008, 04/08/2009, 07/21/2010, 07/27/2011. 07/20/2012, 08/15/2012, 0, 7/17/2013, 12/18/2013, 07/16/2014, 07/15/2015, 07/20/2016, 08/17/2016, 07/19/2017, 08/15/2018, 08/21/2019, 07/15/2020, 03/17/2021, 03/16/2022, 04/20/2022, 04/19/2023, 03/20/2024, 04/17/2024
Administrative Update(s)	09/2005, 04/17/2024

#### References:

#### Pre-04/2016 MPC:

- American <u>Gastrological</u> Association. Guidelines for the use of enteral nutrition. *Gastroenterology*. 1995;108:1280-1301. <a href="http://www3.us.elsevierhealth.com/gastro/policy/v108n4p1280.html">http://www3.us.elsevierhealth.com/gastro/policy/v108n4p1280.html</a>. Accessed February 25, 2016.
- 2. American Society for Parenteral and Enteral Nutrition. Guidelines for the use of parenteral and enteral nutrition in adult and pediatric patients. *J Parenter Enteral Nutr.* January-February 2002;26(1 Suppl):1SA-138SA.
- 3. Bankhead R, Boullata J, Brantley S. Enteral nutrition practice recommendations. *JPEN J Parenter Enteral Nutr.* 2009;33(2):122-167.
- 4. Carey TS, Hanson L, Garrett JM, et. al. Expectations and outcomes of gastric feeding tubes. *Am J Med*. 2006;119(527):e11-e16.
- 5. Centers for Medicare and Medicaid Services (CMS). *National Coverage Determination (NCD)* for Enteral and Parenteral Nutritional Therapy (180.2). <a href="http://www.cms.gov/medicare-coverage-database/search/search-results.aspx?CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Minne">http://www.cms.gov/medicare-coverage-database/search/search-results.aspx?CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Minne</a>



- 6. Chung CK, Whitney R, Thompson CM, et al. Experience with an enteral-based nutritional support regimen in critically ill trauma patients. *J Am Coll Surg*. December 2013;217(6):1108-1117.doi: 10.1016/j.jamcollsurg.2013.08.006.
- 7. Finestone HM, Greene-Finestone LS. Rehabilitation medicine: Diagnosis of dysphagia and its nutritional management for stroke patients. *CMAJ*. November 2003;169(10):1041-1044.
- 8. Haddad RY, Thomas DR. Enteral nutrition and enteral tube feeding: review of the evidence. *Clin Geriatr Med.* November 2002;18(4):867-881.
- 9. Itkin M, DeLegge MH, Fang JC, et.al. Society of Interventional Radiology; American Gastroenterological Association Institute; Canadian Interventional Radiological Association; Cardiovascular and Interventional Radiological Society of Europe. Multidisciplinary practical guidelines for gastrointestinal access for enteral nutrition and decompression from the Society of Interventional Radiology and American Gastroenterological Association (AGA) Institute, with endorsement by Canadian Interventional Radiological Association (CIRA) and Cardiovascular and Interventional Radiological Society of Europe (CIRSE). Gastroenterology. August 2011;141(2):742-765.
- 10. JeeJeebhoy KN. Enteral feeding. *Curr Opin Gastroenterol*. March 2005;21(2)187-191.
- 11. Klein S, Rubin DC. Enteral and Parenteral Nutrition. In: Feldman M, Tschumy WO, Freidman LS, Sleisenger, eds. *Sleisenger & Fordtran's Gastrointestinal and Liver Disease*. 7th ed. Philadelphia PA: Saunders; 2002:287-295.
- 12. Li JY, Yu T, Chen GC, et al. Enteral nutrition within 48 hours of admission improves clinical outcomes of acute pancreatitis by reducing complications: a meta-analysis. *PLoS One*. June 2013;8(6):e64926. doi: 10.1371/journal.pone.0064926.
- 13. Mcclave SA. Enteral Nutrition. In: Goldman L, Shafer AI, eds. *Cecil Medicine*. 24<sup>th</sup> ed. Philadelphia, PA: Saunders Elsevier; 2011:chap 223.
- 14. National Institute for Health and Clinical Excellence. Clinical Guideline 32. *Nutrition Support in Adults: Oral Nutrition Support, Enteral Tube Feeding and Parenteral Nutrition.* February 2006. Accessed December 22, 2014.
- 15. O'Connor NR. Infant Formula. Am Fam Physician. 2009;79(1):565-570.
- 16. Yantis MA, Velander R. American Society for Parenteral and Enteral Nutrition (A.S.P.E.N). Untangling enteral nutrition guidelines. *Nursing*. September 2011;41(9):32-38.

#### 04/2016 MPC:

No new references.

#### 04/2017 MPC:



No new references.

#### 04/2018 MPC:

- 17. ECRI Institute. Health Technology Assessment Information Service<sup>™</sup>. Hotline Response. Indications for Outpatient Nutritional Support in Adults (Age 18 Years or Older). March 3, 2017.
- 18. ECRI Institute. Health Technology Assessment Information Service<sup>™</sup>. Hotline Response. Indications for Inpatient Nutritional Support for Children and Adolescents (Age 2 to 17 Years). March 16, 2017.

## 04/2019 MPC:

No new references.

## 04/2020 MPC:

- Alkaade S, Vareedayah AA. Primer on exocrine pancreatic insufficiency, fat malabsorption, and fatty acid abnormalities. Am J Manag Care. 2017;23(12 Suppl):S203-S209.
- 20. Baker RD, and Baker SS. Cystic fibrosis: Nutritional issues. Last updated: Aug 08, 2019. In: *UpToDate*, Hoppin A (Ed), UpToDate, Waltham, MA, 2019.
- 21.ECRI Institute. *Product Brief: Relizorb Immobilized Lipase Cartridge (Alcresta Therapeutics, Inc.) for Facilitating Absorption of Enteral Formula Fats in Adults.* June 2019. Plymouth Meeting, PA.
- 22. Freedman S, Orenstein D, Black P, Brown P, McCoy K, Stevens J, et al. Increased Fat Absorption From Enteral Formula Through an In-line Digestive Cartridge in Patients With Cystic Fibrosis. *J Pediatr Gastroenterol Nutr.* 2017;65(1):97-101.
- 23. Freedman SD. Options for addressing exocrine pancreatic insufficiency in patients receiving enteral nutrition supplementation. *Am J Manag Care*. 2017;23(12 Suppl):S220-S228.
- 24. Giguere-Rich C, Mathew A, Reid E, Autore K, Guill MF. Use of an In-line Digestive Cartridge With Enteral Nutrition Improves the Weight Trajectory of 2 Children With Cystic Fibrosis Complicated by Another Medical Diagnosis. *Nutr Clin Pract*. 2018;Apr;33(2):286-294. doi: 10.1002/ncp.10080. D: 29658186. PMID: 29658186.
- 25. Hayes Inc. *Hayes Search and Summary. RELiZORB® (Alcresta Therapeutics Inc.).* Oct 2018. Lansdale, PA.
- 26. Katkin J, Baker RD, and Baker SS. Cystic fibrosis: Assessment and management of pancreatic insufficiency. Last updated: Jun 05, 2019. In: *UpToDate*, Hoppin A (Ed), UpToDate, Waltham, MA, 2019.
- 27. Nguyen DL. Guidance for supplemental enteral nutrition across patient populations. *Am J Manag Care*. 2017;23(12 Suppl):S210-S219.
- 28. 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.



- 29. Stevens J, Wyatt C, Brown P, Patel D, Grujic D, Freedman SD. Absorption and Safety With Sustained Use of RELiZORB Evaluation (ASSURE) Study in Patients With Cystic Fibrosis Receiving Enteral Feeding. *J Pediatr Gastroenterol Nutr.* 2018;67(4):527-532.
- 30.U.S. Food and Drug Administration. 510(k) Summary. K161247. Relizorb®. 2016 June 30. Available at URL address: <a href="https://www.accessdata.fda.gov/cdrh">https://www.accessdata.fda.gov/cdrh</a> docs/pdf16/K161247.pdf. Accessed February 9, 2020.

### 04/2021 MPC:

No new references.

## **04/2022 MPC**:

No new references.

## 02/2023 MTAC:

- 31. Baker RD, and Baker SS. Cystic fibrosis: Nutritional issues. Last updated: Aug 2019. In: *UpToDate*, Hoppin A (Ed), UpToDate, Waltham, MA, 2023.
- 32.ECRI Institute. *Product Brief: Relizorb Immobilized Lipase Cartridge (Alcresta Therapeutics, Inc.) for Facilitating Absorption of Enteral Formula Fats in Adults*. Last updated: July 2021. Plymouth Meeting, PA.
- 33. Freswick PN, Reid EK, Mascarenhas MR. Pancreatic Enzyme Replacement Therapy in Cystic Fibrosis. *Nutrients*. 2022 Mar 23;14(7):1341. PMID: 35405954.
- 34. Hayes Inc. Evolving Evidence Review. RELiZORB® (Alcresta Therapeutics Inc.) for Enteral Feeding in Patients with Cystic Fibrosis-Related Pancreatic Insufficiency. September 2021. Lansdale, PA.
- 35. Katkin J, Baker RD, and Baker SS. Cystic fibrosis: Assessment and management of pancreatic insufficiency. Last updated: July 13, 2022. In: *UpToDate*, Hoppin A (Ed), UpToDate, Waltham, MA, 2023.
- 36. Sathe MN, 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 1;72(1):18-23. PMID: 33165085.
- 37.U.S. Food and Drug Administration. Relizorb enzyme packed cartridge. 510(k) No. K163057 (traditional). Silver Spring, MD: FDA; July 12, 2017.