CareSource

MEDICAL POLICY STATEMENT
Ohio Medicaid

Policy Name & Number	Date Effective
Nutritional Supports-OH MCD-MM-0024	09/01/2026
Policy Type	
MEDICAL	

Medical Policy Statements are developed from a review of the available evidence-based, clinical information based on and supported by clinical guidelines from medical specialties, peer-reviewed medical and scientific studies, nationally recognized utilization and technology assessment guidelines, and other medical management industry standards to aid in determining the medical necessity of a service. Medically necessary services are defined in the plan-specific Evidence of Coverage, Member Handbooks, Provider Manuals, Medical Policy Statements, and/or other plan policies and procedures.

Medical Policy Statements do not guarantee an authorization or payment of services. Please refer to the plan contract (e.g., Evidence of Coverage, Member Handbook) for the service(s) referenced in the Medical Policy Statement. Except as otherwise required by law, if there is a conflict between the Medical Policy Statement and the plan contract and/or provider agreement, then the plan contract and/or provider agreement will be the controlling document. Reasonable discretion may be used in interpreting and applying this Policy Statement to services provided in a particular case, and the policy may be modified at any time. Medical Policy Statements may be superseded by federal and state laws and regulations, as applicable. In the case of a discrepancy between the Policy Statement's effective date and any applicable legal or regulatory requirement, the law or regulation will govern.

Coverage for mental health and substance use disorder (MH/SUD) benefits are provided at the same level as coverage for medical and surgical (M/S) benefits, as required by the Mental Health Parity and Addiction Equity Act (MHPAEA). MH/SUD benefits are not subject to limits or requirements that are more restrictive than those that apply to M/S benefits.

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A. Subject
Nutritional Supports

B. Background
Enteral nutrition may be necessary to maintain optimal health status for members with diseases or structural defects of the gastrointestinal (GI) tract that interfere with transport, digestion, or absorption of nutrients. Such conditions may include anatomic obstructions due to cancer, motility disorders such as gastroparesis, or metabolic absorptive disorders such as phenylketonuria (PKU). Considerations are given to medical condition, nutrition and physical assessment, metabolic abnormalities, gastrointestinal function, and expected outcome. Enteral nutrition may be prescribed to serve as a member's primary source of nutrition (ie, total enteral nutrition) or as a supplement to their ordinary diet (ie, supplemental enteral nutrition). Enteral nutrition may be delivered through oral intake or through a tube into the stomach or small intestine.

RELiZORB® is a prescription device that is used to break down fats in enteral formulas from triglycerides into fatty acids and monoglycerides to allow absorption and utilization in the body, processes that are essential for normal growth and development. This process mimics the function of the enzyme lipase in the intestine of members with pancreatic insufficiency. The product is designed to fit in series with currently used enteral feeding circuits.

Breastfeeding is recommended by healthcare professionals and the U.S. Department of Health and Human Services. Research shows that breastfeeding provides health benefits for both the mother and the child. In some situations, parents may look for alternative sources of human breast milk for infants. Donor milk banks take voluntary steps to screen milk donors and safely collect, process, handle, test, and store human breast milk.

C. Definitions
- **Chronological Age** – The time elapsed after birth, usually described in days, weeks, months, and/or years.
- **Corrected Age** – A term most appropriately used to describe children up to 3 years of age who were born preterm or before gestational age of 37 weeks. This term represents the age of the child from the expected date of delivery (mother's due date). Corrected age is calculated by subtracting the number of weeks born before 40 weeks of gestation from the chronological age**.**
- **Donor Human Milk** – Breast milk that is expressed by a mother and processed by a human milk bank for use by a recipient that is not the donor's own infant.
- **Enteral Nutrition** – Nutritional support given via the gastrointestinal (GI) tract, either directly or through any of a variety of tubes used in specific medical conditions. This includes oral feeding, as well as feeding using tubes such as orogastric, nasogastric, gastrostomy, or jejunostomy tubes.
    - **Supplemental Nutrition** – The minority of daily calories are supplied by the enteral nutrition product(s).

  - **Total Enteral Nutrition (TEN)** – The majority of daily calories are supplied by the enteral nutrition products.
- **Human Milk Bank** – A service which recruits human breast milk donors, collects, pasteurizes, and stores donor human milk, tests the donor milk for bacterial contamination, and distributes donor human milk to recipient infants in need.
- **Inborn Errors of Metabolism (IEM)** – Inherited biochemical disorders resulting in enzyme defects that interfere with normal metabolism of protein, fat, or carbohydrate.
- **Malnutrition** – Deficiencies, excesses, or imbalances in a member's intake of energy and/or nutrients, measured by *z*-scores, which are statistical measurements of standard deviation from WHO and CDC growth charts, calculated from weight for length or BMI by age.
  - **Mild Malnutrition** – *z* score equals -1 to -1.9 or *z* score decrease of 1 over time.
  - **Moderate Malnutrition** – *z* score equals -2 to -2.9 or *z* score decrease of 2 over time.
  - **Severe Malnutrition** – *z* score equals -3 or less or *z* score decrease of 3 over time.
- **Medical Food** – Specially formulated and processed food for members who are seriously ill or require the product as a major treatment modality. This term does not pertain to all foods fed to ill members. Medical foods are intended solely to meet the nutritional needs of members who have specific metabolic or physiological limitations restricting an ability to digest regular food. This can include specially formulated infant formulas. According to the Food and Drug Administration (FDA), a product must meet all the following minimum criteria to be considered a medical food:
  - The product must be a food for oral or tube feeding.
  - The product must be labeled for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements.
  - The product must be used under the supervision of a physician.
- **Oral Nutrition (Oral Feeding)** – Nutritional support given via oral route.
- **Ordinarily Prepared Food** – Regular grocery products including typical, not specially formulated, infant formulas.
- **RELiZORB®** – An FDA-approved digestive enzyme cartridge indicated for use in pediatric patients (including neonates and infants) and adult patients to hydrolyze fats during enteral feeding.
- **Therapeutic Oral Non-Medical Nutrition**:
  - **Food Modification** – Some conditions may require adjustment of carbohydrate, fat, protein, and micronutrient intake or avoidance of specific allergens (ie, diabetes mellitus, celiac disease).
  - **Fortified Food** – Food products that have additives to increase energy or nutrient density.
  - **Functional Food** – Food that is fortified to produce specific beneficial health effects.
  - **Texture Modified Food and Thickened Fluids** – Liquidized/thin puree, thick puree, finely minced or modified normal.
  - **Modified Normal** – Eating normal foods but avoiding particulate foods that are a choking hazard.

D. Policy

I. All members will be evaluated for medical necessity.

II. Oral nutrition in Section III refers to the situation where the majority of intake is provided by medical food by mouth or it is supplemental to normal food. Enteral nutrition in Section IV refers to the situation where the majority of intake is provided by medical food through a tube or it is supplemental.

III. **Oral Nutrition**

A. Oral nutrition requests for members with inborn errors of metabolism meet medical necessity criteria and do not require further review when the product is specifically formulated for the member's condition.

B. **Total oral nutrition** is considered medically necessary when **ALL** the following apply:

1. The product is a medical food for oral feeding.
2. The product is used under medical supervision.
3. The member has the ability to swallow without increased risk of aspiration.
4. The product is the member's primary source of nutrition.
5. The product is labeled and used for nutritional management of a member's specific medical condition without which serious morbidities (physical or mental) may develop **OR** the product is used to promote normal development or function for the member.
6. The product is used under the supervision of a physician, physician's assistant, or nurse practitioner, or ordered by a registered dietician upon referral by a health care provider authorized to prescribe dietary treatments.
7. The member has **one** of the following medical conditions:
   a. A condition caused by an inborn error of metabolism, including, but not limited to
      - phenylketonuria
      - homocystinuria
      - methylmalonic academia
      - galactosemia
   b. A condition that interferes with nutrient absorption and digestion, including, but not limited to:
      01. current diagnosis of non-IgE-mediated cow's milk allergy (CMA) as defined by any of the following:
         (1). abnormal stools, defined as hemoccult positive, mucous-containing, foam-containing, or diarrhea
         (2). poor weight gain trajectory for age (eg, malnutrition)
         (3). atopic dermatitis: age of onset less than 3 months, severe eczema, exacerbation of eczema noted with introduction of cow's milk, cow's milk formula or maternal ingestion of cow's milk (if breastfed)

02. allergy to specific foods, including food-induced anaphylaxis, or severe food allergy indicating a sensitivity to intact protein product as diagnosed through a formal food challenge
03. allergic or eosinophilic enteritis (colitis/proctitis, esophagitis, gastroenteritis)
04. cystic fibrosis with malabsorption
05. diarrhea or vomiting resulting in clinically significant dehydration requiring treatment by a medical provider
06. malabsorption unresponsive to standard age-appropriate interventions when associated with failure to gain weight or meet established growth expectations
07. malnutrition (as defined by Nelson's Textbook of Pediatrics and not iatrogenically- or medication-induced) (formerly failure to thrive) that is moderate or severe and unresponsive to standard age-appropriate interventions (eg, commercial shakes, protein bars) when associated with weight loss, failure to gain weight or to meet established growth expectations, including but not limited to:
    (1). premature infants who have not achieved the 25th percentile for weight based on their corrected gestational age
    (2). members with end-stage renal disease and hypoalbuminemia (albumin less than 4 gm/dl)

8. Approval duration can be up to 12 months for all oral nutrition products

C. **Supplemental oral nutrition** (including infant formula) is considered medically necessary when **ALL** the following apply:
1. The product is being used to supplement the member's primary source of nutrition.
2. The product is used as part of a defined and limited plan of care (eg, member transitioning from total enteral nutrition to standard diet for age, member undergoing cancer treatment).
3. There is documentation of a medical basis for the member's inability to maintain appropriate body weight and nutritional status (initial and ongoing) with normal or therapeutic oral nutrition. For example, malnutrition that is moderate to severe and unresponsive to standard age-appropriate interventions.
4. There is documentation of ongoing evidence of member's positive response to the oral nutrition. For example, members who have improved from moderate to severe malnutrition to mild malnutrition or normal health status may require documentation/evidence indicating that without the supplementation there is a risk of decline in nutritional status.
5. The product is used under the supervision of a physician, physician's assistant, or nurse practitioner, or ordered by a registered dietician upon referral by a health care provider authorized to prescribe dietary treatments.
6. The primary reason is not for convenience of the member or caregiver.
7. Approval duration can be up to 12 months for all supplemental oral nutrition products.

IV. **Enteral Nutrition Via Tube**

A. Enteral nutrition requests for members with inborn errors of metabolism and/or low-profile gastrostomy/jejunostomy/gastrojejunostomy tubes (eg, Mic-Key, button) meet medical necessity criteria and do not require further review.

B. **Total enteral nutrition via tube feeding** is considered medically necessary when the member has a functioning, accessible gastrointestinal tract, and **ALL** the following apply:

1. Enteral nutrition comprises the majority of the member's diet.
2. The product is used under the supervision of a physician, physician's assistant, or nurse practitioner, or ordered by a registered dietician upon referral by a health care provider authorized to prescribe dietary treatments.
3. There is documentation that the member cannot ingest nutrients orally due to a medical condition (physical or mental) which meets any of the following:
   a. interferes with swallowing (eg, dysphagia from a neurological condition, severe chronic anorexia nervosa or serious cases of oral aversion in children which render member unable to maintain weight and nutritional status with oral nutrition alone)
   b. puts the member at risk for aspiration if nutrition is given by oral route
   c. is associated with anatomical abnormality of the proximal GI tract (eg, tumor of the esophagus causing obstruction)
4. Approval duration can be up to 12 months for all enteral nutrition products.

C. **Supplemental enteral nutrition via tube** is considered medically necessary when **ALL** the following apply:

1. The product makes up the minority of the member's daily intake (ie, supplement to member's primary source of nutrition).
2. The enteral product is used as part of a defined and limited plan of care (eg, member transitioning from total enteral nutrition to standard diet for age, member undergoing treatment for cancer).
3. There is documentation of a medical basis for the inability of the member to maintain appropriate body weight and nutritional status (initial and ongoing) with normal or therapeutic enteral nutrition. For example, malnutrition that is moderate to severe and unresponsive to standard age-appropriate interventions.
4. There is documentation of ongoing evidence of member's positive response to the enteral nutrition. For example, members who have improved from moderate to severe malnutrition to mild malnutrition or normal health status may require documentation/evidence indicating that without the supplementation there is a risk of decline in nutritional status.
5. The product is used under the supervision of a physician, physician's assistant, or nurse practitioner, or ordered by a registered dietician upon referral by a health care provider authorized to prescribe dietary treatments.
6. The primary reason is not for convenience of the member or caregiver.
7. Approval duration can be up to 12 months for all supplemental enteral nutrition products.

V. Limitations/Exclusions: the following are not indicated:
   A. therapeutic diets where non-medical foods are tolerated, including:
      1. food modification
      2. texture modified food
      3. thickened fluids without a prescription that indicates it is necessary as part of treatment plan
      4. fortified food
      5. functional food
      6. modified normal
      7. flavorings
   B. ordinarily prepared foods including commercial products* such as shakes, smoothies, energy bars, vitamin or mineral supplements, and baby food
   C. food products that a provider receives a Medicaid per diem payment
   D. standard infant formula when alternative coverage is available
   E. products for meal replacements or snack alternatives
   F. products provided for convenience, preference, or lifestyle/social consideration of member/caregiver

*Commercial products represented by HCPCS codes may be provided on a case-by-case basis for members who use the product as their sole source of nutrition.

VI. **RELiZORB®** is considered medically necessary when **ALL** the following criteria are met:
   A. Member meets current FDA approval criteria.
   B. Member has a diagnosis of pancreatic insufficiency, or experiences symptoms of pancreatic insufficiency with current enteral formula such as fat malabsorption symptoms (eg, poor weight gain, diarrhea, abdominal pain, bloating, fatty stools, vomiting, and constipation)

VII. **Donor human milk** is considered medically necessary when **ALL** the following criteria are met:
   A. The provider is in good standing with the Human Milk Banking Association of North America.
   B. Documentation supports medical necessity in alignment with Ohio Revised Code 5164.072.
   C. For donor breast milk use outside of the hospital, documentation must include why elemental formula cannot be used to meet the infant's needs.
   D. Documentation supports that the provider has attested to educating the member in the donation process and about human milk.
   E. Consent supports that the provider discussed the risks and benefits with the member.
   F. Approval duration is up to 3 months.

E. Conditions of Coverage
NA

F. Related Policies/Rules
NA

G. Review/Revision History

	DATE	ACTION
Date Issued	04/14/2004	New policy
Date Revised	09/2005 04/2008 07/2009 03/2012 07/2013 07/2014 01/2015 06/28/2016 06/28/2017 09/09/2019 04/01/2020 08/19/2020 09/15/2021 03/16/2022 02/15/2023 08/02/2023 07/17/2024 06/04/2025 05/20/2026	 Realigned with new guidelines Added Relizorb criteria Removed Medical nutrition therapy and updated PA Updated references. Approved at PGC. Added clinical coverage conditions, updated references, added definitions, split criteria into oral vs tube, and total vs supplemental Annual review: removed WIC information, removed percentage of oral and enteral food criteria, moved exclusions to section VI, added section I for clarity Out of cycle update: clarified requirements for IEM and language on commercial products, added examples, malnutrition definition, and references. Approved at Committee. Review: removed PA language, changed title from Supplements to Supports, updated references. Approved at Committee. Review: updated references, approved at Committee. Review: expanded Relizorb age, clarified lifestyle/social limitation, added documentation requirements and approval time frame for donor milk, updated references, approved at Committee.
Date Effective	09/01/2026	
Date Archived		

H. References

1. American Geriatric Society Committee; Clinical Practice and Models of Care Committee. American Geriatrics Society feeding tubes in advanced dementia position statement. *J Am Geriatrics Soc*. 2014;62(8):1590-1593. doi:10.1111/jgs.12924

2. Bischoff SC, Austin P, Boeykens K. ESPEN practical guideline: home enteral nutrition. *Clin Nutr.* 2022;41(2):468-488. doi:10.1016/j.clnu.2021.10.018
3. Burris A, Burris J, Jarvinen KM. Cow's milk protein allergy in term and preterm infants: clinical manifestations, immunologic pathophysiology, and management strategies. *NeoReviews*. 2020;21(12):e795-e808. doi:10.1542/neo.21-12-e795
4. Cederholm T, Barazzoni R, Austin P, et al. ESPEN guidelines on definitions and terminology of clinical nutrition. *Clin Nutr*. 2017;36(1):49-64. doi:10.1016/j.clnu.2016.09.004
5. Daymont C, Hoffman N, Schaefer E, Fiks AG. Clinician diagnoses of failure to thrive before and after switch to World Health Organization growth curves. *Acad Pediatr.* 2020;20(3):405-412. doi:10.1016/j.acap.2019.05.126
6. Dipasquale V, Ventimiglia M, Gramaglia SMC, et al. Health-related quality of life and home enteral nutrition in children with neurological impairment: report from a multicenter survey. *Nutrients.* 2019;11(12):2968. doi:10.3390/nu11122968
7. DMEPOS: Nutrition Products, OHIO ADMIN. CODE 5160-10-26 (2024).
8. Druyan ME, Compher C, Boullata JI, et al. Clinical guidelines for the use of parenteral and enteral nutrition in adult and pediatric patients: applying the GRADE system to development of A.S.P.E.N. clinical guidelines. *JPEN J Parenter Enteral Nutr*. 2012;36(1):77-80. doi:10.1177/0148607111420157
9. Durable Medical Equipment, Prostheses, Orthoses, and Supplies (DMEPOS): General Provisions, OHIO ADMIN. CODE 5160-10-01 (2026).
10. *Early and Periodic Screening, Diagnostic, and Treatment*. Centers for Medicare and Medicaid Services. Accessed March 31, 2026. www.medicaid.gov
11. Evolving Evidence Review: Relizorb® (Alcresta Therapeutics Inc.) for Enteral Feeding in Patients with Cystic Fibrosis-Related Pancreatic Insufficiency. Hayes; 2021. Updated October 4, 2024. Accessed March 31, 2026. www.evidence.hayesinc.com
12. Fleet SA, Duggan C. Overview of enteral nutrition in infants and children. UpToDate. February 3, 2025. Accessed March 31, 2026. www.uptodate.com
13. Goodwin ET, Buel KL, Cantrell LD. Growth faltering and failure to thrive in children. *Am Fam Physician*. 2023;107(6):597-603. Accessed March 31, 2026. www.aafp.org
14. Grummer-Strawn LM, Reinold C, Krebs NF; Centers for Disease Control and Prevention. Use of World Health Organization and CDC growth charts for children aged 0-59 months in the United States. *MMWR Recomm Rep.* 2010;59(RR-9):1-15. Accessed March 31, 2026. www.cdc.gov
15. *Guidance for Industry: Frequently Asked Questions about Medical Foods*. 3rd ed. US Dept of Health and Human Services; 2023. Accessed March 31, 2026. www.fda.gov
16. Healthchek: Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Covered Services, OHIO ADMIN. CODE 5160-1-14 (2017).
17. Homan GJ. Failure to thrive: a practical guide. *Am Fam Physician*. 2016;94(4):295-299. Accessed March 31, 2026. www.aafp.gov
18. Klek S, Hermanowicz A, Dziwiszek G, et al. Home enteral nutrition reduces complications, length of stay, and health care costs: results from a multicenter study. *Am J Clin Nutr*. 2014;100(2):609-615. doi:103945/ajcn.113.082842
19. Lo L, Ballantine A. Malnutrition. In: Kliegman RM, St Geme JW, Blum NJ, et al., eds. *Nelson Textbook of Pediatrics*. Elsevier Inc; 2020:1869-1875.

20. Marchand V, Motil KJ; NASPGHAN Committee on Nutrition. Nutrition support for neurologically impaired children: a clinical report of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition. *J Pediatr Gastroenterol Nutr*. 2006;43(1):123-135. doi:10.1097/01.mpg.0000228124.93841.ea
21. Medicaid Medical Necessity: Definitions and Principles, OHIO ADMIN. CODE 5160-1-01 (2022).
22. Mehta NM, Skillman HE, Irving SY, et al. Guidelines for the provision and assessment of nutrition support therapy in the pediatric critically ill patient: Society of Critical Care Medicine and American Society for Parenteral and Enteral Nutrition. *J Parenteral and Enteral Nutr*. 2017;41(5):703-900. doi:10.1177/0148607117711387
23. Moro GE, Billeaud C, Rachel B, et al. Processing of donor human milk: update and recommendations from the European Milk Bank Association (EMBA). *Front Pediatr*. 2019;7(49):1-10. doi:10.3389/fped.2019.00049
24. Orphan Drugs, 21 C.F.R. § 312 (2023).
25. Pironi L, Boeykens K, Bozzetti F, et al. ESPEN practical guideline: home parental nutrition. *Clin Nutr*. 2023;42(3):411-430. doi:10.1016/j.clnu.2022.12.003
26. Robinson D, Walker R, Adams SC, et al. American Society for Parenteral and Enteral Nutrition (ASPEN) Definition of Terms, Style, and Conventions Used in ASPEN Board of Directors-Approved Documents. May 2018. Accessed March 31, 2026. www.nutritioncare.org
27. Services Provided by a Dietitian, OHIO ADMIN. CODE 5160-8-41 (2024).
28. U.S. Food and Drug Administration. RELiZORB® K250499. April 17, 2025. Accessed March 31, 2026. www.accessdata.fda.gov
29. U.S. Food and Drug Administration. *Use of Donor Human Milk*. Updated March 22, 2018. Accessed March 31, 2026. www.fda.gov.
30. U.S. Social Security Administration (SSA). *Disability Evaluation Under Social Security - 105.00 Digestive System – Childhood*. Accessed March 31, 2026. www.secure.ssa.gov
31. U.S. Social Security Administration (SSA). *Program Operations Manual System (POMS) - DI 24598.002. Failure to Thrive (FTT).* February 9, 2016. Accessed March 31, 2026. www.secure.ssa.gov
32. Volkert D, Beck AM, Cederholm T, et al. ESPEN practical guideline: clinical nutrition and hydration in geriatrics. *Clin Nutr.* 2022;14(4):958-989. doi:10.1016/j.clnu.2022.01.024
33. Wanden-Berghe C, Patino-Alonso MC, Galindo-Villardón P, et al. Complications associated with enteral nutrition: CAFANE Study. *Nutrients*. 2019;11(9):2041. doi:10.3390-nu11092041
34. World Health Organization. Malnutrition. March 1, 2024. Accessed March 31, 2026. www.who.int
35. Worthington P, Balint J, Bechtold M, et al. When is parenteral nutrition appropriate? *J Parenteral and Enteral Nutr*. 2017;41(3):324-377. doi:10.1177/0148607117695251

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