

MEDICAL POLICY STATEMENT Michigan Medicaid

Wilchigan Wedicald					
Policy Name & Number	Date Effective				
Nutritional Supports-MI MCD-MM-1535	09/01/2025				
Policy Type					
MEDICAL					

Medical Policy Statements are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased, or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage or Certificate of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other plan policies and procedures.

Medical Policy Statements do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage or Certificate of Coverage) 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, then the plan contract will be the controlling document used to make the determination.

According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

Table of Contents

Α.	Subject	. 2
	Background	
	Definitions	
	Policy	
	Conditions of Coverage	
F.	Related Policies/Rules	. 6
G.	Review/Revision History	. 6
Н.	References	6





A. Subject Nutritional Supplements

B. Background

Enteral nutrition may be necessary to maintain optimal health status for individuals 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 an individual's primary source of nutrition (ie, total enteral nutrition) or as a supplement to an 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. 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.

C. Definitions

- Children's Special Health Care Services (CSHCS) A benefit plan designed to
 find, diagnose, and treat children under age 21 years with chronic illness or disabling
 conditions. Persons over age 21 with chronic cystic fibrosis, certain blood
 coagulation disorders, or hereditary blood cell disorders, commonly known as sickle
 cell disease, may also qualify. The program establishes coverage of services related
 to the member's CSHCS-qualifying diagnoses.
- 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.
- **Inborn Errors of Metabolism (IEM)** Inherited biochemical disorders resulting in enzyme defects that interfere with normal metabolism of protein, fat, or carbohydrate.
- Medical Food Specially formulated and processed food for individuals who are seriously ill or who require the product as a major treatment modality. This term does not pertain to all foods fed to ill individuals. Medical foods are intended solely to meet the nutritional needs of individuals 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.
- RELiZORB® An FDA-approved digestive enzyme cartridge indicated for use in pediatric patients (ages 2 years and older) and adult patients to treat exocrine pancreatic insufficiency.
- **Standard Food** Regular grocery products including typical, not specially formulated, infant formulas.
- 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. Enteral nutrition (administered orally)
 - A. For members under age 21
 - 1. Enteral nutrition (administered orally) may be covered for members under the age of 21 when one of the following applies:
 - a. A chronic medical condition exists resulting in nutritional deficiencies, and a 3-month trial is required to prevent gastric tube placement.
 - b. Supplementation to regular diet or meal replacement is required, and the beneficiary's weight-to-height ratio has fallen below the 5th percentile on standard growth grids.
 - c. Physician documentation details low percentage increase in growth pattern or trend directly related to the nutritional intake and associated diagnosis/medical condition.
 - 2. For CSHCS coverage, a nutritionist or appropriate pediatric subspecialist must indicate that long-term enteral supplementation is required to eliminate serious impact on growth and development.
 - 3. Documentation must be less than 30 days old and include the following:
 - a. specific diagnosis/medical condition related to the beneficiary's inability to take or eat food
 - b. duration of need
 - c. amount of calories needed per day
 - d. current height and weight, as well as change over time (for members under 21, weight-to-height ratio)



- e. specific prescription identifying levels of individual nutrient(s) that is required in increased or restricted amounts
- f. list of economic alternatives that have been tried
- 4. For continued use beyond 3-6 months, the Children's Special Health Care Services (CSHCS) Program requires a report from a nutritionist or appropriate pediatric subspecialist.
- 5. For HCPCS code B4162, the member must have a specified inherited disease of metabolism identified by the International Classification of Diseases (ICD).
- B. For members 21 years and older
 - 1. Enteral nutrition (administered orally) may be covered for members aged 21 years and over when one of the following applies:
 - a. The member has a medical condition that requires the unique composition of the formula nutrients that the member is unable to obtain from food.
 - b. The nutritional composition of the formula represents an integral part of treatment of the specified diagnosis/medical condition.
 - c. The member has experienced significant weight loss.
 - 2. Documentation must be less than 30 days old and include the following:
 - a. specific diagnosis/medical condition related to the member's inability to take or eat food
 - b. duration of need
 - c. amount of calories needed per day
 - d. current height and weight, as well as change over time
 - e. specific prescription identifying levels of individual nutrients that are required in increased or restricted amounts
 - f. list of economical alternatives that have been tried
 - For HCPCS code B4157, the member must have a specified inherited disease of metabolism identified by the International Classification of Diseases.
- II. Enteral nutrition (administered by tube)
 - A. Enteral formula are considered medically necessary when the diagnosis/medical condition requires placement of a gastric tube and nutrition is administered by syringe, gravity, or pump.
 - B. Documentation must be less than 30 days old and include
 - 1. specific diagnosis/medical condition requiring tube feeding
 - 2. duration of treatment
 - 3. amount needed per day
 - 4. if a pump is required, the medical reason why syringe or gravity method could not be used
 - C. Medical necessity review is required for the following:
 - 1. all specialized enteral formula requests for tube feedings
 - 2. over-quantity requests for standard formula enteral tube feedings
 - 3. medical need beyond Standards of Coverage



- III. Enteral nutrition payment rules
 - A. The appropriate formula HCPCS code should be requested based on monthly requirements with total calories used (divided by 100) as the unit amount. Medicaid will reimburse for a maximum quantity of up to 900 units for any combination of approved formula.
 - B. Providers should refer to the following chart for additional assistance:

Formula	100 calories = 1 unit (u)	6 (8 oz) cans a day	1 month = 30 days	6 months = 180 days	\$5.00 cost/8 oz liquid or packet or can
Standard @ 250 calories/8 oz	250 cals/100 =2.5 units	2.5 u x 6 = 15 units a day	15 u x 30 = 450 units a month	15 u x 180=2700 units for 6 months	\$5.00 ÷ 2.5 u = \$2.00 per unit
Caloric Dense @ 355 calories/8 oz	355 cals/100 =3.55 units	3.55 u x 6= 21 units a day	21 u x 30 = 630 units a month	21 u x 180 = 3780 units for 6 months	\$5.00 ÷ 3.55 u = \$1.41 per unit
Powder, 1 package = 150 calories	150 cals/ 100 = 1.5 units	1.5 u x 6 = 9 units a day	9 u x 30 = 270 units a month	9 u x 180 =1620 units for 6 months	\$5.00 ÷ 1.5 u = \$3.33 per unit
Powder, 1# can = 112 oz when mixed @ 20 calories/oz* = 2240 calories for the entire can (*can vary with physician orders)	2240 cals/100 = 22.4 units		6 cans per month = 22.4 u x 6 = 134 units a month	134 u x 6 months = 804 units for 6 months	\$5.00 ÷ 22.4 u = \$0.30 per unit

- C. The necessary equipment and supply code for enteral tube feedings should be requested up to specified quantity limits. Feeding bags, anchoring devices, syringes, drain sponges, cotton tip applicators, tape, adaptors, and connectors used in conjunction with a gastrostomy or enterostomy tube are included in the supply kit codes and should not be billed separately.
- D. Dietary formula for oral feedings may be obtained from either a medical supplier or a pharmacy.
- E. Dietary formula for tube feedings are covered only through the medical supplier.
- IV. The following are not considered medical in nature, and are therefore not covered:
 - A. nutritional puddings/bars
 - B. regular or dietetic foods (eg, Slimfast, Carnation instant breakfast)
 - C. sports drinks/juices
 - D. standard infant/toddler formula
 - E. products for meal replacements or snack alternatives
 - F. enteral formula to accommodate psychological or behavioral conditions, food preferences, allergies, loss of appetite, or noncompliance with a specialized diet
 - G. therapeutic diets where non-medical foods are tolerated, including
 - 1. food modification
 - 2. texture modified food
 - 3. thickened fluids without a prescription that indicates necessity as part of treatment plan
 - 4. fortified food
 - 5. functional food
 - 6. modified normal



- 7. flavorings
- H. food products that a provider receives a Medicaid per diem payment
- I. when use of product is for convenience or preference of member/caregiver
- V. RELiZORB is considered medically necessary when **ALL** the following criteria are met:
 - A. The member is at least 2 years of age per the FDA, and
 - B. The 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).
- E. Conditions of Coverage NA
- F. Related Policies/Rules

G. Review/Revision History

C. Review/Revision Filstory				
	DATE	ACTION		
Date Issued	09/13/2023	New policy. Approved at Committee.		
Date Revised	03/13/2024	Review: updated references, removed PA language from V, approved at Committee.		
	07/17/2024	Review: changed title from Supplements to Supports, added references, expanded Relizorb indications. Approved at Committee		
	06/05/2025	Review: updated references, approved at Comittee.		
Date Effective	09/01/2025			
Date Archived				

H. References

- 1. Burris A, Burris J, Jarvinen. 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
- 2. 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
- COVID-19 Response: COVID-19 Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) Supplemental Billing Policy to Bulletin MSA 20-14. Medicaid Services Administration Bulletin MSA 20-25. Issued July 20, 2020. Accessed June 3, 2025. www.michigan.gov
- 4. COVID-19 Response: Home Delivery of Durable Medical Equipment and Medical Supplies. Medicaid Services Administration Bulletin MSA 20-14. Issued March 26, 2020. Accessed June 3, 2025. www.michigan.gov



- 5. Daymont C, Hoffman N, Schaefer E, et al. 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. *Diet for Life*. Michigan Department of Health and Human Services. Accessed June 3, 2025. www.michigan.gov
- 7. 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
- 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. *J Parenter Enteral Nutr.* 2012;36(1):77-80. doi:10.1177/0148607111420157
- 9. Early and Periodic Screening, Diagnostic, and Treatment. US Centers for Medicare and Medicaid Services. Accessed June 3, 2025. www.medicaid.gov
- 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 June 3, 2025. www.evidence.hayesinc.com
- 11. Fleet SA, Duggan C. Overview of enteral nutrition in infants and children. UpToDate. February 3, 2025. Accessed June 3, 2025. www.uptodate.com
- 12. Goodwin ET, Buel KL, Cantrell LD. Growth faltering and failure to thrive in children. *Am Fam Physician*. 2023;107(6):597-603. Accessed July 1, 2024. www.aafp.org
- 13. 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 June 3, 2025. www.cdc.gov
- 14. Guidance for Industry: Frequently Asked Questions about Medical Foods. 3rd ed. US Dept of Health and Human Services; 2023. Accessed June 3, 2025. www.fda.gov
- 15. Homan GJ. Failure to thrive: a practical guide. *Am Fam Physician*. 2016;94(4):295-299. Accessed June 3, 2025. www.aafp.org
- 16. 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:10.3945/ajcn.113.082842
- 17. 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.
- 18. 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
- 19. *Medicaid Provider Manual*. Michigan Dept of Health and Human Services. April 1, 2025. Accessed June 3, 2025. www.mdch.state.mi.us
- 20. 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 Parental and Enteral Nutr.* 2017;41(5):703-900. doi:10.1177/0148607117711387





- 21. 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
- 22. Orphan Drugs, 21 C.F.R. § 312 (2023).
- 23. Reversal of Temporary COVID-19 Durable Medical Equipment, Prosthetics, Orthotics and Medical Supplies (DMEPOS) Policies. Medicaid Services Administration Bulletin MMP 22-40. Issued November 1, 2022. Accessed June 3, 2025. www.michigan.gov
- 24. 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.* ASPEN; 2018. Accessed June 3, 2025. www.nutritioncare.org
- 25. U.S. Food and Drug Administration. RELiZORB® K232784. December 21, 2023. Accessed June 3, 2025. www.accessdata.fda.gov
- 26. U.S. Social Security Administration. *Disability valuation Under Social Security -* 105.00 Digestive System Childhood. Accessed June 3, 2025. www.secure.ssa.gov
- 27. U.S. Social Security Administration. *Program Operations Manual System (POMS) DI 24598.002. Failure to Thrive (FTT).* February 9, 2016. Accessed June 3, 2025. www.secure.ssa.gov
- 28. 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
- 29. World Health Organization. Malnutrition. March 1, 2024. Accessed June 3, 2025. www.who.int
- 30. 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