

MEDICAL POLICY STATEMENT Wisconsin Marketplace

Policy Name & Number	Date Effective		
Nutritional Supports-WI MP-MM-1630	12/01/2024		
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 Administrative 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.

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A. Subject Nutritional Supports

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) 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 their 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.

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 to feed their babies. Donor milk banks take voluntary steps to screen milk donors and safely collect, process, handle, test, and store the milk. Storage and processing of donor milk is not currently reimbursed.

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 mother'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, and jejunostomy tubes.



- 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 an individual'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.
 - o 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 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 their ability to digest regular food. This can include specially formulated infant formulas. According to the Food and Drug Administrations (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.
 - o The product must be used under the supervision of a physician.
- Oral Nutrition (Oral Feeding) Nutritional support given via the 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 (ages 2 years and older) and adult patients to treat exocrine pancreatic insufficiency.
- Therapeutic Oral Non-Medical Nutrition:
 - Food Modification Some conditions may require adjustment of carbohydrate, fat, protein, and micronutrient intake or avoidance of specific allergens (e.g., 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 minces, or modified normal.



Modified Normal – Eating normal foods by avoiding particulate foods that are a choking hazard.

D. Policy

- I. Oral enteral and parenteral nutrition is considered medically necessary when **ALL** the following criteria are met:
 - A. The product must be medical food for oral or tube feeding.
 - B. The product must be the primary source of nutrition, ie more than half the nutritional intake for the individual.
 - C. The product must be labeled and used for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements to avert the development of a serious physical or mental disability or to promote normal development and function.
 - D. The product must be used under the supervision of a Provider or ordered by a registered dietician upon referral by a healthcare provider authorized to prescribed dietary treatments.
- II. When and if the member is medically appropriate, introduction to oral nutrition is preferred and will be worked toward at medically appropriate intervals as soon as medically able at which time enteral or parenteral feeding should be weaned. These services require prior authorization and reasonable quantity limits may be established for certain supplies, equipment, or appliances.

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 criteria are met:
 - 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 (ie, more than half the nutritional intake).
 - 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 condition caused by an inborn error of metabolism, including, but not limited to



- a. phenylketonuria
- b. homocystinuria
- c. methylmalonic academia
- d. galactosemia
- 2. A condition that interferes with nutrient absorption and digestion, including, but not limited to
 - a. current diagnosis of non-IgE-mediated cow's milk allergy (CMA) as defined by any of the following:
 - 01. abnormal stools, defined as hemoccult positive, mucouscontaining, foam-containing, or diarrheal
 - 02. poor weight gain trajectory for age (eg, malnutrition)
 - 03. 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)
 - 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
 - c. allergic eosinophilic enteritis (colitis/proctitis, esophagitis, gastroenteritis)
 - d. cystic fibrosis with malabsorption
 - e. Diarrhea or vomiting resulting in clinically significant dehydration requiring treatment by a medical provider.
 - f. malabsorption unresponsive to standard age-appropriate interventions when associated with failure to gain weight or meet established growth expectations
 - g. malnutrition (as defined by Nelson's Textbook of Pediatrics and not iatrogenically- or medication-induced) (formerly failure to thrive) that is moderate to 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:
 - 01. premature infants who have not achieved the 25th percentile for weight based on corrected gestational age
 - 02. individuals with end-stage renal disease and hypoalbuminemia (albumin less than 4gm/dl)
- 8. Approval duration can be up to 12 months for all 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:
 - 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:
 - 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)
 - 2. puts the member at risk for aspiration if nutrition is given by oral route
 - 3. 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.
- V. **RELIZORB**® is considered medically necessary when **ALL** the following criteria are met:
 - A. Member is at least 2 years of age per the FDA.
 - 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, constipation).
- VI. **Donor human milk**: per the COC, donor human milk processing, storage, and distribution is not a covered service.
- VII. Common Ground Healthcare Cooperative (CGHC) does **NOT** consider the following medically necessary:
 - A. Nutritional formulas and dietary supplements that can be purchased over the counter, which by law do not require either a written prescription or dispensing by a licensed pharmacist.
 - B. Use of a nutritional product for the convenience or preference of the member or caregiver.
 - C. Therapeutic diets where non-medical foods are tolerated, including any of the following:
 - 1. food modification
 - 2. texture modified food
 - 3. thickened fluids
 - 4. fortified food
 - 5. functional food
 - 6. modified normal



7. flavorings

- D. Oral nutrition products for meal replacements or snack alternatives.
- E. Feeding tubes for individuals with advanced dementia.
- F. Products administered in an outpatient provider setting. These items are not separately reimbursable.
- E. Conditions of Coverage NA
- F. Related Policies/Rules NA

G. Review/Revision History

	DATE	ACTION	
Date Issued	08/14/2024	New market. Approved at Committee.	
Date Revised			
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Date Archived			

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