# MEDICAL POLICY STATEMENT
# Marketplace

| Policy Name & Number | Date Effective |
|---|---|
| Nutritional Supports-MP-MM-1330 | 10/01/2024-08/31/2025 |
| **Policy Type** | |
| **MEDICAL** | |

Medical Policy Statement prepared by CareSource and its affiliates 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 documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) 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.

| This policy applies to the following Marketplace(s): | | | | |
|---|---|---|---|---|
| ☒ **Georgia** | ☒ **Indiana** | ☒ **Kentucky** | ☒ **Ohio** | ☒ **West Virginia** |

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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) 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 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.

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.
    - **Supplemental Nutrition** – The minority of daily calories are supplied by enteral nutrition products.

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  - **Total Enteral Nutrition (TEN)** – The majority of daily calories are supplied by 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 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.
  - **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.
  - 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.

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

D. Policy

I. **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.
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 diarrheal
          (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 eosinophilic enteritis (colitis/proctitis, esophagitis, gastroenteritis)
      04. cystic fibrosis with malabsorption

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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 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:
    (1). premature infants who have not achieved the 25th percentile for weight based on their corrected gestational age
    (2). 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.

C. **Supplemental oral nutrition** 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. 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, individuals 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 must be 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. All avenues of coverage available must be exhausted first. For example, members eligible for their county Women, Infant, and Children (WIC) program must apply for an eligibility evaluation before supplemental nutrition coverage will be considered.
8. Approval duration can be up to 12 months for all supplemental oral nutrition products.

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II. **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:
         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 criteria are met:
      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, individuals 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 must be 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. All avenues of coverage available must be exhausted first (eg, members eligible for their county Women, Infant, and Children (WIC) program must apply for an eligibility evaluation before supplemental nutrition coverage will be considered).

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

III. **Donor human milk**: See Section E for additional criteria for Kentucky and Georgia.
   A. CareSource considers human milk medically necessary when **ALL** the following criteria are met:
      1. Provider must be in good standing with the Human Milk Banking Association of North America.
      2. Documentation supports medical necessity.
      3. Documentation supports that the provider has attested to educating the member in the donation process and about human milk.
      4. Documentation supports that the provider discussed the risks and benefits with the member.
   B. Per the Food & Drug Administration, only human milk banks that screen their milk donors and take precautions to ensure the safety of its milk should be utilized.

IV. CareSource 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, UNLESS administered through a pre-existing feeding tube
   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. Relizorb (insufficient published evidence)
   E. oral nutrition products for meal replacements or snack alternatives
   F. feeding tubes for individuals with advanced dementia
   G. products administered in an outpatient provider setting; these items are not separately reimbursable

## E. State-Specific Information

A. Georgia
   1. As per the Evidence of Coverage, a benefit is provided for “100% human diet, if the 100% human diet and supplemented milk fortifier products are prescribed for the prevention of necrotizing enterocolitis and associated co-morbidities and administered under the direction of a physician. 100% human diet means the

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supplementation of a mother's expressed breast milk or donor milk with a milk fortifier."

2. Evidence of Coverage and Health Insurance Contract. Marketplace Plan, Georgia (2024). Accessed July 1, 2024. www.caresource.com

B. Indiana
Evidence of Coverage and Health Insurance Contract. Marketplace Plan, Indiana (2024). Accessed July 1, 2024. www.caresource.com

C. Kentucky
1. As per the Evidence of Coverage, a benefit is provided for "100% human diet, if the 100% human diet and supplemented milk fortifier products are prescribed for the prevention of necrotizing enterocolitis and associated co-morbidities and administered under the direction of a physician. 100% human diet means the supplementation of a mother's expressed breast milk or donor milk with a milk fortifier."
2. Evidence of Coverage and Health Insurance Contract. Marketplace Plan, Kentucky (2024). Accessed July 1, 2024. www.caresource.com

D. Ohio
Evidence of Coverage and Health Insurance Contract. Marketplace Plan, Ohio (2024). Accessed July 1, 2024. www.caresource.com

E. West Virginia
Evidence of Coverage and Health Insurance Contract. Marketplace Plan, West Virginia (2024). Accessed July 1, 2024. www.caresource.com

F. Conditions of Coverage
NA

G. Related Policies/Rules
NA

H. Review/Revision History

| | DATE | ACTION |
|---|---|---|
| **Date Issued** | 08/17/2022 | |
| **Date Revised** | 08/02/2023<br>07/17/2024 | Annual review: updated references, added malnutrition definition, clarified criteria for IEM. Approved at Committee.<br>Review: updated references, title changed from Supplements to Supports. Approved at Committee. |
| **Date Effective** | 10/01/2024 | |
| **Date Archived** | 08/31/2025 | This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy. |

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