MEDICAL POLICY STATEMENT
Marketplace

Policy Name & Number	Date Effective
Nutritional Supplements-MP-MM-1330	IN, GA, WV, KY: 11/01/2022-10/31/2023 OH: 12/01/2022-10/31/2023
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 Supplements

B. Background

Nutrition may be delivered through oral intake or through a tube into the stomach or small intestine. Enteral nutrition may be medically 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 PKU. Considerations are given to medical condition, nutrition and physical assessment, metabolic abnormalities, gastrointestinal function, and expected outcome. Enteral nutrition may be either for total enteral nutrition or for supplemental enteral nutrition.

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.
- **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.

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- **Oral Nutrition (oral feeding)** – Nutritional support given via the oral route.
- **RELiZORB** – The only FDA-approved product indicated to hydrolyze (break down) fats in enteral feeding. RELiZORB is indicated for use in pediatric patients (ages 5 years and older) and adult patients.
- **Standard Food** – Regular grocery products including typical, not specially formulated, infant formulas.
- **Supplemental Nutrition** – Fewer than 50% of daily calories are supplied by enteral nutrition products.
- **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.
- **Total Enteral Nutrition (TEN)** – More than 50% of daily calories are supplied by enteral nutrition products.

D. Policy

I. **Oral Nutrition**: Prior authorization is required except for inborn error of metabolism conditions.

A. **Total oral nutrition** is considered medically necessary when **ALL** the following criteria are met:

1. The product must be a medical food for oral feeding;
2. The product must be used under medical supervision;
3. The member has the ability to swallow without increased risk of aspiration;
4. The product is documented to make up more than 50% of the member's daily intake, which, by definition, is the member's primary source of nutrition;
5. The product must be 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 member must have **one** of the following medical conditions:
   a. A condition caused by an inborn error of metabolism, including but not limited to the following:
      - Phenylketonuria;
      - Homocystinuria;
      - Methylmalonic academia;
      - Galactosemia; **OR**

   b. A condition that interferes with nutrient absorption and digestion, including, but not limited to:

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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 (e.g., failure to thrive);
    (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;
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. Failure to thrive unresponsive to standard age-appropriate interventions (e.g., nutritionally complete liquid meal supplements) 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);

7. 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;
8. Approval duration can be up to 12 months for all oral nutrition products.

B. **Oral supplemental nutrition** is considered medically necessary when **ALL** the following apply:
1. The member's diet consists of less than 50% enteral nutrition and more than 50% standard diet for age;
2. The product is used as part of a defined and limited plan of care for a member transitioning from total enteral nutrition to standard diet for age;
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;
4. 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;
5. The primary reason is not for convenience of the member or caregiver;

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6. 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;
7. Approval duration can be up to 12 months for all oral supplemental nutrition products. Documentation of ongoing evidence of member's positive response to the oral nutrition is required for future approvals.

II. **Enteral Nutrition via Tube**: Prior authorization is required except for inborn error of metabolism conditions and for low-profile gastrostomy/jejunostomy/gastrojejunostomy tubes.
   A. **Total enteral nutrition** via tube feeing is considered medically necessary when the member has a functioning, accessible gastrointestinal tract, and **ALL** the following:
      1. Enteral nutrition comprises the majority (greater than 50%) 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 dur to a medical condition (physical or mental) which:
         a. Interferes with swallowing (e.g., 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); **OR**
         b. Puts member at risk for aspiration if nutrition is given by oral route; **OR**
         c. Is associated with anatomical abnormality of the proximal GI tract (e.g., tumor of the esophagus causing obstruction);
      4. Approval duration can be up to 12 months for all enteral nutrition products.
   B. **Enteral supplemental nutrition** via tube is considered medically necessary when **ALL** the following are met:
      1. The member's diet consists of less than 50% enteral nutrition and more than 50% standard diet for age;
      2. The enteral product is used as part of a defined and limited plan of care for a member transitioning from total enteral nutrition to standard diet for age;
      3. 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;
      4. Documentation of ongoing evidence of member's positive response to the enteral nutrition;
      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 (e.g., 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 breast milk**: prior authorization is required. See Section I 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; and
      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.
   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. Conditions of Coverage

NA

F. Related Policies/Rules

NA

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G. Review/Revision History

	DATE	ACTION
Date Issued	08/17/2022	
Date Revised		
Date Effective	GA, IN, KY, WV: 11/01/2022 OH: 12/01/2022	
Date Archived	GA, IN, KY, WV: 10/31/2023 OH: 10/31/2023	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.

H. References

1. American Geriatric Society Committee and Clinical Practice and Models of Care Committee. (2014). American Geriatrics Society feeding Tubes in Advanced Dementia Position Statement. J American Geriatric Society. 2014;62(8):1590-1593. Retrieved July 26, 2022 from www.agsjournals.onlinelibrary.wiley.com.
2. Burris A, Burris J, Jarvinen. Cow's Milk Protein Allergy in Term and Preterm Infants: Clinical Manifestations, Immunologic Pathophysiology, and Management Strategies. NeoReviews. 2020 December; 21(12):e795-e808.
3. Cederholm T, et al. ESPEN guidelines on definitions and terminology of clinical nutrition. Clinical Nutrition. 2017;36(1):49-64. Doi:10.1016/j.clnu.2016.09.004.
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6. Klek S, Hemanowicz 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.
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9. Robinson D, et al. (2018, May). American Society for Parenteral and Enteral Nutrition (ASPEN) Definition of Terms, Style, and Conventions Used in ASPEN Board of Directors-Approved Documents. Retrieved July 26, 2022 from www.nutritioncare.org.
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The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.

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I. State-Specific Information

A. Georgia
   1. Effective: 11/01/2022
   2. Additional donor milk coverage criteria: 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”.
   3. Evidence of Coverage and Health Insurance Contract. Marketplace Plan, Georgia (2022). Retrieved July 26, 2022 from www.caresource.com.

B. Indiana
   1. Effective: 11/01/2022
   2. Evidence of Coverage and Health Insurance Contract. Marketplace Plan, Indiana (2022). Retrieved July 26, 2022 from www.caresource.com.

C. Kentucky
   1. Effective: 11/01/2022
   2. Additional donor milk coverage criteria: 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”.
   3. Evidence of Coverage and Health Insurance Contract. Marketplace Plan, Kentucky (2022). Retrieved July 26, 2022 from www.caresource.com.

D. Ohio
   1. Effective: 12/01/2022
   2. Evidence of Coverage and Health Insurance Contract. Marketplace Plan, Ohio (2022). Retrieved July 26, 2022 from www.caresource.com.

E. West Virginia
   1. Effective: 11/01/2022

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2. Evidence of Coverage and Health Insurance Contract. Marketplace Plan, West Virginia (2022). Retrieved July 26, 2022 from www.caresource.com.

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