MEDICAL POLICY STATEMENT
Ohio Medicaid

Policy Name & Number	Date Effective
Nutritional Supplements - OH MCD - MM-0024	07/01/2022-05/31/2023
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.

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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 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, or 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 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.
- **RELiZORB** – The only FDA-approved product indicated to hydrolyze (breakdown) 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 the enteral nutrition product(s).
- **Therapeutic Oral Non-Medical Nutrition**:
  - **Food Modification** – Some conditions may require adjustment of carbohydrate, fat, protein, and micronutrient intake or avoidance of specific allergens (i.e., 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.
- **Total enteral nutrition (TEN):** Individual is receiving more than 50% of their daily caloric intake via 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:

i) Current diagnosis of non-IgE-mediated cow's milk allergy (CMA) as defined by any of the following:
   (a) Abnormal stools, defined as hemocult positive, mucous-containing, foam-containing, or diarrheal.
   (b) Poor weight gain trajectory for age (e.g., failure to thrive)
   (c) 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).

ii) 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

iii) Allergic or eosinophilic enteritis (colitis/proctitis, esophagitis, gastroenteritis)

iv) Cystic fibrosis with malabsorption

v) Diarrhea or vomiting resulting in clinically significant dehydration requiring treatment by a medical provider

vi) Malabsorption unresponsive to standard age-appropriate interventions when associated with failure to gain weight or meet established growth expectations

vii) Failure to thrive unresponsive to standard age-appropriate interventions (for example, 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:
   (a) Premature infants who have not achieved the 25th percentile for weight based on their corrected gestational age
   (b) Individuals with end-stage renal disease and hypoalbuminemia (albumin less than 4 gm/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:
   a. 12 months for all oral nutrition products.

B. **Oral supplemental nutrition** (including infant formula) 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. Documentation of ongoing evidence of member's positive response to the oral 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. 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:
   a. 12 months for all oral supplemental nutrition products.

II. **Enteral Nutrition Via Tube:** Prior authorization is required except for inborn error of metabolism conditions and for low-profile gastrostomy/jejunostomy/gastro-jejunostomy tubes.

A. **Total Enteral Nutrition via tube feeding** is considered medically necessary when 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 due to a medical condition (physical or mental) which **EITHER**:
      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 (for example, tumor of the esophagus causing obstruction).
   4. Approval Duration:
      a. 12 months for all oral 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 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. 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:
   a. 12 months for all oral supplemental nutrition products.

III. CareSource does **NOT** consider the following medically necessary:
   A. Therapeutic diets where non-medical foods are tolerated:
      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 that is not used to treat IOM when alternative coverage is available.
   E. Products for meal replacements or snack alternatives.
   F. When use of product is for convenience or preference of member/caregiver.

IV. **RELiZORB:** Prior authorization is required.
   A. RELiZORB is considered medically necessary when **ALL** the following criteria are met:
      1. Member is at least 5 years of age per the FDA; and
      2. Member has a diagnosis of pancreatic insufficiency; or
         Member experiences symptoms of pancreatic insufficiency with curre nt enteral formula such as fat malabsorption symptoms such as poor weight gain, diarrhea, abdominal pain, bloating, fatty stools, vomiting, and constipation.
   B. CareSource does not consider the following medically necessary:
      1. Feeding tubes for advanced dementia (feeding tubes are not recommended by American Geriatrics Society).
      2. Products administered in an outpatient provider setting are not separately reimbursable.
      3. When use of the product is for convenience or preference of the member/caregiver.

V. **Donor human milk:** Prior authorization is required.
   A. Human Donor Milk is considered 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 supporting medical necessity;
      3. Documentation supporting that the provider has attested to educating the member in the donation process and about human milk; and
      4. Consent supporting that the provider discussed the risks and benefits with the member.

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	 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
Date Effective	07/01/2022	
Date Archived	05/31/2023	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

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