MEDICAL POLICY STATEMENT
OHIO MEDICAID

Policy Name	Policy Number	Date Effective
Nutritional Supplements	MM-0024	01/01/2022-06/30/2022

Policy Type			
MEDICAL	Administrative	Pharmacy	Reimbursement

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.

Table of Contents

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 for dietary management to provide sufficient caloric and nutrition needs as a result of limited or impaired ability to ingest, digest, absorb or metabolize nutrients; or for a special medically determined nutrient requirement. 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.

Parenteral nutrition is nutrition provided through an intravenous line. Home Infusion Therapy is covered in the Pharmacy Policy SRx-0044.

This policy includes nutrition that is for medical purposes only.

C. Definitions

- **Enteral Nutrition** – Nutrition delivered through an enteral access device into the gastrointestinal tract bypassing the oral cavity.
- **Oral Nutrition** – Nutrition delivered through oral route.
- **Medical Food** – Food specially formulated and processed to be consumed or administered by oral intake or enteral access device. The intent is to meet distinctive nutritional requirements of a disease or condition when dietary management cannot be met by modifying a normal diet.
- **Enteral Access Device** – A tube or stoma is placed directly into the gastrointestinal tract for the delivery of nutrients.
- **Inborn Errors Of Metabolism (IEM)** – Inherited biochemical disorders resulting in enzyme defects that interfere with normal metabolism of protein, fat, or carbohydrate.
- **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.

D. Policy

I. Oral Nutrition

A. Prior Authorization is required except for inborn error of metabolism conditions.
B. CareSource considers oral nutrition medically necessary when the following criteria are met:
   1. Must be a medical food for oral feeding;
   2. Must be used under medical supervision;
   3. Member has the ability to swallow without increased risk of aspiration; and
   4. Documentation supports all of the following criteria:
      a. Member's diet consists of more than 50 percent enteral nutrition and less than 50 percent standard diet for age;
      b. Member is unable to maintain body weight and nutritional status (initial and ongoing treatment) with regular or therapeutic oral nutrition; and
      c. Member has one of the following:
         01. Inborn error of metabolism conditions including but not limited to
            (1) Phenylketonuria (PKU);
            (2) Homocystinuria; or
            (3) Methylmalonic academia;
            or
         02. A condition that interferes with nutrition absorption and assimilation including, but not limited to:
            (1) Allergy or hypersensitivity to cow or soy milk diagnosed through a formal food challenge;
            (2) Anaphylaxis to food;
            (3) Allergic or eosinophilic enteritis (colitis/proctitis, esophagitis, gastroenteritis);
            (4) Cystic fibrosis with malabsorption;
            (5) Diarrhea or vomiting resulting in clinically significant dehydration requiring treatment by a medical provider;
            (6) Malabsorption that is unresponsive to standard age appropriate interventions when associated with failure to gain weight or meet established growth expectations;
            (7) Failure to thrive that is unresponsive to standard age appropriate interventions (e.g. Whole milk, Carnation Instant Breakfast™) when associated with weight loss, failure to gain weight or to meet established growth expectations, including but not limited to:
               i. Premature infants who have not achieved the 25th percentile for weight based on their corrected age; or
               ii. Individuals with end-stage renal disease and an albumin level of less than 4mg/dl; or
            (8) The product must be ordered and supervised by a health care provider authorized to prescribe dietary treatments.
C. CareSource does NOT consider the following medically necessary:
   1. Therapeutic diets where non-medical foods are tolerated:
      a. Food modification;
      b. Texture modified food;

c. Thickened fluids without a prescription that indicates it is necessary as part of treatment plan;
d. Fortified Food;
e. Functional Food;
f. Modified normal; or
g. Flavorings

2. Ordinarily prepared foods including commercial products such as shakes, smoothies, energy bars, vitamin or mineral supplements, and baby food.
3. Food products that a provider receives a Medicaid per diem payment.
4. Standard infant formula that is not used to treat IOM when alternative coverage is available.
5. Products for meal replacements or snack alternatives.
6. When use of product is for convenience or preference of member/caregiver.

II. Enteral Nutrition
A. Prior authorization is required except for inborn error of metabolism conditions and for gastrostomy/jenuostomy tube, low-profile.
1. The following documentation is required with each PA request per the Ohio Administrative Code:
a. Attestation to one of the following statements:
(i) The individual is able to ingest food but cannot derive sufficient energy and nutrients from ordinary food, even if the food is prepared in a liquefied, puréed, or blended form;
(ii) The individual is unable to ingest food safely but can digest it.
2. PAs are required at initial onset and then annually thereafter.
3. Additional documentation is required to support medical necessity for the following orders:
a. Special nutrients such as enteral formula additives. Enteral formula codes include all nutrient components (vitamins, mineral, and fiber);
b. Caloric intake more than 2000 calories per day; or
c. A pump.

B. Per Ohio Administrative Code, a new prescription is required for a change in the type or increase in the quantity of an item.
C. CareSource considers enteral nutrition medically necessary when the following criteria are met:
1. Must be a medical food for enteral feeding;
2. Must be used under medical supervision;
3. Member has a functioning accessible gastrointestinal tract; and
4. Documentation supports all of the following criteria:
a. Enteral nutrition is the majority of the diet (greater than 50%);
b. Member is unable to maintain body weight and nutritional status (initial and ongoing treatment) with oral nutrition; and
c. Member has a condition impairing the ability to ingest, digest, absorb or metabolize nutrients.

D. CareSource considers Relizorb to be medically necessary when the following criteria are met:

1. Member is at least 5 years of age per the FDA; and
   Member has a diagnosis of pancreatic insufficiency; or

   Member experiences symptoms of pancreatic insufficiency with current enteral formula such as fat malabsorption symptoms such as poor weight gain, diarrhea, abdominal pain, bloating, fatty stools, vomiting, and constipation.

E. CareSource does NOT consider the following medically necessary:
   1. Advanced dementia (Feeding tubes are not recommended by American Geriatrics Society);
   2. Products administered in an outpatient provider setting are not separately reimbursable; or
   3. When use of product is for convenience or preference of member/caregiver.

III. Food Supplements, Nutritional Supplements, and Infant Formula
   A. Prior authorization is required.
   B. Primary reason must not be for convenience of member/caregiver.
   C. CareSource considers food supplements, nutrition supplements, and infant formula medically necessary when the provider documentation supports all of the following criteria:
      1. Item is used for nutritional purposes;
      2. No other means of nutrition is feasible or reasonable; and
      3. Inability of member to maintain body weight and nutrition status (initial and ongoing treatment) with normal or therapeutic oral nutrition.
   D. All avenues of coverage available must be exhausted first
      1. For example, members eligible for their county Women, Infant and Children (WIC) program must apply for an eligibility evaluation before nutritional supplement coverage will be considered.

      NOTE: CareSource does not consider a routine or ordinary diet medically necessary.

IV. Donor human milk
   A. Prior authorization is required.
   B. CareSource considers human milk medically necessary when all of 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

Home Infusion Therapy SRx-0044

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	 Realigned with new guidelines Added Relizorb criteria Removed Medical nutrition therapy and updated PA Updated references. Approved at PGC.
Date Effective	01/01/2022	
Date Archived	06/30/2022	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.* Journal of the American Geriatrics Society, 62 (8), 1590-1593. Retrieved September 10, 2021 from www.agsjournals.onlinelibrary.wiley.com
2. Cederholm, T., Barazzoni, R., Austin, P., Ballmer, P., Biolo, G., Bischoff, S.… Singer, P. (2017). *ESPEN guidelines on definitions and terminology of clinical nutrition.* Clinical Nutrition, *36*(1), 49-64. doi: 10.1016/j.clnu.2016.09.004.
3. Medicaid. (n.d.) *Early and Periodic Screening, Diagnostic, and Treatment.* Retrieved September 10, 2021 from www.medicaid.gov
4. Ohio Administrative Code. (2016, May 8). *5160-8-41 Medical nutrition therapy services.* Retrieved September 10, 2021 from www.codes.ohio.gov/oac
5. Ohio Administrative Code. (2018, July 16). *5160-10-26 DMEPOS: nutrition products.* Retrieved September 10, 2021 from www.codes.ohio.gov/oac
6. Food and Drug administration. (2017, December 6). *Medical Foods Guidance Documents & Regulatory Information.* Retrieved September 10, 2021 from www.fda.gov
7. Robinson, D., Walker R., Adams, S., Allen, K.… Holcombe, B., (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 September 10, 2021 from www.nutritioncare.org
8. Worthington, P., Balint J., Bechtold, M., Bingham, A……. Holcombe, B. (2017) *When is Parenteral Nutrition Appropriate? Journal of Parenteral and enteral Nutrition*, 41(3), 324-377. DOI: 10.1177/0148607117695251.

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.