MEDICAL POLICY STATEMENT
INDIANA MEDICAID

Policy Name	Policy Number	Date Effective
Nutritional Supplements	MM-0726	01/01/2022-08/31/2022

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.

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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 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.
- **Medical Food** – Per Indiana Code it is defined as a formula that is intended for dietary treatment of condition for which nutritional requirements are established by medical evaluation and formulated to be consumed or administered enterally under direction of a physician.
- **Enteral Access Device** – A tube or stoma is placed directly into the gastrointestinal tract for the delivery of nutrients.
- **Inborn Errors Of Metabolism (IEM)** (Also called inherited metabolic disease) – Per Indiana Code it is defined as disease caused by inborn errors of amino acid, organic acid, or urea cycle metabolism and is treatable by the dietary restriction of one or more amino acid.
- **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.

D. Policy

I. Oral Medical Food

A. Prior Authorization is required.

B. CareSource considers oral medical food 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. Medical food consists of more than 50% of intake;
      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
            (3) Methylmalonic acidemia
            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
               ii. Individuals with end-stage renal disease and an albumin level of less than 4mg/dl
            (8) The product must be ordered and supervised by a health care provider authorized to prescribe dietary treatments

C. CareSource considers thickened fluids medically necessary when the following criteria are met:
   1. Prior authorization is approved
   2. A prescription indicates it is necessary as part of treatment plan

D. 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. Fortified Food

d. Functional food
e. Modified normal
f. Flavorings

2. Products for meal replacements or snack alternatives.

3. When use of product is for convenience or preference of member/caregiver.

II. Enteral Nutrition
A. Prior authorization is required
1. A CMS certificate of medical necessity entitled "Parenteral and Enteral Nutrition" is required with each PA request
a. Physician signature and date is required
2. After the initial PA, PAs are required after 3, 9, and 18 months. After two years, the need for a PA is determined on a case by case basis.
3. If member does not require enteral nutrition for 2 consecutive months, a new PA is required.
4. Documentation is required to support medical necessity for the following orders:
a. Special nutrients
b. Caloric intake less than 20 cal/kg/day or greater than 35 cal/kg/day
c. A pump

B. 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.

C. 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
2. 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.

D. CareSource does not consider the following medically necessary:
1. Advanced dementia
2. 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.
   3. Inability of member to maintain body weight and nutrition status (initial and ongoing treatment) with normal or therapeutic oral nutrition

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

E. Conditions of Coverage

NA

F. Related Policies/Rules

NA

G. Review/Revision History

	DATE	ACTION
Date Issued	01/01/2020	
Date Revised	09/02/2020 11/23/2020 12/04/2020 09/15/2021	Annual review - updated PA frequency, D. II.A.1.a. Revision: Relizorb is now considered a covered treatment when medically necessary criteria is met. Added Relizorb criteria Reviewed. No Changes. Approved at PGC.
Date Effective	01/01/2022	
Date Archived	08/31/2022	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. Medical Foods Guidance Documents & Regulatory Information. (2017, December 6). Retrieved September 10, 2021 from www.fda.gov

4. 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
5. 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
6. Volkert, D., Chourdakis, M., Schneider, S. (2015) ESPEN guidelines on nutrition in dementia. Retrieved on September 10, 2021 from www.espen.info
7. Bischoff, S., Austin P., Pironi, L. (2020). ESPEN guideline on home enteral nutrition. Retrieved September 10, 2021 from www.espn.org
8. United States Food & Drug Administration. (2018, March 22). Use of Donor Human Milk. Retrieved September 10, 2021 from www.fda.gov
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10. Indiana Family & Social Services Administration Durable and Home Medical Equipment and supplies (2021, April 6). Retrieved September 10, 2021 from www.in.gov
11. Indiana Administrative Code. (2016, August 1). 405 IAC 5-24-9 Food supplements, nutritional supplements, and infant formulas. Retrieved September 10, 2021 from www.in.gov
12. Department of Health and Human Services Centers for Medicare & Medicaid Services. (2019, June). DME Information Form CMS-10126-Enteral and Parenteral Nutrition. Retrieved September 10, 2021 from www.cms.gov

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

IN-MED-P-381330 Issue date 01/01/2020 Approved by OMPP 01/29/2021