MEDICAL POLICY STATEMENT
KENTUCKY MARKETPLACE

Policy Name		Policy Number	Effective Date
Nutritional Supplement		MM-0784	01/01/2021-12/31/2021
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. 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.

This policy includes nutrition that is for medical purposes only.

Refer to the Evidence of Coverage for Home Infusion Therapy.

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. Conditions include immunoglobulin E and nonimmunoglobulin E medicated allergies to multiple food proteins, severe food protein-induced enterocolitis syndrome, and eosinophilic disorders.
- **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.

B. CareSource considers oral nutrition medically necessary when the following criteria are met:
   1. Must be a medical food for oral feeding;
   2. Have a prescription;
   3. Is under medical supervision; and
   4. Documentation supports the following criteria:
      a. Inborn error of metabolism conditions or genetic conditions including but not limited to
         01. Phenylketonuria (PKU)
         02. Homocystinuria
         03. Methylmalonic acidemia

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
      d. Fortified Food
      e. Functional Food
      f. Modified normal
      g. Flavorings
   2. Products for meal replacements or snack alternatives.
   3. When use of product is for convenience or preference of member/caregiver.
   4. 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.

II. Enteral Nutrition

A. Prior authorization is required
   1. Subsequent PAs are required at initial onset and then annually thereafter.

B. CareSource considers enteral nutrition medically necessary when the following criteria are met:
   1. Must be a medical food for enteral feeding;
   2. Have a prescription;
   3. Must be used under medical supervision;
   4. Member has a functioning accessible gastrointestinal tract; and
   5. Documentation supports all of the following medical necessity criteria:
      a. Member is able to ingest food but cannot obtain sufficient energy and nutrients from ordinary food (even when the food is liquefied, puréed, or blended); or member is unable to ingest food safely but can digest food; and
      b. All of the following:
         01. Enteral nutrition is the majority of the diet (greater than 50%);
         02. Member is unable to maintain body weight and nutritional status (initial and ongoing treatment) with oral nutrition; and
         03. Member has an Inborn error of metabolism or genetic condition including but not limited to
            (1) Phenylketonuria (PKU)
            (2) Homocystinuria

(3) Methylmalonic acidemia

C. CareSource does NOT consider the following medically necessary:
   1. Advanced dementia
   2. Relizorb (Insufficient published evidence).
   3. Products administered in an outpatient provider setting are not separately reimbursable.
   4. When use of product is for convenience or preference of member/caregiver.

IV. Donor breast milk
   A. Requires a prior authorization
      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".
   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.

E. Conditions of Coverage

F. Related Polices/Rules

Evidence of Coverage and Health Insurance Contract Kentucky

G. Review/Revision History

	DATE	ACTION
Date Issued	04/14/2004	
Date Revised	07/01/2005 07/01/2011 03/15/2012 07/15/2013 12/01/2019	Realigned with new guidelines and EOC. Removed other state requirements. Changed policy number from MM-0024.
Date Reviewed	04/14/2004 09/15/2005 04/15/2008 07/15/2009 07/01/2011 03/15/2012 07/15/2013 07/15/2014 07/15/2015 06/28/2016 09/02/2020	Revised to KY statute. Revised D. IV.
Date Effective	01/01/2021	
Archived Date	12/31/2021	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. DOI: 10.1111/jgs.12924
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 August 10, 2020 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 August 10, 2020 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 August 10, 2020 from www.espen.info
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8. United States Food & Drug Administration. (2018, March 22). Use of Donor Human Milk. Retrieved August 10, 2020 from www.fda.gov
9. ECRI. (2019, June). Relizorb Immobilized Lipase Cartridge (Alcresta Therapeutics, Inc.) for Facilitating Absorption of Enteral Formula Fats in Adults. Retrieved August 10, 2020 from www.ecri.org
10. Kentucky Regulatory Statute. (2017, January 1). 304.17A-258 Coverage under health benefit plan for therapeutic food, formulas, supplements, low-protein modified food products, and amino acid-based elemental formula. Retrieved August 14, 2020 from www.apps.legislature.ky.gov

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