



## MEDICAL POLICY STATEMENT KENTUCKY MARKETPLACE

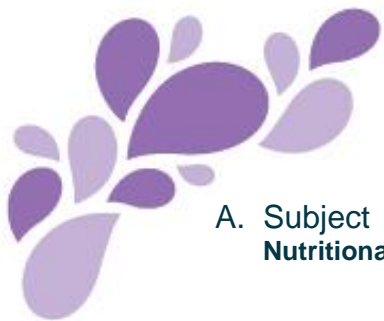
| Policy Name            | Policy Number  | Effective Date |               |
|------------------------|----------------|----------------|---------------|
| Nutritional Supplement | MM-0784        | 12/1/2019      |               |
| Policy Type            |                |                |               |
| <b>MEDICAL</b>         | Administrative | Pharmacy       | Reimbursement |

Medical Policy Statement prepared by CSMG Co. and its affiliates (including CareSource) 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 CSMG Co. and its affiliates (including CareSource) 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.

### Table of Contents

|                                  |   |
|----------------------------------|---|
| A. Subject.....                  | 2 |
| B. Background.....               | 2 |
| C. Definitions .....             | 2 |
| D. Policy .....                  | 3 |
| E. Conditions of Coverage.....   | 4 |
| F. Related Polices/Rules .....   | 4 |
| G. Review/Revision History ..... | 4 |
| H. References .....              | 4 |



## 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.

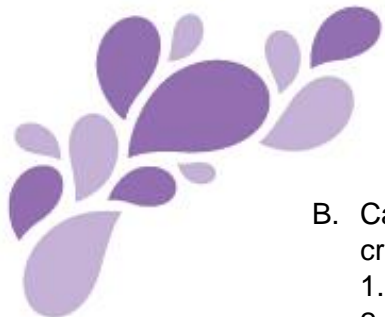
## C. Definitions

- **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.
- **Medical Nutrition Therapy** –specific nutrition services to treat an illness, injury, or condition.



#### D. Policy

- I. Medical nutrition therapy services
  - A. CareSource covers all of the following medical nutrition therapy services
    1. Initial assessment and intervention
    2. Reassessment and intervention
  - B. Nutrition counseling is NOT a covered benefit.
  
- II. 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 AND
    2. Must be used under medical supervision AND
    3. Documentation supports ONE of the following criteria:
      - a. Inborn error of metabolism conditions including but not limited to
        01. Phenylketonuria (PKU)
        02. Homocystinuria
        03. Methylmalonic acidemiaOR
      - b. A condition that interferes with nutrition absorption and assimilation including, but not limited to:
        01. Anaphylaxis to food
        02. Cystic fibrosis with malabsorption
  - 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.
  
- III. Enteral Nutrition
  - A. Prior authorization is required
    1. Documentation must include **ONE** of the following statements with each PA request:
      - 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**
      - b. Member is unable to ingest food safely but can digest food;
    2. 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 **AND**
  2. Must be used under medical supervision **AND**
  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%) **AND**
    - 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 does NOT consider the following medically necessary:
  1. Advanced dementia (Feeding tubes are not recommended by American Geriatrics Society)
  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 milk

- A. Requires a prior authorization
- B. 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”.

E. Conditions of Coverage

F. Related Policies/Rules

G. Review/Revision History

| DATE                 |  | ACTION   |
|----------------------|--|--|
| <b>Date Issued</b>   | 4/14/2004  |  |
| <b>Date Revised</b>  | 07/01/2005,<br>07/01/2011,<br>03/15/2012,<br>07/15/2013<br>12/1/2019                   | Realigned with new guidelines and EOC. Removed other state requirements. Changed policy number from MM-0024. |
| <b>Date Reviewed</b> | 04/14/2004,<br>09/15/2005,<br>04/15/2008,<br>07/15/2009,<br>07/01/2011,<br>03/15/2012, |  |



|                       |   |  |
|-----------------------|---|--|
|                       | 07/15/2013,<br>07/15/2014,<br>07/15/2015,<br>06/28/2016 |  |
| <b>Date Effective</b> | 12/1/2019   |  |

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. CareSource Evidence of Coverage and Health Insurance Contract. (2019). Retrieved on 7.29.2019 from <https://www.caresource.com/documents/2019-ky-mp-enhanced-eoc/>
3. 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.
4. Hayes Knowledge Center. (2018). Relizorb. Retrieved on 2/4/2019 from [https://www.hayesinc.com/subscribers/displaySubscriberArticle.do?articleId=37626&searchStore=%24search\\_type%3Dall%24icd%3D%24keywords%3D2.%09Relizorb%24status%3Dall%24page%3D1%24from\\_date%3D%24to\\_date%3D%24report\\_type\\_options%3D%24technology\\_type\\_options%3D%24organ\\_system\\_options%3D%24specialty\\_options%3D%24order%3DasearchRelevance](https://www.hayesinc.com/subscribers/displaySubscriberArticle.do?articleId=37626&searchStore=%24search_type%3Dall%24icd%3D%24keywords%3D2.%09Relizorb%24status%3Dall%24page%3D1%24from_date%3D%24to_date%3D%24report_type_options%3D%24technology_type_options%3D%24organ_system_options%3D%24specialty_options%3D%24order%3DasearchRelevance)
5. Medical Foods Guidance Documents & Regulatory Information. (2017, December 6). Retrieved on 12/10/2018 from <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/default.htm>
6. KAR 304.17A-258 Coverage under health benefit plan for therapeutic food, formulas, supplements, low-protein modified food products, and amino acid-based elemental formula. (2017). Retrieved on 3/21/2019 from <https://apps.legislature.ky.gov/law/statutes/statute.aspx?id=45441>
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 on 2/4/2019 from [https://www.nutritioncare.org/uploadedFiles/Documents/Guidelines\\_and\\_Clinical\\_Resources/ASPEN%20Definition%20of%20Terms,%20Style,%20and%20Conventions%20Used%20in%20ASPEN%20Board%20of%20Directors%E2%80%93Approved%20Documents.pdf](https://www.nutritioncare.org/uploadedFiles/Documents/Guidelines_and_Clinical_Resources/ASPEN%20Definition%20of%20Terms,%20Style,%20and%20Conventions%20Used%20in%20ASPEN%20Board%20of%20Directors%E2%80%93Approved%20Documents.pdf)
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.**