MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
04/14/2004	07/15/2017	06/28/2016

Policy Name	Policy Number
Nutritional Supplement	MM-0024

Policy Type		
☒ Medical	☐ Administrative	☐ Payment

Medicaid Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) apply to Medicaid health benefit plans administered by CSMG and its affiliates and are derived from literature based on and supported by applicable federal or state coverage mandates, 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 federal or state coverage mandate, Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medicaid 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 benefit document (i.e., Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medicaid Policy Statement and the plan benefit document, then the plan benefit document will be the controlling document used to make the determination. In the absence of any applicable controlling federal or state coverage mandate, benefits are ultimately determined by the applicable plan benefit document

A. SUBJECT

Nutritional Supplement

B. BACKGROUND

Nutritional and medical food products include nutritional formulas or nutritional supplements and may be indicted for patients with physiologic or pathologic inability to swallow or those who are being treated for a medical condition who are unable to receive appropriate nutrition provided by conventional or altered conventional diets.

C. DEFINITIONS

- **Enteral Nutrition** – Nutrition delivered through an enteral access device into the gastrointestinal tract for caloric sustenance in the presence of a disability or life-threatening disease with significant nutritional problems that cannot be managed by ordinary or blenderized foods
- **Enteral Access Device** – A tube or catheter placed directly into the gastrointestinal tract for the delivery of nutrients
- **Low Protein Modified Food** – Mean a product formulated to have less than one (1) gram of protein per serving and intended for the dietary treatment of inborn errors of metabolism or genetic conditions under the direction of a physician
- **Medical Food** – A food which is formulated to be consumed or administered under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive requirements, based on recognized scientific principles, are established by medical evaluation
- **Parenteral Nutrition** – Nutrition delivered in intravenous administration

- **Therapeutic Foods, Formula's Supplements** – Products intended for the dietary treatment of errors or metabolism or genetic conditions under the direction of a physician

D. POLICY

I. CareSource allows for coverage of oral and enteral nutrition when the following criteria have been met:
   A. The product must be a medical food for oral or tube feeding
   B. The product is the primary source of nutrition, i.e., more than half the intake for the individual
   C. The product must be labeled and used for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements to avert the development of serious physical or mental disabilities or to promote normal development or function as listed in A. **OR** B. below:
      1. Conditions associated with an in-born error of metabolism that interfere with the metabolism of specific nutrients, including, but not limited to:
         1.1 Phenylketonuria (PKU)
         1.2 Homocystinuria
         1.3 Methylmalonic academia
      2. Conditions that interfere with nutrient absorption and assimilation, including, but not limited to:
         2.1 Allergy or hypersensitivity to cow or soy milk diagnosed through a formal food challenge
         2.2 Anaphylaxis to food
         2.3 Allergic or eosinophilic enteritis (colitis/proctitis, esophagitis, gastroenteritis)
         2.4 Cystic fibrosis with malabsorption
         2.5 Diarrhea or vomiting resulting in clinically significant dehydration requiring treatment by a medical provider
         2.6 Malabsorption unresponsive to standard age appropriate interventions when associated with failure to gain weight or meet established growth expectations
         2.7 Failure to thrive unresponsive to standard age appropriate interventions (e.g. Whole milk, Carnation Instant Breakfast™) when associate 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 age
            b. Individuals with end-stage renal disease and an albumin less than 4mg/dl
         2.8 The product must be ordered and supervised by a health care provider authorized to prescribe dietary treatments
      3. Oral or enteral nutrition is considered medically necessary when the diet consists of less than 50% enteral nutrition and more than 50% standard diet for age when:
         3.1 The enteral product is used as part of a defined and limited plan of care in transition from a diet of more than 50% enteral products to standard diet for age
         3.2 Medical records document a medical basis for the inability to maintain appropriate body weight and nutritional status prior to initiating or after discontinuing use of an enteral supplement as well as ongoing evidence of response to the enteral nutrition
      4. Enteral Nutrition through an enteral access device considered medically necessary when the enteral nutrition comprises the majority of the diet, and the product is ordered by a health care provider authorized to prescribe dietary treatments, and nutrients cannot be taken orally due to a medical condition which either:

4.1 Interferes with swallowing (e.g. dysphagia from a neurological condition, severe chronic anorexia nervosa, unable to maintain weight and nutritional status with oral nutrition)
4.2 Is associated with obstruction of the proximal gastrointestinal tract (e.g. tumor of the esophagus)

CONDITIONS OF COVERAGE

II. **OHIO MEDICAIDMEMBERS: (Ohio Administrative Code (OAC) 5160-10-26** for Ohio Medicaid members. Enteral nutrition is defined as oral or tube-delivered caloric sustenance products for those Medicaid consumers demonstrating a disability or life-threatening disease with significant nutritional problems that cannot be managed by ordinary or blenderized foods.

A. The following three medical nutrition therapy services are covered for Medicaid consumers:
1. Initial assessment and intervention
2. Reassessment and intervention
3. Group counseling

B. Enteral nutrition will be covered when:
1. The consumer has the ability to swallow, but is unable to meet the caloric and nutritional requirements from ordinary foods, including pureed or blenderized foods, to maintain life-sustaining functions, as determined and documented by a licensed prescriber.
2. The consumer is unable to swallow due to a damaged or diseased (non-functioning) oral pathway and must be tube-fed, as determined and documented by a licensed prescriber.
3. Consumers with infants and children age five or younger whose children require enteral nutrition products, breast-feeding consumers with an infant one year of age or younger, or post-partum mothers with a child six months of age or younger, must apply to their county Women, Infant and Children (WIC) program for an eligibility evaluation before coverage will be considered.

C. Limitations:
1. Enteral nutrition products that are designed to provide meal replacements, or snack alternatives to be eaten within the context of a consumer's individualized meal plan.
2. Enteral nutrition products that are designed as meal replacements, or to be eaten within the context of a consumer's prescribed reduced calorie diet for consumers with diabetes, obesity issues, pre- or post-gastric bypass, or bariatric surgery, are not covered.
3. Enteral nutrition products that are administered in an outpatient provider setting (i.e., a dialysis outpatient clinic or a facility receiving per diem payments from the department) are not separately reimbursable.
4. Adult and pediatric electrolyte replacement is covered under the pharmacy benefit program as described in Chapter 5101:3-9 of the Administrative Code.
5. Benefits are not available for uses other than nutritional purposes

III. **KENTUCKY MEDICAID MEMBERS: (Kentucky Revised Statutes (KRS) 304-17A-258** for Kentucky Medicaid members, therapeutic food, formulas, supplements or low protein modified food will be covered:

A. For the therapeutic treatment of inborn errors of metabolism or genetic conditions under the direction of a physician.
1. Limitations:

a. Benefits limits per member, per plan year will be defined by KRS 304-17A-258 and may be subject to annual inflation adjustments based on the consumer index price
b. Benefits are not available for the treatment of lactose intolerance.

CareSource provides enteral nutrition through participating Durable Medical Equipment (DME) providers allowing for home delivery of medically necessary enteral nutrition. CareSource allows for a 30 day supply of enteral nutrition to be provided by a retail pharmacy to allow time for a DME to be arranged or while arranging for home delivery of the enteral nutrition product. A 30 day extension for retail pharmacy may be granted if needed.

HCPCS
CPT

AUTHORIZATION PERIOD

E. RELATED POLICIES/RULES

F. REVIEW/REVISION HISTORY

Date Issued:	04/14/2004
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
Date Revised:	07/01/2005, 07/01/2011, 03/15/2012, 07/15/2013

G. REFERENCES

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