HAP CareSource™

MEDICAL POLICY STATEMENT
Michigan Medicaid

Policy Name & Number	Date Effective
Nutritional Supplements-MI MCD-MM-1535	06/01/2024-09/30/2024
Policy Type	
MEDICAL	

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

Enteral nutrition may be necessary to maintain optimal health status for individuals with diseases or structural defects of the gastrointestinal (GI) tract that interfere with transport, digestion, or absorption of nutrients. Such conditions may include anatomic obstructions due to cancer motility disorders such as gastroparesis, or metabolic absorptive disorders such as phenylketonuria (PKU). Considerations are given to medical condition, nutrition and physical assessment, metabolic abnormalities, gastrointestinal function, and expected outcome. Enteral nutrition may be prescribed to serve as an individual's primary source of nutrition (ie, total enteral nutrition) or as a supplement to an ordinary diet (ie, supplemental enteral nutrition). Enteral nutrition may be delivered through oral intake or through a tube into the stomach or small intestine.

RELiZORB is a prescription device that is used to break down fats in enteral formulas from triglycerides into fatty acids and monoglycerides to allow absorption and utilization in the body. This process mimics the function of the enzyme lipase in the intestine of members with pancreatic insufficiency. The product is designed to fit in series with currently used enteral feeding circuits.

C. Definitions

- **Children's Special Health Care Services (CSHCS)** – A benefit plan designed to find, diagnose, and treat children under age 21 years with chronic illness or disabling conditions. Persons over age 21 with chronic cystic fibrosis, certain blood coagulation disorders, or hereditary blood cell disorders, commonly known as sickle cell disease, may also qualify. The program establishes coverage of services related to the member's CSHCS-qualifying diagnoses.
- **Enteral Nutrition** – Nutritional support given via the gastrointestinal (GI) tract, either directly or through any of a variety of tubes used in specific medical conditions. This includes oral feeding, as well as feeding using tubes, such as orogastric, nasogastric, gastrostomy, or jejunostomy tubes.
- **Inborn Errors of Metabolism (IEM)** – Inherited biochemical disorders resulting in enzyme defects that interfere with normal metabolism of protein, fat, or carbohydrate.
- **Medical Food** – Specially formulated and processed food for individuals who are seriously ill or who require the product as a major treatment modality. This term does not pertain to all foods fed to ill individuals. Medical foods are intended solely to meet the nutritional needs of individuals who have specific metabolic or physiological limitations restricting an ability to digest regular food. This can include specially formulated infant formulas. According to the Food and Drug Administration (FDA), a product must meet all the following minimum criteria to be considered a medical food:
  - The product must be a food for oral or tube feeding.

- The product must be labeled for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements.
- The product must be used under the supervision of a physician.

- **RELiZORB** – An FDA-approved digestive enzyme cartridge containing lipase which connects in-line with enteral feeding circuits. As the enteral tube feeding formula passes through the cartridge, fats in the formula are broken down into absorbable fatty acids and monoglycerides. The product is indicated in pediatric patients (ages 5 years and older) and adult patients who do not excrete sufficient levels of the lipase enzyme (eg, exocrine pancreatic insufficiency).
- **Standard Food** – Regular grocery products including typical, not specially formulated, infant formulas.
- **Therapeutic Oral Non-Medical Nutrition**:
  - **Food Modification** – Some conditions may require adjustment of carbohydrate, fat, protein, and micronutrient intake or avoidance of specific allergens (ie, 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. Enteral nutrition (administered orally)

A. For members under age 21

1. Enteral nutrition (administered orally) may be covered for members under the age of 21 when one of the following applies:
   a. A chronic medical condition exists resulting in nutritional deficiencies, and a 3-month trial is required to prevent gastric tube placement.
   b. Supplementation to regular diet or meal replacement is required, and the beneficiary's weight-to-height ratio has fallen below the 5th percentile on standard growth grids.
   c. Physician documentation details low percentage increase in growth pattern or trend directly related to the nutritional intake and associated diagnosis/medical condition.
2. Documentation must be less than 30 days old and include the following:
   a. specific diagnosis/medical condition related to the beneficiary's inability to take or eat food
   b. duration of need
   c. amount of calories needed per day
   d. current height and weight, as well as change over time (for members under 21, weight-to-height ratio)

e. specific prescription identifying levels of individual nutrient(s) that is required in increased or restricted amounts
f. list of economic alternatives that have been tried

3. For continued use beyond 3-6 months, the Children's Special Health Care Services (CSHCS) Program requires a report from a nutritionist or appropriate pediatric subspecialist.
4. For CSHCS coverage, a nutritionist or appropriate pediatric subspecialist must indicate that long-term enteral supplementation is required to eliminate serious impact on growth and development.
5. For HCPCS code B4162, the member must have a specified inherited disease of metabolism identified by the International Classification of Diseases (ICD).

B. For members 21 years and older
1. Enteral nutrition (administered orally) may be covered for members aged 21 years and over when one of the following applies:
a. The member has a medical condition that requires the unique composition of the formula nutrients that the member is unable to obtain from food.
b. The nutritional composition of the formula represents an integral part of treatment of the specified diagnosis/medical condition.
c. The member has experienced significant weight loss.
2. Documentation must be less than 30 days old and include the following:
a. specific diagnosis/medical condition related to the beneficiary's inability to take or eat food
b. duration of need
c. amount of calories needed per day
d. current height and weight, as well as change over time (for members under 21, weight-to-height ratio)
e. specific prescription identifying levels of individual nutrients that are required in increased or restricted amounts
f. list of economical alternatives that have been tried
3. For continued use beyond 3-6 months, the CSHCS Program requires a report from a nutritionist or appropriate subspecialist.
4. For HCPCS code B4157, the member must have a specified inherited disease of metabolism identified by the International Classification of Diseases.

II. Enteral nutrition (administered by tube)
A. Enteral formula are considered medically necessary when the diagnosis/medical condition requires placement of a gastric tube and nutrition is administered by syringe, gravity, or pump.
B. Documentation must be less than 30 days old and include
1. specific diagnosis/medical condition requiring tube feeding
2. duration of treatment
3. amount needed per day

4. if a pump is required, the medical reason why syringe or gravity method could not be used

C. Medical necessity review is required for the following:
1. all specialized enteral formula requests for tube feedings
2. over-quantity requests for standard formula enteral tube feedings
3. medical needs beyond Standards of Coverage

III. Enteral nutrition payment rules
A. The appropriate formula HCPCS code should be requested based on monthly requirements with total calories used (divided by 100) as the unit amount. Medicaid will reimburse for a maximum quantity of up to 900 units for any combination of approved formula.
B. Providers should refer to the following chart for additional assistance:

Formula	100 calories = 1 unit (u)	6 (8 oz) cans a day	1 month = 30 days	6 months = 180 days	$5.00 cost/8 oz liquid or packet or can
Standard @ 250 calories/8 oz	250 cals/100 =2.5 units	2.5 u x 6 = 15 units a day	15 u x 30 = 450 units a month	15 u x 180=2700 units for 6 months	$5.00 ÷ 2.5 u = $2.00 per unit
Caloric Dense @ 355 calories/8 oz	355 cals/100 =3.55 units	3.55 u x 6= 21 units a day	21 u x 30 = 630 units a month	21 u x 180 = 3780 units for 6 months	$5.00 ÷ 3.55 u = $1.41 per unit
Powder, 1 package = 150 calories	150 cals/ 100 = 1.5 units	1.5 u x 6 = 9 units a day	9 u x 30 = 270 units a month	9 u x 180 =1620 units for 6 months	$5.00 ÷ 1.5 u = $3.33 per unit
Powder, 1# can = 112 oz when mixed @ 20 calories/oz* = 2240 calories for the entire can (*can vary with physician orders)	2240 cals/100 = 22.4 units		6 cans per month = 22.4 u x 6 = 134 units a month	134 u x 6 months = 804 units for 6 months	$5.00 ÷ 22.4 u = $0.30 per unit

C. The necessary equipment and supply code for enteral tube feedings should be requested up to specified quantity limits. Feeding bags, anchoring devices, syringes, drain sponges, cotton tip applicators, tape, adaptors, and connectors used in conjunction with a gastrostomy or enterostomy tube are included in the supply kit codes and should not be billed separately.
D. Dietary formula for oral feedings may be obtained from either a medical supplier or a pharmacy.
E. Dietary formula for tube feedings are covered only through the medical supplier.

IV. The following are not considered medical in nature, and are therefore not covered:
A. nutritional puddings/bars
B. regular or dietetic foods (eg, Slimfast, Carnation instant breakfast)
C. sports drinks/juices
D. standard infant/toddler formula
E. products for meal replacements or snack alternatives.
F. therapeutic diets where non-medical foods are tolerated, including
1. food modification
2. texture modified food

3. thickened fluids without a prescription that indicates necessity as part of treatment plan
4. fortified food
5. functional food
6. modified normal
7. flavorings

G. food products that a provider receives a Medicaid per diem payment
H. when use of product is for convenience or preference of member/caregiver

V. RELiZORB is considered medically necessary when **ALL** the following criteria are met:
A. The member is at least 5 years of age per the FDA, and
B. The member has a diagnosis of pancreatic insufficiency, or experiences symptoms of pancreatic insufficiency with current enteral formula such as fat malabsorption symptoms (eg, poor weight gain, diarrhea, abdominal pain, bloating, fatty stools, vomiting, and constipation).

E. Conditions of Coverage
NA

F. Related Policies/Rules
NA

G. Review/Revision History

	DATE	ACTION
Date Issued	09/13/2023	New policy. Approved at Committee.
Date Revised	03/13/2024	Review: updated references, removed PA language from V, approved at Committee.
Date Effective	06/01/2024	
Date Archived	09/30/2024	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.

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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.

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