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For Priority Partners see:


- Code of Maryland Regulations ([COMAR](#)) 10.09.67.04 Pharmacy Services
- Code of Maryland Regulations ([COMAR](#)) 10.09.67.20 EPSDT Services
- Medical Assistance Program Transmittal EPSDT No. 31, Pharmacy no. 189, February 3, 2009: [MMCP.Health.Maryland.gov/PT29-09.pdf](#)
- Maryland Department of Health, Women, Infants and Children Program (WIC): <https://phpa.health.maryland.gov/>
- Maryland Department of Health, Division for Clinical Genetic Services, The Metabolic Nutrition Follow-up Program: phpa.health.maryland.gov/genetics/

For US Family Health Plan see:


- [TRICARE Policy Manual 6010.60-M](#) April 1, 2015, Other Services: Chapter 8, Section 7.2. Medically Necessary Food - For Dates of Service On Or After December 23, 2017.
- Enteral and Oral Nutrition Products -Enteral Foods List <https://www.health.mil>

IV. POLICY CRITERIA

- A. General Considerations: When benefits are provided under the member's contract, JHHC considers nutritional treatment medically necessary when ALL of the following are met:
1. The nutritional product must be prescribed, ordered, or recommended (as applicable) by a physician or other health care professional qualified to provide medical treatment for the disease or condition for which the therapy is being prescribed, ordered, or recommended.
 2. The condition for which the nutritional product is being prescribed, ordered, or recommended is expected to persist for a minimum of three months.
 3. Adequate nutrition cannot be achieved by adjustment of regular diet.
 4. There is clear documentation of medical diagnosis and treatment plan indicating medical necessity of the nutritional product.
 5. There is ongoing medical supervision by a physician or other qualified health care professional, who has determined the need for the medical food. The supervision includes instruction on use of the medical food as part of the dietary management of the given disease or condition.
 6. Treatment is for ANY of the conditions listed in Section B or C.
- B. When benefits are provided under the member's contract, JHHC considers nutritional treatment with medical foods/ medical formulas to be medically necessary when ALL the requirements in Section I are met and for ANY of the following:
1. Inborn errors of metabolism (IEM), including the following categories:
 - a. Disorders of amino acid metabolism, including but not limited to:
 - i. maple syrup urine disease,
 - ii. homocystinuria,
 - iii. phenylketonuria,
 - iv. citrullinemia,
 - v. argininosuccinic aciduria,
 - vi. tyrosinemia
 - b. Organic acidemias, including but not limited to:
 - i. methylmalonic acidemia,
 - ii. propionic acidemia,

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- iii. isovaleric acidemia,
 - iv. multiple carboxylase deficiency,
 - v. glutaric acidemia type 1
 - vi. β -Ketothiolase deficiency
 - c. Urea cycle defects, including but not limited to:
 - i. argininosuccinate synthetase deficiency (also known as classic citrullinemia),
 - ii. ornithine transcarbamylase deficiency,
 - iii. carbamyl phosphate synthetase deficiency,
 - iv. arginosuccinic lyase deficiency (also know as arginosuccinic aciduria)
 - v. N-acetyl glutamate synthetase deficiency
 - vi. arginase deficiency (also know as argininemia)
 - d. Fatty acid oxidation disorders requiring dietary treatment, including:
 - i. very long chain acyl-coA dehydrogenase deficiency (VLCADD),
 - ii. long chain 3-hydroxyacyl-coA dehydrogenase deficiency (LCHADD),
 - iii. trifunctional protein (TFP) deficiency,
 - iv. HMG-coA lyase deficiency
 - v. medium-chain acyl-coA dehydrogenase deficiency
 - vi. carnitine uptake defect
 - e. Glycogen storage diseases
- C. When benefits are provided under the member's contract, JHHC considers nutritional treatment with amino acid-based formulas to be medically necessary when ALL the requirements in Section A are met and for ANY of the following:
1. Immunoglobulin E and non-immunoglobulin E mediated allergies to multiple food proteins
 2. Food protein induced enterocolitis syndrome (FPIES)
 3. Eosinophilic gastrointestinal disorders (EGID), as evidenced by the results of a biopsy
 4. Medical disorders resulting in malabsorption of nutrients caused by disorders affecting the absorptive surface, functional length, and motility of the gastrointestinal tract which may include, but is not limited to cystic fibrosis and short gut syndrome.
 5. Failure to initiate nutritional therapy will result in malnutrition, physical or mental disability, or death.
- D. When benefits are provided under the member's contract, nutrition products for oral or enteral tube feeding consumption that may be approved under this policy when ALL the requirements in Section A are met and either the requirements of Section B or C are met (as applicable) include:
1. For conditions listed in Section B above:
 - a. Formulas/products used as a main source of nutrition containing protein, without the offending amino acid, and a range of other nutrients - specially produced for the dietary treatment of the specific disease/condition (e.g. Propimex-1)
 - b. Low protein modified food products (excludes natural foods that are by nature low in protein) (e.g. Loprofin rice)
 - c. Modular food/Supplements:
 - i. Amino acid mixtures (e.g. Nutricia Complete Amino Acid Mix)
 - ii. Single amino acids to be added to the nutritional solution
 - iii. Medically necessary vitamins and minerals, or other compounds used to replace conditionally essential nutrients or enhance enzyme activity
 2. For conditions listed in Section C above:
 - a. Amino acid-based elemental formulas (e.g. PurAmino, Elecare, Neocate)

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- E. Unless specific benefits are provided under the members contract, JHHC considers the following to be NOT MEDICALLY NECESSARY/NOT COVERED, (not an all-inclusive list):
1. Food products consumed as part of a diet or treatment plan designed to reduce the risk of a disease or medical condition or as weight-loss products, even if recommended by a physician or other health care professional
 2. Nutritional supplements administered for the sole purpose of boosting protein or caloric intake in the absence of a medical condition for which the accepted treatment consists of or includes administration of nutritional supplements.
 3. Vitamin or mineral preparations, except as provided in section III.C (also refer to Pharmacy benefit).
 4. Nutritional products as follows:
 - a. Regular grocery items
 - b. baby food
 - c. banked breast milk (unless specifically covered by benefit plan)
 - d. food thickeners, fiber additives
 - e. gluten-free food products for the management of celiac disease or non-celiac gluten sensitivity
 - f. lactose-free products
 - g. food marketed for the management of diabetes
 - h. products marketed to aid weight loss
 - i. products used to replace fluids and electrolytes
 5. Formulas, foods, or additives designed and marketed for the treatment of food intolerances (e.g. formulas for fussiness or gas)
 6. In-line cartridge containing digestive enzyme(s) for enteral feeding (i.e. Relizorb), unless specifically covered by benefit plan (Refer to Tricare Enteral Food List in Policy section above).
 7. Nutrition product(s) covered for a member through a state agency (e.g. Women, Infants and Children (WIC) Nutrition Program)
 8. Products determined to be investigational or experimental in the treatment of a specific disease or condition.


V. DEFINITIONS

Amino Acid-Based Elemental Formula: A class of nutritional formulas designed for use in the treatment of patients with conditions of the bowel which cause maldigestion or malabsorption. These formulas contain 100% free amino acids as the only protein source and are highly osmotic. They can be administered orally or enterally (through nasogastric, gastrostomy or jejunostomy tubes). The nutritional requirements for patients requiring these formulas are established by medical evaluation and medical supervision is required for their usage.

Eosinophilic Gastrointestinal Disorders (EGID): A group of immune-mediated chronic inflammatory disorders characterized by pathologic eosinophilic (WBC) infiltration of the esophagus, stomach, small intestine, or colon leading to organ dysfunction and clinical symptoms. Symptoms include abdominal pain, nausea, vomiting, early satiety, diarrhea, and weight loss (Gonsalves, 2019).

Food Protein–Induced Enterocolitis (FPIES): A non–IgE-mediated food allergy typically presenting in infancy, with repetitive protracted vomiting beginning approximately 1 to 4 hours after food ingestion with absence of classic IgE-mediated allergic skin or respiratory symptoms. Associated symptoms include: lethargy, pallor, diarrhea, hypotension, hypothermia, increased neutrophil count (Nowak-Wegrzyn, 2017).

Inborn Errors of Metabolism (IEM): These include inherited biochemical disorders in which a specific enzyme defect interferes with the normal metabolism of protein, fat, or carbohydrate. The diminished or absent enzyme activity in these disorders, cause certain compounds to accumulate in the body at toxic levels and the levels of others that the body normally makes may become deficient. Left untreated, these metabolic disturbances can result in intellectual disability, severe cognitive impairment or death (Camp, 2012).

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Low Protein Modified Food: A food product that is specially formulated to have less than 1 gram of protein per serving and is intended to be used under the direction of a physician for the dietary treatment of an inherited metabolic disease, excluding natural foods that are naturally low in protein (Maryland Code, Insurance § 15-807).

Medical Food: Food intended for the dietary treatment of a disease or condition for which nutritional requirements are established by medical evaluation and formulated to be consumed or administered enterally under the direction of a physician (Maryland Code, Insurance § 15-807). A medical food must be intended for a patient who has a limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone (21 CFR 101.9(j)(8)(ii)).


Medical Nutrition Therapy: Nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional. MNT is a specific application of the Nutrition Care Process in clinical settings that is focused on the management of diseases. MNT involves in-depth individualized nutrition assessment and a duration and frequency of care using the Nutrition Care Process to manage disease (Academy of Nutrition and Dietetics, 2019). It includes recommendations for foods or nutrients to treat conditions and may involve simple changes in a person's diet, or intravenous or tube feeding. (Also called nutrition therapy) (NIH 2019).

VI. BACKGROUND

Medical Nutrition Therapy (MNT) is a practice which consists of administering personalized diet plans, nutritional therapy and counseling services to patients for the treatment and management of diseases and other medical conditions. MNT is a therapeutic approach often used for patients with diabetes, hypertension, and renal disease.

Dietary management of diseases or conditions also includes the treatment of severe allergies, disorders of the gastrointestinal tract and inborn errors of metabolism (IEM) for which the provision of medical foods may be required to allow for growth and development or to prevent death. Many inborn errors of metabolism for which nutritional treatments serve as the primary medical treatment are identified through newborn screening programs (NSPs). Individual states determine what disorders are included in their NBS program however; most states include the disorders included on the Recommended Uniform Screening Panel supported by the Advisory Committee on Heritable Disorders in Newborns and Children (HRSA.gov, 2019).

Although screening programs may vary, major categories tested include fatty acid oxidation disorders, amino acids disorders and organic acidurias (Camp, 2012). Fatty acid oxidation disorders (FAODs) are inborn errors of metabolism that result in failure of mitochondrial beta-oxidation or the carnitine-based transport of fatty acids into mitochondria (Merritt, 2017). The recommended diet for FAODs is fat restricted with carbohydrate supplementation. Treatment of long-chain FAODs are supplemented with medium-chain triglyceride (MCT) oil to provide a substrate for beta-oxidation. Carnitine supplementation is given when secondary carnitine deficiency is identified. Essential to treatment of FAODs is avoidance of prolonged fasting and maintenance of a constant energy supply during times of catabolism (Merritt). Inborn errors of metabolism involving amino acid metabolism include phenylketonuria (PKU), the first newborn screening disorder. It is the most common IEM requiring nutritional treatment and is caused by insufficient or absent phenylalanine hydroxylase, the enzyme that converts the amino acid phenylalanine to tyrosine (Camp). Medical nutrition therapy for inborn errors of metabolism involving amino acid disorders include two different forms of medical foods - one containing protein without the amino acid(s) specific to the IEM and the other consisting of foods that have been modified to be low in protein (Camp). Organic acidurias, also referred to as organic acidemias, are a class of inborn errors of metabolism characterized by accumulation of abnormal and often toxic organic acid metabolites with increased excretion of organic acids in urine. They result primarily from deficiencies of specific enzymes in the breakdown pathways of amino acids (Bodamer, 2019). Successful treatment of organic acidurias involves synthetic amino acid-based formulas which should provide about 50% of daily protein needs. Simultaneously, the dietary precursor amino acid has to be restricted and fasting must be avoided (Vaidyanathan, 2011).

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Nutritional products classified as medical foods used to treat inborn errors of metabolism include three main categories. Products with a full complement of nutrients excluding the offending nutrient which come in powders to be reconstituted, ready to drink products, and bars. This category includes specialty infant formulas. Secondly, are modular products which include amino acid mixtures, ready to drink products, low volume, low calorie foods, and tablets. Lastly, foods modified to be low in protein include specialty baked goods, pasta, rice, meat and cheese substitutes, and snack foods (Camp, 2016). Medical foods are distinct from the broader category of foods for special dietary use, as medical foods must be intended to meet distinctive nutritional requirements of a disease or condition, be intended for the specific dietary management of a disease or condition, and require medical supervision. Medical foods do not include all foods recommended by a physician as part of an overall diet to manage the symptoms or reduce disease risk, and not all foods administered to patients with a disease, including diseases that require dietary management, like diabetes, are medical foods. Instead, medical foods are foods that are specially formulated and processed for a patient who requires use of the product as a major component of a disease or condition's specific dietary management (HHS, 2016).

VII. CODING DISCLAIMER

CPT Copyright 2018 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.


Note: The following CPT/HCPCS codes are included below for informational purposes and may not be all inclusive. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member's specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee of payment. Other policies and coverage determination guidelines may apply.

Note: All inpatient admissions require preauthorization.

<i>Compliance with the provision in this policy may be monitored and addressed through post payment data analysis and/or medical review audits</i>			
Employer Health Programs (EHP) refer to specific Summary Plan Description (SPD). If there is no criteria in the SPD, apply the Medical Policy criteria.	Priority Partners (PPMCO) refer to COMAR guidelines then apply the Medical Policy criteria.	US Family Health Plan (USFHP), TRICARE Medical Policy supersedes JHHC Medical Policy. If there is no Policy in TRICARE, apply the Medical Policy Criteria.	Advantage MD, LCD and NCD Medical Policy supersedes JHHC Medical Policy. If there is no LCD or NCD, apply the Medical Policy Criteria.


VIII. CODING INFORMATION

CPT CODES	DESCRIPTION
97802	Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes
97803	Medical nutrition therapy; re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes
97804	Medical nutrition therapy; group (2 or more individual(s)), each 30 minutes

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HCPCS CODES	DESCRIPTION
A9152	Single vitamin/mineral/trace element, oral, per dose, not otherwise specified
A9153	Multiple vitamins, with or without minerals and trace elements, oral, per dose, not otherwise specified
B4100	Food thickener, administered orally, per oz
B4102	Enteral formula, for adults, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
B4103	Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
B4104	Additive for enteral formula (e.g., fiber)
B4105	In-line cartridge containing digestive enzyme(s) for enteral feeding, each
B4157	Enteral formula, nutritionally complete, for specific metabolic needs for inherited disease of metabolism, includes proteins, fats carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4161	Enteral formula, for pediatrics, hydrolyzed/amino acids and peptide chain proteins, includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through and enteral feeding tube, 100 calories = 1 unit
B4162	Enteral formula, for pediatrics, special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
G0270	Medical nutrition therapy; reassessment and subsequent intervention(s) following second referral in same year for change in diagnosis, medical condition or treatment regimen (including additional hours needed for renal disease), individual, face-to-face with the patient, each 15 minutes
G0271	Medical nutrition therapy, reassessment and subsequent intervention(s) following second referral in same year for change in diagnosis, medical condition, or treatment regimen (including additional hours needed for renal disease), group (2 or more individuals), each 30 minutes
S9433	Medical food nutritionally complete, administered orally, providing 100% of nutritional intake
S9434	Modified solid food supplements for inborn errors of metabolism
S9435	Medical foods for inborn errors of metabolism
S9470	Nutritional counseling, dietitian visit

ICD10 CODES	DESCRIPTION
E70.0 - E70.9	Disorders of aromatic amino-acid metabolism
E71.0 - E71.548	Disorders of branched-chain amino-acid metabolism and fatty-acid metabolism
E72.00 - E72.9	Other disorders of amino-acid metabolism
E74.00 - E74.09	Glycogen storage disease


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E84	Cystic fibrosis		
K52.21	Food protein-induced enterocolitis syndrome		
K52.81	Eosinophilic gastritis or gastroenteritis		
K91.2	Postsurgical malabsorption, not elsewhere classified		

IX. REFERENCE STATEMENT

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins HealthCare LLC (JHHC) Medical Policy Team during the development and implementation of this medical policy. The Medical Policy Team will continue to monitor and review any newly published clinical evidence and revise the policy and adjust the references below accordingly if deemed necessary.

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XI. APPROVALS

Historical Approval Dates: 03/03/2017, 07/01/2019