Enteral Nutrition, Parenteral Nutrition, Low Protein Food Products, and Special Medical Formulas Clinical Coverage Criteria

Overview

Massachusetts General Law (MGL) chapter 176G § 4D mandates coverage for non-prescription enteral formulas for home use for which a physician has issued a written order and which are medically necessary for the treatment of malabsorption / malnutrition caused by Crohn's disease, ulcerative colitis, gastroesophageal reflux, gastrointestinal motility, chronic intestinal pseudo-obstruction, and inherited diseases of amino acids and organic acids. Coverage for inherited diseases of amino acids and organic acid shall include food products modified to be low protein in an amount not to exceed $5,000 annually for any insured individual. This mandated coverage applies to commercial plan members.

In addition, MGL, chapter 176G § 4(c) mandates coverage for prenatal care, childbirth and postpartum care as set forth in section 47F of chapter 175. Per chapter 175 § 47F coverage for newly born infants and adoptive children shall consist of coverage of injury or sickness including the necessary care and treatment of medically diagnosed congenital defects and birth abnormalities, or premature birth. Such coverage shall also include those special medical formulas which are approved by the Commissioner of the Department of Public Health, prescribed by a physician, and are medically necessary for treatment of phenylketonuria, tyrosinemia, homocystinuria, maple syrup disease, propionic acidemia, or methylmalonic acidemia in infants and children or medically necessary to protect the unborn fetuses of pregnant women with phenylketonuria. This mandated coverage applies to commercial plan members.

Policy

This Policy applies to the following Fallon Health products:

☒ Commercial
☒ Medicare Advantage
☒ MassHealth ACO
☒ NaviCare
☐ PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for Medicare Advantage, NaviCare and PACE plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Effective for claims with dates of service on and after January 1, 2022, CMS has determined that no NCD is appropriate at this time for enteral and parenteral nutritional therapy (Transmittal R11426NCD, May 20, 2022). In the absence of an NCD, coverage determinations are made by the Medicare Administrative Contractors under 1862(a)(1)(A) of the Social Security Act. Enteral and parenteral nutritional therapy is provided on the basis of the prosthetic device benefit. Noridian Healthcare Solutions, LLC is the durable medical equipment (DME) MAC responsible for

processing and paying Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) for Medicare beneficiaries in our service area. Noridian Healthcare Solutions, LLC has an LCD for Enteral Nutrition (L38955) and a related Policy Article: Enteral Nutrition (A58893), and an LCD for Parenteral Nutrition (L38953) and a related Policy Article: Parenteral Nutrition (A58836) (MCD search 5/23/2022. Additionally, benefit and billing guidance for enteral nutrition are outlined in the Medicare Benefit Policy Manual (CMS Pub. 100-02), Chapter 15, Section 120 and the Medicare Claims Processing Manual (CMS Pub. 100-4), Chapter 20, Section 30.7.

For plan members enrolled in NaviCare, Fallon Health follows Medicare guidance for coverage determinations. MassHealth has *Guidelines for Medical Necessity Determination for Enteral Nutrition and Special Medical Formulas*, therefore, in the event a NaviCare member does not meet coverage criteria for enteral nutrition in the Medicare guidance, Fallon Health will then determine if the plan member meets criteria in the *MassHealth Guidelines for Medical Necessity Determination for Enteral Nutrition and Special Medical Formulas.*

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health follows criteria in the *MassHealth Guidelines for Medical Necessity Determination for Enteral Nutrition and Special Medical Formulas* for MassHealth ACO members.

Fallon Health requires prior authorization for enteral nutrition, parenteral nutrition, low protein food products, and special medical formulas. These requests must be supported by documentation from the treating provider's medical records.

Use the following links to go to the corresponding section:
Part I. Fallon Health Clinical Coverage Criteria
Part II. Medicare Advantage and NaviCare
Part III. MassHealth ACO

Part I. Fallon Health Clinical Coverage Criteria

Requests for prior authorization must be accompanied by clinical documentation that supports appropriate medical use of the product. Documentation from the most recent medical evaluation must include all of the following:

1. The primary diagnosis name and code specific to the nutritional disorder for which enteral nutrition products are requested
2. The secondary diagnosis name and code specific to the co-morbid condition, if any
3. Clinical signs and symptoms, including anthropometric measures
4. Comprehensive medical history and physical exam
5. Testing results sufficient to establish the diagnosis of the covered condition (see medical criteria below)
6. Route of enteral nutrition
7. Documentation of past and current treatment regimens
8. Type and estimated duration of the need for enteral nutritional

Covered Services
Inborn Errors of Metabolism
As required by Massachusetts state law, specialized formula appropriate to the condition will be for metabolic diseases for patients with the following diagnoses.

- Tyrosinemia
- Homocystinuria

- Maple syrup urine disease
- Propionic acidemia
- Methylmalonic acidemia
- Urea cycle disorders
- Phenylketonuria (PKU)
- Other organic and amino acidemias
- PKU benefit coverage is provided for infants and children as well as for the
- protection of unborn babies of women who have PKU.

Malabsorption:
Specialized formula appropriate to the condition will be for patients with the following diagnoses:
- Crohn's disease
- Ulcerative colitis
- Gastrointestinal dysmotility
- Gastroesophageal reflux (GERD)
- Chronic intestinal pseudo-obstruction

Documentation required to demonstrate malabsorption includes pertinent clinical records and lab work which supports the diagnosis WITH evidence of growth failure, including a copy of the growth chart.
1. Clinical documentation such as chronic diarrhea, abdominal distention, failure to gain weight/weight loss, fecal fat or reducing substances in stool.
2. Growth failure: Deceleration of growth velocity across 2 major percentiles on a standard growth chart

IgE- Mediated and Non-IgE Mediated Formula intolerance for Infants < 1 Year of Age
Covered Conditions:
IgE mediated Formula Intolerance
    Covered Conditions:
    - Eosinophilic esophagitis
    - Allergic enterocolitis
    - Symptoms such as angioedema, wheezing, anaphylaxis

Documentation requirement includes:
1. Medical records detailing the clinical picture
2. Other clinical information such as consultations, radiological studies, laboratory studies and/or endoscopy reports
3. Gross blood in stool with documentation that other nonformula related etiologies such as fissures and/or infectious issues have been ruled out or documentation of positive heme stool test results

Non-IgE Mediated Formula Intolerance: persistent gastroenterological symptoms such as recurrent vomiting and/or diarrhea:

Documentation requirement includes:
1. Evaluations/assessments for the reported symptoms of formula intolerance with documentation of formula changes and other treatment modalities
2. All other pertinent medical records, AND
3. A copy of the growth chart documenting evidence of growth failure deceleration of growth velocity across 2 major percentiles on a standard growth chart.

When clinical criteria are met, hydrolyzed protein formulas may be approved for up to one year of age. Amino Acid formulas are covered as described above for infants who fail a 5 day trial of hydrolyzed protein formula.

Prematurity:
A transition formula, such as Neosure or Enfacare is authorized through 3 months of age when the weight of a premature infant at the time of hospital discharge is below the 10th percentile when corrected for gestational age. After 3 months of life, requests are reevaluated based on meeting clinical requirements for one of the other covered conditions.

The following do not meet the criteria above and are not covered:

- Standard non-hydrolyzed and non-elemental milk formula and soy-based formulas are not covered; these are not considered treatment for a medical condition and are regarded as food
- Special medical formulas or non-prescription enteral formulas when used for other conditions not listed in the preceding pages of this policy
- Blenderized baby food or regular store-bought food for use with an enteral feeding system
- Over-the-counter or prescription foods when store-bought food meets the nutritional needs of the patient
- Formula or food products used for dieting or for a weight-loss program
- Banked breast milk
- Dietary or food supplements or food thickeners
- Supplemental high protein powders and mixes
- Lactose free foods or gluten-free products
- Baby foods
- Oral vitamins and minerals
- Medical foods (e.g., Foltx, Metanx, Cerefolin, probiotics such as VSL#3) including FDA-approved medical foods obtained via prescription

Part II. Medicare Advantage and NaviCare (Please note Medicare coverage criteria will be used for NaviCare members unless MassHealth provides additional coverage)

Enteral Nutrition

Enteral nutrition is considered medically necessary for Medicare Advantage and NaviCare members when coverage criteria in Noridian Healthcare Solutions, LLC LCD for Enteral Nutrition (L38955) and LCA Enteral Nutrition - Policy Article (A58833) are met.

Links:
LCD: **Enteral Nutrition (L38955)**
LCA: **Enteral Nutrition – Policy Article (A58833)**

Enteral nutrition is the provision of nutritional requirements via an enteral access device[1] and is an option for some plan members who are unable to meet their nutritional requirements orally but have a functional gut and are able to digest/absorb formula introduced into the lumen of the gastrointestinal (GI) tract. Enteral nutrition is covered under the prosthetic device benefit for plan members who qualify under Medicare Benefit Policy Manual (CMS Pub. 100-02), Chapter 15, Section 120. The definition of functional gut has broadened with advancements in enteral nutrition such that in the absence of intestinal failure or absolute contraindications, the GI tract is the preferred route for nutrition support therapy. Based on review of the best available evidence, enteral nutrition is appropriate for the management of; and, improves health outcomes for individuals with a diagnosis of maldigestion/malabsorption.

[1] There are two options for providing enteral nutrition: temporary and permanent. Temporary feeding tubes include nasogastric (NG) tube or nasojejunal (NJ) tube; these tubes are inserted through the nose and advanced through the esophagus and into the stomach (NG tube), through the pylorus, and into the jejunum (NJ tube). Permanent feeding tubes are placed directly into the stomach (gastrostomy [G] tubes) or intestine (jejunostomy [J] tubes or gastrojejunostomy [GJ] tubes), either percutaneously, laparoscopically, or surgically (Brett et al., 2018).

Enteral nutrition is considered medically necessary for a plan member who requires feedings via an enteral access device to provide sufficient nutrients to maintain weight and strength commensurate with the plan member's overall health status and has a permanent:

A. Full or partial non-function or disease of the structures that normally permit food to reach the small bowel; OR,
B. Disease that impairs digestion and/or absorption of an oral diet, directly or indirectly, by the small bowel. Please refer to definition of Test of Permanence below.

Adequate nutrition must not be possible by dietary adjustment and/or oral supplements.

Typical examples of conditions associated with non-function or disease of the structures that permit food from reaching the small bowel that qualify for coverage are head and neck cancer with reconstructive surgery and central nervous system disease leading to interference with the neuromuscular mechanisms of ingestion of such severity that the beneficiary cannot be maintained with oral feeding (not all inclusive).

Typical examples of conditions associated with impaired digestion and/or absorption of an oral diet by the small bowel that may qualify for coverage include inflammatory bowel disease, surgical resection of small bowel, cystic fibrosis, chronic pancreatitis, and advanced liver disease (not all inclusive).

Test of Permanence

Coverage of enteral nutrition or parenteral nutrition under the prosthetic device benefit, as outlined in the Medicare Benefit Policy Manual (CMS Pub. 100-02), Chapter 15, Section 120, requires that a Medicare beneficiary must have a permanent impairment. However, this does not require a determination that there is no possibility that the beneficiary's condition may improve sometime in the future. If the medical record, including the judgment of the treating practitioner, indicates that the impairment will be of long and indefinite duration, the test of permanence is considered met.

- Enteral formulas consisting of semi-synthetic intact protein/protein isolates (B4150 or B4152) are appropriate for the majority of plan members requiring enteral nutrition.

- The medical necessity for special enteral formulas (B4149, B4153, B4154, B4155, B4157, B4161, and B4162) must be justified in each plan member. If a special enteral nutrition formula is provided and if the medical record does not document why that item is medically necessary, it will be denied as not medically necessary.

- Food thickeners (B4100), baby food, and other regular grocery products that can be blenderized and used with the enteral system will be denied as non-covered.

- Electrolyte-containing fluids (B4102 and B4103) are not indicated for the maintenance of weight and strength and are therefore non-covered.

- Self-blenderized formulas are non-covered.

- Code B4104 is an enteral formula additive. The enteral formula codes include all nutrient components, including vitamins, mineral, and fiber. Therefore, code B4104 will be denied as not separately payable.

- Enteral nutrition for temporary impairments will be denied as non-covered.

- Enteral nutrition for plan members with a functioning gastrointestinal tract whose need for enteral nutrition is not due to reasons related to the non-function or disease of the structures that normally permit food to reach the small bowel will be denied as non-covered.

- Orally administered enteral nutrition products, related supplies and equipment will be denied non-covered.

Equipment and supplies for the administration of enteral nutrition
If the coverage requirements for enteral nutrition are met, medically necessary equipment and supplies for the administration of enteral nutrition are covered. Enteral nutrition may be administered by syringe, gravity, or pump. Some patients may experience complications associated with syringe or gravity method of administration.

If a pump (B9002) is ordered, there must be documentation in the plan member's medical record to justify its use (e.g., gravity feeding is not satisfactory due to reflux and/or aspiration, severe diarrhea, dumping syndrome, administration rate less than 100 ml/hr, blood glucose fluctuations, circulatory overload, gastrostomy/jejunostomy tube used for feeding). If the medical necessity of the pump is not documented, the pump will be denied as not reasonable and necessary.

In-line digestive enzyme cartridges (B4105) are medically necessary for plan members who:

A. meet the coverage criteria for enteral nutrition; and,
B. have a diagnosis of Exocrine Pancreatic Insufficiency (EPI) (refer to the Group 1 Codes in the LCD-related Policy Article (A58833) for applicable diagnoses).

More than two in-line digestive enzyme cartridges (B4105) per day will be denied as not reasonable and necessary.

The feeding supply allowance (B4034, B4035, and B4036) must correspond to the method of administration. If it does not correspond, the supply allowance will be denied as not reasonable and necessary.

If a pump supply allowance (B4035) is provided and if the medical necessity of the pump is not documented, it will be denied as not reasonable and necessary.

The unit of service (UOS) for the supply allowance (B4034, B4035, or B4036) is one (1) UOS per day. Claims that are submitted for more than one UOS per day for HCPCS codes B4034, B4035, or B4036 will be denied.

Enteral feeding supply kit allowances (B4034, B4035, and B4036), are all-inclusive, with the exception of B4105 in-line digestive enzyme cartridge. Separate billing for any item including an item using a specific HCPCS code, if one exists, or B9998 (Enteral supplies, not otherwise classified) will be denied as unbundling.

Refer to the LCD-related Policy Article (A58833) Coding Guidelines section for additional information about enteral feeding supply allowances.

More than three nasogastric tubes (B4081, B4082, and B4083), or one gastrostomy/jejunostomy tube (B4087 or B4088) every three months is not reasonable and necessary.

Parenteral nutrition
Parenteral nutrition is considered medically necessary for Medicare Advantage and NaviCare members when coverage criteria in Noridian Healthcare Solutions, LLC LCD for Parenteral Nutrition (L38953) and LCA Parenteral Nutrition (A58836) are met.

Links:
LCD: **Parenteral Nutrition (L38953)**
LCA: **Parenteral Nutrition (A58836)**

Parenteral nutrition is provided intravenously to the patient with pathology of the alimentary tract severe enough, that it does not allow for absorption of sufficient nutrients. Parenteral is covered for plan members who qualify under the Prosthetic Device Benefit defined in the Medicare Benefit Policy Manual (CMS Pub. 100-02), Chapter 15, Section 120.

When nutritional support other than the oral route is necessary, enteral nutrition is usually initially preferable to parenteral nutrition for the following reasons: (1) In a fluid restricted beneficiary, enteral nutrition permits delivery of all necessary nutrients in a more concentrated volume than parenteral nutrition; (2) enteral nutrition allows for safer home delivery of nutrients; and (3) enteral nutrition lowers the risk of Central Line-Associated Bloodstream Infections.

For parenteral nutrition to be considered medically necessary, all of the following criteria must be met:

1. The treating practitioner must document that enteral nutrition has been considered and ruled out, tried and been found ineffective, or that enteral nutrition exacerbates gastrointestinal tract dysfunction.
2. The plan member must have
   a. A condition involving the small intestine and/or its exocrine glands which significantly impairs the absorption of nutrients, or
   b. A disease of the stomach and/or intestine which is a motility disorder and impairs the ability of nutrients to be transported through and absorbed by the gastrointestinal (GI) system.
3. The plan member must have a permanent impairment. Please refer to definition of Test of Permanence above.

The treating practitioner is required to evaluate the plan member within 30 days prior to initiation of parenteral nutrition. If the treating practitioner does not see the plan member within this timeframe, they must document the reason why and describe what other monitoring methods were used to evaluate the plan member's parenteral nutrition needs. There must be documentation in the medical record supporting the clinical diagnosis.

- A total caloric daily intake of 20-35 cal/kg/day is considered reasonable and necessary to achieve or maintain appropriate body weight. The treating practitioner must document the medical necessity for a caloric intake outside this range in an individual beneficiary.

- The treating practitioner must document the medical necessity for protein orders outside of the range of 0.8-2.0 gm/kg/day (B4168, B4172, B4176, B4178), dextrose concentration less than 10% (B4164, B4180), or lipid use per month in excess of the product-specific, FDA-approved dosing recommendations (B4185, B4187).

- Special nutrient formulas, HCPCS codes B5000, B5100, and B5200 are produced to meet the unique nutrient needs for specific disease conditions. The plan member’s medical record must adequately document the specific condition and the necessity for the special nutrient.

- When homemix parenteral nutrition solutions are used, the component carbohydrates (B4164, B4180), amino acids (B4168, B4172, B4176, B4178), additives (B4216), and lipids (B4185 or B4187) are all separately billable. When premix parenteral nutrition solutions are used (B4189, B4193, B4197, B4199, B5000, B5100, B5200) there must be no separate billing for the carbohydrates, amino acids or additives (vitamins, trace elements, heparin, electrolytes). However, lipids (B4185 or B4187) are separately billable with premix solutions.

- For lipids, one unit of service of code B4185 or B4187 is billed for each 10 grams of lipids provided. 500 ml of 10% lipids contains 50 grams of lipids (5 units of service); 500 ml of 20% lipids contains 100 grams (10 units of service); 500 ml of 30% lipids contains 150 grams (15 units of service).

- For codes B4189, B4193, B4197, B4199, one unit of service represents one day's supply of protein and carbohydrate regardless of the fluid volume and/or the number of bags. For example, if 60 grams of protein are administered per day in two bags of a premix solution each containing 30 grams of amino acids, correct coding is one (1) unit of B4193, not two units of B4189.

- For codes B5000, B5100, B5200, one unit of service is one gram of amino acid.

- Parenteral nutrition solutions containing less than 10 grams of protein per day are coded using the miscellaneous code B9999.

Equipment and supplies for the administration of parenteral nutrition
If the coverage requirements for parenteral nutrition are met, medically necessary equipment and supplies for the administration of parenteral nutrition are covered.

Only one infusion pump is covered for plan members in whom parenteral nutrition is required.

Additionally, only one supply kit and one administration kit is covered for each day that parenteral nutrition is administered.

When parenteral nutrition is administered in an outpatient facility, the pump used for its administration and IV pole will be denied as not separately payable. The pump and pole are not considered as rentals to a single plan member, but rather, as items of equipment used for multiple plan members.
When an IV pole (E0776) is used in conjunction with parenteral nutrition, the BA modifier should be added to the code. Code E0776 is the only code with which the BA modifier may be used.

Parenteral nutrition supply allowances (HCPCS codes B4220, B4222 and B4224) describe a daily supply fee rather than a specifically defined "kit" and include all supplies required for the administration of parenteral nutrition to the beneficiary for one day. The use of individual items may differ from beneficiary to beneficiary, and from day to day. Daily allowances are considered all-inclusive and therefore refill requirements are not applicable to HCPCS codes B4220, B4222 and B4224. Only one unit of service may be billed for any one day.

Part III. MassHealth ACO

Fallon Health follows the *MassHealth Guidelines for Medical Necessity Determination for Enteral Nutrition and Special Medical Formulas* for MassHealth members, if approved, the product can be obtained through a DME supplier or at a retail pharmacy.

Enteral nutrition and special medical formulas are nutrition provided via the gastrointestinal cavity by mouth (orally) or through a tube or stoma that delivers the nutrients to the gastrointestinal tract distal to the oral cavity.

Link to MassHealth Guidelines for Medical Necessity Determination: **Enteral Nutrition and Special Medical Formulas**

Coverage Criteria
Medical need must be manifested by the presence of both a medical condition known to cause nutritional risk and evidence of nutritional and/or growth implications that are not amenable to the use of regular food or standard formulas. Applicable medical criteria include, but are not limited to, criteria 1-6 below.

1. The member has been diagnosed with one or more of the medical conditions below in 1.a) through 1.f) and meets the condition-specific criteria set forth below:
   a) An anatomic or metabolic condition that includes
      i. anatomic structures of the gastrointestinal tract that impair digestion and absorption;

ii. neurological disorders that impair swallowing or chewing; and
iii. diagnosis of inborn errors of metabolism that require food products to be modified to be low in protein (for example, phenylketonuria (PKU), tyrosinemia, homocystinuria, maple syrup urine disease, propionic aciduria, and methylmalonic aciduria).

b) Allergy to cow's milk protein and soy infant formulas as manifested by one or more of the conditions listed in Table A that occurs while given a cow's milk formula or breast milk with documented improvement from elimination of dairy from the diet and a successful trial of extensively hydrolyzed protein formula or, if such a trial failed, then a successful trial of amino-acid based formula. Each of the following must be present:
   i. one or more of the conditions listed in Table A (page 6);
   ii. documented allergy to cow's milk;
   iii. documented soy formula intolerance;
   iv. documented multiple protein intolerance;
   v. the primary source of nutrition being 100% hydrolyzed amino acids nutritional formula; and
   vi. the 100% hydrolyzed amino acids nutritional formula being recommended by a Pediatric Allergist, Pediatric Pulmonologist, or Pediatric Gastroenterologist.

c) Prolonged nutrient losses due to malabsorption syndromes or short-bowel syndromes such as or related to diabetes, celiac disease, chronic pancreatitis, renal dialysis, draining abscess, or wounds;

d) Evidence of weight loss during treatment with anti-nutrient or catabolic properties including, but not limited to, anti-tumor treatments, corticosteroids, and immunosuppressants;

e) Evidence of increased metabolic and/or caloric and weight loss due to excessive burns, infection, trauma, prolonged fever, hyperthyroidism, or illnesses that impair caloric intake and/or retention; or

f) diagnosis of failure-to-thrive with increased caloric needs and impaired caloric intake and/or retention.

2. Evidence that the member's nutritional needs cannot be met by the use of regular food; standard, commercial formula and food products; or supplementation with commercially available products.
3. Use of enteral nutrition and special medical formulas, whether orally or by tube feeding, as a therapeutic regimen in a member with a medically diagnosed condition that precludes the full use of regular food.
4. The member presenting clinical signs and symptoms of impaired digestion, malabsorption, or nutritional risk, as indicated by the following:
   a) The member cannot ingest regular food because of a medical condition; or
   b) The member receives all nutrition via tube feeds because of a medical condition resulting in difficulty swallowing and the inability to take nutrition by mouth; or
   c) The member receives nutrition either orally or both through oral and tube feedings and has evidence of weight loss with measurements on more than one consecutive occasion that presents actual, or potential for developing, malnutrition as defined below:
      i. in adults and post-pubertal adolescents, showing involuntary or acute weight loss of greater than or equal to 10 percent of usual body weight during a three-to-six month period, or body mass index (BMI) below 18.5 kg/m2, with consideration for measurement of BMI in members with chronic immobility for whom height is difficult to measure by using another anthropometric method such as height associated with arm span or ration of upper body to lower extremity length;
      ii. in neonates, infants, and children, with
         (a) very low birth weight (VLBW <1500g) within the first three months of life corrected for prematurity even in the absence of gastrointestinal, pulmonary, or cardiac disorders;
         (b) a sustained decrease in weight or weight-for-height-for-age-and-gender across two or more major percentiles after having previously established a stable rate of growth (growth velocity);

(c) a lack of weight gain, or weight gain less than two standard deviations below the age-appropriate mean (i.e., below the 2nd percentile), and not growing at a rate parallel to the growth curve in a three-month period for children under six months, or four-month period for children aged six to 12 months, and that does not reverse with instruction in appropriate diet for age;
(d) no weight gain or abnormally slow rate of gain for six months for children older than one year, or documented weight loss that does not reverse with instruction in appropriate diet for age; or
(e) weight or weight-for-height less than two standard deviations below the mean for age and gender (i.e., below the second percentile) and not growing at a rate parallel to the growth curve;
(f) for individuals with genetic or other syndromes, where syndrome-specific growth charts are available, weight gain and growth are abnormally slow for the specific condition using the condition-specific growth chart;

OR

d) abnormal laboratory tests pertinent to the diagnosis.

5. A recent (within the past year) comprehensive medical history and a physical examination and, if applicable, laboratory tests having been conducted to detect factors contributing to nutritional risk.
6. Enteral nutrition indicated as the primary source of nutritional support essential for the management of risk factors that impair digestion or malabsorption, and for the management of surgical preparation or postoperative care.

Noncoverage

Enteral nutrition products are considered not medically necessary under certain circumstances. Examples of such circumstances include, but are not limited to, the following.

1. A medical history and physical examination have been performed and other alternatives comparable in effect and available to the member that are more conservative or less costly to MassHealth have been identified to minimize nutritional risk.
2. The member is underweight but has the ability to meet nutritional needs through the use of regular food consumption and/or commercially available caloric supplements.
3. Enteral nutrition products are used as supplements to a normal or regular diet in a member showing no clinical indicators of nutritional risk.
4. The member has food allergies, lactose intolerance, or dental problems, but has the ability to meet his or her nutritional requirements through an alternative food source comparable in effect and available to the member that is more conservative or less costly to MassHealth.
5. Enteral nutrition products are to be used for dieting or a weight-loss program.
6. Enteral nutrition and special medical formulas and foods are requested solely because of food preference in the absence of a medical condition.
7. Enteral nutrition products for premature infants older than three months of age. Standard infant formulas for home use (in a setting in which normal life activities take place) are expected to be used for premature infants older than three months of age (corrected for prematurity) and whose weight growth is parallel to or growing faster than the appropriate growth curve for age.
8. Growth parameters are consistent with specialized condition-specific growth charts for members with genetic conditions.
9. Children who are small, but exhibit a normal growth rate parallel to the growth curve.

In addition, MassHealth does not pay for any health care or related services that are available at no cost to a member, including through any agency of the state (see 130 CMR 450.204: Medical Necessity, 503.007(B)(2), 517.008(B)(2)). With respect to formula, MassHealth is the payor of last resort for certain formulae. This is because the Women, Infants and Children (WIC) Nutrition Program administered by the Massachusetts Department of Public Health has primary responsibility for the provision of standard infant formula to WIC-eligible MassHealth members. Accordingly, MassHealth does not consider formula to be medically necessary if there is an available alternative less costly to MassHealth, such as under the following circumstances:

1. The member is WIC-eligible;
2. The enteral nutrition product being requested is listed as a standard infant formula on the current list of formulas covered by WIC; and
3. The formula is available in adequate amounts to the member through the WIC program.

WIC offers many formulas for participants with special medical needs. Providers may visit **WIC Information for Providers** to obtain the current WIC formula list.

Table A

Diagnosis or Symptoms	Description
Severe atopic dermatitis in a child less than a year old	Must be diagnosed by an allergist or other appropriate specialist, and role of commercial formulas in causing the atopic dermatitis confirmed, such as by an immediate reaction after ingestion or improvement after a well-defined elimination diet. For children older than one year, a retrial of commercial food and any reevaluation should demonstrate continued evidence of food allergy.
IgE-mediated cow's milk protein allergy	1. Characterized by one or more of the following symptoms related to the ingestion of cow's milk protein: a. severe vomiting and abdominal pain within minutes to hours of food ingestion; b. severe diarrhea within six hours of food ingestion; c. pruritus or severe itching of the skin (localized or generalized); d. angioedema and urticaria; e. stridor, wheezing, or anaphylaxis. OR 2. Characterized by a non-urticarial rash or with a rash and a negative IgE to soy. The child must fail trials of commercial formulas. For children older than a year, a retrial of commercial food and reevaluation should demonstrate continued evidence of food allergy
Severe and persistent gastrointestinal irritability	2. For infants up to six months of age, characterized by: a. weight loss or lack of weight gain; b. presence of significant vomiting or gastrointestinal bleeding; c. failure of trials of commercial formula; and d. recommended use of specialized formula by a gastrointestinal specialist. 3. For infants from six to 12 months: a. demonstration that symptoms are significantly improved with the use of the requested special medical formula; b. a retrial of commercial formula is unsuccessful; and c. continuation of special formula use is recommended by a gastrointestinal specialist. 4. For children older than one year of age, a retrial of commercial food and re-evaluation should demonstrate continued evidence of need for specialized formula.
Non-IgE mediated conditions associated with cow's milk allergy	For children older than one year of age, a retrial of commercial food and reevaluation should demonstrate continued evidence of food allergy: 1. food protein-induced proctocolitis associated with blood streaked stools not caused by anal fissures, infection, or other common causes of bloody stools; 2. pulmonary hemosiderosis; 3. food protein-induced enterocolitis associated with malabsorption and failure to thrive;

	4. food protein-induced enteropathy associated with malabsorption, failure to thrive, diarrhea, and vomiting; and 5. 5. esophageal eosinophilia and/or eosinophilic gastroenteritis, associated with malabsorption and dysmotility

Exclusions

- Services that do not meet the criteria outlined above.
- Nutritional supplements, medical foods and formulas unless described above as covered.
- Dietary supplements, specialized infant formulas (such as Nutramigen, Elecare and Neocate), vitamins and/or minerals taken orally to replace intolerable foods, supplement a deficient diet, or provide alternative nutrition for conditions such as hypoglycemia, allergies, obesity and gastrointestinal disorders. These products are not covered even if they are required to maintain weight or strength.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Enteral Nutrition

Code	Description
B4034	Enteral feeding supply kit; syringe fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape
B4035	Enteral feeding supply kit; pump fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape
B4036	Enteral feeding supply kit; gravity fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape
B4081	Nasogastric tubing with stylet
B4082	Nasogastric tubing without stylet
B4083	Stomach tube - Levine type
B4087	Gastrostomy/jejunostomy tube, standard, any material, any type, each
B4088	Gastrostomy/jejunostomy tube, low-profile, any material, any type, each
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
B4149	Enteral formula, manufactured blenderized natural foods with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4150	Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, May include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4152	Enteral formula, nutritionally complete, calorically dense (equal to or greater than 1.5 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4153	Enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit

B4154	Enteral formula, nutritionally complete, for special metabolic needs, excludes inherited disease of metabolism, includes altered composition of proteins, fats, carbohydrates, vitamins and/or minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4155	Enteral formula, nutritionally incomplete/modular nutrients, includes specific nutrients, carbohydrates (e.g. glucose polymers), proteins/amino acids (e.g. glutamine, arginine), fat (e.g. medium chain triglycerides) or combination, administered through an enteral feeding tube, 100 calories = 1 unit
B4157	Enteral formula, nutritionally complete, for 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
B4158	Enteral formula, for pediatrics, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit
B4159	Enteral formula, for pediatrics, nutritionally complete soy based with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit
B4160	Enteral formula, for pediatrics, nutritionally complete calorically dense (equal to or greater than 0.7 kcal/ml) with intact nutrients, 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 an 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
B9002	Enteral nutrition infusion pump, any type
E0776	IV Pole

Parenteral Nutrition

B4164	Parenteral nutrition solution: carbohydrates (dextrose), 50% or less (500 ml = 1 unit) - home mix
B4168	Parenteral nutrition solution; amino acid, 3.5%, (500 ml = 1 unit) - home mix
B4172	Parenteral nutrition solution; amino acid, 5.5% through 7%, (500 ml = 1 unit) - home mix
B4176	Parenteral nutrition solution; amino acid, 7% through 8.5%, (500 ml = 1 unit) - home mix
B4178	Parenteral nutrition solution: amino acid, greater than 8.5% (500 ml = 1 unit) - home mix
B4180	Parenteral nutrition solution; carbohydrates (dextrose), greater than 50% (500 ml = 1 unit) - home mix
B4185	Parenteral nutrition solution, not otherwise specified, 10 grams lipids
B4187	Omegaven, 10 grams lipids
B4189	Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 10 to 51 grams of protein - premix
B4194	Parenteral nutrition solution; compounded amino acid and carbohydrates

	with electrolytes, trace elements, and vitamins, including preparation, any strength, 52 to 73 grams of protein - premix
B4197	Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements and vitamins, including preparation, any strength, 74 to 100 grams of protein - premix
B4199	Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements and vitamins, including preparation, any strength, over 100 grams of protein - premix
B4216	Parenteral nutrition; additives (vitamins, trace elements, heparin, electrolytes), home mix, per day
B4220	Parenteral nutrition supply kit; premix, per day
B4222	Parenteral nutrition supply kit; home mix, per day
B4224	Parenteral nutrition administration kit, per day
B5000	Parenteral nutrition solution compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, renal-aminosyn-rf, nephramine, renamine-premix
B5100	Parenteral nutrition solution compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, hepatic, hepatamine-premix
B5200	Parenteral nutrition solution compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, stress-branch chain amino acids-freamine-hbc-premix
B9002	Enteral nutrition infusion pump, any type
B9004	Parenteral nutrition infusion pump, portable
B9006	Parenteral nutrition infusion pump, stationary
B9999	Noc for parenteral supplies
E0776	IV pole

S9435	Medical foods for inborn errors of metabolism

Refill requirements for Medicare Advantage and NaviCare plan members
For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized.

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the treating practitioner that any changed or atypical utilization is warranted.

Regardless of utilization, a supplier must not dispense more than a 1-month quantity at a time.

Supply allowance HCPCS codes (B4034, B4035, and B4036) are daily allowances which are considered all-inclusive and therefore refill requirements are not applicable to these HCPCS codes. Refer to the Coding Guidelines section in the LCD-related Policy Article for Enteral Nutrition (A58833) for further clarification.

Supply allowance HCPCS codes (B4220, B4222 and B4224) are daily allowances which are considered all-inclusive and therefore refill requirements are not applicable to these HCPCS codes. Refer to the Coding Guidelines section in the LCD-related Policy Article for Parenteral Nutrition (A58836) for further clarification.

References

1. General Laws of Massachusetts, Part I, Title XXII, Chapter 176G, § 4 Required coverage for certain conditions and groups, Chapter 175 § 47C Dependent coverage for newborn infants or adoptive children; inclusion in policies of accident and sickness insurance.
2. General Laws of Massachusetts, Part 1, Title XXII, Chapter 176 G, § 4D Nonprescription enteral formulas for home use.
3. MassHealth Guidelines for Medical Necessity Determination for Enteral Nutrition Products. Effective December 1, 2004, last revised October 30, 2019.
4. Medicare National Coverage Determination (NCD) for Enteral and Parenteral Nutritional Therapy (180.2). Version Number 1. Effective Date of this Version 7/11/ 1984.
5. Noridian Healthcare Solutions LLC, Local Coverage Determination (L33783) Enteral Nutrition. Original effective date October 1, 2015. Revision effective date January 1, 2020. Retirement Effective Date 11/12/2020.
6. Krugman SD, Dubowitz H. Failure to Thrive. American Family Physician 2003 Sep;68(5):879-84.
7. Brown B, Roehl K, Betz M. Enteral nutrition formula selection: current evidence and implications for practice. Nutr Clin Pract. 2015 Feb;30(1):72-85.
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9. Escuro AA, Hummell AC. Enteral Formulas in Nutrition Support Practice: Is There a Better Choice for Your Patient? Nutr Clin Pract. 2016 Sep 30.
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11. Martin K, Gardner G. Home Enteral Nutrition: Updates, Trends, and Challenges. Nutr Clin Pract. 2017 Dec;32(6):712-721.
12. Medicare National Coverage Determination (NCD) for Enteral and Parenteral Nutritional Therapy (180.2). Version 2. Effective Date of this Version 1/1/2022.
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16. Noridian Healthcare Solutions, LLC. Local Coverage Article Parenteral Nutrition. Original Effective Date 9/5/2021. Revision Effective Date 9/5/2021.
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Policy history

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Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.