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

Overview

Enteral Nutrition (EN) is used for patients with a functioning intestinal tract, but with disorders of the pharynx, esophagus, or stomach that prevent nutrients from reaching the absorbing surfaces in the small intestine, thus placing the patient at risk for malnutrition. Enteral nutrition involves the administration of calories, protein, electrolytes, vitamins, minerals, trace elements, and fluids directly into the gastrointestinal tract through nasogastric, gastrostomy or jejunostomy tubes. An infusion pump may be used to assist the flow of liquids. Feedings may be intermittent or continuous (infused 24 hours a day).

Total parenteral nutrition (TPN) is used for individuals with medical conditions that impair gastrointestinal absorption to a degree incompatible with life. It is also used for variable periods of time to bolster the nutritional status of severely malnourished individuals with medical or surgical conditions. TPN involves percutaneous transvenous implantation of a central venous catheter into the vena cava or right atrium. A nutritionally adequate hypertonic solution consisting of glucose, amino acids, electrolytes, vitamins, minerals and sometimes fats, is administered daily. An infusion pump is generally used to assure a steady flow of the solution either on a continuous (24-hour) or intermittent schedule. The catheter is kept patent between infusions.

Policy

This Policy applies to the following Fallon Health products:

☒ Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)

☒ MassHealth ACO

☒ NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)

☒ NaviCare SCO (MassHealth-only)

☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)

☒ Community Care (Commercial/Exchange)

Enteral Nutrition, Parenteral Nutrition, Low Protein Food Products, and Special Medical Formulas require prior authorization.

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

Fallon Health Clinical Coverage Criteria

Fallon Health Clinical Coverage Criteria apply to Community Care members.

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 state mandated coverage applies to Community Care 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 state mandated coverage applies to Community Care members.

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

Medicare Variation

Medicare statutes and regulations do not have coverage criteria for enteral or parental nutrition therapy. Effective for 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 (MACs) 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 claims for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) for Medicare beneficiaries in the Plan's 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) (Medicare Coverage Database search 04/15/2025). Coverage criteria for enteral and parenteral nutrition are fully established by Medicare, therefore the Plan's coverage criteria are not applicable.

Benefit and billing guidance for enteral nutrition are further described 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.

MassHealth Variation

MassHealth has Guidelines for Medical Necessity Determination for Enteral Nutrition and Special Medical Formulas. Fallon Health follows the MassHealth Guidelines for Medical Necessity Determination for Enteral Nutrition and Special Medical Formulas when making medical necessity determinations for enteral nutrition and special medical formulas for MassHealth members.

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 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 June 15, 2022, supersedes policy dated March 1, 2011.
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. Krugman SD, Dubowitz H. Failure to Thrive. American Family Physician 2003 Sep;68(5):879-84.
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8. 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. Medicare National Coverage Determination (NCD) for Enteral and Parenteral Nutritional Therapy (180.2). Version 2. Effective Date of this Version 1/1/2022.
12. Noridian Healthcare Solutions, LLC. Local Coverage Determination (LCD) Enteral Nutrition (L38955). Original Effective Date 09/05/2021. Revision Effective Date 01/01/2024.
13. Noridian Healthcare Solutions, LLC. Local Coverage Article Enteral Nutrition – Policy Article (A58833). Original Effective Date 9/5/2021. Revision Effective Date 10/01/2023.
14. Noridian Healthcare Solutions, LLC. Local Coverage Determination (LCD) Parenteral Nutrition (L38953). Original Effective Date 9/5/2021. Revision Effective Date 01/01/2024.
15. Noridian Healthcare Solutions, LLC. Local Coverage Article Parenteral Nutrition. Original Effective Date 9/5/2021. Revision Effective Date 07/02/2023.
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Policy history

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Instructions for Use

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Fallon Health generally follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations

when making medical necessity determinations. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

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.

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.