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

Overview

The General Laws of Massachusetts mandate 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 (low protein food products). Coverage is also mandated for 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. In addition Masshealth and Medicare impose similar rules for coverage of enteral formulas.

Definitions

Contact Lens: A thin lens designed to fit over the cornea and usually worn to correct defects in vision.
Scleral Lens: A contact lens worn directly over the sclera fitting underneath the eyelids.
Scleral Lens Liquid Bandage: A fluid-ventilated, oxygen-permeable lens that vaults over the cornea and helps manage ocular surface disease.
PROSE: Prosthetic Replacement Ocular Surface Ecosystem.

Policy

This Policy applies to the following Fallon Health products:

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

Fallon Health uses 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 or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare has a National Coverage Determination (NCD) for Enteral and Parenteral Nutritional Therapy (180.2). Noridian Healthcare Solutions, LLC, has an LCD for Enteral Nutrition (L33783)

and a related Policy Article (A52515). Statutory coverage criteria for enteral nutrition are specified in the related Policy Article. The Noridian LCD for Enteral Nutrition (L33783) and related Policy Article (A52515) were retired effective for claims with dates of service on or after November 12, 2020 due to the evolution of enteral nutrition clinical paradigms. The proposed LCD is available on the Medicare Coverage Database website for public review at this time.

Fallon Health requires Prior Authorization for Enteral Nutrition, Low Protein Food Products, and Special Medical Formulas. These requests must be supported by the treating provider(s) medical record.

Commercial plans
Requests for preauthorization 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

Fallon Medicare Based Plan Coverage (Please note this criteria will be used for NaviCare members unless MassHealth provides additional coverage)
Enteral nutrition is defined by Medicare as the provision of nutritional requirements through a tube into the stomach or small intestine.

Enteral nutrition is covered for Fallon Medicare plan members who meet the following criteria:
1. Enteral nutrition products that are administered orally are not covered.
2. Enteral nutrition is covered for a patient who has:
    - Permanent non function or disease of the structures that normally permit food to reach the small bowel or
    - Disease of the small bowel which impairs digestion and absorption of an oral diet either of which requires tube feedings to maintain a normal weight.

The member must have a permanent impairment. Permanence does not require a determination that there is no possibility that the member's condition may improve sometime in the future. If the documented judgment of the physician is that the impairment can reasonably be expected to exceed three months (ninety days), the test of permanence is considered met. This is consistent with CMS guidelines.

Medicare National Coverage Determination (NCD) for Enteral and Parenteral Nutritional Therapy (180.2)
Noridian Healthcare Solutions, LLC, **LCD for Enteral Nutrition (L33783)** and related **Policy Article (A52515)** Statutory coverage criteria for enteral nutrition are specified in the related Policy Article.

MassHealth members
Enteral nutrition is defined by MassHealth as nutrition requirements that are provided via the gastrointestinal cavity (orally), or through a tube, or stoma distal that delivers nutrients to the oral cavity. Fallon Health follows the MassHealth Guidelines for Medical Necessity Determination for Enteral Nutrition and Special Medical Formulas for MassHealth members. Link to MassHealth policy: **MassHealth Guidelines for Medical Necessity Determination for Enteral Nutrition and Special Medical Formulas**.

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.

Code	Description
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
S9435	Medical foods for inborn errors of metabolism

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
4. Products. Effective December 1, 2004, last revised October 30, 2019.
5. Medicare National Coverage Determination (NCD) for Enteral and Parenteral Nutritional Therapy (180.2). Effective July 11, 1984.
6. Noridian Healthcare Solutions LLC, Local Coverage Determination (L33783) Enteral Nutrition. Original effective date October 1, 2015. Revision effective date January 1, 2020.
7. Krugman SD, Dubowitz H. Failure to Thrive. American Family Physician 2003 Sep;68(5):879-84.
8. 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.
9. Civardi E, Garofoli F, Mazzucchelli I, et al. Enteral nutrition and infections: the role of human milk. Early Hum Dev. 2014 Mar;90 Suppl 1:S57-9
10. Escuro AA, Hummell AC. Enteral Formulas in Nutrition Support Practice: Is There a Better Choice for Your Patient? Nutr Clin Pract. 2016 Sep 30.
11. Avitzur Y, Courtney-Martin G. Enteral approaches in malabsorption. Best Pract Res Clin Gastroenterol. 2016 Apr;30(2):295-307.
12. Martin K, Gardner G. Home Enteral Nutrition: Updates, Trends, and Challenges. Nutr Clin Pract. 2017 Dec;32(6):712-721.

Policy history

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Approval(s):	Technology Assessment Committee: 08/28/2013, 02/25/2015 (updated template and references), 02/24/2016 (updated references) 01/25/2017 (updated references) 04/01/2017 (clarified which criteria is used by Commercial and NaviCare plans, not reviewed at committee), 01/24/2018 (updated references), 07/01/2018 (code q9994 became effective 7/1/18, not reviewed via committee), 01/23/2019 (removed termed code, added code B4105, updated references), 01/22/2020 (updated references) *06/15/2021 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section).*

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. For Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this policy.