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Subject: Enteral Formulas

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

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DESCRIPTION:

Enteral formulas are liquid food products that are specially formulated and designed to increase the amount of various food elements and nutrients that will maintain proper physiological function of the body. They may also be used to correct an existing deficiency.

Enteral formulas may be administered intermittently or continuously through nasogastric, nasoduodenal, nasojejunal, gastrostomy, or jejunostomy tubes directly into the gastrointestinal tract with or without the assistance of an infusion pump.

Florida state statutes mandate that coverage for prescription and nonprescription enteral formulas for home use be made available for the treatment of inherited diseases of amino acid, organic acid, carbohydrate, or fat metabolism, as well as malabsorption originating from congenital defects present at birth or acquired during the neonatal period. For additional mandate language, please refer to Florida Statute 627.42395 in the section of this MCG entitled [OTHER](#).

Summary and Analysis of Evidence: According to the European Society for Clinical Nutrition and Metabolism, home enteral nutrition (HEN) is indicated in those who are at high nutritional risk or malnourished, who are unable to meet nutritional requirements by the oral route, and who exhibit a functional gastrointestinal tract. An inadequate nutritional state is confirmed if patients cannot eat for a week or if the energy intake is less than 60% of estimated requirements for 1–2 weeks (usually less than 10 kcal/kg/d or a lack of 600–800 kcal/d). Poor nutritional intake is presumed when normal food ingestion covering individual requirements cannot be met despite the most skilled dietetic treatment and medical management. In this situation, initiation of EN should be within the week. Significant impairment of the nutritional state has to be assumed if the patient has lost >5% of bodyweight in 1–3 month. The nutritional state may deteriorate if food absorption is less than 75% of the daily requirements, or if there has been previous weight loss or concomitant catabolic processes or if

chemotherapy is concurrent. (Bischoff et al, 2022). A multi-center randomized controlled trial (RCT) evaluating patients undergoing esophagectomy or total gastrectomy demonstrated that HEN by jejunostomy as a usual practice was feasible, safe and acceptable to patients and their caregivers. Furthermore, the authors showed a substantial increase in anthropometric and functional parameters at a six-month follow-up (Bowrey et al, 2015). Zhang et al (2022) conducted a systematic review and meta-analysis on the use of HEN for patients with esophageal cancer undergoing esophagectomy. The authors concluded that HEN has a favorable impact on postoperative body mass index (BMI), lean body mass, and appendicular skeletal muscle mass index, as compared with a normal oral diet (NOD). Physical function, role function, and social function of the HEN group were better than those of the NOD group at 3 months, and HEN could reduce the fatigue of patients and the incidence of postoperative pneumonia.

POSITION STATEMENT:

Prescription and nonprescription enteral formulas **meet the definition of medical necessity** when:

- Prescribed by the physician as being **medically necessary, AND**
- Enteral formula is the sole source of nutrition, **OR**
- Member requires supplemental enteral nutrition greater than 50% of caloric intake to maintain appropriate body weight and nutritional status, **AND**
 - There is a mechanical, anatomic, or motility disorder affecting the gastrointestinal tract [e.g, dysphagia from a neurological condition; obstruction of the proximal GI tract (e.g., esophageal tumor)], **OR**
 - There is a disorder affecting the gastrointestinal tract that impairs digestion and absorption of an oral diet (e.g., Crohn's), **OR**
- There is an inherited disease of amino acid, organic acid, carbohydrate, or fat metabolism, or [malabsorption](#) originating from congenital defects present at birth or acquired during the neonatal period

Products for inherited diseases of amino acid and organic acid may also include food products modified to be low protein.

Coverage for any associated surgery, durable medical equipment and supplies is independent of whether or not coverage exists for the formula being used.

Digestive enzyme cartridges (e.g. Relizorb™, Alcresta Pharmaceuticals), when used with enteral tube feeding **meet the definition of medical necessity** for treatment of pancreatic insufficiency due to cystic fibrosis, when there is documented failure of pancreatic enzyme replacement therapy (PERT).

BILLING/CODING INFORMATION:

The following codes may be used to report enteral formulas:

HCPCS Coding:

B4102	Enteral formula, for adults, used to replace fluids and electrolytes (e.g., clear liquids), 50 ml = 1 unit (non-covered)
B4103	Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit (non-covered)
B4104	Additive for enteral formula (e.g., fiber) (non-covered)
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 (non-covered)
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, 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
S9432	Medical foods for non-inborn errors of metabolism
S9435	Medical foods for inborn errors of metabolism

ICD-10 Diagnosis Codes That Support Medical Necessity (not all-inclusive):

C00.0 – C21.8	Malignant neoplasm of lip, oral cavity, pharynx, esophagus, stomach, small intestine, colon, rectosigmoid junction, rectum, anus and anal canal
C76.0	Malignant neoplasm of head, face and neck
D81.3	Adenosine deaminase [ADA] deficiency
D81.30	Adenosine deaminase deficiency, unspecified
D81.32	Adenosine deaminase 2 deficiency
D81.39	Other adenosine deaminase deficiency
D81.5	Purine nucleoside phosphorylase [PNP] deficiency
D81.810	Biotinidase deficiency
E40, E41, E42	Kwashiorkor, nutritional marasmus, marasmic kwashiorkor
E70.0	Classic phenylketonuria
E70.1	Other hyperphenylalaninemias
E70.20 – E70.29	Disorders of tyrosine metabolism
E70.30	Albinism, unspecified
E70.40 – E70.49	Disorders of histidine metabolism
E70.5	Disorders of tryptophan metabolism
E70.81	Aromatic L-amino acid decarboxylase deficiency
E70.89	Other disorders of aromatic amino-acid metabolism
E70.9	Disorder of aromatic amino-acid metabolism, unspecified
E71.0	Maple-syrup-urine disease
E71.110	Isovaleric acidemia
E71.111	3-methylglutaconic aciduria
E71.118	Other branched-chain organic acidurias
E71.120	Methylmalonic acidemia
E71.121	Propionic acidemia
E71.128	Other disorders of propionate metabolism
E71.19	Other disorders of branched-chain amino-acid metabolism
E71.2	Disorder of branched-chain amino-acid metabolism, unspecified
E71.310	Long chain/very long chain acyl CoA dehydrogenase deficiency (LCHAD)
E71.311	Medium chain acyl CoA dehydrogenase deficiency
E71.312	Short chain acyl CoA dehydrogenase deficiency
E71.313	Glutaric aciduria type II

E71.314	Muscle carnitine palmitoyltransferase deficiency
E71.318	Other disorders of fatty-acid oxidation
E71.40	Disorder of carnitine metabolism, unspecified
E71.41	Primary carnitine deficiency
E71.42	Carnitine deficiency due to inborn errors of metabolism
E71.43	Iatrogenic carnitine deficiency
E71.448	Other secondary carnitine deficiency
E72.00 – E72.19	Other disorders of amino-acid metabolism
E72.21	Argininemia
E72.22	Arginosuccinic aciduria
E72.23	Citrullinemia
E72.3	Disorders of lysine and hydroxylysine metabolism
E72.4	Disorders of ornithine metabolism
E72.50	Disorder of glycine metabolism, unspecified
E72.51	Non-ketotic hyperglycinemia
E72.52	Trimethylaminuria
E72.59	Other disorders of glycine metabolism
E72.9	Other specified and unspecified disorders of amino-acid metabolism
E74.00 – E74.39	Other disorders of carbohydrate metabolism
E74.4	Disorders of pyruvate metabolism and gluconeogenesis
E74.81	Disorders of glucose transport, not elsewhere classified
E74.810	Glucose transporter protein type 1 deficiency
E74.818	Other disorders of glucose transport
E74.819	Disorders of glucose transport, unspecified
E74.89	Other specified disorders of carbohydrate metabolism
E74.9	Disorder of carbohydrate metabolism, unspecified
E78.6	Lipoprotein deficiency
E78.9	Disorder of lipoprotein metabolism, unspecified
E79.1	Lesch-Nyhan syndrome
E79.2	Myoadenylate deaminase deficiency
E79.8	Other disorders of purine and pyrimidine metabolism
E79.9	Disorder of purine and pyrimidine metabolism, unspecified
E80.3	Defects of catalase and peroxidase
E84.0	Cystic fibrosis with intestinal manifestations
E84.19	Cystic fibrosis with other intestinal manifestations
I69.091 I69.191 I69.291 I69.391 I69.891 I69.991	Sequelae of cerebrovascular disease [dysphagia]
K22.4	Dyskinesia of esophagus
K50.01 – K50.919	Crohn's disease

K55.30, K55.31, K55.32, K55.33	Necrotizing enterocolitis
P70.0 – P70.9	Transitory disorders of carbohydrate metabolism specific to newborn
P71.0 – P71.9	Transitory neonatal disorders of calcium and magnesium metabolism
P72.1	Transitory neonatal hyperthyroidism
P72.8, P72.9	Other specified and unspecified transitory neonatal endocrine disorders
P74.0	Late metabolic acidosis of newborn
P74.1	Dehydration of newborn
P74.4	Other transitory electrolyte disturbances of newborn
P74.8, P74.9	Other specified and unspecified transitory metabolic disturbances of newborn
P94.0	Transient neonatal myasthenia gravis
R13.0 – R13.19	Aphagia and dysphagia

LOINC Codes:

The following information may be required documentation to support medical necessity: Physician history and physical notes, physician treatment and progress notes.

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Attending physician visit note or treatment notes	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Attending physician progress note	18741-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Clinical notes and chart section	28650-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

REIMBURSEMENT INFORMATION:

Refer to section entitled [POSITION STATEMENT](#).

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines (refer to Florida Statute 110.12315 below).

Medicare Advantage products:The following Local Coverage Determination (LCD) was reviewed on the last guideline reviewed date: Local Coverage Determination (LCD) Enteral Nutrition L38955, located at [cms.gov](https://www.cms.gov).

DEFINITIONS:

Malabsorption: inability of the intestines to absorb nutrition from food, leading to malnutrition.

Pancreatic enzyme replacement therapy (PERT): formulations of pancreatic enzymes with different combinations of lipase, protease, and amylase, designed to correct pancreatic sufficiency.

RELATED GUIDELINES:

[External Infusion Pumps \(non-insulin\), 09-E0000-10](#)

OTHER:

Florida Statute 110.12315 – Prescription drug program. [State Account Organization (SAO)]

“The state employees’ prescription drug program is established. (10) In addition to the comprehensive package of health insurance and other benefits required or authorized to be included in the state group insurance program, the program must provide coverage for medically necessary prescription and non-prescription enteral formulas and amino-acid-based elemental formulas for home use, regardless of the method of delivery or intake, which are ordered or prescribed by a physician. As used in this subsection, the term "medically necessary" means the formula to be covered represents the only medically appropriate source of nutrition for a patient.”

* The only medically appropriate source of nutrition (sole source of nutrition) is defined as the primary source of sufficient caloric/nutrient intake to achieve or maintain appropriate body weight.

** Florida Statute 110.12315 applies to enteral formula and amino-acid-based elemental formulas for home use supplied to State Account Organization members through either the medical program or prescription drug program.

Florida Statute 627.42395 – Coverage for certain prescription and nonprescription enteral formulas.

“Notwithstanding any other provision of law, any health insurance policy delivered or issued for delivery, to any person in this state or any group, blanket, or franchise health insurance policy delivered or issued for delivery in this state shall make available to the policyholder as part of the application, for an appropriate additional premium, coverage for prescription and nonprescription enteral formulas for home use which are physician prescribed as medically necessary for the treatment of inherited diseases of amino acid, organic acid, carbohydrate, or fat metabolism as well as malabsorption originating from congenital defects present at birth or acquired during the neonatal period. Coverage for inherited diseases of amino acids and organic acids shall include food products modified to be low protein ...

through the age of 24. This section applies to any person or family notwithstanding the existence of any preexisting condition.”

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 03/28/24.

GUIDELINE UPDATE INFORMATION:

07/15/02	MCG Reformatted; revised to remove information relating to supplies and parenteral nutrition.
03/15/03	Added S9435.
07/15/04	Scheduled review with revisions to coverage statement regarding state mandate language; added Program Exception for Medicare+Choice.
01/01/05	HCPCS coding update: added new codes B4102 – B4104, B4149, B4157 – B4162, revised descriptors for B4150, B4152 – B4155, and removed deleted codes B4151 and B4156.
03/15/05	Revision to guideline consisting of adding clarification of coverage criteria regarding state mandate.
01/01/06	Annual HCPCS coding update: revise B4149.
07/01/06	Updated MCG number from 09-A4000-08 to 09-J0000-61.
08/15/06	Biennial review, no changes, updated references.
10/15/07	Reviewed and reformatted guideline; no change in coverage statement.
08/15/09	Scheduled review; revise position statement for clarification; add fifth-digit specificity to ICD-9 diagnosis code list; update references.
12/15/10	Revisions; related ICD-10 codes added; formatting changes.
09/15/11	Revision; formatting changes.
05/11/14	Revision: Program Exceptions section updated.
11/01/15	Revision: ICD-9 Codes deleted.
02/11/16	Revision: added additional ICD10 codes, updated Medicare Advantage program exception.
06/15/16	Revision: added additional ICD10 codes. Updated references.
05/15/18	Revision: added coverage statement for enzyme cartridges (E/I). Updated references. Reformatted guideline.
07/01/18	Quarterly CPT/HCPCS coding update: added Q9994.
10/01/18	ICD10 coding update: deleted E72.8.
11/15/18	Revision: updated coverage language for associated surgery, durable medical equipment and supplies.
01/01/19	Annual CPT/HCPCS coding update. Added B4105; deleted Q9994.
10/01/19	ICD10 coding update: added D81.30, D81.32, D81.39.
10/15/19	Unscheduled review. Maintained position statement. Revised Medicare Advantage program exception and updated references.
01/01/20	Revision: updated State Account Organization (SAO) program exception, OTHER section, and references.
06/15/20	Scheduled review. Maintained position statement and updated references.
10/01/20	ICD10 coding update: added E70.81, E70.89, E74.81, E74.810 , E74.818, E74.819, E74.89.

02/15/21	Revision. Added coverage statement for digestive enzyme cartridges (e.g. Relizorb). Updated references.
10/01/21	Quarterly CPT/HCPCS coding update: added S9432.
06/15/22	Scheduled review. Maintained position statement and updated references.
01/01/23	Revision. Added coverage criteria for additional conditions. Updated ICD10 coding and references.
04/15/24	Scheduled review. Revised description, maintained position statement and updated references.