**09-J0000-61**

**Original Effective Date: 07/15/02**

**Reviewed: 09/24/26**

**Revised: 10/15/26**

# 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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|---|---|---|---|---|---|
| Position Statement | Billing/Coding | Reimbursement | Program Exceptions | Definitions | Related Guidelines |
| Other | References | Updates | | | |


## 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 one of the following:**
    - 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 but not limited to: complications of diabetes, cystic fibrosis, pancreatitis, pancreatectomy, celiac disease, Crohn's disease, ulcerative colitis, short bowel syndrome or congenital malformations of the pancreas), when there is documented failure of pancreatic enzyme replacement therapy (PERT).

## BILLING/CODING INFORMATION:

### HCPCS Coding:

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| 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 |
| 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 |

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| B4148 | Enteral feeding supply kit; elastomeric control fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape |
| 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 |
| B9002 | Enteral nutrition infusion pump, any type |
| S9341 | Home therapy; enteral nutrition via gravity; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem |
| S9342 | Home therapy; enteral nutrition via pump; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem |
| S9343 | Home therapy; enteral nutrition via bolus; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem |
| S9432 | Medical foods for non-inborn errors of metabolism |

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| S9435 | Medical foods for inborn errors of metabolism |

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

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| 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 kwashiokor |
| 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 |

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| 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<br>I69.191<br>I69.291<br>I69.391<br>I69.891<br>I69.991 | Sequelae of cerebrovascular disease [dysphagia] |
| K22.4 | Dyskinesia of esophagus |
| K50.01 – K50.919 | Crohn's disease |
| K55.30, K55.31,<br>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 |
| P78.89 | Other specified perinatal digestive system disorders |
| P94.0 | Transient neonatal myasthenia gravis |
| Q38.0 – Q38.8 | Other congenital malformations of tongue, mouth and pharynx |
| Q39.0 – Q39.9 | Congenital malformations of esophagus |
| Q40.0 – Q40.9 | Other congenital malformations of upper alimentary tract |
| Q41.0 – Q41.9 | Congenital absence, atresia and stenosis of small intestine |
| Q42.0 – Q42.9 | Congenital absence, atresia and stenosis of large intestine |
| Q43.0 – Q43.9 | Other congenital malformations of intestine |
| Q44.0 – Q44.79 | Congenital malformations of gallbladder, bile ducts and liver |
| Q45.0 – Q45.9 | Other congenital malformations of digestive system |
| 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 |
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| 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:

**Reimbursement for supplies used with enteral nutrition infusion pumps is as follows:**

Codes B4034, B4035, B4036, B4148: each code is limited to 1 unit per day.

Codes B4081, B4082, B4083: each code is limited to1 unit per month.

Codes B4087, B4088: each code is limited to 1 unit every 3 months.

## 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 were reviewed on the last guideline reviewed date: Local Coverage Determination (LCD) Enteral Nutrition L38955 and Enteral Nutrition - Policy Article A58833 located at cms.gov.

## DEFINITIONS:

**Malabsorption:** a complex and multifaceted condition characterized by the defective passage of nutrients into the blood and lymphatic streams. Several congenital or acquired disorders may cause either selective or global malabsorption in both children and adults, such as cystic fibrosis, exocrine pancreatic insufficiency (EPI), celiac disease (CD) and other enteropathies, lactase deficiency, small intestinal bacterial overgrowth (SIBO), autoimmune atrophic gastritis, Crohn's disease, and gastric or small bowel resections.

**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 09/24/26.

## GUIDELINE UPDATE INFORMATION:

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| 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. |

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| 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. |
| 08/15/25 | Revision. Revised HCPCS coding, ICD10 coding, and definitions. Added reimbursement information for supplies and updated references. |
| 02/15/26 | Position statements maintained. |
| 10/15/26 | Revision: Digestive enzyme cartridges position statement and references updated. |