

LCD - Enteral Nutrition (L38955)

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CMS National Coverage Policy

CMS Pub. 100-03 (National Coverage Determinations Manual), Chapter 1, Section 180.2

Coverage Guidance**Coverage Indications, Limitations, and/or Medical Necessity**

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Enteral nutrition is covered for a beneficiary who requires feedings via an enteral access device to provide sufficient nutrients to maintain weight and strength commensurate with the beneficiary'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.

Refer to the LCD-related Policy Article for the definition of test of permanence.

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).

If the coverage requirements for enteral nutrition are met, medically necessary nutrients, administration supplies, and equipment are covered.

For coverage of the following scenarios, see the LCD-related Policy Article:

- Enteral nutrition for temporary impairments
- Enteral nutrition for beneficiaries 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
- Orally administered enteral nutrition products, related supplies and equipment

NUTRIENTS

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

The medical necessity for special enteral formulas (B4149, B4153, B4154, B4155, B4157, B4161, and B4162) must be justified in each beneficiary. 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 reasonable and necessary. (Refer to the LCD-related Policy Article for policy specific documentation requirements.)

EQUIPMENT AND SUPPLIES

Enteral nutrition may be administered by syringe, gravity, or pump. Some enteral beneficiaries may experience complications associated with syringe or gravity method of administration.

If a pump (B9002) is ordered, there must be documentation in the beneficiary'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 reasonable and necessary for beneficiaries 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 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 indicated in question 5 of the DME Information Form (DIF). If it does not correspond, it 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 codes for feeding supply allowances (B4034, B4035, and B4036) are specific to the route of administration. Claims for more than one type of kit code delivered on the same date or provided on an ongoing basis will be denied as not reasonable and necessary.

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 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.

GENERAL

A Standard Written Order (SWO) must be communicated to the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed SWO, the claim shall be denied as not reasonable and necessary.

For Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) base items that require a Written Order Prior to Delivery (WOPD), the supplier must have received a signed SWO before the DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a WOPD, the claim shall be denied as not reasonable and necessary. Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

For DMEPOS base items that require a WOPD, and also require separately billed associated options, accessories, and/or supplies, the supplier must have received a WOPD which lists the base item and which may list all the associated options, accessories, and/or supplies that are separately billed prior to the delivery of the items. In this scenario, if the supplier separately bills for associated options, accessories, and/or supplies without first receiving a completed and signed WOPD of the base item prior to delivery, the claim(s) shall be denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

REFILL REQUIREMENTS

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 further clarification.

Summary of Evidence

Home Enteral Nutrition

Nutritionally-at-risk and malnourished older adults are at greater risk of all-cause hospitalizations, non-surgical hospitalization, increased frequency and length of hospital stays and mortality.¹⁻³ For older adults living at home, identifying and treating malnutrition or its risk can help them maintain their health and function longer, improve recovery time, and lessen the need for hospitalization and other healthcare services.⁴

Enteral nutrition (EN) administered to outpatients via an enteral access device (EAD) is known as home enteral nutrition (HEN) and is an option for some patients 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. In recent years, therapeutic diet interventions, improvements in enteral access, protocols for EN administration, and specialized enteral formulas have led to a broader definition of functional gut.⁵

The term intestinal insufficiency (or deficiency) is used to describe a reduction of gut absorptive function that does

not require intravenous supplementation but may require oral supplementation, EN, and/or vitamin and trace element supplementation to maintain health and/or growth.⁶ In the absence of intestinal failure, defined as the reduction of gut function below the minimum necessary for the absorption of macronutrients and/or water and electrolytes such that intravenous supplementation is required to maintain health and/or growth,⁶ or an absolute contraindications to EN (e.g. severe hemodynamic instability, GI obstruction, or persistent gastrointestinal bleeding), the GI tract is the preferred route for nutrition support therapy.⁷

Based on several epidemiological studies and patient registries, the most frequent indications for HEN in adults are neurological diseases (neurovascular and -degenerative); head and neck cancer, gastrointestinal cancer, and other cancers; cerebral palsy; non-neoplastic gastrointestinal disease (e.g. inflammatory bowel disease, fistulae, esophageal stenosis), head injury, malabsorptive syndromes (e.g., short bowel syndrome), severe intestinal motility disorders, inherited metabolic diseases, and cystic fibrosis.^{4,8-17} Examination of the evidence to support the use of HEN for the management of malabsorption and maldigestion will be the focus of this analysis.

Coverage of HEN for patients with non-function of the structures that normally permit food to reach the digestive tract has been established in the Medicare *National Coverage Determinations (NCD) Manual* (CMS Pub. 100-03), Chapter 1, Part 4, Section 180.2. Additionally, benefit category 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. The guidance outlined in these manuals are reflected in the remainder of the LCD.

Exocrine Pancreatic Insufficiency

Under normal physiological conditions, the pancreas produces the digestive enzymes amylase, protease and lipase to help break down food in the intestine.¹⁸ Lipase is responsible for breaking down undigested triglycerides into fatty acids and monoglycerides, which are then solubilized by bile salts allowing for proper lipid absorption. Exocrine Pancreatic Insufficiency (EPI) is a condition characterized by the inability of the pancreas to produce digestive enzymes in sufficient levels, resulting in maldigestion and malabsorption, and associated steatorrhea, abdominal distention and cramps, weight loss, impaired growth, fatty acid deficiencies, and reduced survival. The etiology of EPI can be classified into pancreatic (e.g. chronic pancreatitis, cystic fibrosis, pancreatic cancer, Shwachman-Diamond Syndrome) and nonpancreatic causes (e.g. celiac disease, inflammatory bowel disease, diabetes, gastrointestinal surgery).¹⁹

Pancreatic enzyme replacement therapy (PERT) is used for the management of EPI²⁰ with the goal of enhancing fat absorption and correction of nutritional deficiencies. Exogenous pancreatic enzymes are administered together with meals and snacks to exert their action on the ingested meal. Gastric emptying of nutrients should occur in parallel with pancreatic enzymes reaching the duodenum. Examination of the evidence to support the use of PERT for treatment of EPI, with a specific review of RELiZORB (immobilized lipase) cartridge (Alcresta Therapeutics, Inc, Newton, MA), an in-line PERT option for patients with EPI who receive EN, will be the focus of this analysis. RELiZORB was FDA approved on July 12, 2017 for pediatric (≥ 5 years of age) and adult patients to hydrolyze fats found in enteral formula as a class II medical device. See https://www.accessdata.fda.gov/cdrh_docs/pdf16/K163057.pdf for additional information.

Literature Analysis

Home Enteral Nutrition

The evidence to support the use of EN for the management of malabsorption and maldigestion of an oral diet was reviewed. Examples of disease states associated with malabsorption/maldigestion include inflammatory bowel

disease (IBD), chronic pancreatitis (CP), advanced liver disease, cystic fibrosis (CF) and short bowel syndrome (SBS).

Braunschweig, et al.²¹ aimed to provide guidance for clinical decision making regarding nutritional support choices in adults with compromised gastrointestinal function secondary to pancreatitis, ulcerative colitis (UC), Crohn's disease (CD), surgery, trauma, or multisystem organ failure via a meta-analysis of randomized controlled trials (RCTs). Outcome variables included infection, nutrition support complications, other complications, and mortality. Twenty studies with a total of 1033 patients had information that allowed relative risk (RR) calculations of the primary outcome variables and compared tube feeding with parenteral nutrition (PN) (n = 508 EN, n = 525 PN). Overall, aggregated results revealed a significantly lower risk of infection with EN (RR: 0.66; 95% CI: 0.56, 0.79), though the risk of nutrition support complications was higher for EN than for PN (RR: 1.36; 95% CI: 0.96, 1.83). To account for the less severe complications of EN, such as diarrhea, vomiting, tube feeding complications were defined as those that required feedings to be stopped for ≥ 24 hours. Of important note, when catheter sepsis was categorized as a nutrition support complication instead of an infection, the risk of nutrition support complications between EN and PN was eliminated (RR: 1.05; 95% CI: 0.79, 1.4). No treatment effect for tube feeding was observed for other complications (RR: 0.92; 95% CI: 0.71, 1.22) or for mortality (RR: 0.96; 95% CI: 0.55, 1.65).

Several literature reviews have examined the role of EN for the management of disease processes associated with malabsorption and maldigestion.^{22,23-27} Wedrychowicz et al.²² and Eiden²³ reviewed the multifactorial causes of malabsorption in IBD, including the loss of intestinal absorptive area due to inflammation, reduced fat absorption because of bile acid and pancreatic enzyme abnormalities, and ileal resection. Nutritional therapy, in the form of EN, has a primary and supportive role in the management of IBD, with down-regulation of mucosal pro-inflammatory cytokines and anti-inflammatory effect of EN formulas on intestinal mucosa associated with histopathological healing cited when used as primary therapy; and, allows for achievement of adequate weight gain and growth, and sustainment of long-lasting effects of pharmacological therapy when used as supportive therapy. PN may be an alternative method of nutrition to enteral intake of nutrients in IBD patients, mainly used for those with contraindications or EN intolerance, especially when there are symptoms of severe malnutrition.

Duggan, et al.²⁴ described the exocrine and endocrine drivers of malnutrition in CP. Loss of acinar cell function in CP results in a reduced production and secretion of digestive enzymes leading to maldigestion and malabsorption of both macronutrients (fat, carbohydrate, protein) and micronutrients. Additionally, slow or rapid gastric emptying may affect nutrient absorption; and, reduction in cholecystokinin (CCK) production may impair gallbladder contraction thereby compromising fat absorption. The passage of undigested nutrients into the ileum then further affects gastric secretion, gastric emptying, pancreatic exocrine function, and intestinal transit. Development of diabetes in 30-50% of patients with CP further complicates dietary management. The treatment of CP includes dietary alterations and pancreatic enzyme supplementation with EN is required in 5% of CP patients who have persistent weight loss. Parenteral nutrition may be necessary when EN is not possible.

Cheung et al.²⁵ reviewed the mechanism of malabsorption and nutritional recommendations in cirrhotic patients. As cirrhosis progresses, portosystemic shunting causes nutrients to bypass the liver without metabolic processing. Additionally, reduced bile production impairs absorption of long chain fatty acids through the usual lymphatic route leading to reduced systemic availability of fat for organic functions. Guidelines recommend use of oral supplements or overnight EN if cirrhotic patients cannot maintain adequate intake from an oral diet, with total PN restricted to patients who have contraindications to oral or enteral nutrition and to situations whereby adequate oral or enteral caloric intake is not being met despite best efforts.

Schindler et al.²⁶ described the mechanism of maldigestion and dietary management of CF patients. As viscous secretions cause luminal obstruction of pancreatic ducts, acinar cell destruction and fibrosis reduce the exocrine pancreatic functions; and, inadequate pancreatic bicarbonate secretion leads to lower duodenal pH and precipitation of bile salts resulting in malabsorption. The association between good nutritional status and better lung function have

been established. Dietary management of CF patients includes an unrestricted high calorie diet in addition to supplemental pancreatic enzyme replacement therapy for 85-90% of the CF population. Nutritional support can be provided by EN for patients if oral supplements have failed; and, is required in approximately 11% of the CF population. Parenteral nutrition is rarely indicated in CF and is mainly used only for patients who have persistent nonfunctioning bowel.

Szczygiel et al.²⁷ described the malabsorption related to SBS. After intestinal resection, adaptive changes in the remaining bowel can be detected for up to 2 years with structural changes such as villous cell hyperplasia and increased crypt depth leading to increased mucosal surface and mass allowing for an increase in nutrient and fluid absorption. Enteral nutrition stimulates bowel function and intestinal adaptation by means of direct contact with epithelial cells, and stimulation of pancreatobiliary and intestinal hormone secretion. The findings of Joly et al.²⁸ support the ability of SBS patients, who are past the immediate post-operative period, to absorb lipids, protein and energy provided with EN. In severe forms of SBS where little or no small bowel is present distal to the duodenum long-term PN is necessary, but is associated with catheter sepsis and thrombosis of the catheterized vein.

Exocrine Pancreatic Insufficiency

The evidence to support the use of PERT for the management of EPI was reviewed, with a specific examination of RELiZORB in-line digestive cartridges for use in patients with EPI who require EN.

A review of the evidence²⁹ related to the effectiveness of PERT in increasing survival and quality of life in patients with EPI concluded that current literature supports the effectiveness of PERT in addressing EPI-related malabsorption in patients with CF, CP, or pancreatic cancer/resection. Despite a lack of long-term trials assessing the effect of PERT on patient survival, the authors believed there is evidence to support that PERT allows patients with EPI to improve body weight, a known risk factor for decreased survival. Additionally, PERT reduces the occurrence of GI symptoms and abdominal pain commonly associated with EPI, improving patients' Quality of Life (QoL).³⁰ A review³¹ of the role of PERT for EPI associated with less common causes such as diabetes mellitus, impaired hormonal stimulation of exocrine pancreatic secretion by CCK, celiac or IBD, and gastrointestinal surgery noted that clinical research is limited in etiologies uncommonly associated with EPI. Using the available literature, the authors concluded that in patients with symptomatic EPI, dietary modifications should be implemented, and PERT should be initiated and titrated to optimal response.

Clinical care guidelines support the use of PERT for EPI associated with disorders including CF^{32,33} and CP.^{34,35} Specifically, a literature review by the American College of Gastroenterology² found that PERT significantly improved the coefficient of fat absorption compared to baseline and placebo, and reduced fecal nitrogen excretion and stool weight. The authors suggested the use of PERT in patients with CP and EPI to improve the complications of malnutrition, improve fat absorption, improve fat-soluble vitamin and trace element levels, reduce consequences of maldigestion, and improve quality of life.

Two studies specifically examining the in-line enzyme cartridge RELiZORB were reviewed. In a 2017, prospective, multicenter, randomized, double-blind crossover trial with a 7-day, open-label safety evaluation period Freedman, et al.³⁶ aimed to assess the safety, tolerability, and fat absorption with the use of RELiZORB in patients with EPI due to CF receiving EN. The change in plasma fatty acid (FA) concentrations of docosahexaenoic acid (DHA), and eicosapentaenoic acid (EPA) were used as markers of fat absorption over 24 hours. The safety and tolerability endpoints of GI events associated with fat malabsorption, and non-GI related adverse events (AEs) were also examined. Thirty-three (33) patients completed the study with a mean age of the 14.5 years, a mean duration of enteral feeds of 6.6 years, a mean BMI of 17.5 kg/m², and a mean (SD) baseline plasma concentration for total DHA+EPA of about 60% of that observed in healthy humans (49.0 ± 25.7 µg/mL). After the single enteral feeding with RELiZORB, plasma levels of DHA + EPA were significantly higher over a 24-hour period by a factor of 2.8 with

the use of RELiZORB when compared with placebo (AUC_{0–24} ± SD, 537.0 ± 400.5 µg × h/mL vs 192.2 ± 198.7 µg × h/mL, respectively; $p < 0.001$). Additionally, the use of RELiZORB increased the maximum concentration of DHA + EPA by a factor of 2.2 when compared to placebo (42.8 ± 22.9 µg/mL vs 20.1 ± 13.5 µg/mL; $p < 0.001$). There were no unanticipated AEs. All non-GI AEs that occurred were not considered to be treatment related. Additionally, the use of RELiZORB was associated with a decrease in the frequency and severity of GI events associated with fat malabsorption. In a 2018, 90-day prospective, single-arm, multicenter, open-label study Stevens, et al.³⁷ evaluated the safety, tolerability and efficacy of sustained use of RELiZORB in patients with EPI due to CF receiving EN. The primary endpoint was defined as the change over time in red blood cell (RBC) uptake of the fatty acids DHA and EPA using a change in the omega-3 index. Safety and tolerability outcomes included the frequency and severity of AEs and unanticipated adverse device events (UADEs). During the study period, participants received enteral formula with a single RELiZORB cartridge used for each overnight feed. Thirty-nine (39) participants were randomized (36 patients completed the study) with a mean age of 13.8 years, a mean duration of enteral tube feeding of 6.2 years, a mean BMI of 17.7 kg/m², and a mean baseline omega-3 index value of 4.4% (target range of 8%). After initiation of RELiZORB treatment, the mean omega-3 index rose to 8.4% at 60 days and to 9.4% at 90 days ($p < 0.001$ for increase from baseline at 60 and 90 days). There was a high percentage of AEs reported, with 29 participants (74%) reporting at least one AE with respiratory disturbances and infections being the most frequently reported. Only one adverse event (constipation) was judged to be related to the device. At least one UADE was reported by 10 (25.6%) of the participants, with one participant discontinuing enteral feeds, however none of the UADE were classified as related to RELiZORB use. Additionally, based on 7-day GI symptom diaries, a decrease in gastrointestinal symptoms was reported over the course of the study.

Clinical Standards

Home Enteral Nutrition

A.S.P.E.N. Standards for Nutrition Support: Home and Alternate Site Care³⁸

Summary (in relevant part):

Standard 11. Nutrition Support Access

The route selected to provide nutrition support therapy shall be appropriate to the patient's medical problems, safety, efficacy, and patient preference.

11.1. When functional, the GI tract is the preferred route for nutrition support therapy and should be used to administer nutrition support therapy.

11.2. PN should be provided only when the GI tract is nonfunctional, cannot be accessed, or when oral or EN would exacerbate GI tract dysfunction.

Evidence Based Guidelines

Home Enteral Nutrition

ASPEN Board of Directors and the Clinical Guidelines Task Force. Guidelines for the use of parenteral and enteral nutrition in adult and pediatric patients.³⁹

Summary of guidelines (in relevant part):

Home Specialized Nutrition Support:

Home SNS [specialized nutrition support] should be used in patients who cannot meet their nutrient requirements by oral intake and who are able to receive therapy outside of an acute care setting. (B)

When HSNS is required, HEN is the preferred route of administration when feasible. (B)

When HSNS is indicated, HPN should be used when the gastrointestinal tract is not functional and in patients who cannot be adequately supported with HEN. (B)

Normal Requirements-Adults:

Determination of nutrient requirements should be individualized, based on assessment of body composition and function, and fall within acceptable ranges, while taking physiologic and patho-physiologic conditions into account. (B)

Pancreatitis:

SNS should be used in patients with acute or chronic pancreatitis to prevent or to treat malnutrition when oral energy intake is anticipated to be inadequate for 5 to 7 days. (B)

EN is the preferred route of SNS in patients with pancreatitis and should be attempted before initiating PN. (A)

Inflammatory Bowel Disease:

EN should be used in CD [Crohn's disease] patients requiring SNS. (B)

ESPEN Guideline on Home Enteral Nutrition⁴⁰

Summary of recommendations (in relevant part):

*Home Enteral Nutrition (HEN) should be offered to patients at nutritional risk or malnourished who cannot meet their nutrient requirements by normal dietary intake, who have a functioning gastrointestinal tract, who are able to receive therapy outside of an acute care setting, and who agree and are able to comply with HEN therapy with the goal of improving body weight, functional status or QoL. **Grade of recommendation: GPP (Good Practice Points)***

*HEN shall not be performed in patients with contraindications such as severe functional disturbances of the bowel, gastrointestinal obstruction, gastrointestinal tract bleeding, severe malabsorption or severe metabolic imbalances. **Grade of recommendation: GPP***

*HEN should be terminated when the desired weight has been reached and the patient's oral intake matches his/her maintenance needs. **Grade of recommendation: GPP***

As home-made blenderized admixtures are less effective than EN formula or commercially produced 'whole food' solutions, they should not be utilized in patients on HEN. **Grade of recommendation: GPP**

ESPEN guideline on clinical nutrition in acute and chronic pancreatitis³⁴

Summary of recommendations (in relevant part):

EN should be administered via the nasojejunal route in patients with pain, delayed gastric emptying, persistent nausea or vomiting and gastric outlet syndrome. **Grade of recommendation: GPP**

Long-term jejunostomy access (percutaneous endoscopic gastrostomy with jejunal extension (PEG-J) or direct percutaneous endoscopic jejunostomy (DPEJ) or surgical jejunostomy) can be used in those requiring EN for more than 30 days. **Grade of recommendation: GPP**

EN should be administered in patients with malnutrition who are not responding to oral nutritional support. **Grade of recommendation: GPP**

PN may be indicated in patients with gastric outlet obstruction and in those with complex fistulating disease, or in case of intolerance of EN. **Grade of recommendation: GPP**

ESPEN Guideline: Clinical Nutrition in Inflammatory Bowel Disease⁴¹

Summary of recommendations (in relevant part):

If oral feeding is not sufficient then tube feeding should be considered as supportive therapy. Enteral feeding using formulas or liquids should always take preference over parenteral feeding, unless it is completely contraindicated. **Grade of recommendation: A**

PN is indicated in IBD (i) when oral nutrition or EN is not sufficiently possible, (e.g. when the GI tract is dysfunctional or in CD patients with short bowel), (ii) when there is an obstructed bowel where there is no possibility of placement of a feeding tube beyond the obstruction or where this has failed, or (iii) when other complications occur such as an anastomotic leak or a high output intestinal fistula. **Grade of recommendation B**

EN in CD should be administered via an enteral feeding pump. **Grade of recommendation: B**

EN appears safe and can be recommended as supportive therapy according to standard nutritional practice in patients with severe UC [ulcerative colitis]. **Grade of recommendation: GPP**

ESPEN Guidelines on Chronic Intestinal Failure in Adults⁴²

Summary of recommendations (in relevant part):

Intestinal rehabilitation strategy - medical short bowel syndrome:

We suggest the use of enteral tube feeding in combination with oral feeding in patients with CIF [chronic

intestinal failure] with a low-level of HPN dependence (i.e. B1 category of clinical classification) and in whom the expected gain with tube feeding could allow them to wean off HPN. **Grade of recommendation: Low**

Chronic intestinal pseudo-obstruction:

We suggest trying enteral tube feeding as a first step in patients with chronic gastrointestinal motility dysfunctions who are not able to meet their energy needs with oral nutrition alone and continue to lose weight, before using HPN. **Grade of recommendation: Very Low**

Radiation enteritis:

We suggest trying enteral tube feeding in patients with radiation enteritis if oral nutrition including use of oral nutritional supplements is inadequate. **Grade of recommendation: Very Low**

ESPEN Guideline on Clinical Nutrition in Liver Disease⁴³

Summary of recommendations (in relevant part):

Alcoholic Steatohepatitis (ASH):

EN should be used when patients with severe ASH cannot meet their caloric requirements through normal food and/or ONS in order to improve survival and infectious morbidity. (BM) **Grade of recommendation: B**

EN can be used in severe ASH to ensure adequate energy and protein intake without increasing the risk of HE. (BM) **Grade of recommendation: 0**

EN should be used in severe ASH, because EN has been shown to be as effective as steroids alone and, in survivors of the first four weeks, to be associated with a lower mortality rate in the following year (BM). **Grade of recommendation: B**

Non-alcoholic fatty liver disease (NAFL):

EN or PN shall be administered in NAFL/NASH [non-alcoholic steatohepatitis] patients during severe intercurrent illness, when oral nutrition alone is inadequate or impossible or contraindicated. **Grade of recommendation: GPP**

Cirrhosis:

In cirrhotic patients, nutritional intervention (either oral, EN or PN) shall be implemented according to current guidelines for non-cirrhotic patients. (BM) [biomedical endpoint] **Grade of recommendation: A**

In cirrhotic patients, nutritional intervention (either oral or EN or PN) should be recommended for potential clinical benefit without an increase in adverse events. **Grade of recommendation: GPP**

In cirrhotic patients, who cannot be fed orally or who do not reach the nutritional target through the oral diet, EN should be performed. (BM) **Grade of recommendation: B**

PN should be used in cirrhotic patients in whom oral and/or EN are ineffective or not feasible. (BM) **Grade of recommendation: B**

Nutrition associated liver injury (NALI):

In infants, children and adults, specialized nutrition protocols making optimal use of EN should be implemented. (BM) **Grade of recommendation: B**

ESPEN-ESPGHAN-ECFS Guidelines on Nutrition Care for Infants, Children, and Adults with Cystic Fibrosis 33

Summary of recommendations (in relevant part):

We recommend a progressive approach to intensification of nutrition interventions as needs increase: preventive nutritional counseling, dietary modification and/or oral nutrition supplements, and enteral tube feeding. (Grade of evidence: low)

We recommend that clinicians consider the use of polymeric enteral tube feeding when oral interventions have failed to achieve acceptable rates of growth and nutritional status. (Grade of evidence: high)

We recommend the use of parenteral nutrition be reserved for exceptional cases when enteral feeding is not possible. (Grade of evidence: low)

National Institute for Health and Clinical Excellence (NICE). Clinical Guideline 32 Nutrition support in adults: oral nutrition support, enteral tube feeding and parenteral nutrition.⁴⁴

Summary of guidelines (in relevant part):

1.3.1 Nutrition support should be considered in people who are malnourished, as defined by any of the following:

- a BMI of less than 18.5 kg/m²
- unintentional weight loss greater than 10% within the last 3–6 months
- a BMI of less than 20 kg/m² and unintentional weight loss greater than 5% within the last 3–6 months.

1.3.2 Nutrition support should be considered in people at risk of malnutrition who, as defined by any of the following:

- have eaten little or nothing for more than 5 days and/or are likely to eat little or nothing for the next 5 days or longer
- have a poor absorptive capacity, and/or have high nutrient losses and/or have increased nutritional needs from causes such as catabolism.

1.7.1 Healthcare professionals should consider enteral tube feeding in people who are malnourished or at risk of malnutrition as defined in 1.3.1 and 1.3.2, respectively, and have:

- inadequate or unsafe oral intake, and
- a functional, accessible gastrointestinal tract.

1.7.2 Enteral tube feeding should not be given to people unless they meet the criteria in 1.7.1, or they are taking part in a clinical trial.

1.7.3 Enteral tube feeding should be stopped when the patient is established on adequate oral intake.

Small Bowel and Nutrition Committee of the British Society of Gastroenterology 2006⁴⁵

Summary of guidelines (in relevant part):

2.1 Aims of treatment in patients with a short bowel

- *To use oral/enteral nutrition in preference to parenteral nutrition whenever the gut is functional and can absorb sufficient nutrients, water, and electrolytes.*

2.2 Patients with a short bowel and an intact ileum and colon rarely need long term enteral or parenteral nutrition.

2.3 Patients with a short bowel (due to loss of ileum) and a retained functional colon

- *May need parenteral nutrition if less than 50 cm small intestine remains (Grade B).*

Spanish Society of Medical Oncology (SEOM) Guidelines⁴⁶

Summary of guidelines (in relevant part):

Enteral nutrition by tube is indicated if intake oral is < 60% of requirement despite nutritional interventions per os, and gastrointestinal function is preserved. When enteral nutrition is expected to last for more than 4–6 weeks, ostomy is preferred. If there is a risk of reflux, gastroparesis, or bronchoaspiration, jejunostomy or nasojejunal tube is preferred over nasogastric or gastrostomy nutrition.

We recommend enteral nutrition (EN) if oral intake remains inadequate despite nutritional counseling, and parenteral nutrition if EN is not sufficient or feasible (strength of recommendation: strong; level of evidence: very low).

Exocrine Pancreatic Insufficiency

Cystic Fibrosis Foundation Pancreatic Enzymes Clinical Care Guidelines³²

Summary of recommendations (in relevant part):

The majority of individuals with CF are pancreatic insufficient. Thus, provision of safe and effective pancreatic enzyme replacement is a key therapy in CF.

Cystic Fibrosis Foundation evidence-informed guidelines on enteral tube feeding for individuals with cystic fibrosis.⁴⁷

Summary of recommendations (in relevant part):

The CF Foundation does not recommend for or against a specific method of providing pancreatic enzyme therapy during enteral feedings in individuals with CF. In the absence of clinical trials, no specific recommendations can be made regarding the use of pancreatic enzyme therapy with enteral feedings.

ESPEN-ESPGHAN-ECFS Guidelines on Nutrition Care for Infants, Children, and Adults with Cystic Fibrosis³³

Summary of recommendations (in relevant part):

We recommend pancreatic enzyme replacement therapy (PERT) for all patients who have evidence of pancreatic insufficiency.

ESPEN guideline on clinical nutrition in acute and chronic pancreatitis³⁴

Summary of recommendations (in relevant part):

*pH-sensitive, enteric-coated microspheres pancreatic enzyme replacement preparations shall be used for treating PEI. **Grade of Recommendation: A***

*Pancreatic enzymes should not be supplemented generally except in patients with obvious pancreatic exocrine insufficiency (PEI). **Grade of Recommendation: B***

*Pancreatic enzymes should be supplemented in patients requiring EN, if signs of exocrine failure manifest. **Grade of Recommendation: GPP***

*When PEI is diagnosed through clinical signs and symptoms and/or laboratory tests of malabsorption, PERT shall be initiated. An accurate nutritional assessment is mandatory to detect signs of malabsorption. **Grade of Recommendation: A***

American College of Gastroenterology Clinical Practice Guideline: Chronic Pancreatitis³⁵

Summary of recommendations (in relevant part):

*We suggest PERT in patients with CP and EPI to improve the complications of malnutrition (**conditional recommendation, low level of evidence**).*

Utilization Parameters for Replacement Tubes

There is minimal guidance or consensus on the replacement frequency of tubes for enteral nutrition. Guidance typically states that manufacturer recommendations should be followed for nasogastric tubes, but these are typically replaced every 4-6 weeks. Guidelines suggest that percutaneous endoscopic gastrostomy (PEG) tubes should be replaced based on the clinical need or at a fixed time interval (such as every 3–6 months) for preventative maintenance. All guidance allows for exceptions such as compromised tube integrity or the presence of tube contamination. A summary of recommendations (in relevant part) for EN tube replacement is described below.

Nasogastric (NG) and Orogastric (OG) Tubes

ASPEN Safe Practices for Enteral Nutrition Therapy.⁴⁸

EADs inserted via the nasal and oral routes are usually intended for short-term use (no more than 4–6 weeks) in the hospitalized patient. However, there may be situations when use of a nasogastric access in the outpatient setting is appropriate. Some patients, particularly pediatric patients in the home, are able to self-place a nasogastric tube as part of their own care.

British Society of Gastroenterology Guidelines for Enteral Feeding in Adult Hospital Patients.⁴⁹

Long term NG tubes should usually be changed every 4–6 weeks swapping them to the other nostril. (grade C)

Gastrostomy/Jejunostomy Tubes

ASPEN Safe Practices for Enteral Nutrition Therapy.⁴⁸

Develop institutional protocols for replacing percutaneous EADs that reflect manufacturers' guidelines:

- a. Routine removal and replacement of a well maintained percutaneous EAD may not be necessary.*
- b. Replace per manufacturer guidelines.*

Consider tube replacement sooner than indicated in manufacturer guidelines if any of the following are identified:

- a. Deterioration and dysfunction of the EAD*
- b. A ruptured internal balloon*
- c. Stomal tract disruption*
- d. Peristomal infection that persists despite appropriate antimicrobial treatment*

e. Skin excoriation

f. Nonhealing ulcer formation that will not heal despite good wound care technique

g. Colocutaneous fistula or gastrocolic fistulas

Consider routine replacement of the percutaneous tube after the stoma tract has matured (>30 days from initial insertion) or per institutional protocols.

Preventive maintenance of balloon gastrostomy tubes, which includes selective change at a fixed time interval (such as every 3–6 months), is the standard of practice in some facilities because of the potential for balloon failure.

ESPEN Guidelines on Artificial Enteral Nutrition—Percutaneous Endoscopic Gastrostomy (PEG).⁵⁰

...the durability of a PEG system is primarily dependent on the quality of aftercare given to the tubing system; and routine removal and replacement of a PEG tube is not necessary as patients have used the same PEG system for more than 10 years without complications.

ESPEN Guideline on Home Enteral Nutrition.⁴⁰

Tube replacement should be accomplished in case of tube breakage, occlusion, dislodgement or degradation.
Grade of recommendation GPP – Strong consensus (93% agreement)

The durability of a PEG tube system is primarily linked to its careful handling. There is no need to exchange a tube system at regular intervals. Replacement will be required eventually because of breakage, occlusion, dislodgement or degradation. A percutaneous enteral access device that shows signs of fungal colonization with material deterioration and compromised structural integrity should be replaced in a non-urgent but timely manner.

Multidisciplinary Practical Guidelines for Gastrointestinal Access for Enteral Nutrition and Decompression from the Society of Interventional Radiology and American Gastroenterological Association (AGA) Institute, with Endorsement by Canadian Interventional Radiological Association (CIRA) and Cardiovascular and Interventional Radiological Society of Europe (CIRSE).⁵¹

With optimal care, most transoral bumper-type gastrostomy tubes can remain in place for 1–2 years.

Preventive maintenance of gastrostomy tubes that includes elective change at a fixed period of time (usually 3–6 months) is the standard practice in some places. This is more common for the balloon-tip gastrostomy tubes because of the potential for balloon failure.

The average longevity for a jejunostomy tube in a gastrojejunostomy is 3–6 months.

Analysis of Evidence (Rationale for Determination)

A systematic approach is employed by the DME MACs when evaluating the strength of evidence to determine if an

intervention is reasonable and necessary per CMS guidance as outlined in the Medicare *Benefit Policy Manual* (CMS Pub. 100-02), Chapter 15, Section 110.1.C and the Medicare *Program Integrity Manual* (CMS Pub. 100-08), Chapter 13. Additionally, the evidence is examined to determine if an intervention will improve health outcomes for Medicare beneficiaries. In conducting reviews, the DME MACs use the current best available evidence of general acceptance by the medical community, such as published original research in peer-reviewed medical journals, systematic reviews and meta-analyses, evidence-based consensus statements and clinical guidelines. While the overall level of evidence for nutritional literature is low and is largely based on data gathered through case/cohort studies, practice experience and expert consensus that is synthesized via narrative literature reviews, the resulting clinical practice guidelines are consistent in their recommendations for the use of EN for the management of disease processes associated with malabsorption/maldigestion; and, for the use of PERT for the management of EPI.

Home Enteral Nutrition Level of Evidence

Quality of Published Literature: Low

Strength of Recommendations: Moderate

Weight of Evidence: Moderate

Exocrine Pancreatic Insufficiency Level of Evidence

Quality of Published Literature: Low

Strength of Recommendations: Moderate

Weight of Evidence: Moderate

Conclusion

Home Enteral Nutrition

Home enteral nutrition refers to nutrition therapy administered to outpatients who require nutrition care and have a functional gut via an enteral access device but are otherwise able to be managed outside of an acute care facility. The definition of functional gut has broadened with advancements in EN 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, HEN is appropriate for the management of; and, improves health outcomes for individuals with a diagnosis of maldigestion/malabsorption. Therefore, the Enteral Nutrition LCD will include coverage of EN as reasonable and necessary as nutritional support therapy for the management of Medicare beneficiaries with a diagnosis of maldigestion and malabsorption. As previously noted, coverage of HEN for patients with non-function of the structures that normally permit food to reach the digestive tract has been established in the Medicare *National Coverage Determinations Manual* (CMS Pub. 100-03), Chapter 1, Part 4, Section 180.2. Additionally, benefit category 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. The guidance outlined in these manuals are reflected in the remainder of the LCD.

Exocrine Pancreatic Insufficiency

Exocrine Pancreatic Insufficiency is a condition characterized by the inability of the pancreas to produce adequate levels of digestive enzymes, resulting in maldigestion and malabsorption. Based on review of the best available evidence, PERT is appropriate for the management of; and, improves health outcomes in Medicare beneficiaries with a diagnosis of EPI. In Medicare beneficiaries with a diagnosis of EPI who require EN to maintain weight and strength commensurate to their health status, oral formulations of PERT taken at the beginning and end of tube feedings may result in suboptimal absorption. In-line digestive enzyme cartridges provide an FDA approved PERT option for this subset of individuals. Therefore, the Enteral Nutrition LCD will include coverage of In-line digestive enzyme cartridges as reasonable and necessary for the management of Medicare beneficiaries with a diagnosis of EPI to maintain weight and strength commensurate with their overall health status.

Coding Information

CPT/HCPCS Codes

Group 1 Paragraph:

The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS:

BA – Item furnished in conjunction with parenteral enteral nutrition (PEN) services

BO – Orally administered nutrition, not by feeding tube

EY – No physician or other licensed health care provider order for this item or service

Group 1 Codes:

CODE	DESCRIPTION
A9270	NON-COVERED ITEM OR SERVICE
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

CODE	DESCRIPTION
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 OUNCE
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,

CODE	DESCRIPTION
	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
B9998	NOC FOR ENTERAL SUPPLIES
E0776	IV POLE

General Information

Associated Information

DOCUMENTATION REQUIREMENTS

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary's medical records include the treating practitioner's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

GENERAL DOCUMENTATION REQUIREMENTS

In order to justify payment for DMEPOS items, suppliers must meet the following requirements:

- SWO
- Medical Record Information (including continued need/use if applicable)
- Correct Coding
- Proof of Delivery

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information regarding these requirements.

Refer to the Supplier Manual for additional information on documentation requirements.

Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

Items covered in this LCD have additional policy-specific requirements that must be met prior to Medicare reimbursement.

Refer to the LCD-related Policy article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information.

Miscellaneous

Appendices

Utilization Guidelines

Refer to Coverage Indications, Limitations and/or Medical Necessity

Sources of Information

Reserved for future use.

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Revision History Information

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Associated Documents

Attachments

[Enteral Nutrition DIF - CMS10126](#) (119 KB) (Uploaded on 07/16/2021)

Related Local Coverage Documents

Articles

[A58833 - Enteral Nutrition - Policy Article](#)

[A58835 - Response to Comments: Enteral Nutrition - DL38955](#)

[A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs](#)

Related National Coverage Documents

N/A

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