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I. COVERAGE

Coverage Statement: Enteral and parenteral nutritional therapy is covered in accordance with Medicare coverage criteria.

Guidelines/Notes:
Coverage of nutritional therapy is provided under the prosthetic device benefit which requires that the patient must have a permanently inoperative internal body organ or function thereof. *See the NCD for Enteral and Parenteral Nutritional Therapy (180.2).* (Accessed April 27, 2016)

1. Enteral Nutritional Therapy
   The following guidelines are based on the DME MAC *LCD for Enteral Nutrition (L33783)* and the DME MAC Local Coverage Article (LCA) for *Enteral Nutrition - Policy Article*
a. Coverage

- Enteral nutrition **is covered** for a patient who has (a) permanent non-function or disease of the structures that normally permit food to reach the small bowel or (b) disease of the small bowel which impairs digestion and absorption of an oral diet, either of which requires tube feedings to provide sufficient nutrients to maintain weight and strength commensurate with the patient's overall health status.
- The patient must have a permanent impairment. Permanence does not require a determination that there is no possibility that the patient's condition may improve sometime in the future. If the judgment of the attending physician, substantiated in the medical record, is that the condition is of long and indefinite duration (ordinarily at least 3 months), the test of permanence is considered met. Enteral nutrition will be **denied as noncovered** in situations involving temporary impairments.
- The patient's condition could be either anatomic (e.g., obstruction due to head and neck cancer or reconstructive surgery, etc.) or due to a motility disorder (e.g., severe dysphagia following a stroke, etc.). Enteral nutrition is **noncovered** for patients with a functioning gastrointestinal tract whose need for enteral nutrition is due to reasons such as anorexia or nausea associated with mood disorder, end-stage disease, etc.
- The patient must require tube feedings to maintain weight and strength commensurate with the patient's overall health status. Adequate nutrition must not be possible by dietary adjustment and/or oral supplements. Coverage is possible for patients with partial impairments - e.g., a patient with dysphagia who can swallow small amounts of food or a patient with Crohn's disease who requires prolonged infusion of enteral nutrients to overcome a problem with absorption.
- Enteral nutrition products that are administered orally and related supplies are **noncovered**.
- If the coverage requirements for enteral nutrition are met, medically necessary nutrients, administration supplies, and equipment are **covered**.

**Note:** *Enteral nutrition provided to a patient in a Part A covered stay must be billed by the SNF. No payment from Part B is available when enteral nutrition services are furnished to a beneficiary in a stay covered by Part A. However, if a beneficiary is in a stay not covered by Part A, enteral nutrition is eligible for coverage under Part B and may be billed by either the SNF or an outside supplier.*

b. Nutrients

- Enteral formulas consisting of semi-synthetic intact protein/protein isolates (B4150 or B4152) are appropriate for the majority of patients requiring enteral nutrition.
- The medical necessity for special enteral formulas (B4149, B4153-B4157, B4161, and B4162) must be justified in each patient. 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.
- Food thickeners (B4100), baby food, and other regular grocery products that can be blenderized and used with the enteral system will be denied as **noncovered**. Codes B4102 and B4103 describe electrolyte-containing fluids that are **noncovered**. Self-blenderized formulas are **noncovered**.
• Code B4104 is an enteral formula additive. The enteral formula codes include all nutrient components, including vitamins, mineral, and fiber. Therefore, code B4104 will be denied as not separately payable.

c. Equipment and Supplies
• Enteral nutrition may be administered by syringe, gravity, or pump. Some enteral patients may experience complications associated with syringe or gravity method of administration.
• If a pump (B9002) is ordered, there must be documentation in the patient’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.
• The feeding supply kit (B4034-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 kit (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 kits (B4034-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.
• More than three nasogastric tubes (B4081-B4083), or one gastrostomy/jejunostomy tube (B4087-B4088) every three months is not reasonable and necessary. Payment for a catheter/tube anchoring device is considered included in the allowance for enteral feeding supply kits (B4034-B4036). Code A5200 should not be billed separately and is not paid in addition to the supplies for enteral nutrition.

2. Parenteral Nutritional Therapy
The following guidelines are based on the DME MAC LCD for Parenteral Nutrition (L33798) and the DME MAC LCA for Parenteral Nutrition - Policy Article. Compliance with these LCDs/LCAs is required where applicable. (Accessed May 9, 2017)

a. Coverage
• Parenteral nutrition is covered for a patient with permanent, severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition.
• The patient must have a permanent impairment. Permanence does not require a determination that there is no possibility that the patient's condition may improve sometime in the future. If the judgment of the attending physician, substantiated in the medical record, is that the condition is of long and indefinite duration (ordinarily at least 3 months), the test of permanence is considered met. Parenteral nutrition will be denied as noncovered in situations involving temporary impairments.
• The patient must have (a) a condition involving the small intestine and/or its exocrine glands which significantly impairs the absorption of nutrients or (b) disease of the stomach and/or intestine which is a motility disorder and impairs the ability of nutrients to be transported through the GI system. There must be objective evidence supporting the clinical diagnosis.
• Parenteral nutrition is noncovered for the patient with a functioning gastrointestinal
tract whose need for parenteral nutrition is only due to any of the following conditions:
- Swallowing disorder
- Temporary defect in gastric emptying such as a metabolic or electrolyte disorder
- Psychological disorder impairing food intake such as depression
- Metabolic disorder inducing anorexia such as cancer
- Physical disorder impairing food intake such as the dyspnea of severe pulmonary or cardiac disease
- Side effect of a medication
- Renal failure and/or dialysis

In order to cover **intradialytic parenteral nutrition (IDPN)**, documentation must be clear and precise to verify that the patient suffers from a permanently impaired gastrointestinal tract and that there is insufficient absorption of nutrients to maintain adequate strength and weight. Records should document that the patient cannot be maintained on oral or enteral feedings and that due to severe pathology of the alimentary tract, the patient must be intravenously infused with nutrients. Infusions must be vital to the nutritional stability of the patient and not supplemental to a deficient diet or deficiencies caused by dialysis. Physical signs, symptoms and test results indicating severe pathology of the alimentary tract must be clearly evident in any documentation submitted. Patients receiving IDPN must meet the parenteral nutrition coverage criteria listed below.

- Maintenance of weight and strength commensurate with the patient's overall health status must require intravenous nutrition and must not be possible utilizing all of the following approaches:
  1. Modifying the nutrient composition of the enteral diet (e.g., lactose free, gluten free, low in long chain triglycerides, substitution with medium chain triglycerides, provision of protein as peptides or amino acids, etc.), and
  2. Utilizing pharmacologic means to treat the etiology of the malabsorption (e.g., pancreatic enzymes or bile salts, broad spectrum antibiotics for bacterial overgrowth, prokinetic medication for reduced motility, etc.).

**Parenteral nutrition is covered in any of the following situations:**

- **A.** The patient has undergone recent (within the past 3 months) massive small bowel resection leaving less than or equal to 5 feet of small bowel beyond the ligament of Treitz, or
- **B.** The patient has a short bowel syndrome that is severe enough that the patient has net gastrointestinal fluid and electrolyte malabsorption such that on an oral intake of 2.5-3 liters/day the enteral losses exceed 50% of the oral/enteral intake and the urine output is less than 1 liter/day, or
- **C.** The patient requires bowel rest for at least 3 months and is receiving intravenously 20-35 cal/kg/day for treatment of symptomatic pancreatitis with/without pancreatic pseudocyst, severe exacerbation of regional enteritis, or a proximal enterocutaneous fistula where tube feeding distal to the fistula isn't possible, or
- **D.** The patient has complete mechanical small bowel obstruction where surgery is not an option, or
E. The patient is significantly malnourished (10% weight loss over 3 months or less and serum albumin less than or equal to 3.4 gm/dl) and has very severe fat malabsorption (fecal fat exceeds 50% of oral/enteral intake on a diet of at least 50 gm of fat/day as measured by a standard 72 hour fecal fat test), or

F. The patient is significantly malnourished (10% weight loss over 3 months or less and serum albumin less than or equal to 3.4 gm/dl) and has a severe motility disturbance of the small intestine and/or stomach which is unresponsive to prokinetic medication and is demonstrated either: (1) Scintigraphically (solid meal gastric emptying study demonstrates that the isotope fails to reach the right colon by 6 hours following ingestion), or (2) Radiographically (barium or radiopaque pellets fail to reach the right colon by 6 hours following administration). These studies must be performed when the patient is not acutely ill and is not on any medication which would decrease bowel motility.

Unresponsiveness to prokinetic medication is defined as the presence of daily symptoms of nausea and vomiting while taking maximal doses.

For criteria A-F above, the conditions are deemed to be severe enough that the patient would not be able to maintain weight and strength on only oral intake or tube enteral nutrition. Patients who do not meet criteria A-F above must meet criteria 1-2 above (modification of diet and pharmacologic intervention) plus criteria G and H below:

G. The patient is malnourished (10% weight loss over 3 months or less and serum albumin less than or equal to 3.4 gm/dl), and

H. A disease and clinical condition has been documented as being present and it has not responded to altering the manner of delivery of appropriate nutrients (e.g., slow infusion of nutrients through a tube with the tip located in the stomach or jejunum).

The following are some examples of moderate abnormalities which would require a failed trial of tube enteral nutrition before parenteral nutrition would be covered

- Moderate fat malabsorption - fecal fat exceeds 25% of oral/enteral intake on a diet of at least 50 gm of fat/day as measured by a standard 72 hour fecal fat test
- Diagnosis of malabsorption with objective confirmation by methods other than 72 hour fecal fat test (e.g., Sudan stain of stool, d-xylose test, etc.)
- Gastroparesis which has been demonstrated (a) radiographically or scintigraphically as described in F above with the isotope or pellets failing to reach the jejunum in 3-6 hours, or (b) by manometric motility studies with results consistent with an abnormal gastric emptying, and which is unresponsive to prokinetic medication
- A small bowel motility disturbance which is unresponsive to prokinetic medication, demonstrated with a gastric to right colon transit time between 3-6 hours
- Small bowel resection leaving greater than 5 feet of small bowel beyond the ligament of Treitz
- Short bowel syndrome which is not severe (as defined in B)
- Mild to moderate exacerbation of regional enteritis, or an enterocutaneous fistula
- Partial mechanical small bowel obstruction where surgery is not an option

Parenteral nutrition is noncovered for patients who do not meet these criteria.
Definition of a Tube Trial

- A concerted effort must be made to place a tube. For gastroparesis, tube placement must be post-pylorus, preferably in the jejunum. Use of a double lumen tube should be considered. Placement of the tube in the jejunum must be objectively verified by radiographic studies or fluoroscopy. Placement via endoscopy or open surgical procedure would also verify location of the tube, however they are not required.

- A trial with enteral nutrition must be made, with appropriate attention to dilution, rate, and alternative formulas to address side effects of diarrhea.

- Examples of a failed tube trial would be
  - A person who has had documented placement of a tube in the post-pyloric area continues to have problems with vomiting and on radiographic recheck the tube has returned to the stomach.
  - After an attempt of sufficient time (5-6 hours) to get a tube into the jejunum, the tube does not progress and remains in the stomach or duodenum.
  - An attempt of enteral tube feeding with a very slow drip was made. It was initially tolerated well but vomiting occurred when the rate was increased.
  - After placement of the tube in the jejunum and 1-2 days of enteral tube feeding, the person has vomiting and distension.
  - A tube is placed appropriately and remains in place. Enteral nutrition is initiated and the concentration and rate are increased gradually. Over the course of 3-4 weeks, attempts to increase the rate and/or concentration and/or to alter the formula to reach the targeted intake are unsuccessful, with increase in diarrhea, bloating or other limiting symptoms, and the person is unable to meet the needed nutritional goals (stabilize at desired weight or gain weight as needed).

NOTES:

- Parenteral nutrition can be covered in a patient with the ability to obtain partial nutrition from oral intake or a combination of oral/enteral (or even oral/enteral/parenteral) intake as long as the following criteria are met: 1a) a permanent condition of the alimentary tract is present which has been deemed to require parenteral therapy because of its severity (criteria A-F); or 1b) a permanent condition of the alimentary tract is present which is unresponsive to standard medical management (criterion H); and 2) the person is unable to maintain weight and strength (criterion G).

- If the coverage requirements for parenteral nutrition are met, medically necessary nutrients, administration supplies, and equipment are covered. Suppliers should monitor the patient’s medical condition to confirm that the coverage criteria for parenteral nutrition continue to be met.

- Parenteral nutrition provided to a patient in a Part A covered stay must be billed by the SNF. No payment from Part B is available when parenteral nutrition services are furnished to a beneficiary in a stay covered by Part A. However, if a beneficiary is in a stay not covered by Part A, parenteral nutrition is eligible for coverage under Part B and may be billed by either the SNF or a supplier.

- When parenteral nutrition is administered in an outpatient facility, the pump used for its administration and IV pole will be denied as not separately payable. The pump and pole are not considered as rentals to a single patient but rather as items of equipment used for multiple patients.

- When nutritional support other than the oral route is needed, tube enteral nutrition is
usually preferable to parenteral nutrition for the following reasons: (1) In a fluid
restricted patient, tube enteral nutrition permits delivery of all necessary nutrients in
a more concentrated volume than parenteral nutrition and (2) tube enteral nutrition
allows for safer home delivery of nutrients.

b. Nutrients

- Parenteral nutrition solutions containing little or no amino acids and/or carbohydrates
  would be covered only in situations A, B or D discussed above.
- A total caloric daily intake (parenteral, enteral, and oral) of 20-35 cal/kg/day is
  considered sufficient to achieve or maintain appropriate body weight. The ordering
  physician must document in the medical record the medical necessity for a caloric
  intake outside this range in an individual patient. This information must be available
  on request.
- The ordering physician must document the medical necessity for protein orders
  outside of the range of 0.8-1.5 gm/kg/day, dextrose concentration less than 10%, or
  lipid use greater than 1500 grams (150 units of service of code B4185) per month.
- The medical necessity for special parenteral formulas (B5000-B5200) must be
  justified in each patient. If a special parenteral nutrition formula is provided and if the
  medical record does not document why that item is reasonable and necessary, it will
  be denied as not reasonable and necessary.

c. Equipment and Supplies

- Infusion pumps (B9004-B9006) are covered for patients in whom parenteral nutrition
  is covered. Only one pump (stationary or portable) will be covered at any one time.
  Additional pumps will be denied as not reasonable and necessary.
- If the coverage requirements for parenteral nutrition are met, one supply kit (B4220
  or B4222) and one administration kit will be covered for each day that parenteral
  nutrition is administered.

II. DEFINITIONS

**Dysphagia:** A swallowing disorder that may be due to various neurological, structural, and
cognitive deficits. Dysphagia may be the result of head trauma, cerebrovascular accident,
neuromuscular degenerative diseases, head and neck cancer, and encephalopathies. While dysphagia
can afflict any age group, it most often appears among the elderly. [NCD for Speech-Language
Pathology Services for the Treatment of Dysphagia (170.3)]. (Accessed May 9, 2017)

**Enteral Nutrition:** The provision of nutritional requirements through a tube into the stomach. It
may be administered by syringe, gravity, or pump. [Multiple LCDs for Enteral Nutrition; available at
http://www.cms.gov/medicare-coverage-database/overview-and-quick-

**Intradialytic Parenteral Nutrition (IDPN):** Method of administering nutritional supplements to
patients undergoing hemodialysis for end-stage renal disease (ESRD). IDPN formulas generally
contain a mix of amino acids, carbohydrate (usually dextrose), and lipids, IDPN is infused through
an existing dialysis access catheter or site, via an infusion pump. [Hayes Technology Brief:
Intradialytic Parenteral Nutrition (IDPN) for End-Stage Renal Disease in Adults. August 29, 2008.

**Parenteral Therapy:** Nutritional support given by means, such as intravenously (IV), other than
through the GI tract. [Multiple LCDs for Parenteral Nutrition; available at
# III. REFERENCES

See above.

# IV. REVISION HISTORY

<table>
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<tr>
<th>Date</th>
<th>Description</th>
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<td>05/16/2017</td>
<td>Annual review; no updates.</td>
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<tr>
<td>04/18/2017</td>
<td>Re-review; deleted reference to HCPCS code B9000 (deleted effective 1/1/2017)</td>
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<td>05/17/2016</td>
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<tr>
<td>06/16/2015</td>
<td>Annual review; added the applicable Local Coverage Articles references.</td>
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<tr>
<td>06/20/2014</td>
<td>Annual review; with the following updates:</td>
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<tr>
<td></td>
<td>- Guideline #1 Enteral Nutritional Therapy and Guideline #2 Parenteral Nutritional Therapy (under Notes) - Deleted “to the fiscal intermediary”, “to the DME MAC” and “outside”</td>
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<tr>
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<td>- Definitions - Updated the definitions of Dysphagia and Intradialytic Parental Nutriton (IDPN) based on applicable reference NCDs</td>
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<tr>
<td>10/04/2013</td>
<td>Guidelines #2 Enteral Nutritional Therapy updated based on the DME MAC LCDs for Enteral Nutrition: CGS L11553, NGS L27214, NHIC L5041, Noridian L11568 Guidelines #3 Parenteral Nutritional Therapy updated based on the DME MAC LCDs for Parenteral Nutrition: CGS L11561, NGS L27006, NHIC L5063 and Noridian L11576</td>
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<td>06/24/2013</td>
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<td>06/18/2012</td>
<td>Guidelines- # 1 updated to further clarify that coverage is based on the NCD that coverage of nutritional therapy is provided under the prosthetic device benefit which requires that the patient must have a permanently inoperative internal body organ or function thereof Guidelines #2 Enteral Nutritional Therapy updated based on the DME MAC LCDs/related key articles for Enteral Nutrition Guidelines #3 Parenteral Nutritional Therapy updated based on the DME MAC LCDs/related key articles for Parenteral Nutrition</td>
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<td>06/30/2011</td>
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<tr>
<td>02/21/2011</td>
<td>Updated Guidelines #1 to include the note pertaining to the new CMS instruction on the Elimination of Least Costly Alternative Language (effective February 4, 2011)</td>
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