Coverage Summary

Nutritional Therapy: Enteral and Parenteral Nutritional Therapy

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Related Medicare Advantage Policy Guideline: Enteral and Parenteral Nutritional Therapy (NCD 180.2)

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The benefit information in this Coverage Summary is based on existing national coverage policy, however Local Coverage Determinations (LCDs) may exist and compliance with these policies are required where applicable.

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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 May 7, 2018)

1. Enteral Nutritional Therapy
   The following guidelines are based on the DME MAC LCDs for Enteral Nutrition (L33783) and the DME MAC Local Coverage Articles (LCAs) 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**. 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**.
- 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**.
- Enteral feeding supply kit allowances (B4034-B4036), are all-inclusive. 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**.
- More than three nasogastric tubes (B4081-B4083), or one gastrostomy/jejunostomy tube (B4087-B4088) every three months is **not reasonable and necessary**.

2. **Parenteral Nutritional Therapy**
The following guidelines are based on the *DME MAC LCDs for Parenteral Nutrition (L33798)* and the *DME MAC LCAs for Parenteral Nutrition - Policy Article (A52515)*. Compliance with these LCDs/LCAs is required where applicable. *(Accessed May 7, 2018)*

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:
  o Swallowing disorder
  o Temporary defect in gastric emptying such as a metabolic or electrolyte disorder
  o Psychological disorder impairs food intake such as depression
  o Metabolic disorder inducing anorexia such as cancer
  o Physical disorder impairing food intake such as the dyspnea of severe pulmonary
    or cardiac disease
  o Side effect of a medication
  o Renal failure and/or dialysis

In order to cover intradialytic parenteral nutrition (IDPN), documentation must be
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
  o 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.
  o 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.
  o 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.
  o After placement of the tube in the jejunum and 1-2 days of enteral tube feeding, the person has vomiting and distension.
  o 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 7, 2018)


**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.

## III. REFERENCES

See above.

## IV. REVISION HISTORY

05/11/2018  Annual review with the following updates:

Guideline 1.c (Equipment and Supplies) –

- Third bullet point – added the following language: “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.”

- Fourth bullet point – deleted the following language: “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.”

- Fifth bullet point – added the following language: “Enteral feeding supply kit allowances (B4034-B4036), are all-inclusive. 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.”

- Last bullet point – deleted the following language: “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.”

05/16/2017  Annual review; no updates.

04/18/2017  Re-review; deleted reference to HCPCS code B9000 (deleted effective 1/1/2017)

05/17/2016  Annual review; no updates.

06/16/2015  Annual review; added the applicable Local Coverage Articles references.

06/20/2014  Annual review; with the following updates:

- Guideline #1 Enteral Nutritional Therapy and Guideline #2 Parenteral Nutritional Therapy (under Notes) - Deleted “to the fiscal intermediary”, “to the DME MAC” and “outside”

- Definitions - Updated the definitions of Dysphagia and Intralipid Parenteral Nutrition (IDPN) based on applicable reference NCDs

05/24/2013  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

06/24/2013  Annual review; no updates
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

06/30/2011 Annual review; no updates

02/21/2011 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)