PARENTERAL NUTRITION THERAPY

Policy Number: BIP113.H
Effective Date: December 1, 2018

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Related Benefit Interpretation Policies:
- Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotics and Medical Supplies Grid
- Enteral and Oral Nutritional Therapy

Covered benefits are listed in three (3) Sections - A, B and C. All services must be medically necessary. Each benefit plan contains its own specific provisions for coverage, limitations and exclusions as stated in the member's Evidence of Coverage (EOC)/Schedule of Benefits (SOB). If there is a discrepancy between this policy and the member's EOC/SOB, the member's EOC/SOB provision will govern.

Essential Health Benefits for Individual and Small Group
For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the member specific plan document to determine benefit coverage.

A. FEDERAL/STATE MANDATED REGULATIONS

None

B. STATE MARKET PLAN ENHANCEMENTS

None

C. COVERED BENEFITS

IMPORTANT NOTE: Covered benefits are listed in Sections A, B and C. Always refer to Sections A and B for additional covered benefits not listed in this Section.

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.

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.

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:
- 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
- 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
- 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
- The patient has complete mechanical small bowel obstruction where surgery is not an option; or
- 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
- 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 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 above must meet criteria 1-2 above (modification of diet and pharmacologic intervention) plus criteria below:

- 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
- 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-xylene test, etc.);
- Gastroparesis which has been demonstrated (a) radiographically or scintigraphically as described 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 above);
- Mild to moderate exacerbation of regional enteritis, or an enteroctaneous 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).
Nutrients:
- Parenteral nutrition solutions containing little or no amino acids and/or carbohydrates would be covered only in situations 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.

Supplies:
Parenteral nutrition infusion pump; Parenteral nutrition solutions; stomach tube; and supplies for self-administered injections are covered.

D. NOT COVERED

1. Member with a functioning gastrointestinal/ GI tract whose need for Parenteral therapy is only due to any of the following:
   a. Swallowing disorder;
   b. Impaired food intake as a result of a psychological disorder such as depression;
   c. Side effect of a medication;
   d. Renal failure and/or dialysis;
   e. Physical disorder impairing food intake such as dyspnea of severe pulmonary or cardiac disease;
   f. Temporary defect in gastric emptying such as a metabolic or electrolyte disorder.

2. Diet modifications and/or use of appetite stimulants and/or medications for treating the cause of malabsorption were not tried first or are working.

3. Member has not had a trial period of tube or enteral feedings where appropriate as determined by the Medical Director or designee.

E. DEFINITIONS

Parenteral Therapy: Nutritional support given by means, such as intravenously (IV), other than through the GI tract.

Permanence: For the purposes of this policy, Permanence does not require a determination that there is no possibility that the member’s condition may improve sometime in the future. If the physician’s opinion is that the condition is of long and indefinite duration (ordinarily at least 3 months), then the qualifier of permanent is met.

F. REFERENCES

CMS Medicare Benefit Policy Manual, Chapter; Chapter 8: § 60.5 Intradialytic Parenteral/Enteral Nutrition (IDPN); § 100.2.2-100.2.2.3 Evidence of Medical Necessity for Parenteral and Enteral Nutrition (PEN) Therapy, § 160-160.2

CMS National Coverage Determination 180.2 Enteral and Parenteral Nutritional Therapy; Enteral and Parenteral Nutritional Therapy (180.2)
## G. POLICY HISTORY/REVISION INFORMATION

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