The supplier must be able to provide all of these items on request:

- Standard Written Order (SWO)
- Beneficiary Authorization
- Proof of Delivery (POD)
- Refill Requirements
- Continued Need
- Continued Use
- DME Information Form (DIF) CMS-10126
- Medical records from treating practitioner as noted below

Medical Records should contain:

- Condition involving the small intestine and/or its exocrine glands which significantly impairs the absorption of nutrients; or
- Motility disorder of the stomach and/or intestine which impairs the ability of nutrients to be transported through gastrointestinal (GI) system; and
- Condition is of long and indefinite duration (ordinarily at least 3 months)

Intradialytic Parenteral Nutrition (IDPN)

- Beneficiary has permanently impaired GI tract; and
- There is sufficient absorption of the nutrients to maintain adequate strength and weight.
  - Beneficiary cannot be maintained on oral or enteral feedings; and
  - Due to severe pathology of the alimentary tract, the beneficiary must be intravenously infused with nutrients
  - Infusions must be vital to the nutritional stability of the beneficiary 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

Maintenance of weight and strength commensurate with overall health status must require intravenous nutrition and must not be possible utilizing the following:

- Modifying the nutrient composition of the enteral diet; and
- Utilizing pharmacologic means to treat the etiology of the malabsorption

Beneficiaries receiving IDPN must meet the parenteral nutrition coverage criteria (1 and 2) listed below

**Parenteral Nutrition (PN)**

- Maintenance of weight and strength commensurate with the beneficiary’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 mobility, etc.)

PN is covered in any of the following situations:

- A. Recent small bowel resection leaving ≤ 5 feet of small bowel beyond the ligament of Treitz; or
- B. Short bowel syndrome that is severe enough that the beneficiary has net GI fluid and electrolyte malabsorption; or
- C. Requires bowel rest for at least 3 months and is receiving intravenously 20-35 cal/kg/day For treatment of symptomatic pancreatitis, severe exacerbation of regional enteritis, or Proximal enterocutaneous fistula where tube feeding distal to the fistula isn’t possible; or
- D. Complete mechanical small bowel obstruction where surgery is not an option; or
- E. Significantly malnourished and has severe fat malabsorption; or
- F. Significantly malnourished and has severe mobility disturbance of the small intestine and/or stomach which is unresponsive to prokinetic medication and is demonstrated either:
  
  - Scintigraphically; or
  - Radiographically

Beneficiaries who do not meet criteria A-F must meet criteria 1-2 (modification of diet and pharmacologic intervention plus the following):

- G. Beneficiary is malnourished; 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
Specific Documentation Requirements

- For situations A-D
  - Copies of the operative report and/or hospital discharge summary and/or x-ray reports and/or physician letter, which demonstrate the condition and the necessity for PN.

- For situations E and H (when appropriate):
  - Results of the fecal fat test and dates of the test

- For situations F and H (when appropriate):
  - Copy of the report of the small bowel motility study and a list of medications that the beneficiary was on at the time of the test.

- For situations E-H:
  - Results of serum albumin and date of test (within one week prior to initiation of PN) and a copy of a nutritional assessment by a physician, dietitian or other qualified professional within one week prior to the initiation of PN, to include the following information:
    - Current weight with date and weight 1-3 mon. prior to initiation of PN; and
    - Estimated daily calorie intake during the prior month and by what route (e.g., oral, tube); and
    - Statement of whether there were caloric losses from vomiting or diarrhea and whether these estimated losses are reflected in the clarion count; and
    - Description of any dietary modifications made or supplements tried during the prior month (e.g., low fat, extra medium chain triglycerides, etc.)

- For situations described in H:
  - Statement from the physician, copies of objective studies, and excerpts of the medical record giving the following information:
    - Specific etiology for the gastroparesis, small bowel dysmotility, or malabsorption
    - Detailed description of the trial of tube enteral nutrition including the beginning and ending dates of the trial, duration of time that the tube was in place, the type and size of tube, the location of tip of the tube, the name of the enteral nutrient, the quantity, concentration, and rate of administration and the results;
    - Copy of the x-ray report or procedure report documenting placement of the tube in the jejunum
    - Prokinetic medications used, dosage, and dates of use;
    - Non-dietary treatment given during prior month directed at etiology or malabsorption (e.g., antibiotic for bacterial overgrowth);
    - Any medications used that might impair GI tolerance to enteral feedings (e.g., anticholinergics, opiates, tricyclics, phenothiazines, etc.) or that might interfere with test results (e.g., mineral oil, etc.) and a statement explaining the need for these medications.
**Moderate abnormalities**

- The following moderate abnormalities require a failed enteral nutrition tube trial before parenteral nutrition is 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
  - Gastroparesis which has been demonstrated:
    - Radiographically or scintigraphically as described in F above with the isotope or pellets failing to reach the jejunum in 3-6 hours; or
    - By manometric motility studies with results consistent with an abnormal gastric emptying, and which is unresponsive to prokinetic medication
  - 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 >5 feet of small bowel beyond the ligament of Treitz
  - Short bowel syndrome which is not severe (as identified in B)
  - Mild to moderate exacerbation of regional enteritis, or an enterocutaneous fistula
  - Partial mechanical small bowel obstruction where surgery is not an option

**Tube Trial**

- A concerted effort was made to place a tube.
  - For gastroparesis, tube placement must be post-pylorus
  - Placement of the tube in the jejunum must be verified by radiographic studies or fluoroscopy
  - Attention must be made to dilution, rate, and alternative formulas to address side affects of diarrhea.

**Miscellaneous**

- Ordering physician is expected to see the beneficiary within 30 days prior to the initial certification; or
- Ordering physician must document why the beneficiary wasn’t seen and what other monitoring methods were used to evaluate their nutritional need.
- Medical records must document necessity for protein orders outside the range of 0.8-1.5 gm/kg/day, dextrose concentration <10%, or lipid use >1500 grams per month.
- Medical records must document necessity for special formulas B5000-B5200.
- Parenteral nutrition can be covered if a beneficiary with the ability to obtain partial nutrition from oral intake or a combination of oral/enteral intake as long as the following criteria are met:
  - 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
☐ A permanent condition of the alimentary tract is present which is unresponsive to medical management (criterion H); and

☐ Beneficiary is unable to maintain weight and strength (criterion G).