Appendix A

(Please refer to National Coverage Determination (NCD) 180.2 for additional guidance regarding Medicare coverage.)

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part3.pdf

Parenteral Nutrition – Indications, Coverage, Documentation Requirements, and Non-Coverage

Parenteral Nutrition – Indications

The beneficiary must have:

- A condition involving the small intestine and/or its exocrine glands which significantly impairs absorption of nutrients; or
- Motility disorder of the stomach and/or intestine impairing the ability of nutrients to be transported through the GI system.
    - The medical record must document objective evidence supporting the clinical diagnosis.

The beneficiary must have a permanent impairment. Parenteral nutrition will be denied as non-covered in situations involving temporary impairments.

> NOTE: Permanence does not require a determination that there is no possibility that the beneficiary'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.

Coverage of intradialytic parenteral nutrition (IDPN)

Documentation must clearly and precisely verify the beneficiary suffers from:

- A permanently impaired gastrointestinal tract; and
- There is insufficient absorption of nutrients to maintain adequate strength and weight.

Medical records should document the 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 submitted.

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

- 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
- 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.)

Beneficiaries receiving IDPN must meet the parenteral nutrition coverage criteria

Parenteral nutrition is covered in any of the following situations:

A. The beneficiary 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 beneficiary has a short bowel syndrome that is severe enough that the beneficiary 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 beneficiary 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 beneficiary has complete mechanical small bowel obstruction where surgery is not an option, or

E. The beneficiary 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 beneficiary 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:

    a. Scintigraphically (solid meal gastric emptying study demonstrates that the isotope fails to reach the right colon by 6 hours following ingestion), or

    b. Radiographically (barium or radiopaque pellets fail to reach the right colon by 6 hours following administration). These studies must be performed when the beneficiary 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 beneficiary would not be able to maintain weight and strength on only oral intake or tube enteral nutrition.

Beneficiaries 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 beneficiary 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).

Parenteral nutrition can be covered in a beneficiary 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.

Examples – Failed Trial of Tube Enteral Nutrition

The following are some examples of moderate abnormalities which would require a **failed trial of tube enteral nutrition**[1] 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 non-covered for beneficiaries who do not meet the criteria listed above.

Additional Coverage Information

[1] 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).

Coverage criteria for continued use of parenteral nutrition continues to be met if documentation of the beneficiary's medical condition continues to support continued need.

Parenteral nutrition provided to a beneficiary in a Part A covered stay must be billed by the SNF to the fiscal intermediary. No payment from Part B is available when parenteral nutrition services are furnished to a beneficiary in a stay covered by Part A.

If a beneficiary is not in a Part A stay, parenteral nutrition is eligible for coverage under Part B and may be billed to the DME MAC by either the SNF or an outside 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 beneficiary but rather as items of equipment used for multiple beneficiaries.

Parenteral Nutrition Documentation Requirements

Documented clinical information in the medical record must describe the medical justification for parenteral nutrition, (must be available upon request), shall describe which criterion (A-H) in Non-Medical Necessity Coverage and Payment Rules, listed above, serves as the basis for coverage. This information is generally recorded in the beneficiary's medical record. Some sources, not all-inclusive, are described below:

- 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 parenteral therapy.
- 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 1 week prior to initiation of parenteral nutrition (PN) and a copy of a nutritional assessment by a physician, dietitian or other qualified professional within 1 week prior to initiation of PN, to include the following information:
    - 1. Current weight with date and weight 1-3 mo. prior to initiation of PN;
    - 2. Estimated daily calorie intake during the prior month and by what route (e.g., oral, tube);
    - 3. Statement of whether there were caloric losses from vomiting or diarrhea and whether these estimated losses are reflected in the calorie count;
    - 4. 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, a statement from the physician, copies of objective studies, and excerpts of the medical record giving the following information:
    - 1. Specific etiology for the gastroparesis, small bowel dysmotility, or malabsorption;

- 2. A 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;
- 3. A copy of the x-ray report or procedure report documenting placement of the tube in the jejunum;
- 4. Prokinetic medications used, dosage, and dates of use;
- 5. Non-dietary treatment given during prior month directed at etiology of malabsorption (e.g., antibiotic for bacterial overgrowth);
- 6. 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.

Parenteral Nutrition – Non-Coverage

Parenteral nutrition is non-covered for the beneficiary 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

Appendix B

Parenteral Nutrient Solutions

Medicare pays for no more than one month's supply of enteral nutrients at any one time.

B4164 - PARENTERAL NUTRITION SOLUTION: CARBOHYDRATES (DEXTROSE), 50% OR LESS (500 ML = 1 UNIT) - HOME MIX

B4168 - PARENTERAL NUTRITION SOLUTION; AMINO ACID, 3.5%, (500 ML = 1 UNIT) - HOME MIX

B4172 - PARENTERAL NUTRITION SOLUTION; AMINO ACID, 5.5% THROUGH 7%, (500 ML = 1 UNIT) - HOME MIX

B4176 - PARENTERAL NUTRITION SOLUTION; AMINO ACID, 7% THROUGH 8.5%, (500 ML = 1 UNIT) - HOME MIX

B4178 - PARENTERAL NUTRITION SOLUTION: AMINO ACID, GREATER THAN 8.5% (500 ML = 1 UNIT) - HOME MIX

B4180 - PARENTERAL NUTRITION SOLUTION; CARBOHYDRATES (DEXTROSE), GREATER THAN 50% (500 ML = 1 UNIT) - HOME MIX

B4185 - PARENTERAL NUTRITION SOLUTION, PER 10 GRAMS LIPIDS

B4189 - PARENTERAL NUTRITION SOLUTION; COMPOUNDED AMINO ACID AND CARBOHYDRATES WITH ELECTROLYTES, TRACE ELEMENTS, AND VITAMINS, INCLUDING PREPARATION, ANY STRENGTH, 10 TO 51 GRAMS OF PROTEIN - PREMIX

B4193 - PARENTERAL NUTRITION SOLUTION; COMPOUNDED AMINO ACID AND CARBOHYDRATES WITH ELECTROLYTES, TRACE ELEMENTS, AND VITAMINS, INCLUDING PREPARATION, ANY STRENGTH, 52 TO 73 GRAMS OF PROTEIN - PREMIX

B4197 - PARENTERAL NUTRITION SOLUTION; COMPOUNDED AMINO ACID AND CARBOHYDRATES WITH ELECTROLYTES, TRACE ELEMENTS AND VITAMINS, INCLUDING PREPARATION, ANY STRENGTH, 74 TO 100 GRAMS OF PROTEIN - PREMIX

B4199 - PARENTERAL NUTRITION SOLUTION; COMPOUNDED AMINO ACID AND CARBOHYDRATES WITH ELECTROLYTES, TRACE ELEMENTS AND VITAMINS, INCLUDING PREPARATION, ANY STRENGTH, OVER 100 GRAMS OF PROTEIN - PREMIX

B4216 - PARENTERAL NUTRITION; ADDITIVES (VITAMINS, TRACE ELEMENTS, HEPARIN, ELECTROLYTES), HOME MIX, PER DAY

B4220 - PARENTERAL NUTRITION SUPPLY KIT; PREMIX, PER DAY

B4222 - PARENTERAL NUTRITION SUPPLY KIT; HOME MIX, PER DAY

B4224 - PARENTERAL NUTRITION ADMINISTRATION KIT, PER DAY

B5000 - PARENTERAL NUTRITION SOLUTION COMPOUNDED AMINO ACID AND CARBOHYDRATES WITH ELECTROLYTES, TRACE ELEMENTS, AND VITAMINS, INCLUDING PREPARATION, ANY STRENGTH, RENALAMINOSYN- RF, NEPHRAMINE, RENAMINE-PREMIX

B5100 - PARENTERAL NUTRITION SOLUTION COMPOUNDED AMINO ACID AND CARBOHYDRATES WITH ELECTROLYTES, TRACE ELEMENTS, AND VITAMINS, INCLUDING PREPARATION, ANY STRENGTH, HEPATIC, HEPATAMINE-PREMIX

B5200 - PARENTERAL NUTRITION SOLUTION COMPOUNDED AMINO ACID AND CARBOHYDRATES WITH ELECTROLYTES, TRACE ELEMENTS, AND VITAMINS, INCLUDING PREPARATION, ANY STRENGTH, STRESS BRANCH CHAIN AMINO ACIDS-FREAMINE-HBC-PREMIX

NOTE: Special nutrient formulas, HCPCS codes B5000-B5200, are produced to meet unique nutrient needs for specific disease conditions. The beneficiary's medical record must adequately document the specific condition and the need for the special nutrient. This information shall be available upon request from Medicare.

Parenteral Nutrient Solutions

Components, Payments, and Units of Service

Payment for the nutrients is based on the reasonable charge for the solution components unless:

- The medical record, (including a signed statement from the attending physician), establishes that the beneficiary, (due to his/her physical or mental state);
    - Is unable to safely or effectively mix the solution, and
    - There is no family member or other person who can do so.
- *Payment will be on the basis of the reasonable charge for more expensive premixed solutions only under the latter circumstances.*

Parenteral Nutrition Solutions	HCPCS	Component	Components Separately Paid	Unit of Service
Home Mix				
	B4164 - 50% OR LESS	Carbohydrates - Dextrose	Yes	(500 ML = 1 UNIT)
	B4180 - GREATER THAN 50%	Carbohydrates - Dextrose	Yes	(500 ML = 1 UNIT)
	B4168 - 3.5%,	Amino Acid	Yes	(500 ML = 1 UNIT)
	B4178 - 7% THROUGH 8.5%	Amino Acid	Yes	(500 ML = 1 UNIT)
	B4216 -	Additives - (vitamins, trace	Yes	PER DAY

		elements, heparin, electrolytes)		
	B4185	Lipids	Yes	PER 10 GRAMS
Premix				
	(B4189-B4199, B5000-B5200)	Compounded Amino Acid and Carbohydrates with Electrolytes, Trace Elements, and Vitamins (includes preparation) – Lipids are added and billed separately		
	B4189 – Any strength	" (+) Protein	No	1 unit of service = 1 day's supply of protein and carbohydrate regardless of fluid volume and/or number of bags. 10 to 51 grams of Protein
	B4193 – Any strength	" (+) Protein	No	1 unit of service = 1 day's supply of protein and carbohydrate regardless of fluid volume and/or number of bags. 52 to 73 grams of Protein
	B4197 – Any strength	" (+) Protein	No	1 unit of service = 1 day's supply of protein and carbohydrate regardless of fluid volume and/or number of bags. 74 to 100 grams of Protein

	B4199	“ (+) Protein	No	1 unit of service = 1 day’s supply of protein and carbohydrate regardless of fluid volume and/or number of bags. Over 100 grams of Protein
	B5000 – Any strength	“ (+) Renalaminosyn-RF. Nephramine, Renamine-Premix	No	1 unit of service = 1 gram of amino acid
	B5100 – Any strength	“ (+) Hepatic, Hepatamine-Premix	No	1 unit of service = 1 gram of amino acid
	B5200 – Any strength	“ Stress Branch Chain Amino Acids-Freamine-HBC-Premix	No	1 unit of service = 1 gram of amino acid
	B9999	“ (+) Protein		<10 grams of protein/day

Access Pricing, Data Analysis and Coding (PDAC) Contractor website for guidance on correct coding of these items.
https://www.dmepdac.com/dmecsapp/do/productsearch;jsessionid=94B0B2C4F3884242AAB8453110AE3D6C

Appendix C

Parenteral Nutrition Infusion Pumps, Administration Kit, and IV Pole

Parenteral Nutrition Infusion Pumps (B9004-B9006)

Parenteral nutrition infusion pumps are covered for beneficiaries in whom parenteral nutrition is covered. Only one pump (stationary or portable) is covered at any one time. Additional pumps are to be denied as not reasonable and necessary.

Parenteral Nutrition Administration Kit (B4220-B4222)

If coverage requirements for parenteral nutrition is met, one supply kit (B4220 or B4222) and one administration kit is covered for each day parenteral nutrition is administered.

- [See question 5 of the Durable Medical Equipment (DME) Information Form (DIF) -- CMS-10126]
- https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/CMS10126.pdf

IV Pole

When an IV pole (E0776) is used in conjunction with parenteral nutrition administered by gravity or a pump, it is covered separately provided it is billed with the BA modifier.

Appendix D

DME INFORMATION FORM (DIF)

A DME Information Form (DIF) which has been completed, signed, and dated by the supplier, must be kept on file by the supplier and made available upon request.
The DIF for PARENTERAL NUTRITION is CMS Form 10126. The initial claim must include an electronic copy of the DIF.

A new Initial DIF is required when PARENTERAL NUTRITION services are resumed when they are not required for two consecutive months.

A revised DIF must be submitted if:

- Change in HCPCS code for the current nutrient provided
- Change (increase or decrease) in the calories prescribed
- Change in the method of administration from gravity to syringe or syringe to gravity (See above for gravity or syringe to pump)
- Change in the number of days per week of administration
- Change in route of administration from tube feedings to oral feedings (if billing for denial)
- When the length of need previously entered on the DIF has expired and the ordering physician is extending the length of need for the item(s).

(https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/CMS10126.pdf)