Parenteral Nutrition

*Adopted from National Government Services website*

For any item to be covered by The Health Plan, it must:

1. Be eligible for a defined Medicare or The Health Plan benefit category
2. Be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member
3. Meet all other applicable Medicare and/or The Health Plan statutory and regulatory requirements

For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity. *Please refer to individual product lines certificates of coverage for possible exclusions of benefit.*

For an item to be covered by The Health Plan, the supplier must receive a written, signed, and dated order before a claim is submitted to The Health Plan. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not covered.

Suppliers are to follow The Health Plan requirements for precertification as applicable.

Parenterals requires precertification.

<table>
<thead>
<tr>
<th>CMS National Coverage Policy</th>
<th>CMS Publication 100-3 Medicare National Coverage Determinations Manual, Chapter 1, Sections 180.2</th>
</tr>
</thead>
<tbody>
<tr>
<td>DME Region LCD Covers</td>
<td>Jurisdiction B-C</td>
</tr>
</tbody>
</table>
| Review/Revisions Effective Date | For services performed on or after 10/31/13  
Reviewed/Revised: 01/01/17, 06/01/16 |
| The Health Plan | Will follow Coverage Determination posted on the CGS website unless otherwise indicated in sections of this policy or contractual agreement |

DESCRIPTION

Parenteral nutrition is the provision of nutritional requirements intravenously, bypassing the usual process of eating and digestion. The person receives nutritional formulae that contain nutrients such as glucose, amino acids, lipids, added vitamins, and dietary minerals.

COVERAGE GUIDELINES

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.
Parenteral nutrition is covered when enteral nutrition is not indicated and/or feasible.

Parenteral nutrition is covered for a permanent, severe pathology of the alimentary tract, either by a condition of the small intestine and or its exocrine glands, or a disease of the stomach, which does not allow absorption or transportation of sufficient nutrients through the GI system to maintain weight and strength commensurate with the patient’s general condition. This information must be submitted with precertification.

Permanence does not require a determination that there is no possibility that the condition may improve sometime in the future. If the treating physician determines that the condition is of long and indefinite duration (ordinarily at least three months), the test of permanence is met. The medical record must support it.

INTRADIALYTIC PARENTERAL NUTRITION COVERAGE GUIDELINES

I. Parenteral nutrition is covered for the maintenance of weight and strength where intravenous nutrition is required and is not possible utilizing any 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. Pharmacologic means to treat the cause of the malabsorption (e.g., pancreatic enzymes, bile salts, broad-spectrum antibiotics for bacterial overgrowth, prokinetic medication for reduced motility, etc.), and must have both of the following,
   3. The patient is malnourished (10 percent weight loss over three months or less and serum albumin less than or equal to 3.4 gm/dl), and
   4. 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).

II. Parenteral nutrition is also covered in any of the following situations:
   A. There is has been a massive small bowel resection within the past three months, leaving less than or equal to five feet of small bowel beyond the ligament of treitz, or
   B. There is a diagnosis of short bowel syndrome severe enough that the net gastrointestinal fluid and electrolyte malabsorption is such that on an oral intake of 2.5 - 3 liters/day, the enteral losses exceed 50 percent of the oral/enteral intake and the urine output is less than 1 liter/day, or
   C. There is a requirement for bowel rest for at least three months and the member is receiving 20 - 35 cal/kg/day intravenously 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. There is a diagnosis of a complete mechanical small bowel obstruction where surgery is not an option, or
   E. There is documentation of significant malnourishment (10 percent weight loss over three 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 percent 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. There is evidence of significant malnourishment (10 percent weight loss over three months or less and serum albumin less than or equal to 3.4 gm/dl). There is documentation of a severe motility disturbance of the small intestine and/or stomach which is unresponsive to prokinetic medication, demonstrated by
   a. Scintigraphically (solid meal gastric emptying study demonstrates that the isotope fails to reach the right colon by six hours following ingestion), or
   b. Radiographically (barium or radiopaque pellets fail to reach the right colon by six hours following administration). These studies must be performed in a stable state and the member must not be taking medication that would decrease bowel motility.

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

NOTE: Parenteral intake may be covered for members with the ability to obtain partial nutrition from oral intake or a combination of oral/enteral or oral/enteral/parenteral, if criteria for I or II above is met.

NOTE: Parenteral nutrition solutions containing little or no amino acids and/or carbohydrates would be covered only in situations A, B, or D.

NOTE: The following are examples of conditions, which would require a failed trial of tube enteral nutrition before parenteral nutrition would be authorized:
   • Moderate fat malabsorption - fecal fat exceeds 25 percent 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 three to six hours, or (b) 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 three and six hours.
   • Small bowel resection leaving greater than 5 ft. 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.

The ordering physician should see the member within 30 days prior to the initial request to assess the medical necessity for parenteral nutrition. The physician is expected to periodically monitor the member to assess the response to the therapy. If the physician does not see the member within this timeframe, he/she must document the reason why and describe what other monitoring methods were used to evaluate the parenteral nutrition needs.

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. This information must be submitted with precertification.
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 percent, or lipid use greater than 1500 grams (150 units of service of code B4185) per month.

Special parenteral formulas (B5000 - B5200) must be justified in each member.

**COVERAGE GUIDELINES FOR EQUIPMENT AND SUPPLIES**

Infusion pumps (B9004 - B9006) are covered if parenteral nutrition is covered. Only one pump (stationary or portable) is covered at any one time. Additional pumps will not be authorized.

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, as the pump and pole are considered equipment used for multiple patients.

One supply kit (B4220 or B4222) and one administration kit will be covered for each day that parenteral nutrition is administered, when kit is considered medically necessary.

**NONCOVERAGE STATEMENT**

Parenteral nutrition is not covered in situations involving temporary impairments.

Parenteral nutrition is not covered when there is a functioning gastrointestinal tract and the need for parenteral nutrition is only due to:

a. A swallowing disorder,
b. A temporary defect in gastric emptying such as a metabolic or electrolyte disorder,
c. A psychological disorder impairing food intake such as depression,
d. A metabolic disorder inducing anorexia such as cancer,
e. A physical disorder impairing food intake such as the dyspnea of severe pulmonary or cardiac disease,
f. A side effect of a medication,
g. Renal failure and/or dialysis

**CODING INFORMATION**

CPT/HCPCS codes: The appearance of a code in this section does not necessarily indicate coverage.

**HCPCS MODIFIERS**

<table>
<thead>
<tr>
<th>BA</th>
<th>Item used in conjunction with parenteral enteral nutrition (PEN) services</th>
</tr>
</thead>
<tbody>
<tr>
<td>EY</td>
<td>NO PHYSICIAN OR OTHER LICENSED HEALTH CARE PROVIDER ORDER FOR THIS ITEM OR SERVICE</td>
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</table>

**HCPCS CODES**

<p>| B4164 | PARENTERAL NUTRITION SOLUTION: CARBOHYDRATES (DEXTROSE), 50% OR LESS (500 ML = 1 UNIT) - HOMEMIX |</p>
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>B4168</td>
<td>PARENTERAL NUTRITION SOLUTION; AMINO ACID, 3.5%, (500 ML = 1 UNIT) - HOMEMIX</td>
</tr>
<tr>
<td>B4172</td>
<td>PARENTERAL NUTRITION SOLUTION; AMINO ACID, 5.5% THROUGH 7%, (500 ML = 1 UNIT) - HOMEMIX</td>
</tr>
<tr>
<td>B4176</td>
<td>PARENTERAL NUTRITION SOLUTION; AMINO ACID, 7% THROUGH 8.5%, (500 ML = 1 UNIT) - HOMEMIX</td>
</tr>
<tr>
<td>B4178</td>
<td>PARENTERAL NUTRITION SOLUTION: AMINO ACID, GREATER THAN 8.5% (500 ML = 1 UNIT) - HOMEMIX</td>
</tr>
<tr>
<td>B4180</td>
<td>PARENTERAL NUTRITION SOLUTION; CARBOHYDRATES (DEXTROSE), GREATER THAN 50% (500 ML = 1 UNIT) - HOMEMIX</td>
</tr>
<tr>
<td>B4185</td>
<td>PARENTERAL NUTRITION SOLUTION, PER 10 GRAMS LIPIDS</td>
</tr>
<tr>
<td>B4189</td>
<td>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</td>
</tr>
<tr>
<td>B4193</td>
<td>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</td>
</tr>
<tr>
<td>B4197</td>
<td>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</td>
</tr>
<tr>
<td>B4199</td>
<td>PARENTERAL NUTRITION SOLUTION; COMPOUNDED AMINO ACID AND CARBOHYDRATES WITH ELECTROLYTES, TRACE ELEMENTS AND VITAMINS, INCLUDING PREPARATION, ANY STRENGTH, OVER 100 GRAMS OF PROTEIN – PREMIX</td>
</tr>
<tr>
<td>B4216</td>
<td>PARENTERAL NUTRITION; ADDITIVES (VITAMINS, TRACE ELEMENTS, HEPARIN, ELECTROLYTES) HOMEMIX PER DAY</td>
</tr>
<tr>
<td>B4220</td>
<td>PARENTERAL NUTRITION SUPPLY KIT; PREMIX, PER DAY</td>
</tr>
<tr>
<td>B4222</td>
<td>PARENTERAL NUTRITION SUPPLY KIT; HOME MIX, PER DAY</td>
</tr>
<tr>
<td>B4224</td>
<td>PARENTERAL NUTRITION ADMINISTRATION KIT, PER DAY</td>
</tr>
<tr>
<td>B5000</td>
<td>PARENTERAL NUTRITION SOLUTION: COMPOUNDED AMINO ACID AND CARBOHYDRATES WITH ELECTROLYTES, TRACE ELEMENTS, AND VITAMINS, INCLUDING PREPARATION, ANY STRENGTH, RENAL - AMINOSYN RF, NEPHRAMINE, RENAMINE – PREMIX</td>
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</tbody>
</table>
PARENTERAL NUTRITION

There are no specific diagnoses or ICD-10 codes that indicate medical necessity.

DOCUMENTATION REQUIREMENTS

For the purposes of this policy, it is expected that the medical record will support the need for the care provided. It is generally understood that the medical record includes the physician’s office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports.

This documentation must be available with precertification.

Medicare has made changes to its requirements for dispensing orders, detailed written orders, and proof of delivery. The Health Plan will require the following:

1. Physician detailed written order. Order must include the following:
   a. Member’s name
   b. Date
   c. Description of item. The medical record must contain the information that supports the request for each item, and must be submitted with the precertification, if the item requires precertification, or with the claim, if no precertification was required.

   Documentation for coverage for intradialytic parenteral nutrition (IDPN), must show that there is a permanently impaired gastrointestinal tract and that there is insufficient absorption of nutrients to maintain adequate strength and weight. Records should document that oral or enteral feedings cannot maintain nutritional status due to a severe pathology of the alimentary tract. Parenteral 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 evident in any documentation submitted.

   Types of testing to be submitted based on diagnosis:
1. Copies of the operative report and/or hospital discharge summary and/or X-ray reports.
2. Dates and results of fecal tests.
3. Small bowel motility study and a list of medications that the patient was on at the time of the test.
4. Results of serum albumin and date of test (within one week prior to initiation of parenteral nutrition.
5. Current weight with date and weight one to three month prior to initiation.
6. Estimated daily calorie intake during the prior month and by what route (e.g., oral, tube).
7. Statement of whether there were caloric losses from vomiting or diarrhea and whether these estimated losses are reflected in the calorie count.
8. Description of any dietary modifications made or supplements tried during the prior month (e.g., low fat, extra medium chain triglycerides, etc.).
9. The specific etiology for the gastroparesis, small bowel dysmotility, or malabsorption.
10. The information regarding the trial on tube enterals must include the beginning and ending dates of the trial, the length of time that the tube was in place, the type and size of tube, the placement of the tube, the name of the enteral nutrient, the quantity, concentration, and rate of administration, and the results.
11. Prokinetic medications used, dosage, and dates of use.
12. Nondietary treatment given during prior month directed at etiology of malabsorption (e.g., antibiotic for bacterial overgrowth).
13. 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.)

d. Order must include diagnosis code

e. Physician signature with date. Date stamps are not appropriate

f. Quantity of items required and duration. A new order is required if there is an increase in the quantity of the supply used per month and/or the type of supply used

The supplier is to contact The Health Plan in this instance to update referral

2. There must be documentation in the supplier’s records to support the medical necessity of that item. This information must be available upon request usually with precertification per The Health Plan policy.

3. Proof of delivery to be kept on file by the provider of the item.

Note: If templates or forms are submitted, (i.e., a Medicare Certificate of Medical Necessity, and/or a provider created form), and all of the required information is not included, The Health Plan reserves the right to request the medical record, that may include, but not limited to, the physician office notes, hospital and nursing facility records, and home health records.
Note: Template provider forms, prescriptions, and attestation letters are not considered part of the medical record, even if signed by the ordering physician.

An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request. Items billed before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.

Information can be submitted in the form of a DIF, however The Health Plan reserves the right to request clinical documentation directly from the medical record. The DIF for Parenteral Nutrition is CMS form 10126.

The provider will need to notify The Health Plan for a new referral or update a current referral when:

1. Nutrients billed with a different code are ordered.
2. Resumption of parental services due to a break in service.

Coverage of Parenteral Nutrition During Facility Stay

Parenteral nutrition provided to a patient in an acute hospital is included in the facility fee. Parenteral treatment provided to a member while in a skilled nursing facility (SNF) will be based on the SNF contract.

Billing Guidelines

For prospective claims, no more than one month’s supply of parenteral nutrients, equipment or supplies are allowed. Claims submitted retroactively, however, may include multiple months.

Some infusion provider contracts may allow S code per diem’s versus B or E codes for supplies. That is dependent on the entity and the particular provider contract. Providers who are primarily DME suppliers should use the appropriate B and E codes.

When homemix parenteral nutrition solutions are used, the component carbohydrates (B4164, B4180), amino acids (B4168 - B4178), additives (B4216), and lipids (B4185) are all separately billable. When premix parenteral nutrition solutions are used (B4189 - B4199, B5000 - B5200) there must be no separate billing for the carbohydrates, amino acids, or additives (vitamins, trace elements, heparin, electrolytes). However, lipids (B4185) are separately billable with premix solutions.

For lipids, one unit of service of code B4185 is billed for each 10 grams of lipids provided. 500 ml of 10 percent lipids contains 50 grams of lipids (five units of service); 500 ml of 20 percent lipids contains 100 grams (10 units of service); 500 ml of 30 percent lipids contains 150 grams (15 units of service).

When an IV pole (E0776) is used in conjunction with parenteral nutrition, the BA modifier should be added to the code. Code E0776 is the only code with which the BA modifier may be used.

For codes B4189 - B4199, one unit of service represents one day’s supply of protein and carbohydrate regardless of the fluid volume and/or the number of bags. For example, if 60 grams of protein are administered per day in two bags of a premix solution each containing 30 grams of amino acids, correct coding is one unit of B4193, not two units of B4189.
For codes B5000 - B5200, one unit of service is one gram of amino acid.

Parenteral nutrition solutions containing less than 10 grams of protein per day are coded using the miscellaneous code B9999.

**DISPENSING SUPPLIES**

**The Health Plan is following Medicare’s guidelines for supplies provided on a reoccurring basis.**

Suppliers are not to automatically dispense supplies according to allowable limits. Suppliers are required to reorder supplies based on actual usage of each member. There must be a specific request for the supplies from the member or caregiver prior to dispensing the supplies. Supplies should not be shipped/delivered sooner than 10 days prior to end of usage.

The DME supplier is responsible to monitor utilization of rented and covered frequently purchase supplies for member owned equipment that they would be requesting reimbursement from The Health Plan.

Precertification is required for requests above the allowable amounts.

**ADVANCED BENEFICIARY NOTICE**

The Health Plan expects providers to follow the Medicare policy on ABN across all Medicare, Medicaid, and Commercial plans.

**NOTE:** Providers may be held financially responsible if they furnish the above items without notifying the member, verbally and in writing, that the specific service being provided is not covered. This must be done prior to the dispensing of the device. The provider must submit the waiver or ABN to The Health Plan with the claim showing the member agreed to pay for the device. Generalized statements on waivers or ABN are not acceptable.

**PRICING, DATA ANALYSIS, AND CODING (PDAC)**

The Health Plan has implemented use of Medicare’s PDAC contractor for review of authorizations. Please refer to PDAC website for the appropriate product classification list. [dmepdac.com](http://dmepdac.com/)

**MISCELLANEOUS**

Some infusion provider contracts may allow S code perdiem’s versus B codes for supplies. That is dependent on entity and particular provider contract. Providers who are primarily DME suppliers should use the appropriate B codes.

**MEDICARE DEFINITIONS AND DESCRIPTION**

**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 (five to six 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 one to two 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 three to four 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).

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INTERNET LINKS AND SOURCES


National Government Services training website. Last accessed. Retrieved from NGSMedicare.com website, then select Suggested Additional Documentation for a Total Parenteral Nutrition Claim

CMS Program Integrity Manual for More Information. (CMS Program Integrity Manual, Internet-Only Manual, CMS Pub. 100-8, Chapter 5, Section 5.2.6)