Enteral and Parenteral Nutritional Therapy (NCD 180.2)

Guideline Number: MPG099.09
Approval Date: September 8, 2021

Policy Summary

Overview

There are patients who, because of chronic illness or trauma, cannot be sustained through oral feeding. These people must rely on either enteral or parenteral nutritional therapy, depending upon the particular nature of their medical condition.

Guidelines

Medicare Coverage of nutritional therapy is provided under the prosthetic device benefit provision which requires that the patient must have a permanently inoperative internal body organ or function thereof. Therefore, enteral and parenteral nutritional therapy are normally not covered in situations involving temporary impairments.

Coverage of such therapy, however, does not require a medical judgment that the impairment giving rise to the therapy will persist throughout the patient’s remaining years. If the medical record, including the judgment of the attending physician, indicates that the impairment will be of long and indefinite duration, the test of permanence is considered met.

If the coverage requirements for enteral or parenteral nutritional therapy are met under the prosthetic device benefit provision, related supplies, equipment and nutrients are also covered under the conditions in the following paragraphs and the Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” §120.

Enteral Nutrition Therapy

Enteral nutrition is considered reasonable and necessary for a patient with a functioning gastrointestinal tract who, due to pathology to, or non-function of, the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition. Enteral therapy may be given by nasogastric, jejunostomy, or gastrostomy tubes and can be provided safely and effectively in the home by nonprofessional persons who have undergone
special training. However, such persons cannot be paid for their services, nor is payment available for any services furnished by non-physician professionals except as services furnished incident to a physician's service.

Enteral nutrition is covered for a beneficiary who requires feedings via an enteral access device to provide sufficient nutrients to maintain weight and strength commensurate with the beneficiary's overall health status and has a permanent:
- Full or partial non-function or disease of the structures that normally permit food to reach the small bowel; or,
- Disease that impairs digestion and/or absorption of an oral diet, directly or indirectly, by the small bowel.

Adequate nutrition must not be possible by dietary adjustment and/or oral supplements.

Typical examples of conditions that qualify for coverage are head and neck cancer with reconstructive surgery and central nervous system disease leading to interference with the neuromuscular mechanisms of ingestion of such severity that the beneficiary cannot be maintained with oral feeding. Each claim must contain a physician’s written order or prescription and sufficient medical documentation (e.g., hospital records, clinical findings from the attending physician) to permit an independent conclusion that the patient’s condition meets the requirements of the prosthetic device benefit and that enteral nutrition therapy is medically necessary.

Typical examples of conditions associated with impaired digestion and/or absorption of an oral diet by the small bowel that may qualify for coverage include inflammatory bowel disease, surgical resection of small bowel, cystic fibrosis, chronic pancreatitis, and advanced liver disease (not all inclusive).

Enteral nutrition for temporary impairments will be denied as non-covered, no benefit.

Enteral nutrition for beneficiaries with a functioning gastrointestinal tract whose need for enteral nutrition is not due to reasons related to the non-function or disease of the structures that normally permit food to reach the small bowel will be denied as non-covered, no benefit.

Orally administered enteral nutrition products, related supplies and equipment will be denied non-covered, no benefit.

Medicare pays for no more than one month’s supply of enteral nutrients at any one time. If the claim involves a pump, it must be supported by sufficient medical documentation to establish that the pump is medically necessary, i.e., gravity feeding is not satisfactory due to aspiration, diarrhea, dumping syndrome. Program payment for the pump is based on the reasonable charge for the simplest model that meets the medical needs of the patient as established by medical documentation.

Nutritional supplements are often given as a medicine between meals to boost protein-caloric intake or the mainstay of a daily nutritional plan. Nutritional supplementation is not covered under Medicare Part B.

**Enteral Nutrition Nutrients**

Enteral formulas consisting of semi-synthetic intact protein/protein isolates (B4150 or B4152) are appropriate for the majority of beneficiaries requiring enteral nutrition.

Special nutrient formulas, HCPCS codes B4149, B4153, B4154, B4155, B4157, B4161, and B4162, are produced to meet unique nutrient needs for specific disease conditions. If a special nutrient formula is ordered, the beneficiary’s medical records must specify why a standard formula cannot be used to meet the beneficiary’s metabolic needs. This documentation may include other formulas tried and failed or considered and ruled out. A diagnosis alone is not sufficient to support the medical need for a specialty formula. For example, an order for a diabetes-specific formula may be supported by documentation in the medical record that the beneficiary has a diagnosis of diabetes mellitus and has experienced severe fluctuations of glucose levels on standard formula. 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.
Electrolyte-containing fluids (B4102 and B4103) are not indicated for the maintenance of weight and strength and are therefore non-covered, no benefit.

Self-blenderized formulas are non-covered by Medicare.

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.

**Enteral Supplies**

Enteral nutrition may be administered by syringe, gravity, or pump. Some enteral beneficiaries may experience complications associated with syringe or gravity method of administration. If a pump (B9002) is ordered, there must be documentation in the beneficiary'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.

If a pump supply allowance (B4035) is provided and if the medical necessity of the pump is not documented, it will be denied as not reasonable and necessary.

The unit of service (UOS) for the supply allowance (B4034, B4035, or B4036) is one (1) UOS per day.

In-line digestive enzyme cartridges (B4105) are reasonable and necessary for beneficiaries who:

- Meet the coverage criteria for enteral nutrition; and,
- Have a diagnosis of Exocrine Pancreatic Insufficiency (EPI)

More than two in-line digestive enzyme cartridges (B4105) per day will be denied as not reasonable and necessary.

The codes for feeding supply allowances (B4034, B4035, and 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. Enteral feeding supply kit allowances (B4034, B4035, and B4036), are all-inclusive, with the exception of B4105 in-line digestive enzyme cartridge. 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, B4082, and B4083), or one gastrostomy/jejunostomy tube (B4087 or B4088) every three months is not reasonable and necessary.

**Enteral Nutrition Coding Guidelines**

If two enteral nutrition products, which are described by the same HCPCS code, are being provided at the same time, they should be billed on a single claim line, with the units of service reflecting the total calories of both nutrients.

Enteral feeding supply allowances (B4034, B4035, and B4036) include all supplies, other than the feeding tube and nutrients, required for the administration of enteral nutrients to the beneficiary for one day. Only one unit of service may be billed for any one day. Codes B4034, B4035, and B4036 describe a daily supply fee rather than a specifically defined “kit.” The use of individual items may differ from beneficiary to beneficiary, and from day to day. Items included in these codes are not limited to pre-packaged “kits” bundled by manufacturers or distributors. These supply allowances include, but are not limited to, a catheter/tube anchoring device, feeding bag/container, flushing solution bag/container, administration set tubing, extension tubing, feeding/flushing syringes, gastrostomy tube holder, dressings (any type) used for gastrostomy tube site, tape (to secure tube or dressings), Y connector, adapter, gastric pressure relief valve, declogging device. These items must not be separately billed using the miscellaneous code (B9998), or using a specific code for any individual item, should a unique HCPCS code for the item exist. Supply allowance HCPCS codes (B4034, B4035, and B4036) are daily allowances which are considered all-inclusive and therefore refill requirements are not applicable to these HCPCS codes.

When an IV pole (E0776) is used for enteral nutrition administered by gravity or a pump, the BA modifier should be added to the code. Code E0776 is the only code with which the BA modifier may be used.
When enteral nutrients (B4149, B4150, B4152, B4153, B4154, B4155, B4157, B4158, B4159, B4160, B4161, and B4162) are administered by mouth, the BO modifier must be added to the code. Products that are only administered orally should be coded as A9270.

Code B4149 describes formulas containing natural foods that are blenderized and packaged by a manufacturer. B4149 formulas are classified based upon this manufacturer requirement, not on the composition of the enteral formula. Code B4149 must not be used for foods that have been blenderized by the beneficiary or caregiver for administration through a tube.

**Parenteral Nutrition Therapy**

Parenteral Nutrition Therapy Daily is considered reasonable and necessary for a patient with 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. Since the alimentary tract of such a patient does not function adequately, an indwelling catheter is placed percutaneously in the subclavian vein and then advanced into the superior vena cava where intravenous infusion of nutrients is given for part of the day. The catheter is then plugged by the patient until the next infusion. Following a period of hospitalization, which is required to initiate parenteral nutrition and to train the patient in catheter care, solution preparation, and infusion technique, the parenteral nutrition can be provided safely and effectively in the patient’s home by nonprofessional persons who have undergone special training. However, such persons cannot be paid for their services, nor is payment available for any services furnished by non-physician professionals except as services furnished incident to a physician’s service.

For parenteral nutrition therapy to be covered, the claim must contain a physician’s written order or prescription and sufficient medical documentation to permit an independent conclusion that the requirements of the prosthetic device benefit are met and that parenteral nutrition therapy is medically necessary. An example of a condition that typically qualifies for coverage is a massive small bowel resection resulting in severe nutritional deficiency in spite of adequate oral intake. If the claim involves an infusion pump, sufficient evidence must be provided to support a determination of medical necessity for the pump. Program payment for the pump is based on the reasonable charge for the simplest model that meets the medical needs of the patient as established by medical documentation.

When nutritional support other than the oral route is necessary, Enteral nutrition (EN) is usually initially preferable to parenteral nutrition for the following reasons:

- In a fluid restricted beneficiary, EN permits delivery of all necessary nutrients in a more concentrated volume than parenteral nutrition;
- EN allows for safer home delivery of nutrients; and
- EN lowers the risk of Central Line-Associated Bloodstream Infections (CLABSI).

For parenteral nutrition to be considered reasonable and necessary, the treating practitioner must document that enteral nutrition has been considered and ruled out, tried and been found ineffective, or that EN exacerbates gastrointestinal tract dysfunction. The beneficiary 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 and absorbed by the gastrointestinal (GI) system.

The treating practitioner is required to evaluate the beneficiary within 30 days prior to initiation of parenteral nutrition. If the treating practitioner does not see the beneficiary within this timeframe, they must document the reason why and describe what other monitoring methods were used to evaluate the beneficiary’s parenteral nutrition needs. There must be documentation in the medical record supporting the clinical diagnosis.

Suppliers are required to monitor the beneficiary’s medical condition to confirm that the coverage criteria for parenteral nutrition continue to be met.

**Parenteral Nutrition Nutrients**

Nutrient solutions for parenteral therapy are routinely covered. However, Medicare pays for no more than one month’s supply of nutrients at any one time. 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.

A total caloric daily intake of 20-35 cal/kg/day is considered reasonable and necessary to achieve or maintain appropriate body weight. The treating practitioner must document the medical necessity for a caloric intake outside this range in an individual beneficiary.

The treating practitioner must document the medical necessity for protein orders outside of the range of 0.8-2.0 gm/kg/day (B4168, B4172, B4176, B4178), dextrose concentration less than 10% (B4164, B4180), or lipid use per month in excess of the product-specific, FDA-approved dosing recommendations (B4185, B4187).

Special nutrient formulas, HCPCS codes B5000, B5100, and B5200 are produced to meet the unique nutrient needs for specific disease conditions. The beneficiary's medical record must adequately document the specific condition and the necessity for the special nutrient.

**Parenteral Nutrition Equipment and Supplies**

Only one infusion pump is covered for beneficiaries in whom parenteral nutrition is required.

Additionally, only one supply kit and one administration kit is covered for each day that parenteral nutrition is administered.

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 Coding Guidelines**

When home mix parenteral nutrition solutions are used, the component carbohydrates (B4164, B4180), amino acids (B4168, B4172, B4176, B4178), additives (B4216), and lipids (B4185 or B4187) are all separately billable. When premix parenteral nutrition solutions are used (B4189, B4193, B4197, B4199, B5000, B5100, B5200) there must be no separate billing for the carbohydrates, amino acids or additives (vitamins, trace elements, heparin, electrolytes). However, lipids (B4185 or B4187) are separately billable with premix solutions.

For lipids, one unit of service of code B4185 or B4187 is billed for each 10 grams of lipids provided. 500 ml of 10% lipids contains 50 grams of lipids (5 units of service); 500 ml of 20% lipids contains 100 grams (10 units of service); 500 ml of 30% 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, B4193, B4197, 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 (1) unit of B4193, not two units of B4189.

For codes B5000, B5100, B5200, one unit of service is one gram of amino acid.

Parenteral nutrition supply allowances (HCPCS codes B4220, B4222 and B4224) describe a daily supply fee rather than a specifically defined “kit” and include all supplies required for the administration of parenteral nutrition to the beneficiary for one day. The use of individual items may differ from beneficiary to beneficiary, and from day to day. Daily allowances are considered all-inclusive and therefore refill requirements are not applicable to HCPCS codes B4220, B4222 and B4224. Only one unit of service may be billed for any one day.
**Enteral and Parenteral Nutrition Refill Requirements**

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized.

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the treating practitioner that any changed or atypical utilization is warranted.

Regardless of utilization, a supplier must not dispense more than a 1-month quantity at a time.

**Documentation Requirements – General**

There are numerous CMS manual requirements, reasonable and necessary requirements, benefit category, and other statutory and regulatory requirements that must be met in order for payment to be justified. In the event of a claim review, a DMEPOS supplier must provide sufficient information to demonstrate that the applicable criteria have been met thus justifying payment. Refer to the LCD, NCD or other CMS Manuals for more information on what documents may be required.

See Article A55426 Standard Documentation Requirements for All Claims Submitted to DME MACs.

**Applicable Codes**

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>Enteral Nutrition</td>
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<tr>
<td>A5200</td>
<td>Percutaneous catheter/tube anchoring device, adhesive skin attachment (Deleted 09/05/2021)</td>
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<tr>
<td>A9270</td>
<td>Noncovered item or service</td>
</tr>
<tr>
<td>B4034</td>
<td>Enteral feeding supply kit; syringe fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape</td>
</tr>
<tr>
<td>B4035</td>
<td>Enteral feeding supply kit; pump fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape</td>
</tr>
<tr>
<td>B4036</td>
<td>Enteral feeding supply kit; gravity fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape</td>
</tr>
<tr>
<td>B4081</td>
<td>Nasogastric tubing with stylet</td>
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<tr>
<td>B4082</td>
<td>Nasogastric tubing without stylet</td>
</tr>
<tr>
<td>B4083</td>
<td>Stomach tube-Levine type</td>
</tr>
<tr>
<td>B4087</td>
<td>Gastrostomy/jejunostomy tube, standard, any material, any type, each</td>
</tr>
<tr>
<td>B4088</td>
<td>Gastrostomy/jejunostomy tube, low-profile, any material, any type, each</td>
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<tr>
<td>HCPCS Code</td>
<td>Description</td>
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<tr>
<td>B4100</td>
<td>Food Thickener, Administered Orally, Per Ounce (Non-Covered)</td>
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<tr>
<td>B4102</td>
<td>Enteral Formula, For Adults, Used to Replace Fluids and Electrolytes (e.g., clear liquids), 500 ML = 1 Unit (Non-Covered)</td>
</tr>
<tr>
<td>B4103</td>
<td>Enteral Formula, For Pediatrics, Used to Replace Fluids and Electrolytes (e.g., clear liquids), 500 ML = 1 Unit (Non-Covered)</td>
</tr>
<tr>
<td>B4104</td>
<td>Additive for Enteral Formula (e.g., fiber) (Not separately payable)</td>
</tr>
<tr>
<td>B4105</td>
<td>In-line cartridge containing digestive enzyme(s) for enteral feeding, each</td>
</tr>
<tr>
<td>B4149</td>
<td>Enteral formula, manufactured blended natural foods with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4150</td>
<td>Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4152</td>
<td>Enteral formula, nutritionally complete, calorically dense (equal to or greater than 1.5 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4153</td>
<td>Enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4154</td>
<td>Enteral formula, nutritionally complete, for special metabolic needs, excludes inherited Disease of metabolism, includes altered composition of proteins, fats, carbohydrates, vitamins and/or minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4155</td>
<td>Enteral formula, nutritionally incomplete/modular nutrients, includes specific nutrients, carbohydrates (e.g., glucose polymers), proteins/amino acids (e.g., glutamine, arginine), fat (e.g., medium chain triglycerides) or combination, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4157</td>
<td>Enteral formula, nutritionally complete, for special metabolic needs for inherited Disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4158</td>
<td>Enteral formula, for pediatrics, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4159</td>
<td>Enteral formula, for pediatrics, nutritionally complete soy based with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4160</td>
<td>Enteral formula, for pediatrics, nutritionally complete calorically dense (equal to or greater than 0.7 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4161</td>
<td>Enteral formula, for pediatrics, hydrolyzed/amino acids and peptide chain proteins, includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4162</td>
<td>Enteral formula, for pediatrics, special metabolic needs for inherited Disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B9002</td>
<td>Enteral nutrition infusion pump, any type</td>
</tr>
<tr>
<td>B9998</td>
<td>NOC for enteral supplies</td>
</tr>
<tr>
<td>E0776</td>
<td>IV pole (BA modifier required)</td>
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<tr>
<td>HCPCS Code</td>
<td>Description</td>
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<tr>
<td>Parenteral Nutrition</td>
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<tr>
<td>B4164</td>
<td>Parenteral nutrition solution; carbohydrates (dextrose), 50% or less (500 ml = 1 unit)-home mix</td>
</tr>
<tr>
<td>B4168</td>
<td>Parenteral nutrition solution; amino acid, 3.5%, (500 ml = 1 unit)-home mix</td>
</tr>
<tr>
<td>B4172</td>
<td>Parenteral nutrition solution; amino acid, 5.5% through 7%, (500 ml = 1 unit)-home mix</td>
</tr>
<tr>
<td>B4176</td>
<td>Parenteral nutrition solution; amino acid, 7% through 8.5%, (500 ml = 1 unit)-home mix</td>
</tr>
<tr>
<td>B4178</td>
<td>Parenteral nutrition solution; amino acid, greater than 8.5% (500 ml = 1 unit)-home mix</td>
</tr>
<tr>
<td>B4180</td>
<td>Parenteral nutrition solution; carbohydrates (dextrose), greater than 50% (500 ml = 1 unit)-home mix</td>
</tr>
<tr>
<td>B4185</td>
<td>Parenteral nutrition solution, not otherwise specified, 10 grams lipids</td>
</tr>
<tr>
<td>B4187</td>
<td>Omegaven, 10 grams lipids (Effective 01/01/2020)</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)-home mix, per day</td>
</tr>
<tr>
<td>B4220</td>
<td>Parenteral nutrition supply kit; premix, per day</td>
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<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-Amirolsyn RF, NephrAmine, RenAmine-premix</td>
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<tr>
<td>B5100</td>
<td>Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, hepatic-HepatAmine-premix</td>
</tr>
<tr>
<td>B5200</td>
<td>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</td>
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<tr>
<td>B9004</td>
<td>Parenteral nutrition infusion pump, portable</td>
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<tr>
<td>B9006</td>
<td>Parenteral nutrition infusion pump, stationary</td>
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<tr>
<td>B9999</td>
<td>NOC for parenteral supplies</td>
</tr>
<tr>
<td>E0776</td>
<td>IV pole (BA modifier required)</td>
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<table>
<thead>
<tr>
<th>Modifier</th>
<th>Description</th>
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<tbody>
<tr>
<td>BA</td>
<td>Item furnished in conjunction with parenteral enteral nutrition (PEN) services</td>
</tr>
<tr>
<td>BO</td>
<td>Orally Administered nutrition, not by feeding tube</td>
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</table>

References

**CMS National Coverage Determination (NCD)**

**NCD 180.2 Enteral and Parenteral Nutritional Therapy**
### CMS Local Coverage Determinations (LCDs) and Articles

<table>
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<tr>
<th>LCD</th>
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<tr>
<td>L38955 Enteral Nutrition</td>
<td>A58833 Enteral Nutrition-Policy Article</td>
<td>CGS</td>
<td>AL, AR, CO, FL, GA, IL, IN, KY, LA, MI, MN, MS, NC, NM, OH, OK, PR, SC, TN, TX, VA, VI, WI, WV</td>
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<td>L38953 Parenteral Nutrition</td>
<td>A58836 Parenteral Nutrition</td>
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<td>L33783 Enteral Nutrition Retired 11/12/2020</td>
<td>A52493 Enteral Nutrition-Policy Article Retired 11/12/2020</td>
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<td>L33798 Parenteral Nutrition Retired 11/12/2020</td>
<td>A52515 Parenteral Nutrition-Policy Article Retired 11/12/2020</td>
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<td>N/A</td>
<td>A55426 Standard Documentation Requirements for All Claims Submitted to DME MACs</td>
<td>CGS</td>
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</table>

### CMS Benefit Policy Manual

- Chapter 15: § 110 Durable Medical Equipment, § 120 Prosthetic Devices
- Chapter 23; § 70-70.1 Parenteral and Enteral Nutrition (PEN) Fee Schedule

### CMS Claims Processing Manual

- Chapter 8; § 60.5 Intradialytic Parenteral/Enteral Nutrition (IDPN)
- Chapter 20; § 30.7-30.7.2 Payment for Parenteral and Enteral Nutrition (PEN) Items and Services, § 40.3 Maintenance and Service of PEN Pumps, § 50.3 Payment for Replacement of Parenteral and Enteral Pumps, § 100.2.2-100.2.2.3 Evidence of Medical Necessity for Parenteral and Enteral Nutrition (PEN) Therapy, § 160-160.2 Billing for Total Parenteral Nutrition and Enteral Nutrition
CMS Transmittals
Transmittal 4478, Change Request 11554, Dated 12/20/2019 (Where to Bill Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Parenteral and Enteral Nutrition (PEN) Items and Services)

MLN Matters
Article MM11554, Manual Update to Publication (Pub.) 100-04, Chapter 20, to Revise the Section 10-Where to Bill Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Parenteral and Enteral Nutrition (PEN) Items and Services

UnitedHealthcare Commercial Policy
Omnibus Codes

Other(s)
Enteral Nutrition - Correct Coding and Billing; Joint DME MAC Article, Posted October 8, 2020 effective for claims with dates of service on or after November 12, 2020, Noridian DME Website
Enteral Nutrition - Correct Coding and Billing; Joint DME MAC Article, Posted October 12, 2020 effective for claims with dates of service on or after November 12, 2020, CGS DME Website
Parenteral Nutrition Calculator; Noridian DME Website
Parenteral Nutrition - Correct Coding and Billing; Joint DME MAC Article, Posted October 8, 2020 effective for claims with dates of service on or after November 12, 2020, Noridian DME Website
Parenteral Nutrition - Correct Coding and Billing; Joint DME MAC Article, Posted October 12, 2020 effective for claims with dates of service on or after November 12, 2020, CGS DME Website
Retirement of Enteral Nutrition Local Coverage Determination (LCD) and Related Policy Article - Effective November 12, 2020; Joint DME MAC Article, Posted October 8, 2020, Noridian DME Website
Retirement of Parenteral Nutrition Local Coverage Determination (LCD) and Related Policy Article - Effective November 12, 2020; Joint DME MAC Article, Posted October 8, 2020, Noridian DME Website
Enteral Nutrition and Parenteral Nutrition - Final LCDs and Response to Comments (RTC) Articles Published; Joint DME MAC Publication, Posted July 22, 2021, Noridian DME Website
Enteral Nutrition and Parenteral Nutrition - Final LCDs and Response to Comments (RTC) Articles Published; Joint DME MAC Publication, Posted July 22, 2021, CGS DME Website

Guideline History/Revision Information
Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

<table>
<thead>
<tr>
<th>Date</th>
<th>Summary of Changes</th>
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<tbody>
<tr>
<td>09/08/2021</td>
<td><strong>Policy Summary</strong>&lt;br&gt;&lt;br&gt;<strong>Guidelines</strong>&lt;br&gt;<strong>Enteral Nutrition Therapy</strong>&lt;br&gt;• Added language to indicate:&lt;br&gt;• Enteral nutrition is covered for a beneficiary who requires feedings via an enteral access device to provide sufficient nutrients to maintain weight and strength commensurate with the beneficiary's overall health status and has a permanent:&lt;br&gt;  ▪ Full or partial non-function or disease of the structures that normally permit food to reach the small bowel; or&lt;br&gt;  ▪ Disease that impairs digestion and/or absorption of an oral diet, directly or indirectly, by the small bowel&lt;br&gt;• Adequate nutrition must not be possible by dietary adjustment and/or oral supplements&lt;br&gt;• Typical examples of conditions associated with impaired digestion and/or absorption of an oral diet by the small bowel that may qualify for coverage include:&lt;br&gt;  ▪ Inflammatory bowel disease</td>
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</tbody>
</table>
### Summary of Changes

- Surgical resection of small bowel
- Cystic fibrosis
- Chronic pancreatitis; and
- Advanced liver disease (not all inclusive)
  - Enteral nutrition for temporary impairments will be denied as non-covered, no benefit
  - Enteral nutrition for beneficiaries with a functioning gastrointestinal tract whose need for enteral nutrition is not due to reasons related to the non-function or disease of the structures that normally permit food to reach the small bowel will be denied as non-covered, no benefit
  - Orally administered enteral nutrition products, related supplies and equipment will be denied non-covered, no benefit

### Enteral Nutrition Nutrients
- Added language to indicate special nutrient formulas (HCPCS codes B4149, B4153, B4154, B4155, B4157, B4161, and B4162) are produced to meet unique nutrient needs for specific disease conditions; if a special nutrient formula is ordered, the beneficiary’s medical records must specify why a standard formula cannot be used to meet the beneficiary’s metabolic needs (relocated from the Enteral Supplies section)
  - This documentation may include other formulas tried and failed or considered and ruled out
  - A diagnosis alone is not sufficient to support the medical need for a specialty formula; for example, an order for a diabetes-specific formula may be supported by documentation in the medical record that the beneficiary has a diagnosis of diabetes mellitus and has experienced severe fluctuations of glucose levels on standard formula
  - 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
- Replaced language indicating “HCPCS codes B4102 and B4103 describe electrolyte-containing fluids that are non-covered by Medicare” with “electrolyte-containing fluids (HCPCS codes B4102 and B4103) are not indicated for the maintenance of weight and strength and are therefore non-covered, no benefit”

### Enteral Supplies
- Added language to indicate:
  - Enteral nutrition may be administered by syringe, gravity, or pump; some enteral beneficiaries may experience complications associated with syringe or gravity method of administration
    - If a pump (HCPCS code B9002) is ordered, there must be documentation in the beneficiary’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
  - If a pump supply allowance (HCPCS code B4035) is provided and if the medical necessity of the pump is not documented, it will be denied as not reasonable and necessary
  - In-line digestive enzyme cartridges (B4105) are reasonable and necessary for beneficiaries who:
    - Meet the coverage criteria for enteral nutrition; and
    - Have a diagnosis of exocrine pancreatic insufficiency (EPI)
  - More than two in-line digestive enzyme cartridges (HCPCS code B4105) per day will be denied as not reasonable and necessary
  - The codes for feeding supply allowances (HCPCS codes B4034, B4035, and 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
    - Enteral feeding supply kit allowances (HCPCS codes B4034, B4035, and B4036), are all-inclusive, with the exception of HCPCS code B4105 in-line digestive enzyme cartridge
<table>
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<td></td>
<td>▪ Separate billing for any item including an item using a specific HCPCS code, if one exists, or HCPCS code B9998 (ental supplies, not otherwise classified) will be denied as unbundling</td>
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<td>o More than three nasogastric tubes (HCPCS codes B4081, B4082, and B4083), or one gastrostomy/jejunostomy tube (HCPCS codes B4087 or B4088) every three months is not reasonable and necessary</td>
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<tr>
<td></td>
<td><strong>Enteral Nutrition Coding Guidelines</strong></td>
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<tr>
<td></td>
<td>▪ Added language to indicate:</td>
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<td>o If two enteral nutrition products, which are described by the same HCPCS code, are being provided at the same time, they should be billed on a single claim line, with the units of service reflecting the total calories of both nutrients (relocated from the Enteral Supplies section)</td>
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<td>o Supply allowance HCPCS codes (B4034, B4035, and B4036) are daily allowances which are considered all-inclusive and therefore refill requirements are not applicable to these HCPCS codes</td>
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<td><strong>Parenteral Nutrition Therapy</strong></td>
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<tr>
<td></td>
<td>▪ Added language to indicate:</td>
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<td>o When nutritional support other than the oral route is necessary, enteral nutrition (EN) is usually initially preferable to parenteral nutrition for the following reasons:</td>
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<td>▪ In a fluid restricted beneficiary, EN permits delivery of all necessary nutrients in a more concentrated volume than parenteral nutrition;</td>
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<td>▪ EN allows for safer home delivery of nutrients; and</td>
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<td>▪ EN lowers the risk of central line-associated bloodstream infections (CLABSI)</td>
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<td>o For parenteral nutrition to be considered reasonable and necessary, the treating practitioner must document that enteral nutrition has been considered and ruled out, tried, and been found ineffective, or that EN exacerbates gastrointestinal tract dysfunction</td>
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<td>▪ The beneficiary must have:</td>
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<td>1. A condition involving the small intestine and/or its exocrine glands which significantly impairs the absorption of nutrients; or</td>
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<td>2. Disease of the stomach and/or intestine which is a motility disorder and impairs the ability of nutrients to be transported through and absorbed by the gastrointestinal (GI) system</td>
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<td>▪ Revised language addressing treatment evaluation to indicate the treating practitioner is required to evaluate the beneficiary within 30 days prior to initiation of parenteral nutrition</td>
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<td>o If the treating practitioner does not see the beneficiary within this timeframe, they must document the reason why and describe what other monitoring methods were used to evaluate the beneficiary’s parenteral nutrition needs</td>
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<td>o There must be documentation in the medical record supporting the clinical diagnosis</td>
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<td>o Suppliers are required to monitor the beneficiary’s medical condition to confirm that the coverage criteria for parenteral nutrition continue to be met</td>
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<td><strong>Parenteral Nutrition Nutrients</strong></td>
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<td>▪ Added language to indicate nutrient solutions for parenteral therapy are routinely covered; however, Medicare pays for no more than one month’s supply of nutrients at any one time</td>
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<td>o 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</td>
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<td>o Payment will be on the basis of the reasonable charge for more expensive premixed solutions only under the latter circumstances</td>
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<td>▪ Replaced language indicating:</td>
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<td>o “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” with “a total caloric daily intake of 20-35 cal/kg/day is considered reasonable and necessary to achieve or maintain appropriate body weight”</td>
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<tr>
<td>Date</td>
<td>Summary of Changes</td>
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<td>○ “The treating practitioner must document in the medical record the medical necessity for a caloric intake outside this range in an individual beneficiary” with “the treating practitioner must document the medical necessity for a caloric intake outside this range in an individual beneficiary”</td>
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<td>○ “The treating practitioner 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 HCPCS code B4185, or B4187) per month” with “the treating practitioner must document the medical necessity for protein orders outside of the range of 0.8 - 2.0 gm/kg/day (HCPCS codes B4168, B4172, B4176, B4178), dextrose concentration less than 10% (HCPCS codes B4164, B4180), or lipid use per month in excess of the product-specific, FDA-approved dosing recommendations (HCPCS codes B4185, B4187)”</td>
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<td>● Revised language pertaining to special nutrient formulas to indicate:</td>
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<td>○ HCPCS codes B5000, B5100, and B5200 are produced to meet the unique nutrient needs for specific disease conditions</td>
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<td></td>
<td>○ The beneficiary’s medical record must adequately document the specific condition and the necessity for the special nutrient</td>
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<td>Parenteral Nutrition Equipment and Supplies</td>
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<tr>
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<td>● Revised language to indicate:</td>
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<td>○ Only one infusion pump is covered for beneficiaries in whom parenteral nutrition is required; additionally, only one supply kit and one administration kit is covered for each day that parenteral nutrition is administered</td>
</tr>
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<td>○ 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</td>
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<td></td>
<td>Parenteral Nutrition Coding Guidelines</td>
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<tr>
<td></td>
<td>● Added language to indicate:</td>
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<td>○ Parenteral nutrition supply allowances (HCPCS codes B4220, B4222 and B4224) describe a daily supply fee rather than a specifically defined “kit” and include all supplies required for the administration of parenteral nutrition to the beneficiary for one day</td>
</tr>
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<td>▪ The use of individual items may differ from beneficiary to beneficiary, and from day to day</td>
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<tr>
<td></td>
<td>▪ Daily allowances are considered all-inclusive and therefore refill requirements are not applicable to HCPCS codes B4220, B4222, and B4224; only one unit of service may be billed for any one day</td>
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<tr>
<td></td>
<td>Enteral and Parenteral Nutrition Refill Requirements (new to policy)</td>
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<td>● Added language to indicate:</td>
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<td>○ For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use</td>
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<td>▪ For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a predetermined basis, even if authorized by the beneficiary; this shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the order</td>
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<td>▪ Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date</td>
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<td>▪ For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product; this is regardless of which delivery method is utilized</td>
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<tr>
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<td>○ For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee prior to dispensing a new supply of items</td>
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<tr>
<td></td>
<td>▪ Suppliers must not deliver refills without a refill request from a beneficiary</td>
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<td>▪ Items delivered without a valid, documented refill request will be denied as not reasonable and necessary</td>
</tr>
</tbody>
</table>
### Summary of Changes

- Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization
  - Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients
  - Suppliers must verify with the treating practitioner that any changed or atypical utilization is warranted
- Regardless of utilization, a supplier must not dispense more than a 1-month quantity at a time

### Applicable Codes
- Added notation to indicate HCPCS code A5200 was “deleted Sep. 5, 2020”
- Revised description for Modifier code BA

### Supporting Information
- Updated References section to reflect the most current information
- Archived previous policy version MPG099.08

### Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

### Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.
You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.