

LCD - Parenteral Nutrition (L38953)

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LCD Information

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CMS National Coverage Policy

CMS Pub. 100-03 (National Coverage Determinations Manual), Chapter 1, Section 180.2

Coverage Guidance**Coverage Indications, Limitations, and/or Medical Necessity**

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Parenteral nutrition is the provision of nutritional requirements intravenously and is covered for beneficiaries who qualify under the Prosthetic Device Benefit defined in the Medicare *Benefit Policy Manual* (CMS Pub. 100-02), Chapter 15, Section 120, based on coverage definitions in the Medicare *National Coverage Determinations Manual* (CMS Pub. 100-03), Chapter 1, Part 3, Section 180.2.

When nutritional support other than the oral route is necessary, enteral nutrition (EN) is usually initially preferable to parenteral nutrition for the following reasons: (1) In a fluid restricted beneficiary, EN permits delivery of all necessary nutrients in a more concentrated volume than parenteral nutrition; (2) EN allows for safer home delivery

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of nutrients; and (3) 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 beneficiary must have a permanent impairment. Please refer to the LCD-related Policy Article for further guidance regarding the test of permanence.

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.

GENERAL

A Standard Written Order (SWO) must be communicated to the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed SWO, the claim shall be denied as not reasonable and necessary.

For Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) base items that require a Written Order Prior to Delivery (WOPD), the supplier must have received a signed SWO before the DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a WOPD, the claim shall be denied as not reasonable and necessary. Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

For DMEPOS base items that require a WOPD, and also require separately billed associated options, accessories, and/or supplies, the supplier must have received a WOPD which lists the base item and which may list all the associated options, accessories, and/or supplies that are separately billed prior to the delivery of the items. In this scenario, if the supplier separately bills for associated options, accessories, and/or supplies without first receiving a completed and signed WOPD of the base item prior to delivery, the claim(s) shall be denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

If the coverage requirements for parenteral nutritional therapy are met under the prosthetic device benefit provision, related supplies, equipment and nutrients are also covered.

No more than one month's supply of parenteral nutrients, equipment or supplies is allowed for one month's

prospective billing. Claims submitted retroactively, however, may include multiple months.

Services associated with the administration of parenteral nutrition in a beneficiary's home are addressed in the Non-Medical Necessity Coverage and Payment Rules section located in the LCD-related Policy Article.

NUTRIENTS:

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.

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.

Supply allowance HCPCS codes (B4220, B4222 and B4224) are daily allowances which are considered all-inclusive and therefore refill requirements are not applicable to these HCPCS codes. Refer to the Coding Guidelines section in the LCD-related Policy Article for further clarification.

Summary of Evidence

Parenteral nutrition (PN) is a type of medical nutrition therapy provided through the intravenous administration of nutrients such as amino acids, glucose, lipids, electrolytes, vitamins, and trace elements. PN can be central through a central venous line, or peripheral through a peripheral intravenous line.

When PN is used outside the hospital, it is often referred to in the literature as home parenteral nutrition (HPN). HPN is often used for patients with chronic intestinal failure for either benign or malignant diseases or provided as palliative nutrition to patients in late phases of end-stage diseases.⁴

A review of the available literature reveals that there is no reliable measure of nutritional status or marker to diagnose clinically significant intestinal malabsorption. Serum albumin and other laboratory tests are no longer used as a measure of nutritional status due to research indicating their link to inflammation and lack of response to nutrition therapy.¹⁻³ Although promising, the available evidence is insufficient to recommend plasma citrulline levels as a marker of small bowel absorption capacity.^{3,5-9}

The available evidence demonstrating the net health outcomes of PN is limited. Pironi et al. (2020)⁴ concluded that "PN is a life-saving therapy to those unable to meet their nutritional requirements by oral/enteral intake. Clearly, no randomized controlled trial (RCT) can be conducted to compare HPN with placebo to confirm the life-saving efficacy of HPN therapy in this condition... However, the presence of organ failures and metabolic diseases, such as heart failure, renal failure, type 1 diabetes, may be associated with reduced tolerance to PN and may require careful and specific adaptations of the HPN program to meet the patient's specific clinical needs."

Current expert consensus and evidence-based guidelines for PN have evolved over the last decade such that PN is only recommended if EN is impossible or inadequate, or when use of EN exacerbates gastrointestinal tract dysfunction (e.g. high-output or complex enterocutaneous fistula, gastric-outlet obstruction, or intolerance of EN).¹⁰⁻²⁴ Additionally, the American Society of Parenteral and Enteral Nutrition (ASPEN) Board of Directors and the Clinical Guidelines Task Force recommends that determination of nutrient requirements should be individualized, based on assessment of body composition and function, and fall within acceptable ranges, while taking physiologic and pathophysiologic conditions into account.²⁵

Analysis of Evidence (Rationale for Determination)

A systematic approach is employed by the DME MACs when evaluating the strength of evidence to determine if an intervention is reasonable and necessary per CMS guidance as outlined in the Medicare *Benefit Policy Manual* (CMS Pub. 100-02), Chapter 15, Section 110.1.C and the Medicare *Program Integrity Manual* (CMS Pub. 100-08), Chapter 13. Additionally, the evidence is examined to determine if an intervention will improve health outcomes for Medicare beneficiaries. In conducting reviews, the DME MACs use the current best available evidence of general acceptance by the medical community, such as published original research in peer-reviewed medical journals, systematic reviews and meta-analyses, evidence-based consensus statements, and clinical guidelines.

There is limited evidence to assess the benefits and harms of initiating PN before EN failure in patients. Studies enrolled too few patients, and data cannot be combined because patient populations, diseases, and therapies differ too much among the studies. Clinical guidelines recommend initiating PN only when EN is unfeasible or insufficient and patients are at risk of malnutrition and with months-long life expectancy. However, the recommendations are based on consensus rather than clinical evidence.

Quality of Published Literature: Moderate

Strength of Recommendations: Moderate

Conclusion

Coverage of PN has been established in the Medicare *National Coverage Determinations Manual* (CMS Pub. 100-03), Chapter 1, Part 3, Section 180.2. Based on review of the best available evidence, parenteral nutrition is considered reasonable and necessary for a beneficiary with severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the beneficiary's general condition.

Coding Information

CPT/HCPCS Codes

Group 1 Paragraph:

The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS:

BA – Item used in conjunction with parenteral enteral nutrition (PEN) services

EY – No physician or other health care provider order for this item or service

HCPCS CODES:

Group 1 Codes:

CODE	DESCRIPTION
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, NOT OTHERWISE SPECIFIED, 10 GRAMS

CODE	DESCRIPTION
	LIPIDS
B4187	OMEGAVEN, 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, RENAL-AMINOSYN-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
B9004	PARENTERAL NUTRITION INFUSION PUMP, PORTABLE
B9006	PARENTERAL NUTRITION INFUSION PUMP, STATIONARY
B9999	NOC FOR PARENTERAL SUPPLIES
E0776	IV POLE

General Information

Associated Information

DOCUMENTATION REQUIREMENTS

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary's medical records include the treating practitioner'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 upon request.

GENERAL DOCUMENTATION REQUIREMENTS

In order to justify payment for DMEPOS items, suppliers must meet the following requirements:

- SWO
- Medical Record Information (including continued need/use if applicable)
- Correct Coding
- Proof of Delivery

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information regarding these requirements.

Refer to the Supplier Manual for additional information on documentation requirements.

Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

Items covered in this LCD have additional policy-specific requirements that must be met prior to Medicare reimbursement.

Refer to the LCD-related Policy article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information.

Miscellaneous

Appendices

Utilization Guidelines

Refer to Coverage Indications, Limitations, and/or Medical Necessity

Sources of Information

N/A

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Revision History Information

N/A

Associated Documents

Attachments

[Parenteral Nutrition DIF - CMS10126](#) (119 KB) (Uploaded on 07/09/2021)

Related Local Coverage Documents

Articles

[A58836 - Parenteral Nutrition](#)

[A58837 - Response to Comments: Parenteral Nutrition - DL38953](#)

[A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs](#)

Related National Coverage Documents

N/A

Public Versions

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