Local Coverage Determination (LCD): Enteral Nutrition (L5041)

Contractor Information

Contractor Name	Contract Number	Contract Type
NHIC, Corp. opens in new window	16003	DME MAC

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LCD Information

Document Information

LCD ID
L5041

LCD Title
Enteral Nutrition

Jurisdiction opens in new window
Connecticut
District of Columbia
Delaware
Massachusetts
Maryland
Maine
New Hampshire
New Jersey
New York - Entire State
Pennsylvania
Rhode Island
Vermont

Original Effective Date
For services performed on or after 10/01/1993

Revision Effective Date
For services performed on or after 05/01/2013

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date 08/01/1993

Notice Period End Date N/A

CMS National Coverage Policy
CMS Pub. 100-3 (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. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following indications and limitations of coverage and/or medical necessity.

For an item to be covered by Medicare, a detailed written order (DWO) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed DWO, the item will be denied as not reasonable and necessary.

GENERAL:

Statutory coverage criteria for enteral nutrition are specified in the related Policy Article.

NUTRIENTS:

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

The medical necessity for special enteral formulas (B4149, B4153-B4155, B4157, B4161, and B4162) must be justified in each beneficiary. 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.

EQUIPMENT AND 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 (B9000-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.

The feeding supply allowance (B4034-B4036) must correspond to the method of administration indicated in question 5 of the DME Information Form (DIF). If it does not correspond, it 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 codes for feeding supply allowances (B4034-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.

More than three nasogastric tubes (B4081-B4083), or one gastrostomy/jejunostomy tube (B4087-B4088) every three months is not reasonable and necessary.

REFILL REQUIREMENTS

For Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) 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. (CMS Program Integrity Manual, Internet-Only Manual, CMS Pub. 100-8, Chapter 5, Section 5.2.6).

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 ordering physicians that any changed or atypical utilization is warranted. Regardless of utilization, a supplier must not dispense more than a one (1) month quantity at a time.

Supply allowance HCPCS codes (B4034-B4036) 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 Policy Article for further clarification.

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Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes

Group 1 Paragraph: The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIER:

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

BO – Orally administered nutrition,not by feeding tube

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

Group 1 Codes:

A5200	PERCUTANEOUS CATHETER/TUBE ANCHORING DEVICE, ADHESIVE SKIN ATTACHMENT
A9270	NON-COVERED ITEM OR SERVICE
B4034	ENTERAL FEEDING SUPPLY KIT; SYRINGE FED, PER DAY, INCLUDES BUT NOT LIMITED TO FEEDING/FLUSHING SYRINGE, ADMINISTRATION SET TUBING, DRESSINGS, TAPE
B4035	ENTERAL FEEDING SUPPLY KIT; PUMP FED, PER DAY, INCLUDES BUT NOT LIMITED TO FEEDING/FLUSHING SYRINGE, ADMINISTRATION SET TUBING, DRESSINGS, TAPE
B4036	ENTERAL FEEDING SUPPLY KIT; GRAVITY FED, PER DAY, INCLUDES BUT NOT LIMITED TO FEEDING/FLUSHING SYRINGE, ADMINISTRATION SET TUBING, DRESSINGS, TAPE
B4081	NASOGASTRIC TUBING WITH STYLET
B4082	NASOGASTRIC TUBING WITHOUT STYLET
B4083	STOMACH TUBE - LEVINE TYPE
B4087	GASTROSTOMY/JEJUNOSTOMY TUBE, STANDARD, ANY MATERIAL, ANY TYPE, EACH
B4088	GASTROSTOMY/JEJUNOSTOMY TUBE, LOW-PROFILE, ANY MATERIAL, ANY TYPE, EACH

B4100 FOOD THICKENER, ADMINISTERED ORALLY, PER OUNCE

B4102 ENTERAL FORMULA, FOR ADULTS, USED TO REPLACE FLUIDS AND ELECTROLYTES (E.G. CLEAR LIQUIDS), 500 ML = 1 UNIT

B4103 ENTERAL FORMULA, FOR PEDIATRICS, USED TO REPLACE FLUIDS AND ELECTROLYTES (E.G. CLEAR LIQUIDS), 500 ML = 1 UNIT

B4104 ADDITIVE FOR ENTERAL FORMULA (E.G. FIBER)

B4149 ENTERAL FORMULA, MANUFACTURED BLENDERIZED 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

B4150 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

B4152 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

B4153 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

B4154 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

B4155 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

B4157 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

B4158 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

B4159 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

B4160 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

B4161 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

B4162 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

B9000 ENTERAL NUTRITION INFUSION PUMP - WITHOUT ALARM

B9002 ENTERAL NUTRITION INFUSION PUMP - WITH ALARM

B9998 NOC FOR ENTERAL SUPPLIES

E0776 IV POLE

ICD-9 Codes that Support Medical Necessity

Group 1 Paragraph: Not specified.

Group 1 Codes:
XX000 Not Applicable

ICD-9 Codes that DO NOT Support Medical Necessity
Paragraph: Not specified.

N/A

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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 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 upon request.

PRESCRIPTION (ORDER) REQUIREMENTS

GENERAL (PIM 5.2.1)

All items billed to Medicare require a prescription. 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 dispensed and/or billed that do not meet these prescription requirements and those below must be submitted with an EY modifier added to each affected HCPCS code.

DISPENSING ORDERS (PIM 5.2.2)

Equipment and supplies may be delivered upon receipt of a dispensing order except for those items that require a written order prior to delivery. A dispensing order may be verbal or written. The supplier must keep a record of the dispensing order on file. It must contain:

- Description of the item
- Beneficiary's name
- Prescribing Physician's name
- Date of the order and the start date, if the start date is different from the date of the order
- Physician signature (if a written order) or supplier signature (if verbal order)

For the "Date of the order" described above, use the date the supplier is contacted by the physician (for verbal orders) or the date entered by the physician (for written dispensing orders).

Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements outlined in PIM 3.3.2.4.

The dispensing order must be available upon request.

For items that are provided based on a dispensing order, the supplier must obtain a detailed written order before submitting a claim.

DETAILED WRITTEN ORDERS (PIM 5.2.3)

A detailed written order (DWO) is required before billing. Someone other than the ordering physician may produce the DWO. However, the ordering physician must review the content and sign and date the document. It must contain:

- Beneficiary's name

- Physician's name
- Date of the order and the start date, if start date is different from the date of the order
- Detailed description of the item(s) (see below for specific requirements for selected items)
- Physician signature and signature date

For items provided on a periodic basis, including drugs, the written order must include:

- Item(s) to be dispensed
- Dosage or concentration, if applicable
- Route of Administration
- Frequency of use
- Duration of infusion, if applicable
- Quantity to be dispensed
- Number of refills

For the "Date of the order" described above, use the date the supplier is contacted by the physician (for verbal orders) or the date entered by the physician (for written dispensing orders).

Frequency of use information on orders must contain detailed instructions for use and specific amounts to be dispensed. Reimbursement shall be based on the specific utilization amount only. Orders that only state "PRN" or "as needed" utilization estimates for replacement frequency, use, or consumption are not acceptable. (PIM 5.9)

The detailed description in the written order may be either a narrative description or a brand name/model number.

Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements outlined in PIM 3.3.2.4.

The DWO must be available upon request.

A prescription is not considered as part of the medical record. Medical information intended to demonstrate compliance with coverage criteria may be included on the prescription but must be corroborated by information contained in the medical record.

MEDICAL RECORD INFORMATION

GENERAL (PIM 5.7 - 5.9)

The **Indications and Limitations of Coverage and/or Medical Necessity** section of this LCD contains numerous reasonable and necessary (R&N) requirements. The **Nonmedical Necessity Coverage and Payment Rules** section of the related Policy Article contains numerous non-reasonable and necessary, benefit category and statutory requirements that must be met in order for payment to be justified. Suppliers are reminded that:

- Supplier-produced records, even if signed by the ordering physician, and attestation letters (e.g. letters of medical necessity) are deemed not to be part of a medical record for Medicare payment purposes.
- Templates and forms, including CMS Certificates of Medical Necessity, are subject to corroboration with information in the medical record.

Information contained directly in the contemporaneous medical record is the source required to justify payment except as noted elsewhere for prescriptions and CMNs. The medical record is not limited to physician's office records but may include records from hospitals, nursing facilities, home health agencies, other healthcare professionals, etc. (not all-inclusive). Records from suppliers or healthcare professionals with a financial interest in the claim outcome are not considered sufficient by themselves for the purpose of determining that an item is reasonable and necessary.

CONTINUED USE

Continued use describes the ongoing utilization of supplies or a rental item by a beneficiary.

Suppliers are responsible for monitoring utilization of DMEPOS rental items and supplies. No monitoring of purchased items or capped rental items that have converted to a purchase is required. Suppliers must discontinue billing Medicare when rental items or ongoing supply items are no longer being used by the beneficiary.

Beneficiary medical records or supplier records may be used to confirm that a DMEPOS item continues to be used by the beneficiary. Any of the following may serve as documentation that an item submitted for reimbursement continues to be used by the beneficiary:

- Timely documentation in the beneficiary’s medical record showing usage of the item, related option/accessories and supplies
- Supplier records documenting the request for refill/replacement of supplies in compliance with the Refill Documentation Requirements (This is deemed to be sufficient to document continued use for the base item, as well)
- Supplier records documenting beneficiary confirmation of continued use of a rental item

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in this policy.

CONTINUED MEDICAL NEED

For all DMEPOS items, the initial justification for medical need is established at the time the item(s) is first ordered; therefore, beneficiary medical records demonstrating that the item is reasonable and necessary are created just prior to, or at the time of, the creation of the initial prescription. For purchased items, initial months of a rental item or for initial months of ongoing supplies or drugs, information justifying reimbursement will come from this initial time period. Entries in the beneficiary's medical record must have been created prior to, or at the time of, the initial DOS to establish whether the initial reimbursement was justified based upon the applicable coverage policy.

For ongoing supplies and rental DME items, in addition to information described above that justifies the initial provision of the item(s) and/or supplies, there must be information in the beneficiary's medical record to support that the item continues to be used by the beneficiary and remains reasonable and necessary. Information used to justify continued medical need must be timely for the DOS under review. Any of the following may serve as documentation justifying continued medical need:

- A recent order by the treating physician for refills
- A recent change in prescription
- A properly completed CMN or DIF with an appropriate length of need specified
- Timely documentation in the beneficiary's medical record showing usage of the item.

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in the policy.

REFILL DOCUMENTATION (PIM 5.2.5-6)

A routine refill prescription is not needed. A new prescription is needed when:

- There is a change of supplier
- There is a change in the item(s), frequency of use, or amount prescribed
- There is a change in the length of need or a previously established length of need expires
- State law requires a prescription renewal

For items that the beneficiary obtains in-person at a retail store, the signed delivery slip or a copy of the itemized sales receipt is sufficient documentation of a request for refill.

For items that are delivered to the beneficiary, documentation of a request for refill must be either a written document received from the beneficiary or a contemporaneous written record of a phone conversation/contact between the supplier and beneficiary. The refill request must occur and be documented before shipment. A retrospective attestation statement by the supplier or beneficiary is not sufficient. The refill record must include:

- Beneficiary's name or authorized representative if different than the beneficiary
- A description of each item that is being requested
- Date of refill request
- For consumable supplies, i.e., those that are used up (e.g., ostomy or urological supplies, surgical dressings, etc.) - the supplier should assess the quantity of each item that the beneficiary still has remaining, to document that the amount remaining will be nearly exhausted on or about the supply anniversary date
- For non-consumable supplies, i.e., those more durable items that are not used up but may need periodic replacement (e.g., PAP and RAD supplies) - the supplier should assess whether the supplies remain functional, providing replacement (a refill) only when the supply item(s) is no longer able to function. Document the functional condition of the item(s) being refilled in sufficient detail to demonstrate the cause of the dysfunction that necessitates replacement (refill).

This information must be kept on file and be available upon request.

PROOF OF DELIVERY (PIM 4.26, 5.8)

Proof of delivery (POD) is a Supplier Standard and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers are required to maintain POD documentation in their files. For medical review purposes, POD serves to assist in determining correct coding and billing information for claims submitted for Medicare reimbursement. Regardless of the method of delivery, the contractor must be able to determine from delivery documentation that the supplier properly coded the item(s), that the item(s) delivered are the same item(s) submitted for Medicare reimbursement and that the item(s) are intended for, and received by, a specific Medicare beneficiary.

Suppliers, their employees, or anyone else having a financial interest in the delivery of the item are prohibited from signing and accepting an item on behalf of a beneficiary (i.e., acting as a designee on behalf of the beneficiary). The signature and date the beneficiary or designee accepted delivery must be legible.

For the purpose of the delivery methods noted below, designee is defined as any person who can sign and accept the delivery of DMEPOS on behalf of the beneficiary.

Proof of delivery documentation must be available to the Medicare contractor on request. All services that do not have appropriate proof of delivery from the supplier will be denied and overpayments will be requested. Suppliers who consistently fail to provide documentation to support their services may be referred to the OIG for imposition of Civil Monetary Penalties or other administrative sanctions.

Suppliers are required to maintain POD documentation in their files. For items addressed in this policy there are three methods of delivery:

1. Delivery directly to the beneficiary or authorized representative

2. Delivery via shipping or delivery service

3. Delivery of items to a nursing facility on behalf of the beneficiary

Method 1—Direct Delivery to the Beneficiary by the Supplier

Suppliers may deliver directly to the beneficiary or the designee. In this case, POD to a beneficiary must be a signed and dated delivery slip. The POD record must include:

- Beneficiary's name
- Delivery address
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description)
- Quantity delivered
- Date delivered
- Beneficiary (or designee) signature and date of signature

The date of signature on the delivery slip must be the date that the DMEPOS item was received by the beneficiary or designee. In instances where the item is delivered directly by the supplier, the date the beneficiary received the DMEPOS item must be the date of service on the claim.

Method 2—Delivery via Shipping or Delivery Service Directly to a Beneficiary

If the supplier utilizes a shipping service or mail order, the POD documentation must be a complete record tracking the item(s) from the DMEPOS supplier to the beneficiary. An example of acceptable proof of delivery would include both the supplier's own detailed shipping invoice and the delivery service's tracking information. The supplier's record must be linked to the delivery service record by some clear method like the delivery service's package identification number or supplier's invoice number for the package sent to the beneficiary. The POD record must include:

- Beneficiary's name
- Delivery address
- Delivery service's package identification number, supplier invoice number or alternative method that links the supplier's delivery documents with the delivery service's records.
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description)
- Quantity delivered
- Date delivered
- Evidence of delivery

If a supplier utilizes a shipping service or mail order, suppliers must use the shipping date as the date of service on the claim.

Suppliers may also utilize a return postage-paid delivery invoice from the beneficiary or designee as a POD. This type of POD record must contain the information specified above.

Method 3—Delivery to Nursing Facility on Behalf of a Beneficiary

When a supplier delivers items directly to a nursing facility, the documentation described for Method 1 (see above) is required.

When a delivery service or mail order is used to deliver the item to a nursing facility, the documentation described for Method 2 (see above) is required.

Regardless the method of delivery, for those beneficiaries that are residents of a nursing facility, information from the nursing facility showing that the item(s) delivered for the beneficiary's use were actually provided to and used by the beneficiary must be available upon request.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

DME INFORMATION FORM (PIM 5.3)

A DME Information Form (DIF), which has been completed, signed, and dated by the supplier, must be kept on file and made available upon request. The DIF for enteral nutrition is CMS Form 10126 (DME form 10.03). The initial claim must include an electronic copy of the DIF.

A new Initial DIF for enteral nutrients is required when:
1. A formula billed with a different code, which has not been previously certified, is ordered, or
2. Enteral nutrition services are resumed after they have not been required for two consecutive months.

A new Initial DIF for a pump (B9000 or B9002) is required when:
1. Enteral nutrition services involving use of a pump are resumed after they have not been required for two consecutive months, or
2. A beneficiary receiving enteral nutrition by the syringe or gravity method is changed to administration using a pump.

A revised DIF for enteral nutrients is required when:
1. The number of calories per day is changed, or
2. The number of days per week administered is changed, or
3. The method of administration (syringe, gravity, pump) changes, or
4. The route of administration is changed from tube feedings to oral feedings (if billing for denial), or
5. The HCPCS code for the current nutrient changes

Special nutrient formulas, HCPCS codes B4149, B4153-B4155, B4157, B4161, and B4162, are produced to meet unique nutrient needs for specific disease conditions. The beneficiary's medical record must adequately document the specific condition and the need for the special nutrient. This information shall be available upon request.

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.

MISCELLANEOUS

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

Appendices

PIM citations above denote references to CMS Program Integrity Manual, Internet Only Manual 100-8

Utilization Guidelines

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

Sources of Information and Basis for Decision
Reserved for future use.

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Revision History Information

Please note: The Revision History information included in this LCD prior to 1/24/2013 will now display with a Revision History Number of "R1" at the bottom of this table. All new Revision History information entries completed on or after 1/24/2013 will display as a row in the Revision History section of the LCD and numbering will begin with "R2".

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
05/01/2013	R2	**Revision Effective Date: 05/01/2013** COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Changed: Word “Patient” to “Beneficiary” Added: Verbiage regarding allowances under the Refill Requirement section DOCUMENTATION REQUIREMENTS: (Note: The effective date above is not applicable to this section. These revised and added requirements are existing Medicare requirements which are now included in the LCD for easy reference) Added: Standard Language Added: 5th bullet under revised DIF requirements **Revision Effective Date: 08/02/2011** INDICATIONS AND LIMITATIONS OF COVERAGE: Revised: Refills information DOCUMENTATION REQUIREMENTS: Added: Delivery language. Added: Refills documentation information **Revision Effective Date: 02/04/2011** INDICATIONS AND LIMITATIONS OF COVERAGE: Deleted: Least costly alternative language for special enteral formulas and supply kits HCPCS CODES AND MODIFIERS: Revised: B4034, B4035, B4036	• Provider Education/Guidance
08/02/2011	R1	3/1/2008- In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC NHIC (16003) LCD L5041 from DME PSC TriCenturion (77011) LCD L5041. Revision Effective Date: 01/01/2008 INDICATIONS AND LIMITATIONS OF COVERAGE: Added B4087, B4088 to utilization statement Deleted B4086 from utilization statement HCPCS CODES AND MODIFIERS: Added B4087, B4088 Deleted B4086 Revised narrative for B4034 Revision Effective Date: 01/01/2007 INDICATIONS AND LIMITATIONS OF COVERAGE: Removed CMN references. Added DIF instructions. DOCUMENTATION REQUIREMENTS: Removed CMN requirements. Added DIF instructions.	• Maintenance (annual review with now changes, formatting, etc)

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change

03/01/2006 - In accordance with Section 911 of the Medicare Modernization Act of 2003, this policy was transitioned to DME PSC TriCenturion (77011) from DMERC Tricenturion (77011).
Revision effective date: 04/01/2005
LMRP converted to LCD and Policy Article
HCPCS CODES AND MODIFIERS:
Added B4102-B4104, B4149, and B4157-B4162
Deleted B4151 and B4156
Narrative modified on B4150, B4152-B4155
DOCUMENTATION REQUIREMENTS:
Replaced references to category IV and V with corresponding HCPCS codes.

Revision effective date: 04/01/2003
HCPCS CODES AND MODIFIERS:
Added: EY BA, and BO modifiers, deleted XA modifier, added HCPCS code B4100
INDICATIONS AND LIMITATIONS OF COVERAGE:
Adds standard language concerning coverage of items without an order.
CODING GUIDELINES:
Revises instructions for billing orally administered enteral nutrients
DOCUMENTATION REQUIREMENTS:
Adds standard language concerning use of EY modifier for items without an order.

The revision dates listed below are the dates the revisions were published and not necessarily the effective dates for the revisions.

04/01/2002 - Code B4086 replaces codes B4084 and B4085. ZY modifier deleted from policy; enteral nutrients not administered through feeding tube now coded A9270. Expected range of calories/kg/day eliminated.

04/01/2000 – Revised language regarding enteral nutrition provided by a SNF in a Part A stay in Coverage and Payment Rules section.

01/01/2000 – Added code A5200. Code descriptions for enteral nutrients have been revised to specify that the codes represent only nutrients that are given through an enteral feeding tube. As a result, nutrients dispensed to the patient for oral administration must no longer be billed to the DMERC using codes B4150-B4156. Enteral nutrition is the provision of nutritional requirements through a tube into the stomach or small intestine. Beneficiaries who are able to take nutrients by mouth (orally) do not qualify for the prosthetic benefit, and the nutrients as well as any related supplies are noncovered. In this situation claim submission is not required. However, if the beneficiary is not in a covered Part A stay and asks the supplier to submit a claim, code A9270 must be used to bill the DMERC for nutrients provided for oral administration. Added reasonable and necessary language in Coverage and Payment Rules section. Added language regarding question 13 on CMN. Revised language for catheter/tube anchoring device stating it is included in the allowance for enteral supply kits.

03/01/1998 – Code K0147 crosswalked to B4085. Deleted all XX codes. Revised Coding Guidelines section adding language regarding product classification. Revised Documentation section.

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
		04/01/1996 - HCPCS code XX004 crosswalked to A4353. Removed HCPCS codes XX060, XX063 & XX067. Added codes B4085 & XX079-XX084. Added modifiers XA and ZY. Revised Coverage and Payment Rules section including language that nutrients administered orally and related supplies are noncovered. Revised language regarding enteral nutrition for patients in a Part A SNF stay. Revised Coding Guidelines section adding information regarding B4034-B4036. Added effective dates of service for codes K0147 and B4085. Revised Documentation section adding information regarding XA and ZY modifiers. 10/01/1995 – Added HCPCS codes XX030-XX078. Revised Coverage and Payment Rules and Documentation sections to include codes XX030-XX078. 07/01/1995 – Revised Coverage and Payment Rules section as follows: Changed: "Enteral nutrition is non-covered for patients with a normally functioning GI tract whose need for enteral nutrition is due to a lack of appetite or a cognitive problem." to "Enteral nutrition is non-covered for patients with a functioning gastrointestinal tract whose need for enteral nutrition is due to reasons such as anorexia or nausea associated with mood disorder, end-stage disease, etc. Changed: "The patient must require tube feedings to sustain life. Adequate nutrition must not be possible by dietary adjustment and/or oral supplements." to "The patient must require tube feedings to maintain weight and strength commensurate with the patient's overall health status. Adequate nutrition must not be possible by dietary adjustment and/or oral supplement. Coverage is possible for patients with partial impairments-e.g., a patient with dysphagia who can swallow small amounts of food or a patient with Crohn's disease who requires prolonged infusion of enteral nutrients to overcome a problem with absorption. 06/01/2007 - In accordance with Section 911 of the Medicare Modernization Act of 2003, Virginia and West Virginia were transitioned from DME PSC TriCenturion (77011) to DME PSC TrustSolutions (77012). 11/10/2007 - The description for CPT/HCPCS code B4034 was changed in group 1 11/10/2007 - CPT/HCPCS code B4086 was deleted from group 1 11/21/2010 - For the following CPT/HCPCS codes either the short description and/or the long description was changed. Depending on which description is used in this LCD, there may not be any change in how the code displays in the document: B4034 descriptor was changed in Group 1 B4035 descriptor was changed in Group 1 B4036 descriptor was changed in Group 1	

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Associated Documents

Attachments

ENT-PEN DIF opens in new window (PDF - 37 KB)

Related Local Coverage Documents

Article(s)
A25229 - Enteral Nutrition – Policy Article – Effective May 2013 opens in new window
Related National Coverage Documents
N/A
All Versions
Updated on 03/22/2013 with effective dates 05/01/2013 - N/A
Updated on 03/02/2012 with effective dates 08/02/2011 - 04/30/2013
Updated on 10/07/2011 with effective dates 08/02/2011 - N/A
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Keywords

N/A
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Local Coverage Article for Enteral Nutrition – Policy Article – Effective May 2013 (A25229)

Contractor Information

Contractor Name	Contractor Number	Contractor Type
NHIC, Corp. opens in new window	16003	DME MAC

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Article Information

General Information

Article ID Number
A25229

Article Type
Article

Key Article
Yes

Article Title
Enteral Nutrition – Policy Article – Effective May 2013

Primary Geographic Jurisdiction opens in new window
Connecticut
District of Columbia
Delaware
Massachusetts
Maryland
Maine
New Hampshire
New Jersey
New York - Entire State
Pennsylvania
Rhode Island
Vermont

DME Region Article Covers
Jurisdiction A

Original Article Effective Date
04/01/2005

Article Revision Effective Date
05/01/2013

Article Text

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

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. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary").

Enteral nutrition is covered under the Prosthetic Device benefit (Social Security Act § 1861(s)(8)). In order for a beneficiary's nutrition to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met). In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

GENERAL:

Enteral nutrition is the provision of nutritional requirements through a tube into the stomach or small intestine.

Enteral nutrition is covered for a beneficiary who has (a) permanent non-function or disease of the structures that normally permit food to reach the small bowel or (b) disease of the small bowel which impairs digestion and absorption of an oral diet, either of which requires tube feedings to provide sufficient nutrients to maintain weight and strength commensurate with the beneficiary's overall health status.

The beneficiary must have a permanent impairment. Permanence does not require a determination that there is no possibility that the beneficiary's condition may improve sometime in the future. If the judgment of the attending physician, substantiated in the medical record, is that the condition is of long and indefinite duration (ordinarily at least 3 months), the test of permanence is considered met. Enteral nutrition will be denied as non-covered in situations involving temporary impairments.

The beneficiary's condition could be either anatomic (e.g., obstruction due to head and neck cancer or reconstructive surgery, etc.) or due to a motility disorder (e.g., severe dysphagia following a stroke, etc.). Enteral nutrition is non-covered for beneficiaries with a functioning gastrointestinal tract whose need for enteral nutrition is due to reasons such as anorexia or nausea associated with mood disorder, end-stage disease, etc.

The beneficiary must require tube feedings to maintain weight and strength commensurate with the beneficiary's overall health status. Adequate nutrition must not be possible by dietary adjustment and/or oral supplements. Coverage is possible for beneficiaries with partial impairments - e.g., a beneficiary with dysphagia who can swallow small amounts of food or a beneficiary with Crohn's disease who requires prolonged infusion of enteral nutrients to overcome a problem with absorption.

Enteral nutrition products that are administered orally and related supplies are noncovered.

If the coverage requirements for enteral nutrition are met, medically necessary nutrients, administration supplies, and equipment are covered.

Enteral nutrition provided to a beneficiary in a Part A covered stay must be billed by the SNF to the fiscal intermediary. No payment from Part B is available when enteral nutrition services are furnished to a beneficiary in a stay covered by Part A. However, if a beneficiary is in a stay not covered by Part A, enteral nutrition is eligible for coverage under Part B and may be billed to the DME MAC by either the SNF or an outside supplier.

NUTRIENTS:

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.

Codes B4102 and B4103 describe electrolyte-containing fluids that are noncovered by Medicare

Self-blenderized formulas are noncovered 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.

SUPPLIES:

Payment for a catheter/tube anchoring device is considered included in the allowance for enteral feeding supply kits (B4034-B4036). Code A5200 should not be billed separately and is not paid in addition to the supplies for enteral nutrition.

CODING GUIDELINES

The codes for enteral feeding supplies (B4034-B4036) include all supplies, other than the feeding tube itself, required for the administration of enteral nutrients to the beneficiary for one day. Codes B4034-B4036 describe a daily supply fee rather than a specifically defined "kit". Some items are changed daily; others may be used for multiple days. Items included in these codes are not limited to pre-packaged "kits" bundled by manufacturers or distributors. These supplies include, but are not limited to, 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, etc. These items must not be separately billed using the miscellaneous code (B9998) or using specific codes for dressings or tape. The use of individual items may differ from beneficiary to beneficiary and from day to day. Only one unit of service may be billed for any one day. Units of service in excess of one per day will be rejected as incorrect coding.

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-B4162) are administered by mouth, the BO modifier must be added to the code.

Code B4149 describes formulas containing natural foods that are blenderized and packaged by a manufacturer. Code B4149 must not be used for foods that have been blenderized by the beneficiary or caregiver for administration through a tube.

Suppliers should refer to the Enteral Nutrition Product Classification list on the Pricing, Data Analysis, and Coding (PDAC) Contractor web site or contact the PDAC for guidance on the correct coding for these items.

Only those products included in the Product Classification List published by the PDAC may be billed using code B4149, B4153, B4154, B4155, B4157, B4161, or B4162. If a manufacturer or supplier thinks that another product meets the definition of this code, they should contact the PDAC for a coding determination.
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Coding Information

No Coding Information has been entered in this section of the article.
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Other Information

Revision History Explanation
Revision Effective Date: 05/01/2013
NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:
Changed: Word "Patient" to "Beneficiary"

Revision Effective Date: 08/02/2011
NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:
Added: Preamble language
Removed: Documentation language

Revision Effective Date: 07/01/2009
NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:
Added: Instructions for delivery of supplies.
Changed: DMERC to DME MAC.
CODING GUIDELINES:
Clarified: Definition for supply kit codes B4034-B4036.
Changed: SADMERC to PDAC.

03/01/2008
In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC NHIC (16003) Article A25229 from DME PSC TriCenturion (77011) Article A25229.

06/01/2007

In accordance with Section 911 of the Medicare Modernization Act of 2003, Virginia and West Virginia were transitioned from DME PSC TriCenturion (77011) to DME PSC TrustSolutions (77012).

03/01/2006
In accordance with Section 911 of the Medicare Modernization Act of 2003, this article was transitioned to DME PSC TriCenturion (77011) from DMERC Tricenturion (77011).

Revision Effective Date: 04/01/2005
LMRP converted to LCD and Policy Article.
NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:
Added: Coverage statements for B4102, B4103, and B4104.
CODING GUIDELINES:
Added: New codes to range requiring BO modifier.
Added: Definition of B4149.
Added: B4149, B4153, B4157, B4161, and B4162 to the list of products requiring a coding verification review by the SADMERC.

Related Document(s)
LCD(s)
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