## Contractor Information

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## LCD Information

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### Original ICD-9 LCD ID
L27214 - Enteral Nutrition

### LCD Title
Enteral Nutrition

### AMA CPT / ADA CDT / AHA NUBC

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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 coverage indications, limitations and/or medical necessity.

Medicare does not automatically assume payment for a durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) item that was covered prior to a beneficiary becoming eligible for the Medicare Fee For Service (FFS) program. When a beneficiary receiving a DMEPOS item from another payer (including Medicare Advantage plans) becomes eligible for the Medicare FFS program, Medicare will pay for continued use of the DMEPOS item only if all Medicare coverage, coding and documentation requirements are met. Additional documentation to support that the item is reasonable and necessary, may be required upon request of the DME MAC.

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. 100-08, 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.

**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 article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.
**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 article 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 article should be assumed to apply equally to all Revenue Codes.

**CPT/HCPCS Codes**

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

**HCPCS MODIFIERS:**
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

**HCPCS CODES:**

**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)
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

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

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

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

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

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

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

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

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

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
ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:
Not specified

Group 1 Codes:

ICD-10 Codes that DO NOT Support Medical Necessity

Group 1 Paragraph:
Not specified

Group 1 Codes:

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. (PIM 5.2.3)

MEDICAL RECORD INFORMATION

GENERAL (PIM 5.7 - 5.9)

The Coverage Indications, Limitations and/or Medical Necessity section of this LCD contains numerous reasonable and necessary (R&N) requirements. The Non-Medical 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 MEDICAL NEED

For all Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (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 date of service (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.
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.

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 (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 document. The POD document 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

The date delivered on the POD must be the date that the DMEPOS item was received by the beneficiary or designee. The date of delivery may be entered by the beneficiary, designee or the supplier. When the supplier’s delivery documents have both a supplier-entered date and a beneficiary or beneficiary’s designee signature date on the POD document, the beneficiary or beneficiary’s designee-entered date is the date of service.

In instances where the supplies are delivered directly by the supplier, the date the beneficiary received the DMEPOS supply 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.

EQUIPMENT RETAINED FROM A PRIOR PAYER

When a beneficiary receiving a DMEPOS item from another payer (including a Medicare Advantage plan) becomes eligible for the Medicare FFS program, the first Medicare claim for that item or service is considered a new initial Medicare claim for the item. Even if there is no change in the beneficiary’s medical condition, the beneficiary must meet all coverage, coding and documentation requirements for the DMEPOS item in effect on the date of service of the initial Medicare claim.

A POD is required for all items, even those in the beneficiary’s possession provided by another insurer prior to Medicare eligibility. To meet the POD requirements for a beneficiary transitioning to Medicare, the supplier:

1. Must obtain a new POD as described above under “Methods of Delivery” (whichever method is applicable); or,
2. Must obtain a statement, signed and dated by the beneficiary (or beneficiary's designee), attesting that the supplier has examined the DMEPOS item, it is in good working order and that it meets Medicare requirements.
For the purposes of reasonable useful lifetime and calculation of continuous use, the first day of
the first rental month in which Medicare payments are made for the item (i.e., date of service)
serves as the start date of the reasonable useful lifetime and period of continuous use. In these
cases, the proof of delivery documentation serves as evidence that the beneficiary is already in
possession of the item.

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.

A Recertification DIF must be submitted when the length of need previously entered on the DIF
has expired and the ordering physician is extending the length of need for the item(s).

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 additional information on documentation requirements.

Appendices
PIM citations above denote references to CMS Program Integrity Manual, Internet Only Manual
100-08
Utility Guidelines
Refer to Coverage Indications, Limitations and/or Medical Necessity

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

Revision History Information

Please note: Most Revision History entries effective on or before 01/24/2013 display with a Revision History Number of "R1" at the bottom of this table. However, there may be LCDs where these entries will display as a separate and distinct row.

<table>
<thead>
<tr>
<th>Revision History Date</th>
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| 10/01/2015            | R1                      | **Revision Effective Date: 10/31/2014**
|                       |                         | COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: Standard Documentation Language to add covered prior to a beneficiary’s Medicare eligibility DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation Language to add who can enter date of delivery date on the POD Added: Instructions for Equipment Retained from a Prior Payer POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: Instructions for Recertification DIF | Provider Education/Guidance |

Associated Documents

Attachments
Enentral and Parenteral NutritionDIF (37 KB) (Uploaded on 05/20/2015)

Related Local Coverage Documents
Article(s)
A52493 - Enteral Nutrition - Policy Article - Effective October 2015

Related National Coverage Documents
This LCD version has no Related National Coverage Documents.
### Contractor Information

<table>
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<th>Contractor Name</th>
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<td>16003</td>
<td>DME MAC</td>
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### Article Information

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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.

The only products which may be billed using codes B4149, B4153, B4154, B4155, B4157, B4161, or B4162 are those for which a written Coding Verification Review has been made by the
Pricing, Data Analysis and Coding (PDAC) Contractor and subsequently published on the appropriate Product Classification List.

Suppliers should refer to the Enteral Nutrition Product Classification list on the PDAC Contractor web site or contact the PDAC for guidance on the correct coding for these items.

**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 article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

**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 article 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 article should be assumed to apply equally to all Revenue Codes.

**CPT/HCPCS Codes**

**Group 1 Paragraph:**

**Group 1 Codes:**

**Covered ICD-10 Codes**

**Group 1 Paragraph:**

**Group 1 Codes:**

**Non-Covered ICD-10 Codes**

**Group 1 Paragraph:**

**Group 1 Codes:**

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**Revision History Information**

**Please note:** The Revision History information included in this Article prior to 06/20/2013 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 06/20/2013 will display as a row in the Revision History section of the Article and numbering will begin with "R2".

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CODING GUIDELINES:
Updated: Standard language documentation for PDAC coding verification
Associated Documents

Related Local Coverage Document(s)
LCD(s)
L33783 - Enteral Nutrition

Related National Coverage Document(s)
This Article version has no Related National Coverage Documents.

Statutory Requirements URL(s)

Rules and Regulations URL(s)

CMS Manual Explanations URL(s)

Other URL(s)