Medicare Coverage of Enteral Nutrition Therapy

AN INFORMATIONAL PRIMER
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>An Overview</td>
<td>4</td>
</tr>
<tr>
<td>Medicare Coverage of Enteral Nutrition Therapy</td>
<td>4</td>
</tr>
<tr>
<td>ENT Coverage Under Part A</td>
<td>4</td>
</tr>
<tr>
<td>ENT Coverage Under Part B</td>
<td>6</td>
</tr>
<tr>
<td>Enteral Nutrition Therapy</td>
<td>7</td>
</tr>
<tr>
<td>Coding, Payments, and Claim Submission for ENT: Suppliers and the DME MACs</td>
<td>7-8</td>
</tr>
<tr>
<td>Formula Reimbursement</td>
<td>8</td>
</tr>
<tr>
<td>Enteral Pump / Administration Supplies Reimbursement</td>
<td>9</td>
</tr>
<tr>
<td>Appendix</td>
<td>10</td>
</tr>
<tr>
<td>Health Insurance Claim Form (CMS-1500)</td>
<td>11</td>
</tr>
<tr>
<td>DME MAC Information Form (DIF) (CMS-10126)</td>
<td>12</td>
</tr>
<tr>
<td>Instructions for Completing DIF (CMS-10126)</td>
<td>13</td>
</tr>
<tr>
<td>Resources and Contact Information</td>
<td>14</td>
</tr>
<tr>
<td>Medicare Regional Offices</td>
<td>15</td>
</tr>
<tr>
<td>Medicare National Coverage Determination Manual</td>
<td>16</td>
</tr>
<tr>
<td>Sample Local Coverage Determination</td>
<td>17-18</td>
</tr>
<tr>
<td>Sample Documentation Checklist – Enteral Nutrition</td>
<td>19-20</td>
</tr>
</tbody>
</table>
The Medicare Program and
Traditional Medicare Plan

An Overview

Medicare is a federally administered health insurance program that generally provides health coverage for Americans who are age 65 or older, certain disabled individuals and certain individuals with end-stage renal disease. The U.S. Department of Health and Human Services (HHS), through the Centers for Medicare and Medicaid Services (CMS), is responsible for administering the Medicare program, and establishing policies relating to Medicare coverage and reimbursement. The traditional Medicare program (sometimes referred to as the “original plan”) is administered and funded under Parts A and B. Part A is funded by the Hospital Insurance Trust Fund and is sometimes known as the Hospital Insurance Benefit. Part B is funded by the Supplemental Medical Insurance Trust Fund and is sometimes referred to as the Supplementary Medical Insurance Benefit or simply the Medical Insurance Benefit.

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 was enacted in November 2003 and became effective on January 1, 2006. Two major changes occurred. A prescription drug benefit (Part D) was added and the managed care program (Part C), formerly known as Medicare + Choice, was redesigned and renamed Medicare Advantage.

Medicare Part C (Medicare Advantage Plan) combines Part A, Part B and, sometimes, Part D (prescription drug) coverage. Medicare Advantage (MA) Plans are managed by private insurance companies approved by Medicare. MA plans provide coverage for medically necessary services. “Medically necessary” is defined as services or supplies that are needed for the diagnosis or treatment of a medical condition, meet the standards of good medical practice in the local area, and aren’t mainly for the convenience of a beneficiary or his physician that the Original Plan provides in accordance with rules set by Medicare. However, plans can charge different co-payments, coinsurance, or deductibles for these services.

Medicare Part D Prescription Drug Coverage is insurance provided by private companies. Beneficiaries choose the drug plan and pay a monthly premium.

As defined by the plan, Part A helps cover medically necessary inpatient hospital stays, skilled nursing facility care (not custodial or long-term care), hospice care and some home health care. Part B helps cover medically necessary doctors’ services, outpatient care, some home health care and some other medical services that Part A does not cover, such as some of the therapy services.

Medicare Coverage of Enteral Nutrition Therapy

Enteral nutrition therapy (ENT), both nutrients and supplies, can be covered under Medicare Part A, Part B or Part C.

ENT Coverage Under Part A

ENT coverage is available under Part A, when coverage criteria are met. Medicare reimbursement for ENT under Part A is provided in an all-inclusive prospective payment system (PPS) rate. Accordingly, ENT is not separately reimbursable under Part A. Under Part A, enteral nutrition therapy is typically administered in either inpatient hospitals or skilled nursing facilities.

Inpatient Hospitals

Medicare Part A covers various inpatient hospital services provided by qualified hospitals participating in the Medicare program. In general, coverage includes services provided to inpatients for up to 150 days during any “spell of illness.” 42 U.S.C. § 1395d(a)(1), 42 C.F.R. § 409.10(a)(6). When a Medicare beneficiary receives therapeutic services during a Part A covered inpatient hospital stay, therapeutic services are not separately reimbursable, rather they are included in the prospective payment system (PPS) rate that is based on the beneficiary’s discharge classification.

Each Medicare beneficiary inpatient stay is classified according to a list of diagnosis-related groups (DRGs), and the payment amount that a hospital receives for an inpatient hospital stay depends on the DRG to which that beneficiary discharge is assigned. DRG payment rates generally constitute payment in full to the hospital for its cost of caring for inpatients. Medicare Claims Processing Manual, Chapter Three, 20 (A)(D).

In general, ENT provided during a covered Part A hospital stay is included in the DRG payment that a hospital receives and therefore is not separately reimbursable.

(DRGs and payment rates are accessible via a variety of government and private payer sources. The “Online Resources” section of this document provides links to the CMS web site where a variety of information on Part A Inpatient Hospital coverage is available.)

Beginning in 2013 programs such as the Value Based Purchasing (VBP), a program authorized by the Patient Protection and Accountable Care Act of 2010 (PPACA), will give Medicare the power to base a portion of hospital reimbursement on the quality of care provided. These programs are intended to transform Medicare from being a passive payer of claims based on volume, to a prudent purchaser or care based on the quality of services that a beneficiary receives. In the coming years other programs that measure quality using various benchmarks as well as the utilization of evidence based medicine guidelines and protocols will be implemented.

Skilled Nursing Facilities

Medicare Part A covers certain “post-hospital extended care services” furnished to a Medicare beneficiary who is an inpatient in a “skilled nursing facility (SNF)” and who, on a daily basis, needs skilled nursing care or other skilled rehabilitation services that are provided in a SNF on an inpatient basis. 42 U.S.C. § 1395f(a)(2) (B); 42 C.F.R. § 409.30. In general, Part A covers up to the first 100 days of a stay in a SNF if various eligibility requirements are met. 42 U.S.C. § 1395d(a)(2).

Patients who enter a SNF must meet all of the following criteria to qualify for Medicare Part A benefits:

- Must have been an inpatient in a hospital for at least 3 consecutive medically necessary days
- Must have been recently discharged (generally within 30 days) from a hospital following an inpatient stay of at least 72 hours
- Must receive treatment in a Medicare-certified SNF
- Must require daily skilled nursing or rehabilitation services
- Must require services that can only be delivered in a SNF

During the Part A-covered portion of a beneficiary’s stay in a SNF, certain benefits are covered under the Part A benefit; ENT is one of these covered services. Medicare reimbursement for ENT under Part A is, therefore, included in the all-inclusive prospective payment rate established by CMS and based on the resource utilization groups (RUGs) created to define a beneficiary’s clinical status and establish a reimbursement rate commensurate with the beneficiary’s condition. RUGs are any of a number of groups into which a nursing home resident is categorized, based on functional status and anticipated use of services and resources.²

Therefore, when a beneficiary receives ENT during a Part A covered SNF stay, the ENT is not separately reimbursable under the Part B program; rather, it is included in the established per diem rate based on RUG classification. RUG classifications are established by CMS and can be accessed via the CMS web site; the address is provided in the “Online Resources” section at the end of this document.3

## ENT Coverage Under Part B

For any ENT item to be covered by Part B, a beneficiary’s medical record must indicate sufficient documentation to substantiate the need for ENT as well as the type, frequency and quantity of enteral formula and supplies. A Durable Medical Equipment Medicare Administrative Contractor Information Form (DIF) is required to be on file with the DMEPOS supplier, which may be reviewed by the DME MAC at the carrier’s discretion. (A copy of the DIF form is located in the back of this document.)

Medicare policy states that ENT formulas consisting of semi-synthetic intact protein/protein isolates (B4150 or B4152) are appropriate for the majority of patients requiring enteral nutrition. The medical necessity for special enteral formulas (B4149, B4153-B4157, B4161, and B4162) must be justified in each patient. 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. The past practice of “downcoding” specialty nutrients by paying them at the payment rate for B4150 was eliminated for dates of services after February 2011. Suppliers should maintain all the necessary documentation supporting payment for the item or service they billed to Medicare. CMS and the DME MACs publish ENT coverage policies that are reviewable on their respective websites. The Local Coverage Determinations (LCDs) and Policy Articles define coverage criteria, payment rules and documentation that will be applied to DMEPOS claims processed by the Durable Medical Equipment Medicare Administrative Contractors (DME MACs). CMS requires that the LCDs published by the DME MACs be identical in each region. An example of a current DME MAC’s LCD and policy article is included in the appendices of this document. LCDs for all DME MACs are available on their respective websites. A sample documentation check list is included in the Appendices.

It is the responsibility of all persons and entities participating in Medicare to be aware of all documentation and other requirements.

Medicare Part B provides for ENT coverage under the prosthetic device benefit. Certain requirements must be satisfied in order to trigger Medicare Part B coverage of ENT. First, the beneficiary must have a permanent functional impairment of the gastrointestinal tract. Second, ENT must be reasonable and necessary for the beneficiary. Third, the beneficiary must require tube feeding to maintain weight and strength commensurate with his or her overall health status. If these coverage requirements for ENT are satisfied, the related enteral equipment, supplies and nutrients may be covered under Medicare Part B.

The Medicare National Coverage Determinations Manual (Chapter 1, Part 3 (Section 180.2)) states the basic guidelines ofENT coverage under Part B as follows:

“Coverage of nutritional therapy as a Part B benefit is provided under the prosthetic device benefit provision which requires that the patient must have a permanently inoperative internal body organ or function thereof. Therefore, enteral and parenteral nutritional therapy are not covered under Part B in situations involving temporary impairments. Coverage of such therapy, however, does not require a medical judgment that the impairment giving rise to the therapy will persist throughout the patient’s remaining years. If the medical record, including the judgment of the attending physician, indicates that the impairment will be of long and indefinite duration, the test of permanence is considered met. If the coverage requirements for enteral or parenteral nutritional therapy are met under the prosthetic device benefit provision, related supplies, equipment and nutrients are also covered under the conditions in the following paragraphs and the Medicare Benefit Policy Manual, Chapter 15, ‘Covered Medical and Other Health Services.’ §120

3 www.cms.hhs.gov/manuals/downloads/clm104c07.pdf

Medicare Claims Processing Manual Chapter 7 - SNF Part B Billing (Including Inpatient Part B and Outpatient Fee Schedule) (Rev. 1472, 03-06-08)
Enteral Nutrition Therapy

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

Typical examples of conditions that qualify for coverage are head and neck cancer with reconstructive surgery and central nervous system disease leading to interference with the neuromuscular mechanisms of ingestion of such severity that the beneficiary cannot be maintained with oral feeding. However, claims for Part B coverage of enteral nutrition therapy for these and any other conditions must be approved on an individual, case-by-case basis. Each claim must contain a physician’s written order or prescription and sufficient medical documentation (e.g., hospital records, clinical findings from the attending physician) to permit an independent conclusion that the patient’s condition meets the requirements of the prosthetic device benefit and that enteral nutrition therapy is medically necessary. Allowed claims are to be reviewed at periodic intervals of no more than 3 months by the contractor’s medical consultant or specially trained staff, and additional medical documentation considered necessary is to be obtained as part of this review.

Medicare pays for no more than one month’s supply of enteral nutrients at any one time.

If the claim involves a pump, it must be supported by sufficient medical documentation to establish that the pump is medically necessary, e.g., gravity feeding is not satisfactory due to aspiration, diarrhea, dumping syndrome. Program payment for the pump is based on the reasonable charge for the simplest model that meets the medical needs of the patient as established by medical documentation.

Coding, Payments, and Claim Submission for ENT Suppliers and the Durable Medical Equipment Medicare Administrative Contractors (DMEMAC)

Claims for Medicare Part B payment for ENT must be submitted by a registered and certified Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) supplier to the appropriate DME MAC. As explained previously in this document, ENT is considered for coverage under Medicare’s prosthetic device benefit because the therapy replaces all or part of an internal body organ or replaces all or part of the function of a permanently inoperative or malfunctioning body organ and is furnished pursuant to a physician’s order. Thus, ENT coverage is available for a beneficiary requiring tube feeding “to provide sufficient nutrients to maintain weight and strength commensurate with the patient’s overall health status” because of either:

- 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.”

A DMEPOS supplier is an entity or individual which provides, sells or rents DMEPOS to Medicare beneficiaries and has obtained a Medicare supplier number (42 C.F.R. § 424.57 (a)(b). Requirements for becoming a Medicare supplier are set forth in the Code of Federal Regulations and information on supplier requirements and controlling regulations is available from CMS and the DME MACs.
In January 2011 Medicare implemented the Competitive Bidding Program for certain DMEPOS items in 9 metropolitan statistical areas (MSAs) across the country. The program was mandated as part of the Medicare Modernization Act of 2003. This program requires Medicare beneficiaries who reside in certain MSAs to obtain competitively bid items such as enteral nutrition from a contracted supplier. Unless there is new legislation to repeal or delay the program, Round 2 will continue as planned in 2013. The Patient Protection and Affordability Act of 2010 mandates that Round 2 occur in 91 of the largest MSAs. The law increased the number of new MSAs from 70. After Round 2, but before 2016, competitively bid rates would need to be implemented across the country with some exceptions (rural areas, MSAs with low population density). For additional information regarding the Medicare DMEPOS Competitive Bidding Program refer to the Competitive Bidding Implementation Contractor’s website:

Part B claims for ENT are submitted by a supplier either electronically or on paper. An example of the paper claim form is included in the back of this document titled Health Insurance Claim Form (CMS-1500). There are four DME MACs selected by the federal government to process claims for DMEPOS. Each DME MAC is responsible for handling DMEPOS claims for beneficiaries in specific regions of the country. (A list of the DME MACs with contact information is provided in the back of this document).

A supplier submits any claim for ENT to the appropriate DME MAC using the Healthcare Common Procedure Coding System (HCPCS) codes. These codes are used to define the nutrients and supplies that may be covered under Medicare. The ENT HCPCS codes were originally established in 2001 by CMS. CMS is responsible for adding or deleting HCPCS and there is a formal process that a manufacturer must follow to request a code determination. ENT HCPCS codes are defined by the type of formula or type of supply (e.g., pump with or without alarm); and each code is assigned a payment rate.

The payment rates for ENT nutrients and supplies are determined on a fee schedule basis as set annually by CMS. This payment rate, per federal law, is uniform across the country and is called the PEN Fee Schedule. Medicare Part B pays 80% of the lesser of the actual charge for the specific item or the fee schedule amount for ENT (and all Part B items and services), with the remaining 20% being the responsibility of the beneficiary or other secondary payer.§ 414.100 42 CFR Ch. IV (10–1–06 Edition)

(PDAC Search for Fees and Codes) www.dmepdac.com/dmecsapp/do/search

Formula Reimbursement

Under Medicare Part B, enteral formula is reimbursed based on the number of “units” of a specific formula provided to a beneficiary. A “unit” is defined based on 100 calories of formula and a supplier must submit the appropriate Medicare billing documents with “units” per day consumed by a beneficiary and not the number of cans or cases used. In the case of enteral formulas, HCPCS code assignments and reimbursement rates are based on the composition and source of ingredients in each individual formula, as well as the formula’s intended therapeutic benefit. Each HCPCS code is assigned a reimbursement rate by CMS, except pediatric enteral formula, which is not assigned a reimbursement rate.4

A “Product Classification List” of ENT formulas with corresponding codes is maintained by the Pricing, Data Analysis and Coding (PDAC). This comprehensive list is updated throughout the year as manufacturers of enteral products submit information on new products for review and coding determinations. The list is available on the PDAC website and a link is provided at the back of this document. Contact information for the PDAC is provided in the Resource Section of this document.
Enteral Pump/Administration Supplies Reimbursement

In the case of ENT pumps, Medicare Part B provides coverage to a beneficiary on a rental or purchase basis. Part B payment for the pumps varies depending on the type of pump AND how the pump is provided to a beneficiary. A pump can be purchased by a beneficiary from a DMEPOS supplier as either new or used/refurbished. The beneficiary then chooses either the rental or purchase option.

Medicare Part B reimburses for the rental of a medically necessary ENT pump on a monthly basis, with a capped rental period of 15 months. During the 10th rental month the supplier must offer the beneficiary the option to own the pump. If the beneficiary elects to purchase the pump the rental payments end and title to the pump is transferred to the beneficiary. The supplier must confirm that it holds title before it can transfer title. If title transfers to the beneficiary, Medicare will pay for necessary maintenance and servicing pursuant to Medicare policy. If the beneficiary elects not to purchase the pump the supplier must continue to provide the pump to the beneficiary (assuming continued medical necessity) even after the rental payments end after the 15th month of use however, maintenance and/or servicing fees established under Medicare Part B will continue to be paid, as deemed appropriate by the fiscal intermediary. Medicare Part B will also cover IV poles and other administration supplies as needed for the delivery of nutrients.

Administration supply reimbursement is based on the method of administration (e.g., syringe/bolus, gravity, and pump) and each supply kit is assigned a specific rate based on HCPCS coding. IV poles are reimbursed as a rental item on a monthly basis.

A supplier must utilize appropriate billing codes and modifiers depending on what pump option a beneficiary chooses. Information from DME MAC policy is provided in the back of this document and suppliers can obtain comprehensive information from their DME MAC.

Suppliers should consult the LCDs and Policy Articles to ensure awareness of all relevant regulations concerning the provision and coverage of enteral pumps.

\^ In the rare cases where pediatric enteral therapy is covered by Medicare Part B, the reimbursement rates are based on their adult counterparts; e.g., a standard pediatric formula will be paid at the rate for a standard adult formula, etc. Payment for pediatric enteral formula by other government payment systems (e.g., State Medicaid Programs) is established by that payer source.
Health Insurance Claim Form (CMS-1500) ........................................ 11
DME MAC Information Form (DIF) (CMS-10126) ............................. 12
Instructions for Completing DIF (CMS-10126) ............................. 13
Resources and Contact Information ............................................. 14
Medicare Regional Offices ............................................................ 15
Medicare National Coverage Determination Manual ..................... 16
Sample Local Coverage Determination ........................................ 17-18
Sample Documentation Checklist – Enteral Nutrition ................. 19-20
Health Insurance Claim Form, with Instructions

FORM CMS-1500:

## DME INFORMATION FORM

**CMS-10126 - ENTERAL AND PARENTERAL NUTRITION**

**ALL INFORMATION ON THIS FORM MAY BE COMPLETED BY THE SUPPLIER**

<table>
<thead>
<tr>
<th>Certification Type/Date: INITIAL</th>
<th>REVISED</th>
<th>RECERTIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Name:</td>
<td>Supplier Name:</td>
<td></td>
</tr>
<tr>
<td>Patient Address:</td>
<td>Supplier Address:</td>
<td></td>
</tr>
<tr>
<td>Patient Phone:</td>
<td>Supplier Phone:</td>
<td></td>
</tr>
<tr>
<td>HICN:</td>
<td>NSC or NPI #:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Place of Service:</th>
<th>HCPCS Code</th>
<th>PT DOB</th>
<th>Sex:</th>
<th>Ht:</th>
<th>Wt:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility Name:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facility Address:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**EST. LENGTH OF NEED (# OF MONTHS): 1-99 (99=LIFETIME) | DIAGNOSIS CODES (ICD-9):**

**ANSWERS**

1. Is there documentation in the medical record that supports the patient having a permanent non-function or disease of the structures that normally permit food to reach or be absorbed from the small bowel?  

   - ○ Yes  
   - ○ No

2. Is the enteral nutrition being provided for administration via tube? (i.e., gastrostomy tube, jejunostomy tube, nasogastric tube)

   - ○ Yes  
   - ○ No

3. Print HCPCS code(s) of product.

   - A)  
   - B)

4. Calories per day for each corresponding HCPCS code(s).

   - A)  
   - B)

5. Circle the number for method of administration?

   - 1 - Syringe  
   - 2 - Gravity  
   - 3 - Pump  
   - 4 - Oral (i.e. drinking)

6. Days per week administered or infused (Enter 1 - 7)

   - ○ 1  
   - ○ 2  
   - ○ 3  
   - ○ 4  

7. Is there documentation in the medical record that supports the patient having permanent disease of the gastrointestinal tract causing malabsorption severe enough to prevent maintenance of weight and strength commensurate with the patient's overall health status?

   - ○ Yes  
   - ○ No

8. Formula components:

   - Amino Acid (ml/dy)  
   - Dextrose (ml/dy)  
   - Lipids (ml/dy)  

   - concentration %  
   - concentration %  
   - concentration %

   - gms protein/day  
   - days / week

   - ○ 1  
   - ○ 2  
   - ○ 3

9. Circle the number for the route of administration.

   - 1 - Central Line (Including PICC)  
   - 2 - Hemodialysis Access Line  
   - 3 - Peritoneal Catheter

**Supplier Attestation and Signature/Date**

I certify that I am the supplier identified on this DME Information Form and that the information provided is true, accurate and complete, to the best of my knowledge. I understand that any falsification, omission, or concealment of material fact associated with billing this service may subject me to civil or criminal liability.

**SUPPLIER SIGNATURE**  
**DATE**

---

Form CMS-10126 (09/05) EF 08/2006
### INSTRUCTIONS FOR COMPLETING DME INFORMATION FORM FOR ENTERAL AND PARENTERAL NUTRITION (CMS-10126)

| CERTIFICATION TYPE/DATE: | If this is an initial certification for this patient, indicate this by placing date (MM/DD/YY) needed initially in the space marked "INITIAL." If this is a revised certification (to be completed when the physician changes the order based on the patient's changing clinical needs), indicate the initial date needed in the space marked "INITIAL," and also indicate the revision date in the space marked "REVISED." If this is a recertification, indicate the initial date needed in the space marked "INITIAL," and also indicate the recertification date in the space marked "RECERTIFICATION." Whether submitting a REVISED or a RECERTIFICATION DIF, be sure to always furnish the initial date as well as the REVISED or RECERTIFICATION date. |
| PATIENT INFORMATION: | Indicate the patient's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on his/her Medicare card and on the claim form. |
| SUPPLIER INFORMATION: | Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC) or applicable National Provider Identifier (NPI). If using the NPI Number, indicate this by using the qualifier XX followed by the 10-digit number. If using a legacy number, e.g. NSC number, use the qualifier 1C followed by the 10-digit number. (For example: 1C0000000)

| PLACE OF SERVICE: | Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to the DMEIC supplier manual for a complete list. |
| FACILITY NAME: | If the place of service is a facility, indicate the name and complete address of the facility. |
| HCPCS CODES: | List all HCPCS procedure codes for items ordered that require a DIF. Procedure codes that do not require certification should not be listed in this section of the DIF. |
| PATIENT DOB, HEIGHT, WEIGHT AND SEX: | Indicate patient's date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if required. |
| PHYSICIAN NAME, ADDRESS: | Indicate the physician's name and complete mailing address. |
| PHYSICIAN INFORMATION: | Accurately indicate the treating physician's Unique Physician Identification Number (UPIN) or applicable National Provider Identifier (NPI). If using the NPI Number, indicate this by using the qualifier XX followed by the 10-digit number. If using UPIN number, use the qualifier 1G followed by the 6-digit number. (For example: 1G000000) |
| PHYSICIAN'S TELEPHONE NO.: | Indicate the telephone number where the physician can be contacted (preferably where records would be accessible pertaining to this patient) if more information is needed. |
| QUESTION SECTION: | This section is used to gather clinical information about the item or service billed. Answer each question which applies to the items ordered, circling "Y" for yes, "N" for no, a number if this is offered as an answer option, or fill in the blank if other information is requested. |
| SUPPLIER ATTESTATION: | The supplier's signature certifies that the information on the form is an accurate representation of the situation(s) under which the item or service is billed. |
| SUPPLIER SIGNATURE AND DATE: | After completion, supplier must sign and date the DME Information Form, verifying the Attestation. |

---

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0679. The time required to complete this information collection is estimated to average 12 minutes per response, including the time to review instructions, search existing records, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to CMS, Attn: PRA Reports Clearance Officer, 7500 Security Blvd, Baltimore, Maryland 21244.

DO NOT SUBMIT CLAIMS TO THIS ADDRESS. Please see http://www.medicare.gov/ for information on claim filing.

Form CMS-10126 (09/05) INSTRUCTIONS # 08/2006
Resources and Contact Information


Durable Medical Equipment Medicare Administrative Contractors (DME MACs):

Jurisdiction A – NHIC, Corp
Connecticut, District of Columbia, Delaware, Massachusetts, Maryland, Maine, New Hampshire, New Jersey, New York - Entire State, Pennsylvania, Rhode Island and Vermont
NHIC, Corp. (16003 - DME MAC)
75 Sgt. William B. Terry Drive
Hingham, MA, 02043
www.medicarenhic.com
866-590-6731

Jurisdiction B – National Government Services
Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio, Wisconsin
National Government Services, Inc.
P.O. Box 6036
Indianapolis, IN 46207-7027
http://www.ngsmedicare.com/wps/portal/ngsmedicare/home
866-590-6727

Jurisdiction C – CGS
Alabama, Arkansas, Colorado, Florida, Georgia, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, Puerto Rico, South Carolina, Tennessee, Texas, U.S. Virgin Islands, Virgin Islands, and West Virginia.
CGS
P.O. Box 20010
Nashville, TN 37202
http://www.cgsmedicare.com/jc/index.html
http://www.cgsmedicare.com/jc/coverage/mr/Enternal_Nutrition_Resources.html
866-270-4909

Jurisdiction D – Noridian Administrative Services
Noridian Administrative Services
P.O. Box 6727
Fargo ND 58108-6727
https://www.noridianmedicare.com/dme/%3f
866-243-7272

Medicare Learning Network: www.cms.hhs.gov/MLNGenInfo

On-line Manuals: www.cms.hhs.gov/manuals

Medicare Pricing, Data Analysis and Coding (PDAC) HCPCS Review: https://www.dmepdac.com/

HCPCS Code look-up: https://www.dmepdac.com/dmecsapp/do/search

Medicare Coverage Database: www.cms.hhs.gov/mcd/results.asp?show=all&t=200863182835

Skilled Nursing Facilities PPS, RUG-IV Education and Training:
https://www.cms.gov/SNFPPS/03_RUGIVEdu.asp

Beneficiaries Customer Service Line: 1-800-MEDICARE (1-800-633-4227)
### Medicare Regional Offices

The Regional Offices generally serve as the agency’s main link to beneficiaries, health care providers, state and local governments and should be an initial point of contact for Medicare issues for the general public.

<table>
<thead>
<tr>
<th>Region 1</th>
<th>Responsibilities: Connecticut, Massachusetts, Maine, New Hampshire, Rhode Island, Vermont</th>
<th>617-565-1331</th>
</tr>
</thead>
<tbody>
<tr>
<td>Region 2</td>
<td>Responsibilities: New Jersey, New York, Puerto Rico, Virgin Islands</td>
<td>212-616-2500</td>
</tr>
<tr>
<td>Region 3</td>
<td>Responsibilities: Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia</td>
<td>215-861-4140</td>
</tr>
<tr>
<td>Region 4</td>
<td>Responsibilities: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee</td>
<td>404-562-7304</td>
</tr>
<tr>
<td>Region 5</td>
<td>Responsibilities: Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin</td>
<td>312-353-9841</td>
</tr>
<tr>
<td>Region 6</td>
<td>Responsibilities: Arkansas, Louisiana, New Mexico, Oklahoma, Texas</td>
<td>214-767-6441</td>
</tr>
<tr>
<td>Region 7</td>
<td>Responsibilities: Iowa, Kansas, Missouri, Nebraska</td>
<td>816-426-5033</td>
</tr>
<tr>
<td>Region 8</td>
<td>Responsibilities: Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming</td>
<td>816-426-5033</td>
</tr>
<tr>
<td>Region 9</td>
<td>Responsibilities: American Samoa, Arizona, California, Commonwealth of the Northern Mariana Islands, Guam, Hawaii, Nevada</td>
<td>415-744-3654</td>
</tr>
<tr>
<td>Region 10</td>
<td>Responsibilities: Alaska, Idaho, Oregon, Washington</td>
<td>206-615-2331</td>
</tr>
</tbody>
</table>
National Coverage Determination (NCD) for ENTERAL and PARENTERAL Nutritional Therapy (180.2)

Publication Number: 100-3
Manual Section Number 180.2

Manual Section Title:
ENTERAL and Parenteral Nutritional Therapy

Version Number: 1
Effective Date of this Version: 7/11/1984

Benefit Category Prosthetic Devices

Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

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

Indications and Limitations of Coverage
Coverage of nutritional therapy as a Part B benefit is provided under the prosthetic device benefit provision which requires that the patient must have a permanently inoperative internal body organ or function thereof. Therefore, enteral and parenteral nutritional therapy are not covered under Part B in situations involving temporary impairments. Coverage of such therapy, however, does not require a medical judgment that the impairment giving rise to the therapy will persist throughout the patient’s remaining years. If the medical record, including the judgment of the attending physician, indicates that the impairment will be of long and indefinite duration, the test of permanence is considered met.

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

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

Typical examples of conditions that qualify for coverage are head and neck cancer with reconstructive surgery and central nervous system disease leading to interference with the neuromuscular mechanisms of ingestion of such severity that the beneficiary cannot be maintained with oral feeding. However, claims for Part B coverage of enteral nutrition therapy for these and any other conditions must be approved on an individual, case-by-case basis. Each claim must contain a physician’s written order or prescription and sufficient medical documentation (e.g., hospital records, clinical findings from the attending physician) to permit an independent conclusion that the patient’s condition meets the requirements of the prosthetic device benefit and that enteral nutrition therapy is medically necessary. Allowed claims are to be reviewed at periodic intervals of no more than 3 months by the contractor’s medical consultant or specially trained staff, and additional medical documentation considered necessary is to be obtained as part of this review.

Medicare pays for no more than one month’s supply of enteral nutrients at any one time.

If the claim involves a pump, it must be supported by sufficient medical documentation to establish that the pump is medically necessary, i.e., gravity feeding is not satisfactory due to aspiration, diarrhea, dumping syndrome. Program payment for the pump is based on the reasonable charge for the simplest model that meets the medical needs of the patient as established by medical documentation.

Nutritional Supplementation
Some patients require supplementation of their daily protein and caloric intake. Nutritional supplements are often given as a medicine between meals to boost protein-caloric intake or the mainstay of a daily nutritional plan. Nutritional supplementation is not covered under Medicare Part B.
Local Coverage Determination (LCD) for Enteral Nutrition (L11568)

NOTE: Sample Local Coverage Determination for Enteral Nutrition from Region A. LCDs are the same in all coverage areas. This is NOT the complete LCD. Refer to the DME MAC website or CMS Coverage Determination links for complete LCDs.

AMA CPT/ADA CDT Copyright Statement: CPT codes, descriptions and other data only are copyright 2010 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Clauses Apply. Current Dental Terminology, (CDT) (including procedure codes, nomenclature, descriptors and other data contained therein) is copyright by the American Dental Association. © 2002, 2004 American Dental Association. All rights reserved. Applicable FARS/DFARS apply.

CMS National Coverage Policy

CMS Pub. 100-3 National Coverage Determinations Manual, Chapter 1, Section 180.2
Indications and Limitations of Coverage 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 written signed and dated order 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 order, the item will be denied as not reasonable and necessary.

General Information:

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 patients requiring enteral nutrition.

The medical necessity for special enteral formulas (B4149, B4153-B4157, B4161, and B4162) must be justified in each patient. 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 patients may experience complications associated with syringe or gravity method of administration.

If a pump (B9000-B9002) is ordered, there must be documentation in the patient’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 kit (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 kit (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 kits (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.

**Documentations 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 patient’s medical records will reflect the need for the care provided. The patient’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.

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

A DME Information Form (DIF), which has been completed, signed, and dated by the supplier, must be kept on file by the supplier and made available upon request. The DIF for Enteral Nutrition is CMS Form 10126. 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 resummed 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 resummed after they have not been required for two consecutive months.
2. A patient 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).

Special nutrient formulas, HCPCS codes B4149, B4153-B4157, B4161, and B4162, are produced to meet unique nutrient needs for specific disease conditions. The patient’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.

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

*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
**Documentation Checklist**

**Enteral Nutrition**

**REQUIRED DOCUMENTATION**

### All Claims for Enteral Nutrition

- **Written Documentation of Dispensing Order** *(written, fax or verbal order):*
  - *Only required if items are dispensed prior to the signature date on the detailed written order:
    - **Description of the item**
    - **Name of the beneficiary**
    - **Name of the physician**
    - **Start date of the order**

- **Detailed Written Order**
  - **Beneficiary’s name**
  - **Description or name of nutrient to be administered**
  - **Method of administration (syringe, gravity or pump)**
  - **Rate/frequency of administration and/or number of calories per 24 hour period**
  - **List of all separately billed items (supply kits, IV pole, pump, feeding tube, etc.)**

**NOTE:** Suppliers should not submit claims to the DME MAC prior to obtaining a detailed written order. Items billed to the DME MAC before a signed and dated detailed written order has been received must be submitted with modifier ET.

### Refill Request

- **Beneficiary’s name**
- **Description of each item**
- **Confirmation statement that the beneficiary is requesting a refill**

**For telephone requests:**
- **Date of contact**
- **Name of person contacted**
- **Relationship to beneficiary**

**For written requests:**
- **Signature of person requesting refill**
- **Signature date**
- **Date supplier received the request**

- **Refill request was received or call was made no sooner than 14 calendar days prior to the delivery/shipping date**
- **Shipment/delivery was no sooner than 10 calendar days prior to the end of usage for the current product**

### DME MAC Information Form (DIF) for Enteral Nutrition

#### Beneficiary Authorization

#### Delivery Documentation

<table>
<thead>
<tr>
<th>Direct Delivery</th>
<th>Shipped/Mail Order Tracking Slip</th>
<th>Shipped/Mail Order Return Post-Paid Delivery Invoice</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Beneficiary’s name</td>
<td>• Beneficiary’s name</td>
<td>• Shipping invoice</td>
</tr>
<tr>
<td>• Quantity delivered</td>
<td>• Detailed description of item(s) shipped</td>
<td>• Beneficiary’s name</td>
</tr>
<tr>
<td>• Detailed description of item(s)</td>
<td></td>
<td>• Delivery address</td>
</tr>
<tr>
<td>• Signature of person accepting delivery</td>
<td>• Delivery address</td>
<td>• Date shipped</td>
</tr>
<tr>
<td>• Relationship to beneficiary</td>
<td>• References each</td>
<td>• Reference number links the invoice and tracking slip may be entered by supplier</td>
</tr>
<tr>
<td>• Signature date</td>
<td>• Delivery address</td>
<td>• Quantity shipped</td>
</tr>
</tbody>
</table>

---

*Page 1 of 2 • Revised December 9, 2011. © 2011 Copyright, CGS Administrators, LLC. Disclaimer: This document was prepared as an educational tool and is not intended to grant rights or impose obligations. This checklist may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either written law or regulations. Suppliers are encouraged to consult the DME MAC Jurisdiction C Supplier Manual and the Local Coverage Determination/Policy Article for full and accurate details concerning policies and regulations.*
Documentation Checklist Enteral Nutrition

Medical Records
- The patient has a permanent (at least 3 months) impairment due to:
  - Non-function or disease of the structures that normally permit food to reach the small bowel; OR
  - A disease of the small bowel which impairs digestion and absorption of an oral diet.
- The patient requires tube feedings to maintain weight and strength commensurate with the patient’s overall health status. Adequate nutrition is not possible through dietary adjustment and/or oral supplements.
- The nutrition is being provided via a tube into the stomach or small intestine (the beneficiary is not drinking the nutrient).

Claims for Special Nutrient Formulas (B4149, B4153 – B4157, B4161, & B4162)
- The records document the medical condition requiring the special formula as opposed to a B4150 formula and the severity of that condition as shown by history, physical exam and diagnostic/laboratory studies.
- The records document a response of the medical condition to a B4150 formula as compared to the response to the prescribed special B4154 formula or, if this comparison was not made, the medical reason for its absence is explained for the individual beneficiary and not a generalized statement such as the diagnosis.

Claims for Enteral Nutrition Infusion Pumps
- The medical record contains documentation that justifies the use of a pump:
  - Gravity feeding is not satisfactory due to reflux and/or aspiration; or
  - Severe diarrhea; or
  - Dumping syndrome; or
  - Administration rate less than 100 ml/hr; or
  - Blood glucose fluctuations; or
  - Circulatory overload; or
  - Gastrostomy/jejunostomy tube used for feeding.

Reminders
- A new initial DIF is required for the enteral nutrient when:
  - A formula billed with a different code which has not been previously certified is ordered; or
  - Enteral nutrition services are resumed after they have not been required for two consecutive months.
- A new initial DIF for an infusion pump is required when:
  - The administration method changes from syringe or gravity to pump, or
  - Enteral nutrition services involving use of a pump are resumed after they have not been required for two consecutive months.
- A revised DIF for enteral nutrition is required when:
  - The method of administration changes; or
  - The number of calories per day changes; or
  - The number of days administered per week changes; or
  - The route of administration changes from tube feedings to oral feedings (if billing for denial).
  - Self-administered formulas are noncovered by Medicare.
  - Items billed to the DME MAC before a signed and dated order has been received must be submitted with modifier FY.
  - An IV pole (G0776) used for enteral nutrition administered by gravity or a pump should be billed with modifier IA.
  - When enteral nutrients are administered by mouth, modifier BO must be added to the code.
  - Enteral nutrition provided to a patient in a Part A covered stay must be billed by the SNF to the fiscal intermediary. No payment from Part B is available.

Online Enteral Nutrition Resources
http://www.cmsmedicare.com/jcr/coverage/mr/Enteral_Nutrition_Resources.html

Note: It is expected that the patient’s medical records will reflect the need for the care provided. These records are not routinely submitted to the DME MAC but must be available upon request. Therefore, while it is not a requirement, it is a recommendation that suppliers obtain and review the appropriate medical records and maintain a copy in the beneficiary’s file.