Abstract
Clinical coordination, monitoring, documentation, and consistency are the key issues related to obtaining favorable Medicare coverage. The Centers for Medicare and Medicaid Services outline specific requirements related to medical conditions for which enteral and parenteral nutrition may be the therapy of choice.

Medicare outlines specific criteria with guidelines that must be addressed for proper payment. This article provides a brief overview of the requirements for successful reimbursement along with the documentation required.

Introduction
Medicare is a federal program enacted by Congress as part of Title 18 of the Social Security Act of 1965. It is the largest insurance program in the United States.
Medicare is one of the most challenging payors for home infusion therapy. Medicare coverage is divided into Parts A, B, C, and D, each of which provides different covered benefits (Table 1). Enrolling in Part B Medicare is strictly the choice of the recipient/beneficiary. Medicare Part B covers home infusion therapy under prosthetic devices because parenteral nutrition and enteral tube feeding replace the normal oral route of receiving nutrition.

Medicare Eligibility/Coverage
Medicare is available to select recipients. To qualify for Medicare coverage, an individual must be:
- 65+ years of age
- Entitled to Social Security benefits and/or Railroad Retirement
- Younger than age 65 years, but disabled for >2 years
- Younger than age 65 years, with end-stage renal disease

For purposes of management, Medicare beneficiaries are assigned to one of four Durable Medical Equipment Regional Carrier (DME MAC) regions (based on their permanent address). The DME MACs will be the governing and coordinating entities that administer federally mandated Medicare policy (Table 2).

Qualification for Home Nutrition Therapy
To qualify patients for Nutritional Coverage (Parenteral and Enteral Nutrition)/Therapy (Part B – Medicare), the following must be ascertained:
- Has the patient/beneficiary been “qualified” for services under Part B Medicare? Has this information been confirmed?
- When does the patient turn age 65?
- What is the state of primary residence of the recipient? (This determines in what jurisdiction the patient will be processed.)
- Is the patient or spouse the primary holder of the insurance? Are there other supplemental insurances that may affect overall coverage?
- What is the duration of the services provided? Are specific criteria obtained for provision of services under Medicare policy?
- Are the patient, health-care practitioner, and health-care providers in agreement with sound, long-term plans of care?
- Is the patient fully informed of services provided and costs associated with the therapy he or she is receiving?
- Is there anatomic impairment to the gastrointestinal tract and a need for “permanent” or ongoing long-term therapy?

Table 1. Medicare Covered Benefits

<table>
<thead>
<tr>
<th>Medicare Part A</th>
</tr>
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<tbody>
<tr>
<td>- Inpatient health coverage</td>
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<tr>
<td>- Intermittent skilled care</td>
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<tr>
<td>- Rehabilitation treatment</td>
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<tr>
<td>- Short-term skilled nursing therapy</td>
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<tr>
<td>- Hospice care</td>
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<tr>
<td>- Some medical equipment/supplies</td>
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<td>- Blood/blood products</td>
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<table>
<thead>
<tr>
<th>Medicare Part B</th>
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<tbody>
<tr>
<td>- Outpatient hospital services</td>
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<tr>
<td>- Physician services and advanced practice nurse services</td>
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<tr>
<td>- Emergency department visits and services</td>
</tr>
<tr>
<td>- Laboratory services and diagnostic tests</td>
</tr>
<tr>
<td>- Home health services not covered under Part A</td>
</tr>
<tr>
<td>- Durable medical equipment and supplies</td>
</tr>
<tr>
<td>- Medical nutrition therapy</td>
</tr>
<tr>
<td>- Prosthetic devices</td>
</tr>
</tbody>
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<thead>
<tr>
<th>Medicare Part C</th>
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<tbody>
<tr>
<td>- Programs that might help an individual to pay health care costs that Medicare does not cover*</td>
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<table>
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<tr>
<th>Medicare Part D</th>
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<tr>
<td>- Prescription drug costs</td>
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*More details can be found at: www.medicare.gov in the Personal Plan Finder section.
**Enteral Therapy**

A number of parameters must be documented when providing enteral therapy for patients/beneficiaries with Medicare benefits. Governing rules for coverage may be found at: http://www.cignamedicare.com/articles/Jan05/Cope1879.html. Among the information that must be fully documented is:

- Does the patient/beneficiary meet the need for permanence of enteral therapy? Permanence is defined by Medicare as more than 90 days.
- Is there documentation that the patient is receiving enteral therapy by means other than orally (showing that the patient is not taking his/her formula orally as a supplement)?
- Is there an identifiable diagnosis of impaired gastrointestinal dysmotility or inability to swallow, as evidenced by objective testing and ICD-9 code?
- Is there documented evidence of disease that prevents food or nutrition from reaching the bowel and being absorbed?
- Is there a documented trial of a lower “B-code” before use of a specialty enteral formula when a specialty product is required?
- Is there an ongoing program of monitoring patient/beneficiary compliance with the therapy established?
- Is there a signed Certificate of Medical Necessity (CMN) completed by the physician showing the need and justification for the enteral therapy?
- Is there documentation showing that the patient requires tube feedings to maintain weight and strength commensurate with overall health status?
- Is it not possible to provide adequate nutrition by dietary adjustment and/or oral supplements?

**Enteral Pump – Assisted Feedings**

If a patient requires an enteral pump for therapy, justification of the need and rationale for providing this device is required and can be provided through a statement on the CMN or documentation through an ICD-9 code. Common reasons for needing a pump include failure to tolerate gravity feedings due to:

- Reflux with potential for aspiration
- Severe diarrhea
- Dumping syndrome
- Required administration of feeding at a rate of less than 100 mL/hr
- Use of a jejunostomy tube for feedings
- Blood glucose fluctuations
- When developing and maintaining the CMN, the clinician should be aware of the differences required for initial, revised, and recertified CMNs. CMN recertifications are based on the timing, such as when the length of therapy exceeds the anticipated time period on the previous CMN, and when there are changes to the prescription, such as a change in the enteral formula category.

**Enteral Documentation Requirements for Medicare Coverage**

To assist with overall documentation needs and qualification, Medicare has outlined the requirements/documentation required for enteral coverage. A documentation checklist can be downloaded from http://www.cignamedicare.com/dmerc/mr/CERT/Pdf/Enteral.pdf. When assembling and maintaining documentation on a patient who is receiving enteral therapy, a properly documented patient chart should include:

- MD orders (updated accordingly)
- Objective laboratory and diagnostic tests
- Evidence of tube placement
- Calories, type of feeding, administration instructions
- Method of administration (e.g., pump, syringe)
- Appropriate diagnostic codes
- Ongoing proof of delivery (supplier delivery records)
- Ongoing proof of patient compliance (regular calls and clinician monitoring records/assessments)
- Copy of CMN (enteral CMN) on file
- Reasons for the need/use of any specialty enteral formulas

When addressing the need or use of a specialty enteral formula, it is important to evaluate critically the clinical indications for a specialty formula based on organ function or digestive/absorptive capability. Documentation supporting the use of a specialty formula is required for reimbursement at the higher rate. If documentation is inadequate, the reimbursement rate will be down-coded to the lowest enteral formula category. Down-coding is reimbursement at the standard rate when the patient is receiving a specialized formula that is associated with a higher rate of reimbursement related to its increased cost. This can result in increased costs incurred by the home infusion provider. The following are examples of documentation needed for a specialty formula:

- If an elemental enteral formula is indicated, there must be documentation that a standard formula resulted in intolerance and changing to the elemental formula improved

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tolerance, such as reducing stool output.
• Justification for a diabetic enteral formula is improved glucose control with the specialized formula versus a standard enteral formula.
• Objective documentation to support the need for a specialized product, such as abnormal fecal fat, D-xylose or beta carotene, or serial blood glucose measurements, noting elevated status with a standard product and controlled blood glucose values with the specialized product.

Parenteral Therapy Conditions for Medicare Coverage
To qualify for payment, patients receiving parenteral nutrition must qualify for criteria according to Medicare Policy. Table 3 lists the conditions for which parenteral nutrition is not covered. To qualify for coverage, the patient must have a permanent impairment of the gastrointestinal (GI) tract that will last a minimum of 3 months. The patient also must have impaired function of the GI tract that has resulted in significant malabsorption or GI dysmotility. Results of diagnostic tests and procedures must support the claim of a malfunctioning GI tract. The most common ICD-9 codes requiring parenteral nutrition under Medicare criteria are listed in Table 4. A decision tree to guide the clinician through the qualification process for home parenteral therapy is shown in the three-part Figure. Criteria for Situation G/H are for patients who do not fit into other situations (e.g., >5 ft of small bowel left, absorbing >50% of intake, radiographic contrast reaches right colon after 5 hours). The use of G/H criteria requires more documentation and often is scrutinized more closely when submitted. It frequently requires documentation of an attempted and failed tube feeding trial.

Definition of a Tube Trial
A concerted effort must be made to place a feeding tube. For gastroparesis, tube placement must be postpylorus, preferably in the jejunum. Use of a double-lumen tube should be considered. Adjustments in the enteral formulation selection, formula strength, and infusion rate must also be attempted to reduce stool output and improve tolerance before a tube feeding trial can be said to have failed.

Oral Diet with Parenteral Nutrition
It is not necessary to keep a patient nil per os (NPO) for Medicare to approve parenteral nutrition coverage. Patients receiving parenteral nutrition are often taking food in small amounts for social reasons as well as to maintain the integrity of the GI tract for its immunologic properties. However, it is imperative to document that oral intake alone is insufficient to maintain the strength and weight of the patient.

Documentation
According to the AdmiraStar Federal Web Site, a CMN is required for the Medicare patient to qualify for home parenteral nutrition. The CMN for parenteral nutrition must be signed by the physician, but can be completed by the physician’s designee as long as the designee is not the home infusion supplier. Regardless of the individual completing the CMN, the prescribing physician must sign the CMN to indicate approval of the home parenteral nutrition set. A decision tree to guide the clinician through the qualification process for home parenteral therapy is shown in the three-part Figure. Criteria for Situation G/H are for patients who do not fit into other situations (e.g., >5 ft of small bowel left, absorbing >50% of intake, radiographic contrast reaches right colon after 5 hours). The use of G/H criteria requires more documentation and often is scrutinized more closely when submitted. It frequently requires documentation of an attempted and failed tube feeding trial.

Table 3. Conditions That Do Not Qualify a Patient for Parenteral Nutrition Under Medicare

- Swallowing disorder
- Temporary impaired gastric emptying (e.g., metabolic or electrolyte disorder)
- Impaired nutrient intake due to depression or other psychological disorder
- Anorexia related to a metabolic disorder (e.g., cancer)
- Impaired oral intake of food with physical disorder (e.g., dyspnea of severe pulmonary or cardiac disease)
- Adverse effects of pharmacotherapy
- End-stage renal disease

Table 4. Common ICD-9 Codes Associated With Home Parenteral Therapy and Medicare Criteria

- 263.0 Malnutrition of moderate degree
- 263.1 Malnutrition of mild degree
- 536.3 Gastroparesis
- 555.0 Crohn’s/Regional enteritis of the small intestine
- 555.1 Crohn’s/Regional enteritis of the large intestine
- 555.2 Crohn’s/Regional enteritis of the small and large intestine
- 557.0 Acute vascular insufficiency of intestine
- 557.9 Unspecified vascular insufficiency of intestine
- 560.1 Paralysis of the intestine or colon
- 560.81 Intestinal or peritoneal adhesions with obstruction
- 560.89 Other intestinal obstruction
- 560.9 Unspecified intestinal obstruction
- 564.9 Unspecified functional disorder of intestine
- 569.81 Fistula of the intestine, excluding rectum and anus
- 577.0 Acute pancreatitis
- 577.1 Chronic pancreatitis
- 577.2 Pancreatitis with cyst/pseudocyst
- 579.3 Other and unspecified postsurgical nonabsorption
- 579.8 Other specified intestinal malabsorption
- 579.9 Unspecified intestinal malabsorption
- 783.21 Abnormal loss of weight
- 998.6 Persistent postoperative fistula
Required Documentation for Any Payment Submission

When submitting a claim for payment, specific pieces of documentation are required to achieve favorable results. When initial/subsequent claims are submitted, the following documentation may be required:

- Completed/signed CMN
- Signed and dated physician orders
- Letter of Medical Necessity outlining/summarizing the criteria and reasons for parenteral nutrition and any need for specialized formulations.
- Appropriate documentation as required: laboratory tests, diagnostic tests, intake/output, history and physical examination, documented weight history, progress notes, etc.
- Consultant/operative reports
- Objective tests and notations as related to the patient's case

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and to the supplier that outlines the reasons for the claim being rejected. At that time, the supplier can appeal the denial and correct/supply additional information and/or documentation to reverse the denial.

**Appeals/Grievances**

Medicare has specific guidelines related to an appeals process when submitted claims are denied. Should these claims be denied for payment, Medicare uses an appeals process with specific deadlines/timeframes:

<table>
<thead>
<tr>
<th>Deadline</th>
<th>Step for Filing</th>
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<tbody>
<tr>
<td>Redetermination</td>
<td>120 days from date of receipt of the notice of initial determination.</td>
</tr>
<tr>
<td>Reconsideration</td>
<td>180 days from the date of receipt of the reconsideration notice.</td>
</tr>
<tr>
<td>Hearing</td>
<td>60 days from the date of receipt of the reconsideration decision.</td>
</tr>
<tr>
<td>Departmental Appeals Board</td>
<td>60 days from the date of receipt of the Administrative Law Judge hearing decision/dismissal.</td>
</tr>
<tr>
<td>Judicial Review – Federal Court</td>
<td>60 days from date of receipt of DAB (Departmental Appeals Board) decision or declination of review by DAB.</td>
</tr>
</tbody>
</table>

When an initial claim submitted is denied, the first step of appeal is the “redetermination.” At that time, the supplier or person supplying the information may appeal the decision. Subsequent denials advance the appeals process to Reconsideration, Hearing, Department Appeals Board, and Judicial Review–Federal court.

The DME MACs have compiled lists of the most common errors related to denials in payment:
- Illegible documentation
- Biller error
- Incomplete CMNs
- Orders and documentation that do not substantiate the material submitted
- ICD-9 codes that are not specific
- Unsigned CMNs
- MD orders that do not agree with the therapy billed
- Lack of permanence in patient therapy

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**TPN Decision Tree**

**SITUATION D**
Pt. has complete mechanical small bowel obstruction

- Yes
  - Surgery is not an option
  - Patient meets Medicare coverage criteria for home TPN therapy under Situation D

- No

**SITUATION E**
Pt. had 10% wt. loss in ≤ 3 months

- Yes
  - Serum Albumin is ≤ 3.4 gm/dl
  - Pt. had 72 hour fecal fat test
    - Yes
      - Fecal fat exceeds 50% of oral/enteral intake on a diet ≥ 50 gm fat/day
      - Patient meets Medicare coverage criteria for home TPN therapy under Situation E
    - No

- No

**SITUATION F**
The following situations must also be considered when evaluating for home TPN therapy under Situation F:
- Pt. has daily symptoms of N&V
- Pt. had diagnostic test that documents motility disturbance
  - Yes
    - Radioisotope study demonstrates that isotope fails to reach the rt. colon by 6 hrs. or
    - X-ray study demonstrates that barium or pellets fail to reach the rt. Colon by 6 hrs.
      - Yes
        - Pt. is not acutely ill or on any medication which would decrease bowel motility
        - Patient meets Medicare coverage criteria for home TPN therapy under Situation F
      - No
    - Patient meets Medicare coverage criteria for home TPN therapy under Situation F
  - No
Transposition of numerical digits when submitting claims electronically

Therapies that do not meet Medicare coverage criteria

When a denial is obtained from Medicare, it is important to ascertain the exact reason for denial and address the documentation and/or other needs based on why the claim was not paid. Medicare can provide a written reason for the denial of any service submitted. The amount of documentation required and the case presented must be based on correction of the material submitted. A clear case must be submitted to Medicare to show the appropriateness and need for payment of the services provided.

Frank R. Wojtylak, RD/CDN, is a private consultant working in the field of Medicare reimbursement and qualification.

Regulation and Guidance:
http://www.cms.hhs.gov/home/regsguidance.asp

FAQs:

CMS Homepage:
http://www.cms.hhs.gov/

Medicare Information:
http://www.cms.hhs.gov/home/medicare.asp

Medicare Appeals Information:
http://www.cms.hhs.gov/MMCAG/

Mailing List Resource: