

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**Coverage of Enteral Nutrition Therapy:
Medicare and Other Payers**



JUNE GIBBS BROWN
Inspector General

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PHILADELPHIA REGION

Donna M. Millan, *Lead Program Analyst*
Linda M. Ragone, *Program Analyst*
Cynthia Hansford, *Program Assistant*
Nancy J.W. Lewis, PharmD, MPH, *Consultant*

HEADQUARTERS

Jennifer Antico, *Program Specialist*

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EXECUTIVE SUMMARY

PURPOSE

This report describes and compares Medicare and non-Medicare payers' coverage policies for enteral nutrition therapy.

BACKGROUND

Enteral nutrition therapy provides liquid nourishment directly to the digestive tract of a patient who cannot ingest an appropriate amount of calories to maintain an acceptable nutritional status.

Medicare classifies enteral nutrition therapy under the prosthetic device benefit. Coverage is only for therapy required due to the absence or malfunctioning body part which normally permits food to reach the digestive tract.

The Health Care Financing Administration (HCFA) administers the Medicare program. In an effort to aid the Durable Medical Equipment Regional Carriers' revision and standardization of Medicare coverage policy, HCFA requested the Office of Inspector General to survey other payers to determine their coverage policies for enteral therapy.

We surveyed Medicare risk-contracted and private health maintenance organizations, facilities from Department of Veterans Affairs, Medicaid State agencies, commercial payers, and Blue Cross/Blue Shield associations.

FINDINGS

MOST PAYERS SURVEYED ROUTINELY COVER ENTERAL NUTRITION THERAPY.

Twenty out of 25 different payers routinely cover enteral nutrition therapy. The five payers who do not would only cover it under extraordinary circumstances.

COMPARED TO OTHER PAYERS, MEDICARE'S COVERAGE REQUIREMENTS ARE SIMILAR IN SOME AREAS AND MORE RESTRICTIVE IN OTHERS.

Both Medicare and other-payers routinely cover enteral nutrition therapy when the patient requires tube feeding, when enteral nutrition is the patient's exclusive source of nutrition, and if the patient has an anatomical or physiological malfunction of the gastrointestinal tract. Both types of payers also require a certificate of medical necessity or a prescription for coverage. Like Medicare, about half of the other payers do not routinely cover cognitive disorders such as Alzheimer's Disease.

Medicare's coverage requirement is based on the malfunction of the gastrointestinal tract. Medical documentation must then prove the beneficiary's need for enteral nutrition therapy meets this criteria. Although some other payers classify enteral therapy as a prosthetic device as Medicare does, these other payers still provide coverage for patient's with a functioning gastrointestinal tract and special nutrient needs; Medicare does not. Medicare guidelines require specific documentation for category of nutrient product and caloric intake, and the use of pumps, while other payers do not.

We hope the issues resulting from this report answer HCFA's request for information on other payers' coverage policies for enteral nutrition therapy, and aid HCFA in their effort to revise and standardize Medicare policy.

Our work is continuing. We will review how other payers price enteral nutrition therapy products and compare their units of pricing, payment mechanisms, and supplier networks to Medicare's policy.

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INTRODUCTION

PURPOSE

This report describes and compares Medicare and other payers' coverage policies for enteral nutrition therapy (ENT).

BACKGROUND

Medicare covers ENT under the Part B prosthetic device benefit.

Enteral nutrition therapy (ENT) is a means to provide nourishment directly to the digestive tract of a patient who cannot, for a variety of reasons, ingest an appropriate amount of calories to maintain an acceptable nutritional status. The beneficiary consumes a liquid nutrient formula which can be administered one of three ways:

- nasogastric tube: inserted through the nostril,
- jejunostomy tube: inserted through a surgical incision leading to the small intestine,
- gastrostomy tube: inserted through a surgical incision leading to the stomach.

The Medicare guidelines classify ENT under the prosthetic device benefit because coverage is only for therapy required due to an absent or malfunctioning body part which normally permits food to reach the digestive tract.¹

Medicare covers ENT for conditions based on the malfunction of the gastrointestinal tract. According to Medicare guidelines, ENT is reasonable for:

- a beneficiary with a non-functioning gastrointestinal tract, who cannot maintain appropriate weight due to disease or non-function of the structures that normally permit food to reach the digestive tract, or
- a beneficiary with a disease of the small bowel that precludes digestion and absorption of sufficient nutrients and necessitates tube feeding to maintain the appropriate weight.

Many medical conditions can cause malfunction of structures so as to preclude normal ingestion of food. Examples of conditions that would qualify for coverage are head and neck cancer with reconstructive surgery and central nervous system disease which

¹Medicare Carrier's Manual, section 2130 and Medicare Coverage Issues Manual, section 65-10.

leads to interference with the neuromuscular mechanisms of digestion so severe as to prohibit oral feeding. Medicare does not allow coverage for beneficiaries with a normally functioning gastrointestinal tract whose only need for ENT stems from lack of appetite or an organic brain syndrome².

Medicare requires thorough documentation for the medical necessity of ENT.

Under Medicare guidelines, all enteral nutrition claims submitted to the Durable Medical Equipment Regional Carrier (DMERC) must be approved on an individual case-by-case basis. Each claim must have a certificate of medical necessity (CMN) signed by the attending physician and sufficient medical documentation (such as medical records and clinical findings from the attending physician) to permit an independent conclusion that the beneficiary meets the requirements of the prosthetic device benefit. A CMN must be renewed three, nine, and 24 months after the initial CMN. A new CMN is additionally required under these circumstances:

- when there is a change in the category of nutrients or calories prescribed,
- a change from enteral to parenteral (intravenous) therapy,
- or when there is a need for a pump.

If a documented need exists for ENT, Medicare will cover related supplies, equipment, and nutrients. Additional documentation is needed for the use of a pump to administer ENT. Only services rendered by a physician or by a non-physician professional whose services are incident to a physician's service are covered.

Medicare guidelines also require justification for certain types of ENT products.

Medicare classifies ENT products into six categories based on the composition and source of ingredients in each product. Category I products are the most commonly used; they consist of natural intact protein or protein isolates. The guidelines state that if a physician prescribes a formula from Categories III through V, additional documents must justify the reason for prescribing a higher category formula. According to the policy, if the request cannot be substantiated, payment is based on the allowance for the least costly alternative. The categories of products, their composition and indications for use are listed in the table on the following page:

²Any mental disorder, such as senile dementia or Alzheimer's disease, resulting from or associated with organic changes in brain tissue.

**MEDICARE'S CLASSIFICATION OF ENTERAL NUTRITION PRODUCTS
BY COMPOSITION AND INDICATIONS FOR USE**

Product Category	Composition and Indications for Use
Category I	semi-synthetic intact protein/protein isolates which are standard products for most patient use
Category II	intact protein/natural protein isolates that are low sodium, high calorie products
Category III	hydrolyzed amino acid formula used for patients unable to absorb intact protein isolates
Category IV	formulas designed to meet metabolic needs associated with specific disease conditions
Category V	individual nutrition components (fat, protein, carbohydrates) that allow the making of customized formulas
Category VI	formulas with high protein content

The Durable Medical Equipment Regional Carriers process ENT claims.

The Health Care Financing Administration (HCFA) administers the Medicare Part B program. In October 1993, HCFA designated four DMERCs to process claims for durable medical equipment, prosthetics, orthotics, and supplies, including ENT. The DMERCs replace two previous carriers who had processed ENT claims. Each DMERC is responsible for its specific region of the country and processes claims originating from its respective geographic region. The HCFA has been active in aiding the DMERCs in transitioning to their new responsibility for ENT. The HCFA has also used this transition period to reexamine coverage policies and to standardize coverage decisions. On-going meetings led by HCFA have included discussions among DMERC representatives and nutritional experts.

To aid the DMERCs in their evaluation and application of Medicare coverage policy, HCFA requested the Office of Inspector General to survey other payers about their ENT coverage policies. The request included gathering information related to criteria and documentation required for coverage. The HCFA also specifically expressed interest in information on the coverage of products designed for patients with special metabolic conditions.

METHODOLOGY

Using a standardized data collection instrument, we obtained information on each payer's coverage criteria, documentation requirements, and product information. We also asked respondents to enclose a copy of their medical review guidelines and/or coverage policies for additional review.

Individuals from each HCFA bureau reviewed our instrument and provided insight on appropriate questions and pertinent issue areas. We also pre-tested the questions with two payers not in our sample. We consulted with DMERC medical directors and their medical review staff as well. Each offered input on the questions and issues we should address.

We surveyed Medicare contractors to assess payment policies for beneficiaries under fee-for-service claims and services under managed care arrangements. Non-Medicare payers include the Department of Veterans' Affairs (VA), Medicaid agencies, and private payers. The largest payers were selected from each group (with the exception of the VA facilities which are selected randomly in the Medicaid States in the sample).

We surveyed a total of 34 payers and received responses from 28 respondent. Our analysis is based on the information from these payers:

Medicare	Other Payers
<ul style="list-style-type: none">●four DMERCs●four Medicare risk-contracted health maintenance organizations (HMOs)	<ul style="list-style-type: none">●four Department of Veterans Affairs (VA) facilities●five Medicaid State agencies●four private HMOs●three private indemnity/commercial insurers●four Blue Cross/Blue Shield Associations (BC/BS)

Although, not all payers responded to all our questions, we grouped valid responses into pertinent coverage issues such as benefit classification, patient condition, and documentation. We report how other payer's policies differ or correspond with Medicare's policies for ENT.

For the purposes of our analysis, we designate the four DMERCs as representing one payer, Medicare. Where the Medicare risk-contracted HMOs' coverage policies are similar to that of the DMERCs, we also designate the Medicare risk-contracted HMOs as Medicare. We also distinguish any issues where Medicare risk-contracted HMOs differ in their application of Medicare policy. These risk-contracted HMOs must provide, at minimum, what Medicare guidelines require for coverage; Medicare risk-contracted HMOs can also be more generous in benefit coverage.

We gathered and analyzed this information from August through early November, 1994. This inspection was conducted in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

MOST PAYERS SURVEYED ROUTINELY COVER ENTERAL NUTRITION THERAPY BUT CLASSIFY THE BENEFIT SEVERAL DIFFERENT WAYS.

Twenty out of 25 different payers routinely cover enteral therapy, while five payers do not. Those five payers gave different reasons for not routinely covering it. Two Blue Cross/Blue Shield (BC/BS) payers stated that it is not a standard benefit in their plans. One Medicaid payer only covers ENT for individuals under the age of 21 because the cost of ENT is seen as prohibitive. One Veterans' Affairs (VA) payer only covers persons on an inpatient basis. The fifth, a private indemnity payer, stated that while it covers the supplies and pumps, it does not cover the nutritional product since it is considered food.

These five payers would cover ENT under exceptional circumstances. For example, the private indemnity payer would cover the product where it is mandated by State law. The BC/BS payers provide coverage if it were included in a specific group contract. The inpatient VA payer would provide ENT on an outpatient basis if the individual were indigent and if ENT were the patients's sole source of nutrition.

According to Medicare, ENT is a prosthetic device; however, other payers differ in their classification of ENT. Medicare's classification of ENT as a prosthetic device benefit comes from the basis that ENT serves the function that an otherwise normal gastrointestinal structure would perform. Different classifications of ENT may result from other medical reasoning. Table 1 below illustrates how payers classify the ENT benefit.

HOW PAYERS CLASSIFY ENT AS A BENEFIT

Table 1.

Type of Payer	Durable Medical Equipment (DME)	Prosthetic Device	Pharmaceutical	Standard Benefit ³	Nutrition
Medicare	—	YES	—	—	—
Medicare Risk-Contracted HMOs	1/4	3/4	—	—	—
Other Payers	6/18	4/18	5/18	6/18	1/18

³This term includes the following classifications: "major medical benefit," "under the benefit plan," "as part of total care," and "expendable medical supply."

Three Medicare risk-contracted HMOs designate ENT as a prosthetic device benefit. Three other payers put ENT under prosthetic device as well. Five non-Medicare payers grouped ENT as a pharmaceutical benefit, while six place ENT in the durable medical equipment (DME) category. One Medicare HMO also classifies ENT under general durable medical equipment. The remaining payers cover ENT as a major medical/standard benefit or as nutrition.

Note that the 18 other payers include the Medicaid agency who only covers children, the inpatient VA facility, and the private indemnity/commercial payer who only covers the pumps and supplies, not the product. It does not contain the two BC/BS payers who do not routinely cover ENT. In addition, four other (non-Medicare) payers use dual classifications for the ENT benefit. These four specifically differentiate between the actual ENT product and the supplies and pumps to administer the nutrition. In this case, typically, the ENT product is a pharmaceutical benefit, while the supplies and pumps are covered as DME or as a prosthetic device.

Medicare and other payers use similar strategies to formulate their coverage policies. In defining their coverage policy for ENT, payers employed a combination of common strategies to compose their ENT policies, including consultation with nutritional experts, individual providers and manufacturers, and review of scientific literature.

COMPARED TO OTHER PAYERS, MEDICARE'S COVERAGE REQUIREMENTS ARE MORE RESTRICTIVE IN SOME AREAS AND SIMILAR IN OTHERS.

While almost all payers require their beneficiaries to have specific health conditions for ENT coverage, the Medicare guidelines dictate that ENT must serve the purpose of a prosthetic device, which is to replace a malfunctioning body part.

Patient Conditions and Circumstances

As Table 2 on the following page illustrates, both Medicare and other payers routinely cover ENT under three circumstances: 1) when the patient requires tube feedings, 2) when ENT is the patient's exclusive source of nutrition, and 3) when the patient has an anatomical or physiological malfunction of the gastrointestinal tract. For these three circumstances, both Medicare and other payers policies' appear to be similar.

**CIRCUMSTANCES WHERE MEDICARE COVERS ENT
AND HOW OTHER PAYERS RESPOND**

Table 2.

Circumstance	Medicare	Other Payers
patient requires tube feedings	COVERED	15/17
ENT is the exclusive source of nutrition	COVERED	16/17
patient has an anatomical or physiological malfunction of the digestive track	COVERED	16/17

The seventeen other payers include the inpatient VA facility and the Medicaid State agency who serves only children. This figure does not include the two BC/BS payers who do not routinely cover ENT and a private indemnity payer who only covers pumps and supplies, not the product.

The table below shows circumstances where payers and non-Medicare payers differ in their coverage policies. Medicare does not cover ENT that is orally ingested, while almost half of the non-Medicare payers do. Medicare guidelines also set standards for the length of therapy, while other payers do not.

**CIRCUMSTANCES WHERE MEDICARE DOES NOT COVER ENT
AND HOW OTHER PAYERS RESPOND**

Table 3.

Circumstance	Medicare	Medicare Risk-Contracted HMOs	Other Payers
patient orally ingests the nutrition product	NOT COVERED	0/4	7/17
need for ENT is less than 90 days	NOT COVERED	2/4	13/17

For some non-Medicare payers, patient diagnosis is sufficient to warrant routine coverage of ENT, while other non-Medicare payers will initially only cover ENT for specific diagnoses. Three non-Medicare respondents require that the patient have one of a variety of specific diagnoses, such as Crohn's disease or enteritis. For other payers, another circumstance warranting ENT coverage is if a physician declares ENT medically necessary to maintain the patient's body weight and general nutritional status. If the physician's order in the patient's medical record states a need for ENT or if prior authorization is issued, it is covered. An individual medical review for appropriateness can also be required. In two instances, State law mandated coverage of ENT for specific diseases. Often, for non-Medicare payers, physician evidence and documentation for the medical need of the therapy can repeal most coverage restrictions.

Non-Gastrointestinal Related Disorders

In contrast to Medicare guidelines, just over two-thirds of non-Medicare payers will cover ENT for patients with a functioning gastrointestinal tract, but still have special nutritional needs. Three Medicare risk-contracted HMOs classify ENT as a prosthetic device, but do cover patients with special nutritional needs. Again, Medicare HMOs may offer more coverage according to their negotiated contracts. Also, even though some non-Medicare payers classified ENT as a prosthetic device, they would still cover the therapy for a person with a functioning gastrointestinal tract. Table 4 below illustrates this point.

PAYERS WHO COVER ENT FOR PATIENTS WITH SPECIAL NEEDS

Table 4.

Type of Payer	Payers Who Cover ENT For Patients With Special Needs	How Those Payers Classify ENT Benefit For Patients With Special Needs ⁴				
		DME	Prosthetic Device	Pharmacy Benefit	Standard Benefit	Nutrition
Medicare Fee-for-Service	NONE					
Medicare Risk-Contracted HMOs	3/4		3			
VA Facilities	3/4		1	1	1	1
Medicaid Agencies	5/5	3		1	1	
Private HMOs	2/4	1	1			
Private Indemnity/Commercial Payers	3/3 ⁵	1	1		2	
BC/BS Association	1/4	1		1	1	

According to the current Medicare definition of ENT, unless the criteria for a prosthetic device benefit is met, patients with cognitive disorders cannot be covered. Technically, with a cognitive disorder, the malfunctioning body organ is the brain, not a gastrointestinal structure. During this condition, the brain is unable to transmit the

⁴Again, note that some payers use dual classification for defining the ENT benefit. We counted each classification separately.

⁵This figure does include the private indemnity/commercial payer who only covers the pump and supplies for ENT, not the product.

appropriate nerve impulses to direct the activity of other body organs. Cognitive disorders such as Alzheimer’s Disease or pre-senile dementia can make chewing and swallowing difficult for a patient with an otherwise functioning gastrointestinal tract. Defining the therapy under the prosthetic device benefit narrows the scope for its application to patients with cognitive disorders. The table below shows the number of payers who routinely cover ENT for patients with cognitive disorders.

**PAYERS WHO ROUTINELY COVER ENTERAL NUTRITION
FOR PATIENTS WITH COGNITIVE DISORDERS**

Table 5.

Medicare Policy	Medicare Risk- Contracted HMO	Other Payers
NOT COVERED	0/4	8/17

Medicare does not routinely cover patients with cognitive disorders unless very specific medical evidence can support the need for ENT. Documentation for the patient’s functional inability to swallow are necessary. Abnormal results from a swallowing function test and the absence of a gag reflex (of the muscular reflex contraction in the throat which enables one to swallow) and additional related laboratory and blood tests build a case for coverage under the prosthetic device benefit.

The Medicare risk-contracted HMOs do not routinely cover patients who only have a cognitive disorder and no digestive track malfunction. These respondents would make exceptions to this rule if ENT were the patient’s only source of nutrition. Additional documentation of abnormal swallowing function tests and loss of gag reflex are also necessary.

In contrast, almost half of non-Medicare payers would routinely cover ENT for persons with cognitive disorders. Other additional payers would cover patients with cognitive disorders as long as the ENT is the patient’s sole source of nutrition, or if the patient is only able to obtain nutrition through a tube. Some additional documentation for swallowing tests and severity of the dysfunction are necessary, but as long as the primary physician or physician reviewer deems therapy medically necessary, it is covered.

Enteral Nutrition Pumps and Supplies

Pumps may administer ENT for patients whose medical conditions require a calibrated and timed flow of nutrients. As Table 6 on the following page shows, Medicare policy requires separate documentation for the pump, while two Medicare risk-contracted HMOs automatically cover the pump. In contrast, more than three-quarters of non-Medicare payers automatically cover the pump when therapy is needed.

**PAYERS WHO AUTOMATICALLY COVER PUMPS
WITH ENTERAL NUTRITION THERAPY**

Table 6.

Medicare Policy	Medicare Risk-Contracted HMOs	Other Payers
NOT COVERED WITHOUT SEPARATE DOCUMENTATION FOR NEED	2/4	14/18 ⁶

Supplies such as tubing and administration kits are necessary for using ENT. Medicare automatically provides these items with the therapy. Similarly, three Medicare risk-contracted HMOs and fifteen other payers also follow this coverage practice.

Certificates of Medical Necessity and Prescriptions

Medicare guidelines are explicit in their requirements for documentation for determining coverage. Medicare policy requires a CMN for ENT coverage. Three Medicare risk-contracted HMOs do not require a CMN; instead they require a physician's prescription. Eleven out of seventeen non-Medicare payers require a letter of need or CMN for ENT coverage.

In addition to a CMN, more than half of the non-Medicare payers also require a prescription for the coverage of ENT. Those who do not initially require a CMN either require a prescription or allow the patient's diagnosis or the physician's order in the medical chart to suffice.

Medicare not only requires a new CMN for reassessment, but a new CMN must be revised whenever there is a change in the caloric intake, a change in nutrient products, and also when there is a need for a pump.

Reassessment for Therapy

Both Medicare and non-Medicare payers require patient reassessment to determine whether the patient still needs ENT. This reassessment calls for an update on the beneficiary's medical condition and a new CMN. The Medicare risk-contracted HMOs also require periodic assessment for ENT coverage. Their intervals for reassessment range from monthly to every three months continually.

Almost all non-Medicare respondents require periodic assessment to continue therapy. The intervals for continued assessment vary from monthly to quarterly. Two payers call for yearly assessments. Unlike Medicare, non-Medicare payers require on-going assessment even after 24 months. An update on the patient's condition is the most

⁶This figure includes the private indemnity/commercial payer who only covers pumps and supplies for ENT, not the product.

common information required. These payers require renewed letters of need or CMNs on a continuing basis ranging from every 30 days to 6 months. One non-Medicare payer reported an interval of one year.

Documentation for Types of Products

Medicare also has special documentation provisions for the kinds of products that physicians prescribe. The Medicare risk-contracted HMOs did not specify that they use categories of products.

Only one non-Medicare payer's coverage policy contained a similar distinction for groups of products. This payer reported that if a physician requests a product not listed on the "First Line Usage Enteral Nutrition Product Table," additional documentation must accompany the physician's prior authorization request. The extra information must show the patient experienced "therapeutic failure" with the "First Line" product or state results of a consultation between the physician and a registered dietician. Other payers did not provide information about product distinction.

Caloric Requirements

Medicare policy requires documentation to justify any caloric intake less than 20 calories/kilogram or greater than 35 calories/kilogram per day. The Medicare risk-contracted HMOs do not have this requirement, while only one non-Medicare payer requires a minimum number of calories/kilogram per day.

CONCLUSION

We hope the issues resulting from this report answer HCFA's request for information on other payers' coverage policies for ENT, and will aid HCFA in their effort to revise and standardize Medicare policy.

Our work is continuing. We will review how other payers price ENT products and compare their units of pricing, payment mechanisms, and supplier networks to Medicare's policy.