Enteral Nutrition Reimbursement – The Rationale for the Policy: The US Perspective

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Abstract
Enteral nutrition (EN) is generally defined by third party payers as tube feeding for patients who cannot take food orally. EN is widely accepted in the United States as an effective, often life-sustaining therapy. Coverage and payment policies for EN differ among payers and settings. These differences often may depend on whether EN is reimbursed as a discrete therapy or subsumed into a larger benefit. In the US, the Medicare and Medicaid programs are the major public payers for EN. EN may be susceptible to overuse, especially in the long-term care setting. The trends in coverage and payment for EN suggest tighter reimbursement; competitive bidding between suppliers and data-driven performance measurement and payments may be in the future for EN reimbursement.

Introduction

Enteral nutrition, generally defined by third party payers as tube feeding for patients who cannot take food orally, has been covered in the United States by public and private payers for several decades in a variety of care settings. This paper provides an overview of how these payers cover and pay for enteral nutrition, the factors that influence their policies, and trends that could affect these policies in the future.

The topic of enteral nutrition coverage is often not very straightforward because in several important instances enteral nutrition is not covered for what it is. Rather, it often has been shoe-horned into an ill-fitting coverage niche that creates confusion and uncertainty. In addition, while enteral nutrition is increasingly seen as a cost-effective alternative to parenteral nutrition, policymakers' general
concerns about possible fraud and abuse activities within the Medicare program have affected their perceptions of enteral nutrition (and many other product and therapy areas) and will undoubtedly continue to do so in the future.

Public Payers: Coverage and Reimbursement for Enteral Nutrition under Medicare

Introduction to Medicare

Medicare, the federal health insurance program for individuals over 65 and the permanently disabled administered by the Centers for Medicare and Medicaid Services (CMS) within the Department of Health and Human Services (DHHS), is a critical and influential source of coverage for enteral nutrition. Given the size and scope of the Medicare program, it influences coverage and reimbursement policies of other public and private payers. Medicare now covers nearly 43 million beneficiaries [1].

Medicare has several programs of relevance to enteral nutrition: Part A, Part B, and Part C. Part A covers inpatient hospital costs, excluding physicians services (which are covered under Part B), as well as costs of skilled nursing facilities and home healthcare under certain conditions. Part B is the medical insurance portion of Medicare, which covers the cost of physician services, outpatient hospital care, and medical supplies and equipment. Under Part C, known as the Medicare Advantage (MA) program, privately managed care companies contract the federal government to offer inpatient and outpatient benefits to Medicare beneficiaries through their own policies.

Inpatient Hospital Coverage for Enteral Nutrition through Medicare Part A

Enteral nutrition provided in an inpatient hospital setting may be covered under Medicare Part A. Medicare coverage extends to medications, medical supplies and equipment that are determined to be reasonable and medically necessary.

Medicare Part A reimburses providers of inpatient hospital services through an inpatient hospital prospective payment system (PPS) that sets a single payment amount for a type of patient case based on the patient’s primary diagnosis [2]. Psychiatric, rehabilitation, children’s, long-term care and certain cancer hospitals and units, among others, are excluded from the inpatient hospital PPS. Generally, Medicare reimburses these excluded hospitals based on reasonable costs. However, recent legislation has called for the implementation of PPS in rehabilitation, long-term care, and psychiatric hospitals.

Under the inpatient hospital PPS, each patient’s case is categorized into one of approximately 530 diagnosis-related groups (DRGs) in 25 diagnostic categories [3]. Each DRG has a payment weight assigned to it, based on the average resources used to treat Medicare patients in that group. Beginning in
2007, DRG weights will be based on hospital costs rather than hospital charges, leading to potentially lower reimbursement rates [4]. There are a number of DRGs that may be used to classify patients receiving enteral nutrition.

While the DRG system sets predetermined payment rates for all cases within a DRG, additional payments are possible for exceptionally costly cases, known as outliers, to protect hospitals from potentially large financial losses in these cases and to ensure that hospitals have the appropriate financial incentive to accept such patients. An outlier must have costs that exceed prospective Medicare payments by a fixed amount [5]. (Previously, a case could also qualify for outlier payments if the patient had an exceptionally long length of stay compared to other patients in that DRG, but these ‘day outlier’ payments were phased out ending in 1998.) In addition, reimbursement may be altered based on the presence of a secondary condition at the time of admission (comorbidity) or which develops after admission (complicating condition) that results in a longer hospital stay. Secondary diagnoses of malnutrition or other nutrition-related conditions can qualify as comorbidities or complicating conditions, potentially allowing for additional reimbursement.

Medicare Part A does not dictate precisely how enteral nutrition must be provided for a hospital to receive payment. As Medicare pays hospitals a fixed prospective rate based on patient diagnosis rather than for the individual treatments provided, hospitals have incentives to contain costs while providing appropriate care. Each hospital thus has discretion as to the proper use of nurses, dietitians, and other health professions in the provision of enteral nutrition. Medicare has established federal quality standards for hospitals known as Conditions of Participation, but these conditions do not specifically address enteral nutritional therapy. The current condition related to nutrition services requires hospitals to meet the nutritional needs of patients ‘in accordance with recognized dietary practices . . . and orders of the practitioner or practitioners responsible for the care of patients’ [6].

CMS is beginning a Hospital Quality Initiative, wherein hospital reimbursement eventually will be linked to performance on designated quality measures. The clear trend in Medicare is to link payment to performance, whereby payments may be modified (up or down) based on compliance (or lack of compliance) with certain measurements. CMS recently published regulations requiring hospitals to collect and submit data on 21 clinical quality measures related to acute myocardial infarction, heart failure, pneumonia, and surgical care improvement. Hospitals that do not submit data will not receive a full update in the inpatient PPS rates for fiscal year 2008. Eventually, quality measures could be expanded to include nutrition care.

Medicare Part B Coverage and Reimbursement for Home Enteral Nutrition

As described above, Medicare Part B is the medical insurance portion of Medicare that covers the cost of physician services, outpatient hospital care,
and medical supplies and equipment. This coverage may be increasingly important to the enteral nutrition community, as patients and government programs are increasingly moving in the direction of home care as a cost-effective alternative to inpatient hospital care. Medicare Part B covers enteral nutrition in the home and in nursing homes for patients who do not qualify for Part A skilled nursing care. Historically, the majority of Part B enteral patients have resided in nursing homes, although the division of enteral patients between home care and nursing home care is approaching 50–50. Part B enteral suppliers primarily are durable medical equipment (DME) companies or infusion pharmacies.

**Coverage**

Since 1981, Medicare Part B has covered enteral nutrition in the home and alternate care settings under the prosthetic device benefit. How this came about is an interesting example of creative policymaking. Medicare coverage for an item or service can be established in one of two ways: Congress can mandate coverage through legislation which CMS then implements through regulation or Medicare manual instructions, or CMS can establish coverage without an authorizing statute through regulations or manuals by establishing coverage for an item or service within an existing coverage policy. CMS decided to cover enteral nutrition based on a House Ways & Means Committee report from the 1980 Omnibus Budget Act suggesting that DHHS should consider covering enteral nutrition in the home setting as a cost-effective alternative to inpatient care. However, as report language simply indicates congressional intent but does not have the force of law, CMS had to find an existing niche into which it could fit enteral nutrition. CMS considered several options, including the home health benefit, the DME benefit, and the prosthetic device benefit.

To qualify for the home health benefit, patients must be homebound, i.e., be in such a condition that ‘there exists a normal inability to leave home and, consequently, leaving their homes would require a considerable and taxing effort usually requiring the use of supportive devices such as crutches, cranes, wheelchairs, walkers, or the assistance of another person’ [7]. Most home enteral patients would not meet this criterion, and thus CMS rejected this option. CMS also considered using the DME benefit because a significant number of enteral suppliers would likely be DME companies. However, Medicare does not cover DME in nursing homes, where close to 80% of the enteral patient population was located at the time, so this option was discarded.

Ultimately, CMS determined that the prosthetic device benefit would enable Medicare to reach the highest number of beneficiaries without the limitations of the other options. CMS reasoned that the tube can be likened to a replacement for a body part – in this case, a part of the digestive tract – thus meeting the literal definition of a prosthetic device. And, to make coverage of the tube meaningful, CMS also decided to cover the nutrients that flow through the
tube as well as the enteral pumps that may be used in the provision of the therapy. However, as a result of this decision, enteral nutrition must satisfy the coverage requirements of the prosthetic device benefit.

Clinical Conditions

CMS has developed detailed requirements related to the clinical conditions for which enteral therapy is covered. Under Medicare guidelines, all enteral nutrition claims must be approved on a case-by-case basis. The prosthetic device benefit requires that the patient has ‘a permanently inoperative internal body organ or function thereof’ [8]. CMS further defines this requirement as follows:

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 [8].

The requirement that there be a permanent injury or malfunction received a lot of attention when enteral nutrition was first placed in the prosthetic device benefit. In selecting the prosthetic device benefit as the coverage niche for enteral nutrition, CMS realized that this requirement, taken literally, made little sense for a patient who may need enteral nutrition for some period of time after surgery. CMS ultimately decided the issue by ruling that permanent injury means being of a long and indefinite duration, which was further refined for enteral nutrition to mean at least 90 days. Thus, enteral nutrition for a prescribed period that is less than 90 days is not covered under Part B.

Medicare Part B does not cover enteral nutrition for patients who have a functioning gastrointestinal tract but nevertheless have nutritional needs due to cognitive disorders such as anorexia, mood disorders, Alzheimer’s disease, etc. Though these conditions can make chewing and swallowing difficult, the malfunctioning organ or body part under these circumstances is not the gastrointestinal tract. There may, however, be specific instances in which documentation of a patient’s functional inability to swallow can satisfy the coverage requirements.

Importantly, Medicare Part B does not cover enteral nutrition that is orally administered. At the time that CMS decided to cover enteral nutrition in 1981, it was thought that if a formula could be consumed orally, then it was simply food and not a medical treatment. In addition, there were concerns that continue to be present about high costs and potential abuse if the formulas could be taken orally.

The Medicare program carefully monitors the use of enteral nutrition in nursing homes to protect against overuse and possible abuse. The concerns center around the possibility that a thinly staffed nursing home may opt to put some of their residents on tube feeding rather than bring them to the dining halls and assist in their oral feeding.
Enteral Pump Coverage

If patients require the use of a pump due to complications with a syringe or gravity method of administration, the medical necessity of the pump must be justified and documented or coverage will be denied as not medically necessary [9]. In actual practice, however, especially in light of the more sophisticated enteral formulas introduced into the market over the past decade, enteral pumps are considered to be medically necessary in most situations.

Product Coding

For the purpose of standardizing claims processing, Medicare suppliers must classify the enteral nutrient, supply, or pump provided using the appropriate Healthcare Common Procedure Coding System (HCPCS) code. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) made the use of HCPCS mandatory for transactions involving healthcare information. Enteral nutrition codes are grouped into codes B4000 through B9999, with enteral nutrition formula products into seven codes or product categories. Medicare recently expanded the number of codes available for classifying enteral nutrition to better group products of similar composition and like ingredients. However, it is important to note that some codes continue to group non-substitutable products. For example, B4154 is used to classify nutritionally complete formulas for special metabolic includes diabetes, hyperglycemia, renal failure, pulmonary disease, and respiratory illness.

Reimbursement

Equipment

Patients may rent or purchase enteral nutrition pumps and intravenous poles. Medicare pays for rental pumps on a monthly basis [10], but for no more than 15 months. Suppliers are also entitled to periodic maintenance and servicing payments on rental equipment, even after the 15th month of use [11].

Formulas and Supplies

From 1981, when Medicare Part B coverage for enteral nutrition began, through 2001, enteral nutrition was reimbursed on the basis of reasonable charges submitted by enteral suppliers. Beginning January 1, 2002, Medicare changed from a reasonable charge-based payment methodology for enteral nutrition to a fee schedule, as authorized by Section 4315 of the Balanced Budget Act of 1997. At the time, enteral nutrition was one of the few remaining therapies reimbursed on the basis of reasonable charges. In actual effect, the change to a fee schedule has not modified reimbursement to a great extent because the first year of the fee schedule was required to be budget neutral. CMS basically used the prior reasonable charge amounts as the initial fee schedule.

The fee schedule provides a single payment amount per HCPC code. For formulas, the amount reimbursed is then determined based on the number
of units of formula used, with a unit defined as 100 kcal. Fee schedules are updated annually by the change in the CPI-Urban Index, unless Congress enacts a payment freeze or reduction (enteral nutrition payments have been frozen by Congress on several occasions since the 1980s).

**Medicare Competitive Acquisition Program**

In the Medicare Modernization Act of 2003, Congress directed CMS to develop and phase-in a national competitive acquisition program for most Part B therapies, items and services. The first phase of this new program will begin during the fourth quarter of 2007 in 10 metropolitan statistical areas (MSAs). The program must be expanded to 80 of the largest MSAs in 2009 and to additional MSAs thereafter.

This competitive acquisition program is a significant departure from the traditional Medicare program in that it will purposely limit the number of Part B suppliers available to provide Part B-covered therapies, items and equipment in competitive bidding areas. Importantly, Congress also mandated that CMS develop quality standards that would apply to virtually all Part B items and services, regardless of whether the particular items or services are subjected to the competitive acquisition program. Congress clearly thought that the application of quality standards to the competitive acquisition program would ensure that beneficiaries would receive care in compliance with the standards, despite the financial pressures on suppliers to bid lower than current payment levels.

As of this date, the final regulation implementing the competitive acquisition program has not been issued. It is not clear at this juncture whether enteral nutrition will be included in the first phase of the program. There are reasons to suspect that enteral nutrition could be included in the first phase, principal among them being that Medicare expenditures for enteral nutrition rank fourth among expenditures for all items potentially subject to the competitive acquisition program. On the other hand, there are strong arguments why enteral nutrition should be exempted from the competitive acquisition program. Enteral nutrition is the only area possibly subject to competitive acquisition where the majority of the patients reside in long-term care facilities rather than in their homes. This creates a complicating dynamic and involves integrating another setting and a different type of provider (long-term care facilities) into what is already a complex and largely untested new system. CMS is expected to clarify which items will be subject to competitive acquisition within the next month of this writing.

**Medicare Reimbursement for Enteral Nutrition Provided in Skilled Nursing Facilities**

The Medicare program pays for care provided in a skilled nursing facility (SNF) under Part A according to a PPS in which providers are reimbursed on a per diem basis for covered services. Prior to the enactment of the SNF PPS,
Medicare reimbursed facilities based on a retrospective reasonable cost basis. To account for differing patient needs under this prospective system, per diem payments are case-mix adjusted based on assignment of patients to 1 of 53 Resource Utilization Groups III (RUG-III). RUG-III further organizes these patient types into 9 broader categories: Rehabilitation, Rehabilitation plus Extensive, Extensive Services, Special Care, Clinically Complex, Impaired Cognition, Behavior Problems, and Reduced Physical Function, and designates groups of patients for whom SNFs should receive higher payment.

The medical need for enteral nutrition may allow patients to be classified in the Extensive Services, Special Care, and recently added Rehabilitation plus Extensive categories for which higher payments are available to better account for higher costs of medically complex patients [12, 13]. Thus, assuming that a patient meets the conditions for Medicare coverage of SNF services, the provision of enteral nutrition could lead to higher reimbursement for the SNF. To receive payment for SNF coverage, the ‘beneficiary must have been an inpatient of a hospital for at least 3 consecutive calendar days … and must have been transferred to a participating SNF within 30 days after discharge from the hospital[;] the SNF care services must be needed for a condition that was treated during the hospital stay, or for a condition that arose while in the SNF for treatment of a covered condition[;] and the services must be reasonable and necessary to diagnose or treat the beneficiary’s condition’ [14].

**Coverage of Enteral Nutrition by Medicare Advantage Plans**

The vast majority of MA plans are based on the Medicare Part A and Part B coverage policies. However, there is some variation in plans, particularly in instances when a payer tacks a MA plan on to a commercial product. While some MA plans strictly follow Medicare’s requirements for medical necessity, a general selling point of the MA program is that plans can cover more than traditional Medicare. The MA plans provide at least the same coverage for enteral nutrition as are provided under Parts A and B of the program, and plans have the flexibility to provide more expansive coverage.

**Public Payers: Coverage of Enteral Nutrition under State Medicaid Programs**

The other major source of public coverage for enteral nutrition is the Medicaid program. Medicaid provides healthcare coverage for over 55 million low-income people. It is also a primary source of financing for long-term care services, with the majority of Medicaid spending (70%) attributable to the elderly and people with disabilities [15].

Medicaid is jointly administered and funded by the states and the federal government. The states administer Medicaid within broad federal guidelines.
and subject it to oversight by CMS. The Medicaid statute sets out certain minimum services that state programs must provide and populations that must be covered. Within these broad guidelines, states have considerable discretion regarding eligibility, benefits, and provider payments, leading to variation in coverage of enteral nutrition among Medicaid programs. In addition, states can offer additional benefits, such as a drug benefit, at their discretion. Increasingly, DHHS is granting waivers to the states that allow further flexibility to deviate from federal guidelines, in some instances to provide coverage beyond federal limits and in others to implement more efficient programs.

Variation in Medicaid Coverage Standards for Enteral Nutrition in Outpatient and Home Care Settings

Not surprisingly, coverage of enteral nutrition varies across states. State Medicaid programs generally cover and reimburse enteral nutrition in inpatient hospital settings as they pay for inpatient benefits. With respect to enteral nutrition provided in an outpatient or home setting, although Medicare coverage standards have influenced coverage in Medicaid, states deviate in important ways from some Medicare requirements. Some states have relaxed restrictive requirements linked to Medicare coverage of enteral nutrition as a prosthetic device, and states may cover enteral nutrition as part of a DME benefit, a pharmacy benefit, or a standard medical benefit [16].

A recent survey of State Medicaid programs by the Government Accountability Office (GAO) [17] compared coverage standards of Medicaid programs with Medicare’s main coverage requirements, using the following criteria:

- Pathology: The patient has to have a pathology or nonfunction of the structures that normally permit food to reach the small bowel (e.g., inability to swallow), which impairs the ability to maintain weight and strength;
- Permanent Condition: The impairment has to be considered a permanent condition, (i.e., lasting at least 3 months);
- Tube Feeding: The patient’s condition must necessitate tube feedings to provide sufficient nutrients to maintain weight and strength (i.e., the patient must be unable to obtain adequate nutrition through dietary adjustment and/or oral supplements);
- Partial Impairments: The program will cover enteral nutrition for patients with partial impairments, as Medicare does, and
- Documentation: Specific documentation has to be provided in the patient’s medical record.

The GAO also obtained information on whether the state covers orally administered enteral nutrition products, which Medicare Part B does not (table 1; see column indicating that states cover orally administered ‘products and supplies”).
### Table 1.

Reported Enteral Nutrition therapy coverage standards by the state Medicaid program.  

- **Pathology**
- **Permanent condition**
- **Tube feeding**
- **Partial impairment**
- **Products and supplies**
- **Documentation required**

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- ☺ Applies to both adults and children
- ☺ Applies to adults only
- ☺ Applies to children only
- ☺ State does not cover therapy
- ☺ Coverage standard or requirement does not apply

This survey clearly illustrates the variation among states and between the Medicaid and Medicare programs (table 1). As of 2005, all state Medicaid programs, except West Virginia’s, provided some coverage for enteral nutrition. The greatest deviation from Medicare standards centers on the requirements that the condition be permanent (last more than 3 months) and the lack of coverage for orally administered nutrition.

- Thirty states do not require that the impairment be a permanent condition in order to cover enteral nutrition, with an additional 4 applying this requirement only to adults, and 2 applying it only to children. For example,

- More than half of all states choose to cover orally administered nutrition therapy, with 34 covering it for both adults and children, and 8 states covering it for children only.

To a lesser extent, states also deviate from the required Medicare pathology, with 12 states not requiring this pathology, 5 requiring it only for adults and 2 only for children. On the other hand, like Medicare, nearly all states require specific documentation of enteral therapy in the medical record. Twelve states tend to have less restrictive coverage standards for children [15].

The GAO also found that state Medicaid programs vary in coverage of enteral nutrition supplies in home health and outpatient delivery settings (table 2). As the GAO concluded:

Based on our survey, state Medicaid programs’ payment for seven of the most commonly used enteral nutrition supplies varies depending on the type of product, delivery setting, and whether the patient is an adult or a child. Table 2 shows that states reported that their Medicaid programs pay for enteral feeding supply kits and tubing more than other therapy supplies. In addition, more states pay for enteral supplies for children than adults and more states pay for supplies in outpatient delivery settings than in home health delivery settings.

Further analysis revealed that 15 states pay for all 7 supplies listed in our survey in both home health and outpatient delivery settings for adults and children. Thirty states pay for five or more enteral nutrition supplies for adults and children in these same settings. We also found that additives for enteral formula, such as fiber, are the least covered product, with only 21 states covering it in both home health and outpatient delivery settings for adults and children [17].

Coverage and Reimbursement of Enteral Nutrition by Private Third-Party Payers

Private payer coverage of enteral nutrition varies depending on the particular benefit. While Medicare Part B covers enteral nutrition under the prosthetic device benefit, private payers may cover enteral nutrition as part of an infusion benefit, a home medical equipment benefit, or even under a drug benefit.
Product Coding

Most private sector payers must use Medicare HCPCS codes to classify products for claims processing. Private payers, like Medicare, have adopted HCPCS codes in an attempt to standardize the codes used by different payers and providers and to comply with HIPAA standards for healthcare-related transactions. When CMS added additional HCPCs for enteral nutrition to separate adult formulas from pediatric and children’s formulas, private payers followed suit.

Private sector payers also employ ‘per diem’ S-codes, created ‘to report drugs, services and supplies for which there are no national codes; but for which codes are needed by the private sector to implement policies, programs, or claims processing’ [18]. The per diem code includes enteral formula as well as supplies and equipment (pumps and poles are not coded separately). Some Medicaid programs have adopted these codes as well for reporting purposes, although ‘they are not payable’ [18].

Reimbursement

Private payers usually negotiate reimbursement rates with enteral nutrition suppliers through a process that has some elements of competitive bidding. In bidding for these contracts, suppliers often offer to provide enteral nutrition supplies and equipment among a range of other infusion drug therapies. In return for accepting the negotiated rates, suppliers often are ensured a certain level of business and prompt payment.

The majority of private insurers reimburse suppliers using the negotiated rate for the particular HCPC code on a per 100-calorie unit basis for enteral formulas. Whether the reimbursement rate varies between different

Table 2. State Medicaid programs that reported payment for common enteral nutrition therapy supplies for adults and children in home health and outpatient delivery settings

<table>
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<td>Enteral feeding supply kit</td>
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<td>Tubing</td>
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<td>Additive for enteral feeding</td>
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<td>Enteral nutrition infusion pump</td>
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<tr>
<td>Intravenous pole</td>
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<td>Percutaneous catheter/tube</td>
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codes as it does in Medicare (for example, for a more complex nutrition formula) depends entirely on the negotiated contract. Private payers may also provide opportunities for enhanced reimbursement for particularly expensive products within a code through the use of a modifier if special medical needs are present. This has been particularly important for nutritionally complete formulas that were previously included with other less expensive products and were often not profitable to provide at reimbursement levels under the former HCPC code. As in Medicare Part B, pumps and poles are separate rental products for which providers receive payment on a monthly basis.

Private payers that use ‘S’ codes reimburse providers on a per diem basis using rates based on the average wholesale price. The per diem rate includes payment for pumps and poles.

Medical Necessity

Private payers may not follow the stringent Medicare requirements for medical necessity for Medicare reimbursement, though specific coverage again varies from payer to payer. Generally, if a physician prescribes enteral nutrition, it will be reimbursed.

Coverage for oral nutrition varies depending on the payer. Increasingly, the trend is not to pay for oral administration. Payers are generally looking to control expenditures and believe that they should not be paying for enteral nutrition in circumstances where the patient can purchase food and blend it if necessary. For certain products, however, such as elemental products for patients who have an absorption impairment, payers are still likely to cover and reimburse. There is a HCPC modifier, BO, to indicate orally administered nutrition not by feeding tube.

Conclusion

- Enteral nutrition is widely accepted as an effective mainstream, often life-sustaining, therapy
- Coverage and payment policies for enteral nutrition differ among payers and settings. These differences largely depend on whether enteral nutrition is covered and reimbursed as a discrete therapy or whether it is subsumed into a larger benefit
- There is some concern among policymakers that enteral nutrition is susceptible to overuse, particularly in the long-term care setting
- The trends in coverage and payment for enteral nutrition suggest
  - Tighter reimbursement
  - Introduction and expansion of competitive bidding approaches
  - Data-driven performance measurement and payments
References

2 Section 1886(d) of the Social Security Act.
6 42 C.F.R. § 482.28 (Condition of participation: Food and dietetic services).
7 Medicare and Medicaid Guide, ¶1.56.
9 Medicare NCD Manual, § 180.2; Medicare and Medicaid Guide. Coverage and Payment Rules.
10 42 C.F.R. §§414.104 (a) (PEN Items and Service, Payment Rules).
12 Medicare and Medicaid Guide ¶8.120.
14 Medicare and Medicaid Guide ¶8.120.

Discussion

Dr. Elia: I have a question about disease-specific formulas. How does the reimbursement process works here? By and large, disease-specific formulas are more expensive than standard formulas. What kind of information or evidence needs to be acquired to inform the reimbursement process? For example, is it sufficient to demonstrate safety and a rational concept or do you require formal evidence that the disease-specific formula is superior to a standard formula, and does that determine the reimbursement rate?

Mr. Parver: That’s a good question and the short answer is if the disease-specific formula is more costly than the standard formula, they will look for more evidence. There was a phase for a while when patients were being put on special metabolic formulas all over the place, and some of these formulas did not look as though they were supported by a lot of clinical evidence. Reimbursement was materially higher for disease-specific formulas, and the industry was not able to say why these patients were all of a sudden being switched to these disease-specific formulas, other than reimbursement. So, reimbursement levels came down for those formulas and they are all now at the same level. That is going to be one of the challenges; we will have to be able to give better justifications for the use of such formulas than may have been provided in the past. What also affects the issue is that there are some disease-specific formulas in the codes and categories with the other formulas. There are categories for other disease-specific formulas that are reimbursed at a higher level and there are almost similar disease-specific formulas in the cheaper category. So, policymakers are justified in asking if industry can provide this one for that price, why are we asked to pay at this higher level? We need something besides ‘we make more money from it’.
Mrs. Gailing: I have a question on the difference between the reimbursement and putting the product on the market. Are all food products eligible for reimbursement or do they first have to go through medical food clearance in the US?

Mr. Parver: Be careful with medical food. Some enteral products are regulated as medical foods by the Food and Drug Administration, but a lot aren’t. They are just regulated as food. Your price is not that relevant, as Medicare does it. They already have their particular codes, and will take your product based on how you describe it and will put it in the code. Once it is in the code, that is the reimbursement rate for that product. Your own costs are interesting, but not that relevant to that decision.

Dr. Bistrian: There is fairly good evidence that oral supplements in many disease states can, when added to regular food intake, increase the total caloric intake and be beneficial. If it were not covered in a particular state, could you say that it would have to be provided by tube and that would be more expensive?

Mr. Parver: That would be a dangerous route unless the person is already receiving tube feeding. Tube feeding is only implicated when they cannot take food orally. You can’t just do that to get coverage. It would not be a proper way to gain coverage.

Dr. Hoffer: Thank you for a very clear presentation for material which is completely new to me. It was a real eye-opener. You said that there is some concern among policymakers that enteral nutrition is susceptible to overuse in long-term care. That sounds very plausible to me because it would be economically beneficial to a facility to insert a tube and get a packet of money for it as opposed to paying someone to hand-feed a person, even though the second would be far preferable from every aspect of medical and social wellbeing. I wouldn’t say that there is concern, but it is a recipe for that sort of abuse to take place.

Mr. Parver: There is a concern that thinly staffed nursing homes would find it easier to stick a tube into someone than wheel them down to the dining hall and feed them by hand, no question. The nursing homes have to meet quality standards and the surveyors are supposed to be watching for this. They are supposed to be concerned if there are too many patients on enteral feeding. Keep in mind that most facilities only have a handful of patients who are getting tube feeding. So, if there is a large number, the surveyors are suspicious, unless the home is competing for sicker patients. If their staffing doesn’t reflect that, the surveyors will probably conclude that they are gaming the system and doing exactly what you said. Certainly, there are a lot of biases about that and they have to be very careful. My wife is a nursing home administrator and they always see it as a failure if they have to put someone on tube feeding. It should only be under the most rigorous criteria. The surveyors are trained to look for that.

Dr. Seidner: I would assume that the reimbursement process works quite easily for the patient with a degenerative disease or head-neck cancer who can’t swallow and needs a tube. What are your views on the patient who is able to eat but has severe malabsorption and has a tube for supplemental feeding while they are not eating over the evening? I would assume that those are the patients with some hurdles to cross.

Mr. Parver: This issue came up a lot in the beginning, but I don’t see it as much any more. First of all, they will not pay for patients who are just recalcitrant. If people refuse to eat, they will not be covered by Medicare in most cases. Tube feeding as a supplemental benefit is not covered either. Let me read this sentence, ‘Enteral is considered reasonable and necessary for a patient with a functioning gastrointestinal tract, who, due to pathology 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’. CMS has interpreted this to mean total nutrition. They want the tube feeding and they want parenteral feeding to be the great percentage of the feeding the patient gets. I understand that parenteral patients are told to
keep eating because they need to keep the systems working. The fact that you can take some food orally but not enough to survive is the issue. There is a line some place, they say it is total but there are coverages for people who have something less than total but it has to be a small portion of that. Again, tube feeding has to be the dominant means of keeping the patient thriving.

Mrs. Anthony: You said that enteral nutrition has not been cut heavily so far by Medicare. Why do you think it is protected?

Mr. Parver: One of the things that worked in our favor is the absolute confusion about what it is and how it is covered. The fact that it is in the prosthetic device benefit is not something people get their minds around easily. Medicare doesn't work well when things fall across different spectra, when you have nutrients, equipment, supplies and different players working; there are dieticians and different settings. They are uncomfortable with it and the fact is that, for a while, they were targeting enteral feeding every year, and we were relatively successful in pushing that back. Now, they see enteral as a cost-effective alternative to parenteral feeding. One of the things that has helped the enteral area is that many patients who would have been on parenteral are now on enteral feeding, at much greater savings to the program. So, they see this as a good story; though, if you talk to anyone at CMS, they really have a hard time understanding what they are doing, and why their predecessors created this thing. It is not a model for future policy development. They use this area as an example of being a little too creative and this may not have been the way to do it. In other areas, they looked for more linear ways as opposed to what they came up with for us.

Mrs. Anthony: I would like you to comment on the advocacy. I am fairly familiar with your work which you have been doing for a long time, and you get a lot of credit for letting the CMS realize how complicated it is. Could you comment on the advocacy for enteral nutrition? Are there other groups that, if we need to be more aggressive advocates, we could model ourselves after or look to as examples?

Mr. Parver: The best advocacy is one that involves patient organizations and patient groups right up front. The Oley Foundation in the United States represents patients. The best advocacy involves patient groups, suppliers, providers, distributors, manufacturers and physicians all saying the same thing and for the same reasons. We are not quite there, we can do better. The manufacturers have been one of the principle advocates for enteral policy. The enteral suppliers have grown reliant on manufacturers such as Nestlé to carry the ball here. One of the things we have been doing is to get the suppliers more active in their own right. We have done alright, but we can do better if we get more of the stakeholders at the table being aggressive and articulating their concerns. In terms of whom to pattern ourselves after, I don't know how to answer that. There are a lot of groups that we emulate. The best example of how to do advocacy in Washington DC in healthcare is the oncology community. Cancer is something that policymakers know, they understand it and have seen how it affects their families. Crohn's disease does not have that same identification. The cancer community has done a fantastic job of organizing beneficiaries and physicians. Congress knows that the cancer community can generate 60–70,000 letters in a week protesting something a month before the election. So they are extremely good at what they do. I am not sure if we will ever be at that level but I think we should strive for better grassroots; have the patients and physicians involved and understand what the consequences are. One of the good things about what we have done is that we have had to invent our benefit under Medicare, as silly as it may sound. In terms of the evolving Medicare structures, we are probably better positioned than some to reinvent it and readjust it to what the new realities are. Some groups that have just been handed a coverage scheme may feel that is the way life is and should always be. We have never
been that sanguine about it and understand that we have always had to fine-tune it in very technical ways to make it work. I think that will help us in the future.

**Dr. Kondrup:** I can’t help thinking that, in the end, the system that is most profitable for lawyers and accountants will win and the patients will not benefit very much from that. In Denmark, we have reimbursement for 60% of the cost of enteral feeding in the homecare setting. The reason why it is not 100% is that these people will spend money on food anyway. The only thing that it requires is a prescription written by the doctor that there is a medical indication for this, and the prescription has to be renewed every 3rd month. This system was introduced about 10 years ago. We had an expectation about the cost, and it has increased over the years to 50% more than the expected, but still it’s accepted. This is a very non-bureaucratic way of running things.

**Mr. Parver:** Medicare is the opposite of a non-bureaucratic way of running things. To quote Rumsfeld, ‘this is the system you have, not the system you want’. We also need a physician to write the prescription and it has to be renewed every 90 days. It is quite bureaucratic but not just in this area, it is bureaucratic across the board. All of our advocacy efforts were not to enrich ourselves but to benefit our clients, the manufacturers, the providers, and it only works for them if it works for the beneficiaries. The reason Medicare has been good about leaving us alone, relatively speaking, is because they see it working for the beneficiary. The bottom line is if the beneficiaries were not getting access to quality care, this thing would be a lot different.

**Dr. Labadarios:** My questions may be seen a little naive but I want your opinion. To what extent do you think all of this rigmarole inhibits professional development? Who are these people actually and do they interfere with my professional rights as a practitioner? Who put them there in the first place and why are they there? This next question is addressed to everybody: have we lost control of our profession? If we have, what are we doing about it?

**Mr. Parver:** That it is not naive at all. It is not limited to nutrition; it runs across the board. Most physicians and health practitioners who have to do business with this program feel that they are being turned into clerks and, to some degree they are; they spend far too much time dealing with the program than dealing with their patients. There is no question about it, and it is not limited to nutrition. Who put them there? When you talk to policymakers about Medicare, they will use two words and you know immediately where the conversation will go after that; those words are ‘trust fund’. When they mention trust fund, those are public dollars that are put into this fund for the Medicare program, which is going to go bankrupt in 11 years by the way, unless something is changed. Once they mention trust fund, they ask what we have to do to protect the sanctity of the fund. The fact is that a lot of public money is involved in this. Medicare treats 43 million beneficiaries annually and the cost is astronomical. People have criticized the American system for being so expensive and not producing results commensurate with those expenses. One of the ways Medicare works, this might be a bit of an aside, is they will often tell you that their administrative costs are 2%, which is terrific. The reason they are 2% is that they shift the administrative burden to everybody else so that the practitioners and the institutions are saddled with all these coding documentation issues and just the daily business of the program. That is where the costs are too. Who put them there? The system grew that way because so many public dollars were involved and it was increasing at a tremendous rate. Here is the rub, to fix it, if it can be fixed, it’s not going to mean less bureaucracy but more, at least in the short-term, to deal with those issues. Medicare has to evolve into something else. It will not happen from our vantage point but from the governmental perspective, and it will require a lot of those people.
Mr. de Man: In terms of bureaucracy, does the contracting out to managed care organizations decrease the bureaucracy to a certain extent?

Mr. Parver: Absolutely, yes. The managed care operation does not work like a Swiss watch either. Right now, Medicare pays managed care more than it pays fees for service. So how did this happen? I thought that managed care was supposed to save us money but they are spending more as a premium. The argument is that they are doing more. The Democrats, especially Pete Stark who is the chair of the health subcommittee, is a real non-fan of managed care and he wants to find out why we are paying more money to them, what are they doing extra and where is it documented. There will be a whole set of hearings dragging managed care people in front of the Congress. There is no question that the managed care initiatives, even in Medicare, cut through a lot of that. For example, the Medicare advance plans have to provide the services that are covered by Medicare A and B but they can provide more and a lot of them do it without a lot of crazy paperwork.

Dr. Labadarios: This is perhaps a less naive question, and before I make it I will declare that I have no political inclinations. Are we not doing a disservice to our profession by allowing these things? When are we actually going to learn? The UK is a good example if you believe the conservative leader, the NHS is in the mess that it is because of the so-called administrators who come in, cut the best salaries for themselves, and then there is no money elsewhere. I am sure that Dr. Elia will second that. The question is, at what level do we professionals come in and try to do something about this? Surely we must have a say in the matter.