Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

INAPPROPRIATE PAYMENTS FOR TOTAL PARENTERAL NUTRITION (TPN)

MAY 1993

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MAY 1993 OEI-12-92-00460

EXECUTIVE SUMMARY

PURPOSE

The purpose of this report is to examine Medicare coverage of total parenteral nutrition, a "high tech" means of feeding patients who do not have a functioning intestinal tract.

BACKGROUND

Total parenteral nutrition is lifesaving for the small number of patients who lack a functioning intestinal tract, usually because of severe bowel disease or a surgical shortening of the bowel, so that insufficient length remains to absorb nutrients. Medicare covers this very expensive therapy as long as strict coverage guidelines are met. Prior to the advent of the common working file, inconsistent carrier reporting of payments hampered analysis of payment data. Claims paid in 1991 represent the first reliable source of data for analysis and are available at a time when the infusion therapies, of which parenteral nutrition is one, are undergoing rapid expansion. This is the first in a series of reports examining infusion therapy.

METHODS

We based this inspection on three data sources: a 1-percent sample of paid claims for parenteral services; a telephone survey of 93 randomly-selected dialysis facilities; and interviews with experts in the field. We examined the claims data to determine for whom and for what conditions parenteral nutrition is being used, and the survey information supplements the claims data for a subset of patients, those with end-stage renal disease (ESRD).

FINDINGS

- Medicare overpaid $69 million for total parenteral nutrition in 1991, 43 percent of the total of $162 million paid for this service.

- More than half the patients in the sample (53 percent) had ESRD, and received parenteral nutrition as a supplement, three times a week. The benefit of supplemental parenteral nutrition for these patients is unproven, and the charges are disproportionately high for the nutrients supplied.

- Review of total parenteral nutrition use in the non-ESRD population reveals inappropriate patient selection and over- and under-feeding.

RECOMMENDATIONS

The Health Care Financing Administration (HCFA) should:

- instruct carriers to adhere to a strict interpretation of the coverage guidelines. We estimate this will result in savings of $69 million a year.

- require the carriers to intensify review of certificates of medical necessity, discuss therapeutic options with physicians, and monitor the use of nutrients over time. One approach might be the use of "case managers," to interact with suppliers and physicians.

- review research into the clinical appropriateness of and payment methodologies for intra-dialytic parenteral nutrition.

AGENCY COMMENTS

We received comments on the draft report from HCFA and the Assistant Secretary of Management and Budget (ASMB), both of whom concurred with these recommendations; HCFA has taken steps to implement them. The HCFA will defer responding to the question of appropriate payment methods for intra-dialytic parenteral nutrition until a coverage decision has been made. The HCFA's comments are appended in full.

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INTRODUCTION

PURPOSE

The purpose of this inspection was to examine Medicare coverage of total parenteral nutrition (TPN), a "high tech" means of feeding patients who do not have a functioning intestinal tract.

BACKGROUND

Clinical: Total parenteral nutrition (TPN) is a therapy designed to maintain adequate nutrition in those patients who cannot eat normally. Early attempts at enriched, easy-to-digest formulas included carbohydrate-rich "joy juice," taken by mouth, and vitamin-enriched intravenous (IV) feedings. Generically called "hyperalimentation," both enteral and parenteral nutrition have become treatments of choice for nutritionally-impaired patients.

Oral or tube feedings meet the needs of those patients with a functioning gastrointestinal tract. Enteral formulas, which can be milk-based or milk-free, are available in drugstores. The formulas can be merely protein or calorie supplements, or nutritionally complete. These are administered by mouth for debilitated patients; through naso-gastric tubes for patients who cannot swallow or who have a damaged alimentary tract; and directly into the stomach or intestines via surgically-implanted tubes for patients requiring long-term maintenance. A simple pump can be used to maintain a steady flow, although gravity will suffice for all but those patients fed into the jejunum. These are comparatively "low tech" therapies, easily managed in terms of the patient's nutritional status, cleanliness and patency of the tubes, and ease of administration. Many patients on tube feedings are residents of nursing homes, although the technique can be used in the patient's own home, managed by the patient or a family member, with the help of a visiting nurse.

An intermediate nutritional supplement, used mainly in conjunction with surgery, is enriched IV feedings. Normally, IVs hydrate patients who should not take liquids orally, for fear of vomiting and aspirating the fluid into the lungs during or following surgery. They can be glucose solutions, to provide some calories, or other chemical solutions to maintain the patient's electrolyte balance. If a patient cannot tolerate solid food, he or she can be maintained on IVs with additives, such as vitamins, purified fats, and amino acids, for about 10 days. These solutions cannot be used for longer than that since the patient's peripheral veins cannot tolerate the enriched solutions, and because these solutions may not be not sufficient to meet a patient's nutritional needs over time.

When a patient lacks a functioning gastrointestinal tract, nutrition must be supplied directly into the blood stream, from which it can be absorbed by the tissues. This is known as TPN. A catheter is advanced into a large vein, usually the superior vena

cava, through the chest wall. The catheter can be tunnelled through the fatty tissue of the chest, both to anchor it and to prevent air from entering during dressing changes. All stages of this therapy require the use of sterile technique - during surgery to insert the tube, during dressing changes, during the preparation of the nutritional fluid, and during the attachment of the fluid containers to the catheter.

Manufacturers sell standard nutrient solutions in quantity; these solutions are then modified by prescription, depending on the patient's condition, blood counts, organ function, weight, etc. In the hospital, a pharmacist would add trace minerals, additional amino acids, vitamins, etc., based on the physician's order. The solution's composition might change daily, depending on the results of frequent blood tests, urinalyses, and monitoring of fluid balance. A nurse attending the patient would add medications such as insulin just before administering the solution. A pump maintains a steady rate of flow, and a filter inserted in the line filters out bacteria or any other particulate matter.

Although the TPN technique is more complex than other feeding regimens, patients can learn to administer their own feedings. Teaching begins in the hospital, and can be reinforced at home by visiting nurses. By the time the patient goes home, he or she would not require such frequent adjustments of the formula, and would add medication, vitamins, etc., by injecting them through the sterile rubber diaphragm over the neck of the bottle or bag before hanging it. To successfully administer their own TPN, patients (or family members) must be able to understand and maintain sterile technique, monitor their weight and physical condition, and be alert for complications. Patients who are otherwise healthy can infuse overnight, and go to work during the day, plugging the catheter when not in use. Other patients are too debilitated by their underlying disorder to lead a normal life.

Complications of TPN can be life-threatening. Among the metabolic complications of the therapy are electrolyte imbalances, which can lead to irregularities of the heartbeat, diabetic coma, fainting, etc., and fluid imbalances. Other complications of long-term TPN are bone pain and liver dysfunction. Among other risks are pneumothorax (lung collapse) caused by the catheter, and thrombosis or air embolism, caused by a clot's breaking loose or air entering the superior vena cava, usually associated with a dressing or tube change. Another serious complication is septicemia ("blood poisoning") associated with use of the indwelling catheter. Some patients cannot be maintained on TPN because of recurrent infection, intolerable diarrhea, or an inability to manage their own care.

Among the conditions for which TPN is indicated are short-bowel syndromes, in which the intestines have been removed due to cancer or necrosis of the tissues. In other conditions such as Crohn's disease, TPN may be used during acute phases of the disease, and normal food may be tolerated during remissions. (Patients with Crohn's disease can use enteral nutrients during some stages of their disease.) Hospitalized patients who have extensive burns can be given TPN, as can patients with multiple organ failure. Surgeons will sometimes want to prepare poorly-nourished patients for

the demands of extensive surgery by putting them on TPN pre-operatively. Healing can be delayed when nutrition needs are unmet, so TPN is sometimes used on a short-term basis for patients who have functioning gastrointestinal tracts, but fail to take in enough food to nourish themselves.

Other patients for whom TPN may be ordered are those who are cachectic, i.e., in a disease-related state of profound ill health and malnutrition. Two conditions in which cachexia is common are terminal cancer and renal failure. Acquired immunodeficiency syndrome (AIDS) is associated with a wasting syndrome, in which weight loss, fever, night sweats, oral thrush, and diarrhea are common.

Medicare coverage: Medicare covers TPN both at home and in the hospital. When TPN is administered in the hospital, payment for it is included in the diagnosis-related group (DRG) payment. No justification for using it is needed. In the home setting, however, Medicare covers TPN as a prosthetic device, which replaces an inoperative body organ or function. Most prostheses replace a missing body part, so they are by definition permanent conditions. As discussed above, however, some patients use TPN only intermittently. The Coverage Issues Manual addresses this, by providing for a presumption of permanence if the impairment, in the judgment of the attending physician, will be of long and indefinite duration.

A physician must certify the medical necessity of the therapy, the pump, and pre-mixed (as opposed to patient-mixed) compounds. Only a one-month supply of nutrients will be paid for at one time.

Medicare requires that the certifying physician describe the "functional impairment" which necessitates the use of TPN. A diagnosis of "colon cancer" or "colostomy," for example, does not describe a functional impairment, since most patients with either or both conditions could ingest and digest food normally. Generalized debility and weight loss, as in cachexia, would similarly not meet the coverage guidelines, since no functional impairment is identified. Thus, for example, a patient terminally ill with cancer of the throat would be eligible for treatment with enteral therapy, most likely through a tube into the stomach or intestines; while another very ill cancer patient, with severe weight loss but no functional impairment, would not qualify at all; and yet another patient, whose treatment included radiation treatment which scarred the intestines so that they no longer function, would be eligible for parenteral therapy.

While such coverage guidelines may appear to restrict access for patients who would benefit from nutritional therapy, such restriction can be justified by the invasive nature of the treatment, the risk of complications, and the lack of proven benefit. A review of the limited medical literature discussing parenteral therapy (in The New England Journal of Medicine, Vol. 325, No. 8, August 22, 1991, pp 573-5) refers to the few, largely inadequate clinical trials, mixed results of therapy, and the need to balance the theoretical benefit with the risk of serious complications.

Both the Coverage Issues Manual and the Carriers Manual specifically exclude coverage of nutritional supplements. While the manual pages do not address the question of oral food intake (except in excluding nutritional supplements), the certification form does ask if TPN is the patient's only form of intake.

Beginning in 1985, the Health Care Financing Administration (HCFA) established two carriers for all hyperalimentation claims. Transamerica Occidental Life Insurance Company, Los Angeles, handles claims west of the Mississippi, and Blue Cross/Blue Shield of South Carolina processes those in the East, with the geographic determinant the location of the supplier's head office. The Eastern carrier, South Carolina Blue Shield, processes the majority of all parenteral claims. The carriers have established special units to certify and process claims for enteral and parenteral patients. (Claims for Railroad Retirement beneficiaries are processed by the Travelers Insurance Company.) A Final Rule with comment period published in June 1992 outlined a change in the way durable medical equipment claims, including those for prosthetic devices and thus TPN, will be processed. Four specialty carriers with responsibility for segments of the nation will process these claims based on the beneficiary's residence.

METHODS

We relied on three data sources developed for this inspection. The first involved a 1-percent, random sample of all patients who had claims paid on their behalf by Medicare for a parenteral pump or parenteral nutrients in 1991. A total of 58 patients were identified in June 1992. We selected this sample from the common working file (CWF), and it is the source of the summary payment data presented in this report. Patients whose first claims were submitted later than May 1992, even if the services were rendered in 1991, may not be represented in this sample. These data represent patients with claims paid as of December, 1991, updated for the final report with claims paid through March 1993. We further identified the patients appearing in the sample in the enrollment data base, for information on their age, date of death (when applicable), and basis of eligibility.

We also asked the three carriers for copies of a certification of need for TPN for each sample patient. We did not examine medical records, but rather obtained diagnostic information from the Part A payment records and from the certification of the need for TPN.

The second data set was information received from a randomly-selected sample of 93 outpatient dialysis facilities. We surveyed the facilities by telephone, asking for the number of patients currently receiving intra-dialytic parenteral nutrition (IDPN) (that is, parenteral nutrition given to a patient who is being dialyzed), whether any of these patients were on TPN at home, whether they received the nutrients through a central line, and how many days a week they were given IDPN, among other questions.

We also interviewed a number of experts in the field. Among those to whom we spoke were a physician who prescribes TPN, a home health agency nurse, a hospital

pharmacist, hospital discharge planners, a hospital nurse specializing in infusion therapy, a dietician, supplier representatives, infusion therapy and nutritional therapy association staff members, dialysis facility staff, and HCFA and carrier staff.

We conducted this review in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

Medicare overpaid $69 million for TPN in 1991

- ***Of $162 million paid in claims for TPN in 1991, 43 percent or $69 million was improperly paid for patients who did not meet Medicare's coverage guidelines. Most of these were end-stage renal disease (ESRD) patients.***

Based on our sample results, we estimate that $68,862,240 (90 percent confidence interval: $53,910,825 to $83,813,654) could be saved. Appendix A provides information about the classes of patients for whom Medicare made payments. The following discussion centers around their status as ESRD enrollees or not ESRD-eligible, since the two groups are very different in their use of parenteral nutrition.

- ***The ESRD patients in the sample (53 percent) do not meet coverage guidelines. The entire $545,000 spent for parenteral nutrition on their behalf is an overpayment, projected to $54.5 million nationally in 1991.***

As discussed earlier, coverage guidelines prohibit payment for supplemental feedings, and require that patients have a functional impairment of the gastrointestinal tract. None of the 31 ESRD patients in the sample was totally dependent on parenteral feedings. Generally, documentation of functional impairments of the gastrointestinal tract was not found in our review of certificates of medical necessity (CMNs) and hospital admission data. Only one patient in the sample had a diagnosis code associated with a hospital admission that indicated any failure of the gastrointestinal tract.

The CMNs for these patients were incomplete, non-specific, and misleading. Ten of the 31 certificates did not indicate how many days a week the patient received nutrients. This was not merely a failure to document the number of times the patients were fed, since payment amounts and the survey of dialysis facilities discussed in appendix C indicate that these patients are given nutrients three times a week, as are the ESRD patients whose CMNs were completed. The average number of grams of protein ordered per day was 42, which is suboptimal for most patients. The average daily equivalent (i.e., the grams given per day times the three days given, divided by the 7 days a week most TPN patients are fed) is less than 17 grams of protein a day, which is clearly supplemental, since it is not enough protein to sustain life in infants, much less in adults. Non-ESRD patients were given an average daily equivalent of 74 grams of protein per day, every day in most cases.

The diagnoses entered on the CMNs were non-specific, referring to, for example, "malnutrition syndrome with weight loss and visceral protein depletion." "Malabsorption" is mentioned for many patients. However, the medical literature uses the term malabsorption to describe the impaired absorption of nutrients due to specific disorders of the digestive tract, not to episodes of nausea, vomiting and

diarrhea in the absence of digestive disease. The most specific term used in the CMNs was "diabetic gastroparesis," or paralysis of the stomach. This evidently refers to delayed gastric emptying seen in some patients with diabetes. Regardless of the presence or absence of a functional impairment of the gastrointestinal tract, these patients used parenteral nutrition to supplement their oral intake. Thus it is not a covered service.

We also saw misrepresentations in the CMNs. For example, 6 CMNs indicated incorrectly that parenteral nutrition was the patient's only form of intake; and all indicated the reason pre-mixed formula was required was "sterility" or "patient unable to learn," when in fact the patient need not touch the nutrients or equipment, since nurses in the dialysis facility administer the nutrients. The "Beneficiary is in . . . " field was shown as "home" or "SNF" in all instances in which it was filled in, although in fact the nutrients were administered in a dialysis facility. Additional information concerning carriers and the number of ESRD beneficiaries they cover is in appendix B.

- ***Non-ESRD patients who are not dependent upon TPN had $144,000 overpaid, which projects to $14.4 million nationally in 1991.***

Of the 27 non-ESRD patients in the sample, 11 received too few grams of protein to sustain life; or received TPN for only a short while (less than 3 months) and did not die; or both. This indicates that the therapy was not necessary to sustain life and/or not required as a result of a functional impairment, in violation of coverage guidelines.

We calculated the overpayment for non-ESRD patients as follows:

One patient who received too little protein to survive, on TPN for a year	$41,407.20
Eight patients who were on TPN for less than 3 months, averaging 37 days	$91,644.43
Two patients who received too little protein to survive, for an average of 42 days	$10,584.61
Total overpayment	$143,636.24

The benefits of parenteral nutrition for ESRD patients are unproven, its use is associated with a high rate of complication, and the cost of care is disproportionate to the resources expended.

The basis for giving dialysis patients nutrients appears to rest on the perceived connection between raising serum albumin levels and reducing mortality in ESRD patients, rather than on gastrointestinal impairments. This connection does not appear to have been rigorously tested, with few clinical trials and mixed results. The

current strict requirements for Medicare payment make it unlikely that such trials would be conducted within dialysis facilities largely supported by Medicare (since trials would include patients who do not meet the coverage guidelines), unless a separate grant were to support such research.

The high rate of complications may be related to using dialysis patients' access ports for both IDPN and the returning flow of dialyzed blood. (In contrast, indwelling central catheters used by TPN patients are not to be used for any other purpose.) The 31 ESRD patients had 30 readmissions with mechanical complications of their shunts, and 12 readmissions with other complications of treatment (many related to fluid overload). Eleven of these 42 readmissions were also for septicemia. These admissions may have been for complications of their dialysis treatments, their IDPN treatments, or both. Only six patients had no readmissions. We do not know how this compares to the rate of readmission for dialysis patients not receiving IDPN.

The Medicare Carriers Manual, Part 3, Chapter III, section 3329, refers to 1 to 1.5 grams of protein per day per kilogram of body weight as a guideline for adult TPN patients. Using a rough measure of ideal body weight (100 pounds plus or minus 5 pounds for each inch over or under five feet in height), we calculated the range of grams of protein required and received by those patients whose CMNs contained adequate information to perform the analysis. We considered patients over- or under-weight if they deviated from their ideal weight by 10 percent or more. Note that for ESRD patients, the prescribed grams "per day" were actually administered only three days a week. We found that only six of 29 patients were underweight and two overweight. Taking the CMNs at face value, only 5 were fed within the range of 1 to 1.5 grams of protein per day per kilogram of body weight, and none were overfed.

ESRD patients	fed too little	fed within correct range	fed too much
Underweight	6	0	0
Within 10 % of ideal weight	16	5	0
Overweight	2	0	0
Totals	24	5	0

The costs associated with delivering nutrients to ESRD patients should be less per infusion than for non-ESRD patients for the following reasons: The nutrients can be stored in bulk in the facility, with less wastage than at home (particularly when patients are hospitalized); the facility's nurses should be expert at handling the equipment, resulting in less contamination and thus waste; no catheter is involved, as the solution goes into the patient's blood stream with the cleansed blood; pumps and IV poles could be shared between patients infused on different schedules. The daily cost per gram of protein delivered, however, for the 25 non-disabled ESRD patients

($5.96) does not reflect such savings, since the equivalent cost per gram per day for the 9 disabled, non-ESRD patients is $3.72. A representative of one major supplier of both dialysis and nutritional therapy indicated that savings should not be expected, because suppliers cannot become simply "shippers;" rather, according to the representative, the demands on the clinical expertise of the supplier remain the same, including training of the facility's nurses (rather than the patients and families). This does not, however, explain why the costs for ESRD patients are higher than for non-ESRD patients.

The payments for nutrients and supplies associated with the 328 days that ESRD patients spent in the hospital were $29,257. We cannot be sure of the days on which ESRD patients would have received dialysis and nutrients if they had not been hospitalized, or if they received nutrients in the hospital (in contrast to TPN patients, who are infused every day).

The use of TPN in the non-ESRD population, while adhering more closely to the coverage requirements for a demonstrable functional impairment, is not closely monitored by the carriers, resulting in inappropriate patient selection and over- and under-feeding.

We saw patterns of stopping TPN - a life-saving therapy - which raise questions. Seven of the 27 patients stopped using TPN following an admission due to complications of the therapy (although one of those patients spent 212 days in the hospital, and may have been on TPN then). Only five patients who used TPN intensively did not cease its use even when serious complications ensued.

Some of the high-intensity, longer-term patients who stopped therapy (and who are not included in the overpayment calculation) may have gone into remission, although this cannot be determined from the available data. We believe that the pattern of stopping what is supposed to be a life-saving therapy on which the patient is dependent may indicate poor patient selection by prescribing physicians, or exaggerated claims on CMNs, or both. In only two cases of the six who were on TPN for very short periods of time were the CMNs completed in such a way that the carrier reviewer could reasonably have thought the patient qualified for TPN. In one of the cases, the patient appeared to qualify for enteral rather than parenteral therapy, based on the diagnosis and functional impairment.

Again using the Medicare Carriers Manual guidelines and a rough measure of ideal body weight, we calculated the grams of protein required and received by those patients whose CMNs contained adequate information to perform the analysis. We considered patients over- or under-weight if they deviated from their ideal weight by 10 percent or more. The results are displayed on the next page.

Non-ESRD patients	fed too little	fed within correct range	fed too much
Underweight	3	4	2
Within 10 % of ideal weight	1	4	0
Overweight	0	0	4
Totals	4	8	6

Patients who are on TPN for only short periods (less than a month) have higher-than-average monthly bills (in one instance $17,470 for a 30-day period). This is probably due to (1) high contamination rates when patients are not familiar with the therapy, (2) intense efforts to overcome nutritional deficits, and (3) the delivery of a month's supply when the patient only uses the therapy for a short time. Conversely, some long-term, stable patients can (and should, according to a physician who sees many "overfed" TPN patients) reduce their intake, and thus achieve economies that short-term patients do not. This is not true of all long-term patients, some of whom excrete large quantities of fluid through fistulae, for example. One such patient had payments for 12 months in 1991 of $122,130, for 145 grams of protein a day. The other long-term, relatively-stable patients in whom economies might be achieved do not appear to bear out this possibility. One who received 85 grams of protein a day for $73,781 (for 12 months) was hospitalized 7 times for a total of 70 days, so the low total payment could reflect failure to bill while the patient was hospitalized (i.e., the $73,781 actually covered services for fewer than 10 months.) Another long-term patient had payments of $105,098 for 11 months, for 85 grams of protein a day, but was able to maintain a weight of only 100 pounds.

Non-ESRD patients in the sample spent a total of 252 days in the hospital while TPN was being billed. Using average daily costs, we estimate Medicare paid $58,195 for TPN that was not used because the patient was hospitalized, although, as mentioned above, some suppliers may reduce charges when patients are hospitalized. Because suppliers ship a month's supply at a time (unless the patient or a care giver asks for a smaller shipment because of a planned admission or likely prescription change), and because nutrients have a limited shelf life, this wastage is largely unavoidable as cases are currently managed. Patients cannot take their prescription nutrients into the hospital when they are admitted, because the hospital will not accept the liability for infusing solutions their pharmacy did not prepare and store. Neither nutrients nor sterile supplies can be returned to stock, because of the chance that they may have been stored at an improper temperature or have been contaminated. Close communication between the supplier and patient (directly or through an agent) can help to reduce the provision of unnecessary supplies, as can proper training and supervision of patients, particularly in the early stages of therapy.

RECOMMENDATIONS

- **The HCFA should instruct carriers to adhere to the coverage guidelines.** Failure to do so puts patients at risk of developing severe complications, and wastes resources. We estimate that a strict application of coverage guidelines would result in $69 million in savings yearly.

- **Carriers should intensify their review of CMNs, discuss therapeutic options with physicians, and monitor the use of nutrients over time.** One approach to carrying out these responsibilities would be the use of case managers to interact with physicians and suppliers, and to monitor patients on TPN. Case managers should have clinical backgrounds and extensive training in the use of TPN and Medicare's requirements. They should have the authority to approve hydration therapy, brief home health agency coverage, and other benefits for TPN patients. They should give prior approval to TPN, and monitor "weaning" of patients with some functioning intestinal tract. They should monitor as well those patients who use excessive TPN (more than 100 grams of protein per day, for example) or who are not given enough protein to sustain life. Case managers should pay particular attention to ESRD patients for whom IDPN is proposed.

- **The HCFA, as the major payer, should review research concerning the use of IDPN.** Among the questions to be answered are the relationship of low serum albumin levels to mortality, whether blood samples drawn within days of infusing amino acids can give an accurate reading of albumin levels, whether a history of complications with the venous shunt should be a contraindication to the infusing of IDPN through the shunt, whether IDPN results in better nutritional status than enteral supplements, whether the low level of treatment (an average of 42 grams of protein three times a week) can be expected to improve nutritional status, whether the fluid used in IDPN is excessive for ESRD patients, whether albumin levels (or nutritional status) can be raised in some less-invasive way, whether it is necessary to use pumps to deliver the nutrients. Until these and related questions are answered, parenteral nutrition should be used only in those ESRD patients who would qualify for it based on a documented, life-threatening, functional impairment of the gastrointestinal tract, and in whom it is not a supplement to oral intake.

- **If IDPN is considered reasonable and necessary for the treatment of a subset of ESRD patients, it should be paid for on a per-capita basis, with discounts negotiated by each facility or the networks, or by using some other method that takes into account the efficiencies associated with facility administration of the nutrients.**

AGENCY COMMENTS

We received comments on the draft report from HCFA and the Assistant Secretary of Management and Budget (ASMB), both of whom concurred with these recommendations; HCFA has taken steps to implement them. The HCFA will defer responding to the question of appropriate payment methods for intra-dialytic parenteral nutrition until a coverage decision has been made. The HCFA's comments are appended in full.

APPENDIX A

MEDICARE PAYMENTS FOR TPN

Medicare made payments of approximately $162 million in 1991 for TPN for 5,800 patients, projecting from a randomly-selected one-percent file of patients who received TPN.

These patients fell into four classes:

Class (number) from enrollment data	1991 TPN payments from one-percent sample, CWF ▲	average daily TPN payments	average age	average number of days with TPN bills
disabled, not ESRD (9)	$653,255.83	$255.28	49.9	284#
not disabled, not ESRD (18)	$420,176.11	$232.27	74.9	101
disabled, ESRD (6)	$122,910.58	$97.70*	49.8	210
not disabled, ESRD (25)	$422,075.67	$99.29*	70.9	170#
Total (58)	$1,618,418.19			

* ESRD patients do not receive nutrients daily; they are given nutrients three times a week during their outpatient dialysis treatments. These "daily" payments are calculated from the total paid for the patients and the number of days (inclusive) for which payments were made. They receive so few grams of protein, however, that their costs per gram are twice that of patients fed more and daily.

These represent the number of days billed in 1991. Including the days billed in 1990, the first class of patients had an average time of use of 397 days, and the last class, 173 days.

▲ See a discussion of the limitations of the data in the footnotes, appendix B.

PATIENT CHARACTERISTICS

These patients varied in intensity of therapy, and in the length of time they received TPN, as the table on the previous page shows. They also varied in their underlying conditions and in their outcomes:

Class (number)	Most frequent diagnoses (from hospital claims)	admitted with complication of therapy	stopped TPN, did not die	died in 1991
disabled, not ESRD (9)	Crohn's disease, short-bowel syndrome, septicemia	67 % admitted, 1 to 7 times	22 %	11 %
not disabled, not ESRD (18)	metastatic cancer, septicemia, dehydration, intestinal obstruction	42 % admitted, 1 to 3 times	56 %	44 %
disabled, ESRD (6)	chronic renal failure, diabetes	50 % admitted, 1 to 3 times	100 %	17 %
not disabled, ESRD (25)	chronic renal failure, hypertensive renal disease, diabetes, congestive heart failure, fluid overload, sepsis	40 % admitted, 1 to 4 times	44 %	52 %

APPENDIX B

CARRIER DETERMINATIONS

Carriers varied widely in their coverage determinations

Carrier	Patients in sample	Sample patients with ESRD: number (percent)	Number of CMNs missing critical data
South Carolina Blue Shield	48 (83 %)	27 (56 %)	19
Transamerica Occidental	7 (12 %)	2 (29 %)	1
Travelers for Railroad Retirement Board (RRB)	3 (5 %)	2 (66 %)	1
Totals	58 (100 %)	31 (53 %)	21

South Carolina Blue Shield pays for the majority of TPN/IDPN claims; inconsistent and incomplete reporting make it impossible to determine payment trends

	South Carolina Blue Shield	Transamerica Occidental	Travelers for RRB	
1991	$125,535,876	$32,061,953	$4,243,990	$161,841,819●
	78 %	20 %	2 %	100 %*
1990	$122,911,719	$32,285,943	$2,492,626	$156,690,280
	78 %	20 %	2 %	100 %*
1989	$69,289,206▲	$28,474,910	$2,260,578	$100,024,695▲
	69 %	28 %	2 %	100 %*

● This amount is projected from the cases in the sample discussed in this report. The 1990 and 1989 figures are from summary Part B files maintained by HCFA.

* These totals understate total TPN payments slightly, since other carriers made minimal, sporadic payments for TPN nutrients and supplies in all three years.

▲ This probably understates payments made by South Carolina Blue Shield, which has a history of inconsistent and incomplete reporting of TPN payments. Thus, these figures should not be used to attempt to determine trends in TPN use and payment.

APPENDIX C

ESRD PATIENTS RECEIVING NUTRIENTS IN DIALYSIS FACILITIES

An average of 2.4 percent of patients in dialysis facilities receive intra-dialytic parenteral nutrition (IDPN), in all cases only 3 times a week through their shunt.

Facility size*; number in sample	Facilities which have never used IDPN	Have used IDPN in the past	Currently have patients on IDPN	Number of patients on IDPN
Small; 27	12	5	10	24
Medium; 44	13	11	20	64
Large; 22	4	3	15	72
Total	29	19	45	160

* Small = 1-9 stations; medium = 10-19; large = 20 or more.

Status; number	Do not use IDPN	Past use	Now use IDPN	Patients on IDPN
For-profit; 53	12	9	32	109
Not for-profit; 40	17	10	13	51
Total	29	19	45	160

All patients in the 45 sample facilities currently using IDPN are fed 3 times a week, in all cases through their access ports or venous shunts (rather than a central line). None of them are on TPN at home.

We asked respondents (usually the nursing supervisor, but in some cases a staff nurse or staff dietician) to discuss their facility's use of IDPN. We did not speak to patients. These responses are all anecdotal, since few facilities had any historic information about patients' use of IDPN and their outcomes.

The changes in patients' health and quality of life most often cited by the respondents (in descending order) were improved laboratory values (particularly serum albumin); weight gain; the patients' feeling better, more energetic, or stronger; or the patients' having a better outlook. The responses ranged from saying that IDPN "maintains life" and "decreases mortality," to saying that improvements are "not dramatic" or patients had negative reactions. Two patients were cited who improved enough to qualify for

transplants, and indeed were transplanted. Another respondent noted that in her experience, only 10 percent of patients improve, 50-60 percent maintain their status, and the rest are too late in the course of their disease to be helped.

Fifty-one of the facilities outlined their criteria for putting patients on IDPN. The criteria mentioned most frequently were low serum albumin levels and weight loss. Five mentioned Medicare's requirements, one cited guidance from their network, and 18 mentioned gastrointestinal disorders. Among the reasons for using IDPN were that "enteral fills them up and they don't want to eat" and that "enteral products don't work because of fluid retention and no reimbursement for them." Other respondents noted, however, that "oral supplements work if patients will take them" and that IDPN is used infrequently in children, because "children can't refuse NG (naso-gastric) tubes."

Among the reasons given for stopping IDPN were "dramatic improvements," reaching a "target goal," elevated blood glucose levels, chest pain (from fluid retention), diarrhea, the treatment's not helping, and the patient's death. When IDPN is stopped because of improvements, respondents noted that some patients maintain their improved status, but many do not. Those patients who use IDPN to recover from the demands of surgery reportedly tend to maintain their status. Most respondents noted that patients are reevaluated, usually every three months, with one respondent noting "no patient has ever needed to go off treatment."

APPENDIX D

COMMENTS OF THE HEALTH CARE FINANCING ADMINISTRATION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

Memorandum

Date APR 22 1993

From William Toby, Jr.
Acting Administrator

Subject Office of Inspector General (OIG) Draft Report: Inappropriate Payments for Total Parenteral Nutrition (TPN) (OEI-12-92-00460)

To Bryan B. Mitchell
Principal Deputy Inspector General

We reviewed the above-referenced draft report which examined Medicare coverage of total parenteral nutrition (TPN), a "high tech" means of feeding patients who do not have a functioning intestinal tract.

Our detailed comments on the report findings and recommendations are attached for your consideration. Thank you for the opportunity to review and comment on this draft report. Please advise us if you agree with our position at your earliest convenience.

Attachment