POSITION STATEMENT

Inadequacy of Medicare Part B and Medicare Part D (Prescription Drug Coverage) To Meet the Needs of Patients Requiring Parenteral Nutrition

The American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) is a professional society of physicians, nurses, dietitians, pharmacists, allied health professionals, and researchers dedicated to assuring that every patient receives optimal nutrition care. A.S.P.E.N.‘s mission is to serve as the preeminent, interdisciplinary nutrition society dedicated to patient-centered, clinical practice worldwide through advocacy, education, and research in the field of specialized nutrition support.

Before addressing the specific issues and citing case studies and clinical examples, the following points are of utmost importance:

- In January 2000, the Institute of Medicine issued the report *The Role of Nutrition in Maintaining Health in the Nation’s Elderly: Evaluating Coverage of Nutrition Services for the Medicare Population*. The report addresses the issue of parenteral nutrition in the ambulatory care and home health care settings:
  
  “Recommendation 4.3. In ambulatory and home care settings, the regulation that excludes coverage for enteral and parenteral nutrition if the gut functions within the next 90 days needs to be reevaluated.”

The report continues:

“The committee identified a major gap in the coverage of enteral and parenteral nutrition for undernourished ambulatory and home care patients. The current regulation, which excludes coverage for enteral and parenteral nutrition unless the gut is expected to be dysfunctional for at least 90 days, needs to be reevaluated. To avoid the complications of extended semi-starvation and possible re-hospitalization, reimbursement for enteral or parenteral nutrition in selected Medicare beneficiaries who would otherwise be unable to eat or to assimilate adequate nutrition due to gastrointestinal dysfunction or neurological impairment for longer than 7 days, must be evaluated as a prudent, potentially cost-saving, alternative. Patients who are already malnourished or highly stressed due to infection or response to trauma may not even tolerate this duration of starvation or semi-starvation.

“In addition, monitoring of patients while on enteral and parenteral nutrition regimes is crucial to avoid both the under- and the overuse of this type of expensive therapy. The registered dietitian is an integral member of the multidisciplinary team and should be involved in the transition of feeding from enteral and parenteral therapies to oral or other modalities, when appropriate or indicated by the referring physician.”

- One of the IOM’s recommendations relating to provision of nutrition services in the home care setting is as follows:
“Recommendation 4.2. The availability of nutrition services should be improved in the home health care setting. Both types of nutrition services are needed in this setting: nutrition education and nutrition therapy. A registered dietitian should be available to serve as a consultant to health professionals providing basic nutrition education and follow-up, as well as to provide nutrition therapy, when indicated, directly to Medicare beneficiaries being cared for in a home setting.”

If parenteral nutrition is to be a benefit to Medicare beneficiaries who do not meet Medicare Part B criteria, regardless of how the benefit is administered, it must be offered as a comprehensive healthcare service, not as a “drug only” benefit. The ability to provide the appropriate level of professional services along with the drug component of the therapy is essential to providing a safe and effective home care therapy.

The IOM report continues:
“Medicare beneficiaries are often discharged from hospitals to home care settings with, or at high risk for, overt malnutrition. Yet there is currently no HCFA regulation that requires a nutrition professional to participate in the nutritional management of homebound patients. The adequate provision of services and the staffing of appropriately credentialed nutrition professionals in home care are essential for the training and education of home health nurses and nurses aides so that they may adequately provide appropriate basic nutrition screening and other services. In addition, nutrition professionals should provide nutrition therapy directly to homebound patients when indicated.”

Without coverage of the necessary professional services under Medicare Part D, supervision of home parenteral nutrition by competent credentialed nutrition professionals will be impossible. Reimbursement for drugs alone cannot adequately solve this dilemma.

- Clinical Monitoring for complex patients requiring artificial nutritional support (i.e., parenteral and enteral nutrition at home) is not covered in either of the Medicare criteria. A.S.P.E.N. believes that monitoring these complex therapies is essential for good patient care. The A.S.P.E.N. home care standards state:
  “Patient monitoring shall be designed to determine the effectiveness and appropriateness of nutrition support. The process of patient monitoring must insure that the nutritional goals are achieved. The monitoring process is also intended to reduce the risk of complications due to nutrition support. Each patient’s nutrition status is monitored on a regular basis.
  - “The referring physician, home care organization, and nutrition support practitioner(s) should monitor the clinical status and response to nutrition therapy.
  - “Monitor the clinical status and compliance of the patient. This shall include but not be limited to: review of systems and physical examination; assessment of laboratory data; compliance with procedures to administer therapy.”

- When patients transition from private insurance to the point at which Medicare becomes effective, they have to undergo a complete re-evaluation and apply for Medicare Part B coverage. If the patient is already receiving home parenteral nutrition, there are usually
difficulties in this transition resulting in patients not receiving coverage on time, or not getting coverage at all, as the patient must qualify based on the malady they already have that is being treated successfully. If the patient does not meet Medicare Part B criteria, at the present time the patient does not have a covered benefit for home parenteral nutrition even though they are already receiving this therapy. It is assumed, that such a patient would be entitled to parenteral nutrition under Medicare Part D under these circumstances.

- While the guidelines as published appear straightforward, the interpretation of the guidelines is inconsistent from one regional provider of Medicare benefits to the next. This leads to delays in obtaining coverage after meeting the stringent criteria.

In Appendix I, A.S.P.E.N. will provide, through case study and documentation the justification for an expanded medical necessity beyond the present Medicare Part B coverage; and the justification that Medicare Part D will also not meet the needs of patients requiring Parenteral Nutrition who must rely solely on the drug coverage provided under Medicare Part D.

**SUMMARY**

A.S.P.E.N. has reviewed coverage for patients requiring parenteral nutrition under Medicare Parts B and D. A.S.P.E.N. believes that without expanding Medicare Part D coverage so that it encompasses all of the needs of the Parenteral Nutrition patient, the fragmentation in this benefit will create a population of needy Medicare beneficiaries that are under-served, or not able to be served at all. And, without revisions to the Medicare Part B benefit, those patients who do not meet the current medical necessity criteria under Part B, but who still have medically justifiable needs for parenteral nutrition will be under-served.

On December 8, 2003, President George W. Bush signed into law the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108-173), frequently referred to as MMA. This landmark legislation for the first time provides seniors and individuals with disabilities with a prescription drug benefit under Medicare. Currently Medicare lacks an outpatient Prescription Drug Benefit. Drug coverage for present Medicare beneficiaries is limited to drugs that are incident to a physician's services or delivered in institutional settings.

Medicare also covers certain drugs administered in the home care setting under the Medicare Part B benefit. Under Medicare Part B, if an infusion pump is required the drug administered via the required infusion pump may also be covered. The pump must be either a portable or stationary pump operated either by electrical current or battery power. However, a medical necessity determination with extremely limited qualifying criteria is also in place for most of these drug therapies. It is under Medicare Part B, within the coverage for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) that coverage is currently provided for parenteral and enteral nutrition (PEN). At present, any patient who receives parenteral or enteral nutrition under Medicare as an outpatient benefit must meet the strict Medicare criteria proscribed in Medicare Part B DMEPOS coverage.

A.S.P.E.N. supports the efforts of Congress to expand Medicare coverage to include prescription drugs. Since Medicare Part D deals entirely with prescription drugs, and since most components of parenteral nutrition are classified as prescription drugs, A.S.P.E.N. is concerned with the adequacy of Medicare Part D to cover parenteral nutrition should a Medicare beneficiary have to rely solely on Medicare Part D for their coverage. It is within
this context that A.S.P.E.N. offers these comments regarding the adequacy of Medicare Part B coverage for parenteral nutrition, and the likely inadequacy of Medicare Part D, as a prescription drug only benefit. As the pre-eminent organization for medical professionals practicing in clinical nutrition, A.S.P.E.N. supports broadening the coverage under Medicare for both parenteral and enteral nutrition.

**DEFICIENCIES IN MEDICARE PART D COVERAGE AS A HOME PARENTERAL NUTRITION BENEFIT**

In passing this legislation, it was the intent of Congress to provide a prescription drug plan that provided coverage beyond Medicare Part B, but not remove those benefits provided by Medicare Part B. However, Medicare Part D is constructed solely as a prescription drug benefit, with no provision to provide equipment, supplies or coverage for professional services. These additional requirements make Medicare Part D’s adequacy to cover Parenteral Nutrition for beneficiaries not meeting Medicare Part B criteria suspect and highly unworkable. Solely reimbursing for the drug component of Parenteral Nutrition makes this benefit unworkable as coverage for patients requiring this therapy who do not meet Medicare Part B criteria. One can easily make the case that Parenteral Nutrition is not merely a drug therapy but a treatment modality requiring drugs, supplies, equipment and professional services. The elimination of any one of these requirements renders the provision of the other requirements moot and insufficient to safely and adequately provide the needed care to these patients.

Any patient who fails to meet Medicare Part B criteria and must rely on the Medicare Part D benefit will face significant obstacles and potential financial hardship if this is their sole coverage for home parenteral nutrition. The following case study is offered to exemplify what a Medicare beneficiary may face in using the Medicare Part D “drug only” benefit through a PDP.

- A 71-year-old female with Inflammatory Bowel Disease (IBD) and resulting enterocutaneous fistula (high output intestinal leak) is admitted to a hospital for bowel rest, parenteral nutrition, and octreotide therapy. After assessment in the hospital and reduction in her fistula output, JR’s physician presents her with a plan for 4 weeks of conservative management and home parenteral nutrition to determine if fistula output can be further reduced without the need for surgery. If bowel rest is unsuccessful in reducing the fistula output, surgery is contemplated. She is informed that Medicare Part B will probably deny home parenteral nutrition under Medicare guidelines because her therapy will not require home parenteral nutrition for the minimum of 90 days and her impairment is not permanent. The patient lives on a fixed income consisting of social security and the earnings from her savings totaling $1356 per month before taxes, and she has Medicare Part D. She has limited financial resources and assets of approximately $12,000 consisting mostly of her savings, which do not entitle her to any financial assistance or low-income subsidy. The patient requests that her hospital case manager obtain an estimate from a home infusion provider of her out of pocket cost for 4 weeks of home parenteral nutrition to assist her in making this decision.

**Comments:**
The patient will find that only those components of her parenteral nutrition classified as drugs will be covered under Medicare Part D. Some actual components of her parenteral nutrition such as multivitamins will not be covered and will have to be paid for separately. Also,
supplies for care of her peripherally inserted central catheter (PICC will not be covered by Medicare Part D, nor will the heparin and saline flushes needed to keep the catheter patent, since they are considered medical devices and not prescription drugs. JR will also have to meet her $250 deductible under Medicare Part D, and also have a 25% co-pay for the prescription drug portion of parenteral nutrition components until total drug charges of $2250 under Medicare Part D are met. This means she will pay an additional $500. Also, under Medicare Part D for all drug costs between $2,250 and $5,100 she will be 100% financially responsible, and she will have an additional out of pocket expense of $2,850. The home infusion pharmacy indicates that based on her prescription for parenteral nutrition the Medicare Part D total drug charges for 4 weeks of home parenteral nutrition will likely exceed $5,100.

The home infusion company quotes $40 per day for the supplies she will need for her catheter care, and indicates that this will also cover the cost of rental on the infusion pump she will need to infuse her parenteral nutrition, the disposable pump sets and tubing needed daily for her infusions, the professional fees for compounding her parenteral nutrition, the cost of home deliveries, and the monitoring of her therapy. The home infusion provider communicates that none of this per diem is covered under Medicare Part D.

The home infusion provider also indicates that it is willing to dispense her prescriptions for heparin flush, saline flush, and multivitamin injection additives for her parenteral nutrition at a charge of AWP – 15% plus a $2.00 dispensing fee for each since this is the rate they would be reimbursed by a PDP if these were covered under Medicare Part D. The home infusion provider estimates that the total out of pocket cost to JR for her 4 weeks of home parenteral nutrition will be $4953. They also indicate that this will be payable upon delivery.

Faced with an expense for the 4 weeks of home parenteral nutrition that equals nearly 5 months of her disposable income and nearly 50% of her total assets, JR options to remain in the hospital for the next 4 weeks to determine if bowel rest will help reduce her fistula output, and to await a decision regarding the need for surgery.

The hospital at which JR is a patient states that its average cost per day for a Medicare patient is $1400, estimating the cost for her additional 28-day stay at approximately $39,200.

**MEDICARE PART B COVERAGE FOR PARENTERAL NUTRITION**

If it is the intent of Congress to fill the gap created by Medicare Part B’s limitations to coverage for parenteral nutrition, then Part D must address more than the prescription drug needs of the patient. Medicare Part B covers parenteral nutrition under what is known as the “prosthetic device benefit” under Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). In an attempt to shoehorn parenteral nutrition into the existing Medicare Part B Benefit for prosthetic devices, Medicare devised a cumbersome set of criteria that must be met. The Region C DMEPOS Supplier Manual (Summer 2005) states,

“For any item to be covered by Medicare, it must (1) be eligible for a defined Medicare benefit category, (2) be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member, and (3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, the
criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity."

Parenteral nutrition, under Medicare Part B, is covered for a patient with permanent, severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition. The Region C DMEPOS Supplier Manual offers this description a permanent impairment:

“The patient must have a permanent impairment. Permanence does not require a determination that there is no possibility that the patient's condition may improve sometime in the future. If the judgment of the attending physician, substantiated in the medical record, is that the condition is of long and indefinite duration (ordinarily at least 3 months), the test of permanence is considered met. Parenteral nutrition will be denied as non-covered in situations involving temporary impairments. The patient must have (a) a condition involving the small intestine and/or its exocrine glands which significantly impairs the absorption of nutrients or (b) disease of the stomach and/or intestine which is a motility disorder and impairs the ability of nutrients to be transported through the GI system. There must be objective evidence supporting the clinical diagnosis.

Parenteral nutrition is non-covered for the patient with a functioning gastrointestinal tract whose need for parenteral nutrition is only due to:

a) a swallowing disorder,
b) a temporary defect in gastric emptying such as a metabolic or electrolyte disorder,
c) a psychological disorder impairing food intake such as depression,
d) a metabolic disorder inducing anorexia such as cancer,
e) a physical disorder impairing food intake such as the dyspnea of severe pulmonary or cardiac disease,
f) a side effect of a medication,
g) renal failure and/or dialysis”

The Region C DMEPOS Supplier Manual (Summer 2005) offers the following guidance regarding patients who may meet the criteria for home parenteral nutrition:

“Parenteral Nutrition is covered in any of the following situations:

A) The patient has undergone recent (within the past 3 months) massive small bowel resection leaving less than or equal to 5 feet of small bowel beyond the ligament of Treitz, or
B) The patient has a short bowel syndrome that is severe enough that the patient has net gastrointestinal fluid and electrolyte malabsorption such that on an oral intake of 2.5-3 liters/day the enteral losses exceed 50% of the oral/enteral intake and the urine output is less than 1 liter/day, or
C) The patient requires bowel rest for at least 3 months and is receiving intravenously 20-35 cal/kg/day for treatment of symptomatic pancreatitis with/without pancreatic pseudocyst, severe exacerbation of regional enteritis, or
A proximal enterocutaneous fistula where tube feeding distal to the fistula isn’t possible, or

D) The patient has complete mechanical small bowel obstruction where surgery is not an option, or

E) The patient is significantly malnourished (10% weight loss over 3 months or less and serum albumin less than or equal to 3.4 gm/dl) and has very severe fat malabsorption (fecal fat exceeds 50% of oral/enteral intake on a diet of at least 50 gm of fat/day as measured by a standard 72 hour fecal fat test), or

F) The patient is significantly malnourished (10% weight loss over 3 months or less and serum albumin less than or equal to 3.4 gm/dl) and has a severe motility disturbance of the small intestine and/or stomach which is unresponsive to prokinetic medication and is demonstrated either (1) scintigraphically (solid meal gastric emptying study demonstrates that the isotope fails to reach the right colon by 6 hours following ingestion), or (2) radiographically (barium or radiopaque pellets fail to reach the right colon by 6 hours following administration). These studies must be performed when the patient is not acutely ill and is not on any medication which would decrease bowel motility.”

For criteria A-F above, the conditions are deemed to be severe enough that the patient would not be able to maintain weight and strength on only oral intake or tube enteral nutrition.

Patients who do not meet criteria A-F above must, meet criteria 1-2 below (modification of diet and pharmacologic intervention) plus also meet additional criteria G and H below. According to the Region C Supplier Manual,

“Maintenance of weight and strength commensurate with the patient’s overall health status must require intravenous nutrition and must not be possible utilizing all of the following approaches:

1) modifying the nutrient composition of the enteral diet (e.g., lactose free, gluten free, low in long chain triglycerides, substitution with medium chain triglycerides, provision of protein as peptides or amino acids, etc.), and
2) utilizing pharmacologic means to treat the etiology of the malabsorption (e.g., pancreatic enzymes or bile salts, broad spectrum antibiotics for bacterial overgrowth, prokinetic medication for reduced motility, etc.)

G) The patient is malnourished (10% weight loss over 3 months or less and serum albumin less than or equal to 3.4 gm/dl), and

H) A disease and clinical condition has been documented as being present and it has not responded to altering the manner of delivery of appropriate nutrients (e.g., slow infusion of nutrients through a tube with the tip located in the stomach or jejunum).”

It is A.S.P.E.N.’s studied opinion that a more judicious approach would be to lift the test of permanence from Medicare Part B, and broaden Part B’s coverage to include those situations where medical judgment dictates that it is in the patient’s best interest to administer home parenteral nutrition in lieu of therapeutic trials of drugs or enteral formula manipulation, unreasonable clinical tests, or the requirement for anatomical documentations that may not exist or be pertinent to the patient’s course of therapy. A.S.P.E.N. further believes that
coverage under Part B is preferred to attempting to retool Medicare Part D to include coverage for professional services, supplies and equipment solely to accommodate the need to cover parenteral nutrition under this benefit. Medicare Part B already possesses the mechanisms and structure for the administration of a broader parenteral nutrition program. Inventing an additional program to accommodate those patients who will be covered under Part D but do not meet Part B criteria is not in the interest of any Medicare beneficiary and may severely limit access to care.

MEDICARE PART D AS A PARENTERAL NUTRITION BENEFIT

The Intent of Congress, by passing the MMA enacting Medicare Part D, was to provide a prescription drug plan with coverage beyond Medicare Part B, without removing benefits provided by Medicare Part B. However, Medicare Part D is constructed solely as a prescription drug benefit, with no provision to provide equipment, supplies or coverage for professional services. These additional requirements beyond the coverage of the drug make Medicare Part D’s adequacy to cover Parenteral Nutrition for beneficiaries not meeting Medicare Part B criteria suspect and highly unworkable. Drugs such as those requiring administration by intravenous infusion can be safely administered in the home if the proper equipment and supplies are provided, and appropriate professional supervision and assistance is available to the patient.

There are also numerous gaps in Medicare Part B coverage for Parenteral Nutrition that necessitate a close scrutiny. The most onerous requirement under Medicare Part B is the test of permanence requiring that a patient have a permanent impairment of the GI tract that will necessitate nutrition support for 90 days or longer. Additionally, for patients whose medical condition precludes being able to meet the rigors of testing for qualification under one or more of the criteria outlined under Medicare Part B further reduces access to care for this population. Medical literature supports the need and virtual medical necessity for Parenteral Nutrition for patients who do not meet and cannot meet the strict guidelines of Medicare Part B.

If it is the intent of Congress to fill the gap created by Medicare Part B’s limitations to coverage for parenteral nutrition, then Part D must address more than the prescription drug needs of the patient. It is A.S.P.E.N.’s studied opinion that a more sensible approach would be to lift the test of permanence from Medicare Part B, and broaden Part B’s coverage to include those situations where medical judgment dictates that it is in the patient’s best interest to administer home parenteral nutrition in lieu of therapeutic trials of drugs or enteral formula manipulation, unreasonable clinical tests, or the requirement for anatomical documentations that may not exist or be pertinent to the patient’s course of therapy. A.S.P.E.N. further believes that coverage under Part B is preferred to attempting to retool Medicare Part D to include coverage for professional services, supplies and equipment solely to accommodate the need to cover parenteral nutrition under this benefit. Medicare Part B already possesses the mechanisms and structure for the administration of a broader parenteral nutrition program. Inventing an additional program to accommodate those patients who will be covered under Part D but do not meet Part B criteria is not in the interest of any Medicare beneficiary and may severely limit access to care.
APPENDIX: CASE STUDIES AND CLINICAL EXAMPLES

The following case studies will be used to illustrate the inadequacy of the coverage criteria to cover all the clinically appropriate situations in which parenteral nutrition is prescribed. If Medicare beneficiaries who do not meet Medicare Part B criteria but for whom sound medical evidence and reasoning indicates that parenteral nutrition at home is needed are to still have parenteral nutrition therapy available under a Medicare benefit, then Medicare Part B criteria must be expanded to encompass these the needs for these patients, or Medicare Part D will require a completely new set of criteria.

A sizable number of the Medicare beneficiaries who do not meet Medicare Part B criteria but still need parenteral nutrition in the home care setting are dual eligibles. When not covered by Medicare Part B, these patients are receiving parenteral nutrition through coverage from their state Medicaid program or through secondary insurance coverage. Those dual eligibles who lose Medicaid prescription drug coverage and will be covered by Medicare Part D as of January 1, 2006 present a real dilemma for the system, and may not have access to continuation of care that they are currently receiving through their Medicaid eligibility without a modification to Medicare Part D to include coverage of services, supplies and equipment necessary to continue delivery of their therapy. Movement of this benefit under Medicare Part B with an expansion of coverage criteria to encompass these patients offers the best opportunity to equitably administer this benefit to the beneficiary.

The bolded statements below are the actual descriptive language from the Region C DMEPOS Supplier Manual (Summer 2005), with clinical case studies, examples and comments added by A.S.P.E.N. to describe the limitations of each section of the Medicare Part B benefit.

General Test of Permanence

Parenteral nutrition, under Medicare Part B, is covered for a patient with permanent, severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition. The patient must have a permanent impairment. Permanence does not require a determination that there is no possibility that the patient's condition may improve sometime in the future. If the judgment of the attending physician, substantiated in the medical record, is that the condition is of long and indefinite duration (ordinarily at least 3 months), the test of permanence is considered met. Parenteral nutrition will be denied as non-covered in situations involving temporary impairments.

Clinical Examples:
- An 80-year-old-male with Inflammatory Bowel Disease (IBD) and resulting enterocutaneous fistula (high output) admitted to hospital for bowel rest, parenteral nutrition, octreotide. Plan for 4-6 weeks of conservative management and home parenteral nutrition. Denied for home parenteral nutrition under Medicare guidelines because will not require parenteral nutrition for minimum of 90 days. Patient will stay in the hospital for 4-6 weeks to receive parenteral nutrition. Not able to obtain nursing home placement with wound care and parenteral nutrition.
An 81-year-old man discharged on home parenteral nutrition because of a colo-vesicular fistula (colon to bladder leak), confirmed by an abdominal CT scan that occurred after his bowel resection for colon cancer. Because of the fistula, he was required to take no food or fluid intake by mouth. At hospital discharge his weight was 50 kg, 71% ideal, and his body mass index was 18 kg/m² reflecting protein-energy malnutrition. His albumin concentration was 2.4 g/dL (normal 3.5-5 g/dL), reflecting protein malnutrition. After 18 days at home with parenteral nutrition, his fistula closed. The surgeon gradually advanced his diet with no further fistula formation. Parenteral nutrition was stopped after day 20. Insurance coverage was by Medicare Part B, and the claim for 20 days home parenteral nutrition supplies and infusions was denied because he did not meet the “permanence” rule. The cost to Medicare of a surgical procedure to close the fistula, however, would have been considerably more expensive than the cost of 20 days of home parenteral nutrition. In addition, the patient may not have survived further surgical intervention.

An 80-year-old woman with extensive medical problems including colon cancer treated by colectomy (surgical removal of the entire colon) in 1986. She had a history of gallstones, a stroke, diabetes mellitus, gastroparesis (slow emptying of her stomach), high blood pressure and high cholesterol. She recently experienced a 20-pound weight loss due to intermittent nausea, reflux, and inability to eat. GI workup was negative except for gastroparesis (impaired stomach emptying). A feeding tube was not placed in her stomach because of the gastroparesis and in her small intestine because a report showed the dysmotility extended to her upper small intestine as well. Her physician documented that a trial of tube feedings would cause more harm than benefit. Based on the clinical assessment of the patient, she was started on parenteral nutrition. She was so weak that she could not administer parenteral nutrition herself. Her husband had severe limitations to his vision and could not administer the parenteral nutrition. The patient was discharged to a skilled nursing facility, in order to receive parenteral nutrition, convalesce, gain strength and be trained to administer her own parenteral nutrition. After 30 days in the facility, she was discharged to her home where she successfully administered her parenteral nutrition. Within six weeks, the patient was weaned off parenteral nutrition because she was able to eat adequately and maintain her weight. Medicare denied the claim for home parenteral nutrition because she did not meet the 90-day requirement for permanent GI dysfunction.

Comments:
1. In all three examples above, each patient has a documented clinical indication for parenteral nutrition. Enterocutaneous fistulae may heal with bowel rest, parenteral nutrition and octreotide. The decrease in fistula output due to this conservative therapy will usually be evident in a few weeks. If conservative treatment fails, the patient would likely require surgery. There is no good clinical reason to “wait” 3 months (90 days) or to keep this patient hospitalized solely to receive parenteral nutrition. Costs would be less expensive for such patient to receive short courses of parenteral nutrition at home than in the hospital. Similarly the patient with gastroparesis clearly benefited from a course of parenteral nutrition less than 90 days as demonstrated by weight gain and improvement in strength.

Parenteral nutrition is covered in any of the following situations:

A. The patient has undergone recent (within the past 3 months) massive small bowel resection leaving less than or equal to 5 feet of small bowel beyond the ligament of Treitz
Clinical Example:
- The operative note for a 67 year old woman indicated she had undergone “massive” small bowel resection resulting in short bowel syndrome. The surgeon provided documentation of medical necessity based on the extent of surgery, severe weight loss, and the inability for this patient to maintain weight, strength, nutrition and hydration status without parenteral nutrition. Initial Medical claims were denied because the term “massive” could not be quantified to meet the stated “less than or equal to 5 feet of small bowel beyond the ligament of Treitz”.

Comments:
- Obtaining the proper documentation to qualify someone for home parenteral nutrition can be a problem. For example, a patient may have short gut syndrome, however, there are no operative reports showing how much bowel was resected and even less frequently no notes stating how much intestine is remaining. Measurements, even if made at surgery, are often inadequate.
- It is not only intestinal length that is important, but also the anatomy and function of the remaining bowel that are critical. The patient may have greater than 5 feet of intestine, but part of that remaining intestine is dysfunctional and not properly assimilating nutrients. For example, functional short bowel syndrome is common with high output ileostomies in patients with inflammatory bowel disease. If a patient has significant surgical resections of ileum and large bowel, they may well require parenteral nutrition despite having more than 5 feet of intestine. There is nothing magic about 5 feet, as there are many other considerations that have been documented in the literature since the Medicare Guidelines were initially developed.

B. The patient has a short bowel syndrome that is severe enough that the patient has net gastrointestinal fluid and electrolyte malabsorption such that on an oral intake of 2.5-3 liters/day the enteral losses exceed 50% of the oral/enteral intake and the urine output is less than 1 liter/day

Comments:
- It is very difficult to operationalize this recommendation. We cannot accurately measure intake and output suggested by this statement. Patients with massive diarrhea have great difficulty measuring urine output because every time they go to the bathroom they pass urine with diarrhea and this cannot be separated for the purpose of measuring output. A patient sent a diary of his urine and stool output to the nutrition support team but every recording stated “urine mixed with diarrhea”. It would be better to define severe short bowel syndrome by a definition such as “patient unable to maintain weight or volume status on maximized enteral therapy”.

C. The patient requires bowel rest for at least 3 months and is receiving intravenously 20-35 cal/kg/day for treatment of symptomatic pancreatitis with/without pancreatic pseudocyst, severe exacerbation of regional enteritis, or a proximal enterocutaneous fistula where tube feeding distal to the fistula isn't possible

Clinical examples:
- A 68 year old male with severe Crohn’s disease involving most of the ileum and parts of the jejunum, with multiple previous resections of the small bowel resulting in short bowel syndrome, and residual strictures remaining, experiences a flare of his Crohn’s s disease that
does not respond to high-dose steroid therapy and Imuran. Parenteral nutrition is needed to promote bowel rest for 6 weeks. In this situation, the patient would have to stay in the hospital to get coverage from Medicare. He was not accepted by any skilled nursing facilities, Medicare would not pay if he received this therapy in the home. Permanence here is an arbitrary designation and this rule would exclude less costly medical care that could be provided in the patient’s home through home parenteral nutrition.

- A 66 year old female with a long history of ileal and jejunal Crohn’s disease, develops an enterocutaneous fistula (intestinal leak) following her second surgery for small bowel resection. Placement on home parenteral nutrition for 4-6 weeks could succeed in closing the fistula. The patient has received Flagyl for 6 weeks, and Imuran for 3 years. Both of these drugs are indicated to heal such fistulas, but have been unsuccessful in this patient. Like the patient above, the patient would have to be hospitalized to receive 6 weeks of parenteral nutrition to get Medicare coverage. Medicare would not cover home parenteral nutrition for this time period.

Comments:
- Three months is far too long, as a criterion for permanence in the treatment of inflammatory bowel disease complications, and will often result in increased costs to Medicare.
- Many such patients do not require 3 months of parenteral nutrition but can gain significant benefits from shorter courses of therapy.

D. The patient has complete mechanical small bowel obstruction where surgery is not an option

Clinical Example:
- Patients may have symptoms of vomiting every time they try to eat solids or drink liquids, but when they undergo an upper GI series (diagnostic imaging/x-ray) a bowel obstruction is not demonstrated. This condition is referred to as idiopathic pseudo-obstruction and this would be a clinically appropriate reason for parenteral nutrition.

Comments:
- Patients may have symptoms of vomiting every time they try to eat solids or drink liquids, but when they undergo an upper GI series (diagnostic imaging/x-ray), a bowel obstruction is not demonstrated. This condition is referred to as idiopathic pseudo-obstruction and this would be a clinically appropriate reason for parenteral nutrition.
- Many inflammatory bowel disease patients have partial obstructions with vomiting (but no obstruction seen on small bowel x-ray). Criteria should be based on symptoms as well, not just on x-ray.
- It is unusual for patients to have complete mechanical obstruction and yet not go to surgery. What is much more common is incomplete or partial obstruction, or even a functional obstruction. X-rays are not reliable in this situation. Patients who are asymptomatic from Crohn’s disease may have severe strictureing throughout the small bowel. On the other hand, patients who have an area of dysmotility because of inflammation may not have a severe stricture on x-ray but may have a functional obstruction for the segment of small bowel in which there are little or no peristaltic contractions. It would be better to define “partial or incomplete obstruction preventing effective enteral therapy to maintain weight and hydration”.
E. The patient is significantly malnourished (10% weight loss over 3 months or less and serum albumin less than or equal to 3.4 gm/dl) and has very severe fat malabsorption (fecal fat exceeds 50% of oral/enteral intake on a diet of at least 50 gm of fat/day as measured by a standard 72 hour fecal fat test)

Comments:
- Patients with intestinal diseases and malabsorptive symptoms often benefit from shorter courses of therapy when they have an exacerbation of their underlying disease. If home parenteral nutrition could be covered for patients with malabsorption even if therapy was required for less than 3 months, it would result in lower hospital admissions, lower overall costs, lowered iatrogenic infections and a higher quality of life for the patient.
- It is not medically appropriate to withhold nutritional intervention until a patient has 10% weight loss or a serum albumin level that is less than 3.4. In addition, in pure starvation states (marasmus) it is quite possible to have normal albumin and yet suffer life-threatening malnutrition.
- A fecal fat test cannot be easily conducted for patients who have malabsorptive syndromes as they cannot tolerate the required 100 gm fat diet. Furthermore, patients who already have diarrhea more than 20 times per day, have great difficulty collecting their stools for 72 hours and keeping it refrigerated when they are in the home setting, for the purposes of this test. Clinical evidence of steatorrhea or other standard tests of malabsorption like a spot fecal fat should be sufficient.
- The diagnosis of malnutrition should be based on assessment of body composition, clinical exam, evidence of nutrient deficiency, and evaluation of performance status. These components of the nutritional assessment are preferable to a laboratory diagnosis. Serum albumin level < 3.5 g/dl should be omitted as criteria defining malnutrition. Albumin is an insensitive marker of nutritional status and may be elevated in dehydration, normal in patients with severe weight loss, or altered due to disease, stress, inflammation, or injury.

F. The patient is significantly malnourished (10% weight loss over 3 months or less and serum albumin less than or equal to 3.4 gm/dl) and has a severe motility disturbance of the small intestine and/or stomach which is unresponsive to prokinetic medication and is demonstrated either (1) scintigraphically (solid meal gastric emptying study demonstrates that the isotope fails to reach the right colon by 6 hours following ingestion), or (2) radiographically (barium or radiopaque pellets fail to reach the right colon by 6 hours following administration). These studies must be performed when the patient is not acutely ill and is not on any medication which would decrease bowel motility.

Comments:
- This should be done at the first sign of inadequate intake
- This test should not be completed when patient is acutely ill.
- Taking patients off medication is cruel and illogical since they will be taking that medication for treatment of their disease.

When patients who require parenteral nutrition fail to meet one of the A-F criteria:

Patients who do not meet criteria A-F above must meet criteria 1-2 below (modification of diet and pharmacologic intervention) plus also meet additional criteria G and H below:

Maintenance of weight and strength commensurate with the patient's overall health status
must require intravenous nutrition and must not be possible utilizing all of the following approaches:

1. modifying the nutrient composition of the enteral diet (e.g., lactose free, gluten free, low in long chain triglycerides, substitution with medium chain triglycerides, provision of protein as peptides or amino acids, etc.), and
2. utilizing pharmacologic means to treat the etiology of the malabsorption (e.g., pancreatic enzymes or bile salts, broad spectrum antibiotics for bacterial overgrowth, prokinetic medication for reduced motility, etc.).

G. The patient is malnourished (10% weight loss over 3 months or less and serum albumin less than or equal to 3.4 gm/dl), and
H. A disease and clinical condition has been documented as being present and it has not responded to altering the manner of delivery of appropriate nutrients (e.g., slow infusion of nutrients through a tube with the tip located in the stomach or jejunum).

Comments:
When patients fail to meet one of the A-F criteria but already meet the definition of malnourished with 10% weight loss and an albumin of less than 3.4gm/dl, these patients may be too debilitated to begin a trial of enteral nutrient manipulation (lactose free, gluten free, etc.) or to backtrack therapeutically to attempt pharmacologic interventions (pancreatic enzymes, prokinetic medication, etc.). In cases where severe malnutrition is already present, the primary objectives should be to reverse the weight loss and restore visceral proteins (albumin). If these patients have not been fed recently orally, enteral nutrition must be reinstituted gradually. In the interim, parenteral nutrition may be needed to sustain the patient until refeeding of enteral nutrition can be instituted. It is during this refeeding period that the use of dietary nutrient manipulation and pharmacologic interventions may be in order. While parenteral nutrition is sustaining such patients, the gradual re-establishment of enteral nutrition may proceed, with the ultimate goal of partially or completely weaning the patient from parenteral nutrition if possible. To withhold parenteral nutrition while attempting to re-establish enteral nutritional feedings, may place the patient at additional risk.

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