NHIA TALK INFUSION WEBINAR

Medicare's Changing Coverage Criteria for Parenteral and Enteral Nutrition

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National Home Infusion Association

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The National Home Infusion Association is a trade association and the leader in home and specialty infusion. We provide grassroots advocacy, education, and resources to the home and specialty infusion community so the patients they serve can lead healthy, independent lives.

NHIA is committed to meeting the needs of its growing and diverse membership—and to advocating on behalf of our members and the home-based infusion patient.

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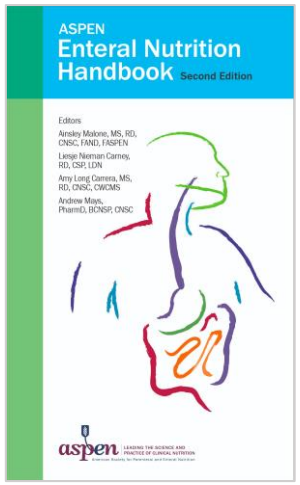

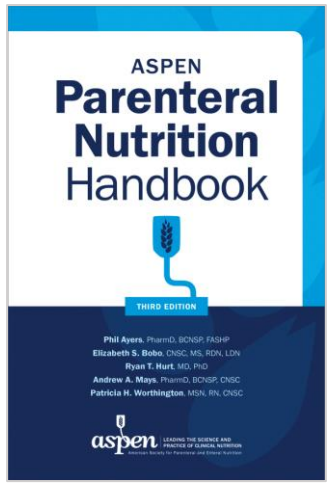

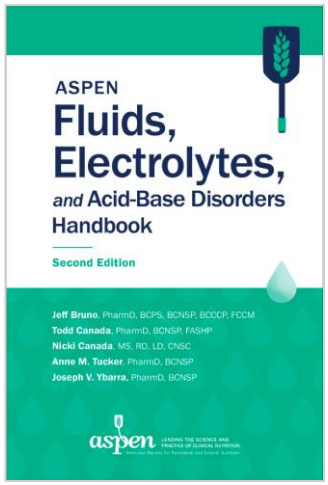

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NHIA TALK INFUSION WEBINAR

Tell Congress: Support the Preserving Patient Access to Home Infusion Act (H.R. 6218 & S. 3457)

ACTION ALERT

Members of Congress need to hear from you now about why it is important to fix the Part B home infusion therapy services benefit, so that patients can continue to receive these crucial therapies in the comfort of their homes.

NHIA has worked with our congressional champions to introduce legislation that will ensure providers are paid each day of infusion, and to remove the face-to-face requirement for billing.

Support NHIA's efforts to pass this legislation and **send your Representatives and Senators a letter now.**

Access and send a customizable letter now at bit.ly/action-alert-patient-access

NHIA TALK INFUSION WEBINAR

Today's Presenters

Bill Noyes

Sr. Vice President Reimbursement Policy, NHIA

Penny Allen, RD, CNSC

Chair, ASPEN Public Policy Committee

National Director of Nutrition Support, Optum Infusion Pharmacy

Agenda

Review	Review history of CMS coverage for home PN and EN under the Prosthetic Device Benefit.
Describe	Describe limitations to the previous policies.
Understand	Understand supporting documentation that will be required upon retirement of current PN and EN policies, based on the National Coverage Determination (NCD), and Billing and Coverage Guidance.
Learn about	Learn about NHIA and ASPEN's collaborative advocacy efforts to bring policies up to date with evidence based medicine.

History of CMS
Parenteral and Enteral Nutrition Coverage

- National Coverage Determination (NCD) issued in 1984
- Parenteral and Enteral Nutrition (PEN) falls under the Prosthetic Device Benefit of Part B Durable Medical Equipment
- The tube or the pump is serving as the “prosthesis” for an organ or function of an organ (ie. esophagus, stomach or small intestine) that is not working
- Coverage criteria has not been updated since inception

Prosthetic Device Benefit: PEN

Issue of Permanence

- Judgment of the attending physician
- Substantiated in the medical record
- Long “indefinite” duration - ie. at least 3 months
- Beneficiary’s condition may improve
- Temporary impairments not covered

Enteral Nutrition NCD

"Enteral therapy is covered for permanent non-function or disease of the structures that normally permit food to reach or be absorbed from the small bowel and require tube feeding to provide sufficient nutrients to maintain weight and strength commensurate with the patient's overall health status".

No coverage for oral supplements or shorter term tube feeding

Parenteral Nutrition NCD

“Parenteral nutrition (PN) is covered for 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.”

Basis of the PN NCD

Issue of Permanence

- Permanence is met if it is the judgment of the attending physician, substantiated in the medical record, that the condition is of long and indefinite duration (90 days or longer).

Functional impairment

- The patient must have either a condition involving the small intestine and/or its exocrine glands, which significantly impairs absorption of nutrients, or
- Disease of the stomach and/or intestine which is a motility disorder and impairs the ability of nutrients to be transported throughout the GI system

TPN Decision Tree

Directions: Start in the far left column and examine medical records as you check for a covered situation. Keep going down the tree as long as you can answer "Yes" to a criterion. If/When the answer is "No" move one column to the right and begin going down that column. Continue checking the medical records against the criteria until you verify that the patient's condition meets a covered situation or you determine that the patient does not qualify for home TPN.

Patient's condition is permanent (at least 3 mos.)

NO → **Patient does not meet Medicare coverage criteria for home TPN therapy.**

Yes

Pt. has condition that significantly impairs absorption of nutrients or pt. has severe motility disorder

NO → **Patient does not meet Medicare coverage criteria for home TPN therapy.**

Yes

Check Situation A

SITUATION A

Pt. had massive small bowel resection leaving ≤ 5 ft. small bowel beyond the ligament of Treitz

NO → **Check Situation B**

Yes

The surgery occurred within the past 3 months.

NO → **Check Situation B**

Yes

Patient meets Medicare coverage criteria for home TPN therapy under Situation A

SITUATION B

Pt. has short bowel syndrome

Yes

Enteral losses exceed 50% of the oral or enteral intake

NO → **Check Situation C**

Yes

Oral Intake is at least 2.5-3 l/day

NO → **Check Situation C**

Yes

Urine Output is < 1 liter per day

NO → **Check Situation C**

Yes

Patient meets Medicare coverage criteria for home TPN therapy under Situation B

SITUATION C

Pt. requires bowel rest for at least 3 mos.

NO → **Check Situation D on page 2**

Yes

Pt. is receiving 20-35 cal/kg/day IV

NO → **Check Situation D on page 2**

Yes

Pt. has:
* symptomatic pancreatitis ***or***
* severe exacerbation of regional enteritis ***or***
* proximal enterocutaneous fistula and tube feeding distal of fistula is not possible

Yes

Patient meets Medicare coverage criteria for home TPN therapy under Situation C

TPN Decision Tree
Page 2

SITUATION D

Pt. has complete mechanical small bowel obstruction

NO → **Check Situation E**

Yes

Surgery is not an option

NO → **Check Situation E**

Yes

Patient meets Medicare coverage criteria for home TPN therapy under Situation D

SITUATION E

Pt. had 10% wt. loss in ≤ 3 months

NO → **Check Situation F**

Yes

Serum Albumin is ≤ 3.4 gm/dl

NO → **Check Situation F**

Yes

Pt. had 72 hour fecal fat test

Yes

Fecal fat exceeds 50% of oral/enteral intake on a diet ≥ 50 gm fat/day

Yes

Patient meets Medicare coverage criteria for home TPN therapy under Situation E

SITUATION F

Pt. had 10% wt. loss in ≤ 3 months

Yes

Serum Albumin is ≤ 3.4 gm/dl

Yes

Pt. is taking maximum doses of prokinetic medication

Yes

Pt. has daily symptoms of N&V

Yes

Pt. had diagnostic test that documents motility disturbance

Yes

* Radioisotope study demonstrates that isotope fails to reach the rt. colon by 6 hrs.

or

* X-ray study demonstrates that barium or pellets fail to reach the rt. Colon by 6 hrs.

No

Yes

Pt. is not acutely ill or on any medication which would decrease bowel motility

Yes

Patient meets Medicare coverage criteria for home TPN therapy under Situation F

TPN Decision Tree
Page 3

SITUATIONS G/H

Pt. had 10% wt. loss in ≤ 3 months
AND
Serum Albumin is ≤ 3.4 gm/dl
AND
Altering the nutrient composition of an enteral diet will not maintain the patient's health status
AND
The patient's health status cannot be maintained by administering medications to treat the etiology of the malabsorption

Yes

Pt. has moderate abnormality such as:
*72º fecal fat study shows fecal fat is > 25% of oral/enteral intake on a diet ≥ 50 gm fat/day
or
*Dx of malabsorption with objective confirmation by methods other than 72º fecal fat test (Sudan stain of stool, d-xylose, etc.
or
*Gastroparesis demonstrated by study that shows the isotope, barium or pellets failed to reach the rt. colon in 3-6 hr or results ***or*** manometric motility study was consistent with abnormal gastric emptying that was unresponsive to prokinetic medication
or
*Small bowl motility disturbance which is unresponsive to prokinetic medication, demonstrated with a gastric to rt colon transit time between 3-6 hrs
or
*Small bowel resection that left > 5 ft of small bowel beyond the ligament of Treitz
or
*Short bowel syndrome not as severe as Situation B
or
*Mild to moderate exacerbation of regional enteritis or enterocutaneous fistula
or
*Partial mechanical small bowel obstruction where surgery is not an option

Yes

Medical Records document a failed Tube Trial

Yes

Patient meets Medicare coverage criteria for home TPN therapy under Situations G/H

NO → **Patient does not meet Medicare coverage criteria for home TPN therapy.**

NO → **Patient does not meet Medicare coverage criteria for home TPN therapy.**

PN LCD in a checklist format

Table 1. Medicare Checklist for Determination of Coverage for Home Parenteral Nutrition

Section 1. All Patients must meet **1** and either **2a** or **2b** in **Section 1.**	1. The patient will require PN for a minimum of 90 days. Documentation by the attending physician must be in the medical record prior to discharge. PN will be denied as non-covered in situations involving temporary impairments. 2. The patient must have: 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 to support the clinical diagnosis.
Section 2. In addition to Section 1, patients must meet any **one** of **A – F, OR,** All of Section 3. Below	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. B. The patient has a short bowel syndrome that is severe enough that the patient has net gastrointestinal fluid and electrolyte malabsorption evidenced by: 1. Electrolyte malabsorption and abnormalities **AND** 2. GI Fluid intake of 2.5-3 L/day resulting in enteral losses that exceed 50% of the oral/enteral intake **AND** 3. Urine output of < 1 L/day C. Patient requires bowel rest for at least 3 months and is receiving intravenously 20-35 cal/kg/day for: 1. Symptomatic pancreatitis with or without pancreatic pseudocyst **OR** 2. Severe exacerbation of regional enteritis **OR** 3. Proximal enterocutaneous fistula where tube feeding distal to the fistula is not possible D. Patient has COMPLETE mechanical small bowel obstruction where surgery is not an option. E. Patient is malnourished and has severe fat malabsorption as evidenced by: 1. 10% weight loss < 3 months **AND** 2. Serum albumin 3.4gm/dl **AND** 3. Severe fat malabsorption where fecal fat exceeds 50% of oral/enteral intake on a diet of at least 50gms of fat/day as measured by a standard 72-hour fecal fat test F. Patient is significantly malnourished and has a severe motility disturbance as evidenced by: 1. 10% documented weight loss over < 3 months **AND** 2. Serum albumin 3.4gm/dl **AND** 3. Severe motility disturbance of the small intestine and/or stomach that is unresponsive to prokinetic medications and is demonstrated scintigraphically or radiographically. These studies must be performed when the patient is not acutely ill and is not on any medication which would decrease bowel motility (see reference below (2) for more specific detail for Situation F)
Section 3. Patients who **do not** meet criteria A-F but have a moderate abnormality of A-F in Section 2 **must** meet criteria 1 and 2, **PLUS** G and H.	1. Modification of the nutrient composition of the enteral diet (i.e., 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.) **AND** G. The patient is malnourished (10% documented 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).
Adapted from: Parenteral Nutrition LCD L33798, Policy Article A52515; CMS Pub. 100-03 (National Coverage Determinations Manual), Chapter 1, Section 180.2, October 2015 (2).	

Barriers to home nutrition support for Medicare beneficiaries

- NCD and LCDs for PEN not updated in greater than 30 years
- Practice patterns, testing, diagnoses and indications for therapy have changed over time
- Not all patients need long term nutrition support (PN or EN)
- PN LCD is heavily weighted to GI diagnoses where PN was prescribed in the 1970s and 1980s-- not allowing for oncology related nutritional issues, bariatric surgery complications or other conditions where PN may be medically necessary
- Patients often remain in hospital or are referred to a skilled facility ie. higher cost site of care to receive PN or EN if they do not meet criteria, or they pay for it themselves

Limited options when Medicare does not cover home PN

- Secondary major medical insurance policy may cover HPN
- Skilled nursing facility for completion of therapy if short term (less than 90 days)
- Hospital might pay the infusion provider a per diem/daily rate for HPN
- Patient/family pays for HPN therapy
- PN is discontinued before discharge if possible

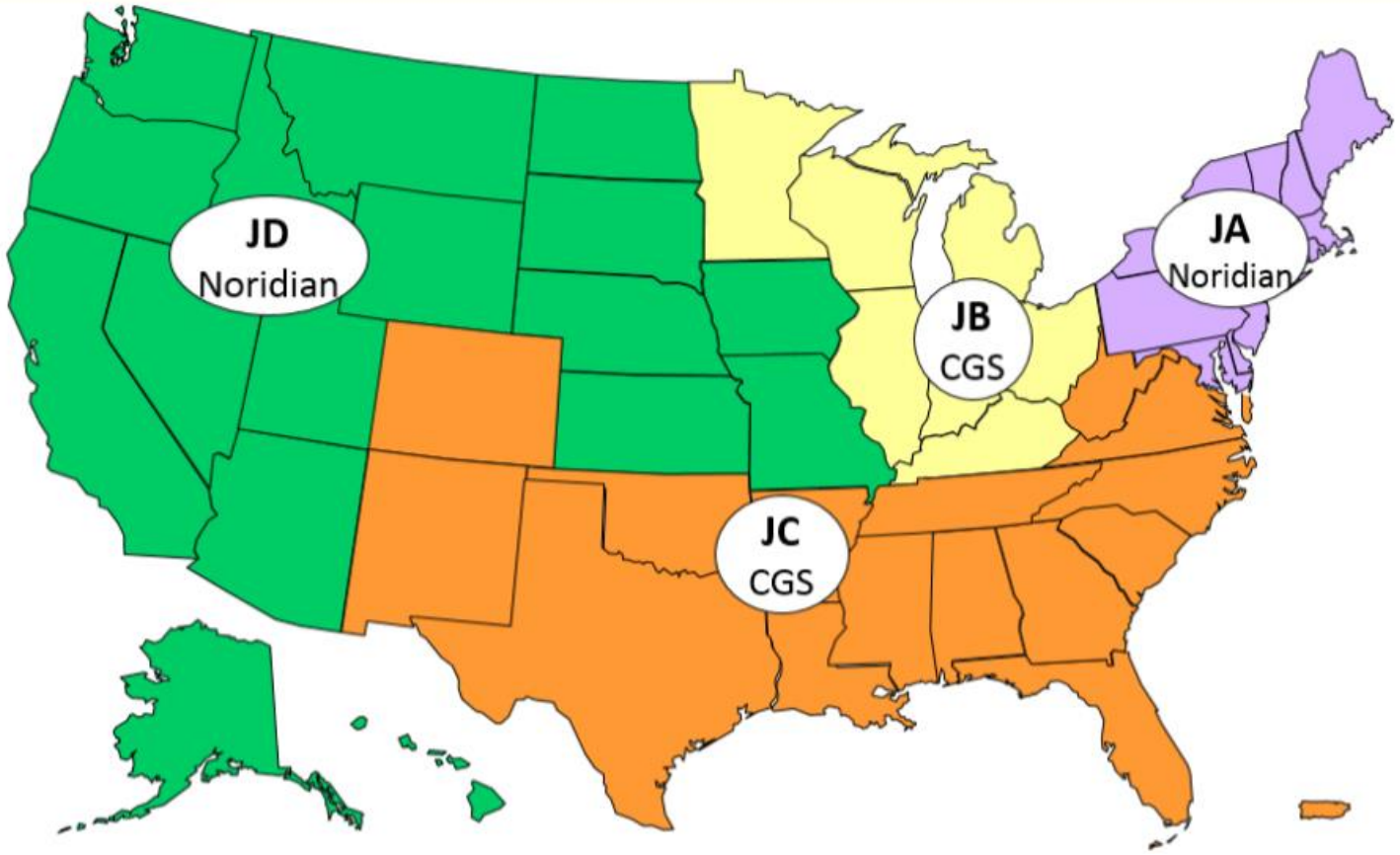
What's Changing?

DME MACs to Retire Enteral & Parenteral Nutrition LCDs

On October 8, the DME MACS released a joint publication stating that the existing Local Coverage Determinations (LCD) for **parenteral** and **enteral** nutrition are being retired effective November 12, 2020. “due to the evolution of parenteral nutrition clinical paradigms.”

Retirement Date
ANTICIPATED 11/12/2020

DME MAC Jurisdictions



What guidance should suppliers refer to going forward?

Effective for DOS on or after November 12, 2020

- Billing and Coding articles
  - Enteral Nutrition - Correct Coding and Billing
  - Parenteral Nutrition - Correct Coding and Billing

- Reasonable & Necessary (R&N) criteria based on the National Coverage Determination (NCD) for Enteral and Parenteral Therapy 180.2

Billing and Coding Articles – The new LCD?

- Includes many details that you would find in a LCD
  - References the NCD for R&N
  - General Documentation Requirements – SWO, POD, Continued need/use, etc.
  - Nutrients - A total caloric daily intake
  - Equipment and Supply Coverage
  - DME Information Form (DIF)
  - Coding Guidelines
  - HCPCS Codes

NCD for Enteral and Parenteral Nutrition Therapy (180.2)

There are patients who, because of chronic illness or trauma, cannot be sustained through oral feeding. These people must rely on either enteral or parenteral nutritional therapy, depending upon the particular nature of their medical condition.

Coverage of nutritional therapy as a Part B benefit is provided under the prosthetic device benefit provision which requires that the patient must have a permanently inoperative internal body organ or function thereof. Therefore, enteral and parenteral nutritional therapy are normally not covered under Part B in situations involving temporary impairments.

Coverage of such therapy, however, does not require a medical judgment that the impairment giving rise to the therapy will persist throughout the patient's remaining years. If the medical record, including the judgment of the attending physician, indicates that the impairment will be of long and indefinite duration, the test of permanence is considered met.

If the coverage requirements for enteral or parenteral nutritional therapy are met under the prosthetic device benefit provision, related supplies, equipment and nutrients are also covered under the conditions in the following…….

NCD - Reasonable and Necessary for PN

"Daily parenteral nutrition is considered reasonable and necessary for a patient with 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."

"For parenteral nutrition therapy to be covered under Part B, the claim must contain a physician's written order or prescription and sufficient medical documentation to permit an independent conclusion that the requirements of the prosthetic device benefit are met and that parenteral nutrition therapy is medically necessary."

Meeting the NCD for PN:

Permanence must always be substantiated in the medical record by the attending physician

GI

- Beneficiary has a diagnosis of short bowel syndrome and cannot be maintained on oral or enteral nutrition. It is clearly documented that there is no longer enough functional small bowel to absorb enough nutrients to maintain weight and strength.

Oncology

- Beneficiary has a diagnosis of ovarian cancer and has a bowel obstruction which cannot be relieved with surgery or treatment. Oral and enteral feeding are not possible and the medical record supports this.

Surgery

- Beneficiary has had bariatric surgery in the past, has documented long term GI complications that preclude the use of oral or enteral feedings and the beneficiary cannot maintain weight or strength commensurate with overall health status.

NCD - Reasonable and Necessary for Enteral

"Enteral nutrition is considered reasonable and necessary for a patient with a functioning gastrointestinal tract who, due to pathology to, 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."

Meeting the NCD for EN

Permanence must always be substantiated in the medical record by the attending physician

Neurology

- Beneficiary has a diagnosis of ALS and can no longer consume oral intake due to permanent loss of swallowing mechanism and risk of aspiration.

Oncology

- Beneficiary has a diagnosis of esophageal cancer and due to radiation treatments and related side effects as well as tumor location it is well documented in the medical record that oral intake is not possible for the next 3-6 months of therapy.

Insights

- NCD is 36 years old, 1984
- The NCD has been in place since before the creation of the DME MAC
- The NCD was in place prior to the retirement of the LCDs and has always trumped the LCD
- DME MACs will now refer to NCD use for R&N

NCD Language Concerns

- Need to qualify need for PN Pump?
- Home Mix over Pre-mix PN?
- Initial and ongoing (at least every 3-month) “approval”?

NHIA Advocacy Efforts

- NHIA's Medicare Contractor Advisory Committee & DME MAC Advisory Councils
- DME MAC Provider Outreach and Education Advisory Group (POEAG)
- In 2014 NHIA filed a Reconsideration Request with the DME MAC regarding the PN LCD.
- NHIA partnered with ASPEN to communicate to CMS mutual concerns and recommendations for revising the PN LCDs.
  - Such as: Need for a 72-hour fecal fat test, need for tube feeding trial in moderate abnormalities, documentation of daily nausea and vomiting in motility conditions, the use of serum albumin level as a nutrition marker, and addition of Smart Pill® to identify motility issues.

Additional Education Opportunities

- Noridian Webinar scheduled for November 17, 2020

  Nutrition Q&A for Correct Coding after November 12, 2020

  Link to register: https://med.noridianmedicare.com/web/jddme/education/training-events

ASPEN Advocacy and Partnership Efforts

- 2008 ASPEN renews emphasis on advocacy by reinstating the Public Policy Committee with the charge to set a public policy agenda and develop initiatives related to public policy and advocacy.
- Efforts regarding HPN reimbursement were to support the Medicare Home Infusion Act in its various iterations by appealing to Congress to pass such legislation. This was done in partnership with the NHIA and through membership in the Digestive Diseases National Coalition (DDNC).
- In late 2014 the ASPEN Public Policy Committee surveyed providers and consumers about how healthcare reform was affecting their ability to provide or access nutrition care.
- ASPEN partnered with NHIA to communicate to CMS mutual concerns and recommendations for revising the PN LCDs.
    - Such as: Need for a 72-hour fecal fat test, need for tube feeding trial in moderate abnormalities, documentation of daily nausea and vomiting in motility conditions, and the use of serum albumin level as a nutrition marker.

ASPEN Public Policy Efforts

Nutrition in Clinical Practice

March 2018

Invited Commentary

aspen

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Home Parenteral Nutrition Reimbursement and American Society for Parenteral and Enteral Nutrition Public Policy Efforts

Lynne Murphy, RN, MSN, FASPEN[1]; Penny Allen, RD, LDN, CNSC[2]; Bettemarie Bond, BS[3]; and Peggi Guenter, PhD, RN, FAAN, FASPEN[4]

Abstract
Home parenteral nutrition (HPN) has been considered a lifesaving intervention since the late 1960s for patients with gastrointestinal (GI) failure and other conditions that affect the GI tract who are well enough to be at home. Payment for this therapy under federal programs requires significant documentation and complex processes to qualify. Medicare parenteral nutrition policy, qualification processes and challenges, and advocacy supported by the American Society for Parenteral and Enteral Nutrition are reviewed with the goal of increasing clinician awareness of the complexity surrounding Medicare HPN reimbursement. (*Nutr Clin Pract.* 2018;00:1–9)

Keywords
consumer advocacy; healthcare financing; health insurance reimbursement; home parenteral nutrition; Medicare; parenteral nutrition

Parenteral nutrition (PN) is considered a lifesaving intervention for patients with gastrointestinal (GI) failure with home PN (HPN) no longer considered extraordinary. The Oley Foundation exists to support HPN consumers. Payment for HPN confuses nearly all practitioners and patients regardless of the healthcare financing environment. The American Society for Parenteral and Enteral Nutrition (ASPEN) organized a key group of members into a Public Policy/Advocacy Committee in 1984 under the direction of the late Executive Director, Barney Sellers. This committee worked with legislators, executive branch "bureaucrats," insurance companies, home care providers, practitioners, and patients to assure both funding and research for HPN. This paper will discuss a brief history of ASPEN involvement, the current state of affairs, views from both a provider and a patient, and how ASPEN has advocated for improved coverage for Medicare beneficiaries. The scope is limited to HPN to avoid confusion with home EN.

Funding for healthcare in the United States comes from several sources, public and/or private. President Lyndon Johnson signed Medicare and Medicaid into Public Law 89–97 in July 1965. Although it was not popular at the time, it is now the reference for payment used by some private insurers. Medicare provides insurance for 96% of those >65 old and other groups, specifically those with a disability for >2 years, patients with end-stage renal disease, and those with amyotrophic lateral sclerosis.[1,2] The increase in Medicare spending from inception to 1971 was 72%; this was just before HPN began being widely used.[1] The rise in spending has dictated many changes in payment structure and methodology over the years. Payment structures are based on scientific research for each of many categories.

Home care is thought to reduce the cost of care because there is no hospital overhead expense. Evaluation of that effort showed that spending on home care rose on average 31% per year from 1988 to 1996.[1] This rise in budget expense did not go unnoticed. The Balanced Budget Act of 1997 slashed reimbursement for home care and brought the end to many home health nursing agencies. However, by the first

From the [1]Past chair of ASPEN Public Policy Committee Silver Spring, MD; [2]National Director, Nutrition Support, BriovaRx Infusion Services, Lenexa, Kansas; [3]Patient Advocate Levittown, PA; Public Member of ASPEN Public Policy Committee Silver Spring, MD; and [4]Senior Director of Clinical Practice, Quality, and Advocacy ASPEN Silver Spring, MD.

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