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Medicare Coverage for Home Parenteral Nutrition – An Oxymoron? Part I



Penny Allen

A 67 year old female patient with Stage III ovarian cancer presenting with partial small bowel obstruction, intractable nausea and vomiting is referred to a home infusion provider for home parenteral nutrition on a Friday afternoon. The patient has Medicare as her primary insurance as well as a supplemental policy. The physician and case manager are informed: “I am sorry, your patient does not meet the Medicare criteria for home parenteral nutrition.”

INTRODUCTION

Physicians and healthcare providers charged with caring for patients requiring home parenteral nutrition (HPN) face increasing pressure to discharge patients earlier from the acute care setting. Patients with gastrointestinal (GI) disorders, GI and nutritional complications from cancer, and other conditions may require continuation of parenteral nutrition (PN) therapy in the home setting. As the population of Medicare eligible beneficiaries grows, it is often a surprise at the time of discharge that many patients do not meet criteria for HPN and related medically necessary infusion therapies under Medicare. In a recent abstract by a home infusion provider, 42% of medical records reviewed for Medicare PN coverage over a 7 month period did not include objective testing required for reimbursement coverage, even though the diagnoses with potential for meeting criteria were present in the records.¹

This article provides the clinician with a review of the very dated Medicare policy for HPN, the criteria

and objective documentation still required by law today, as well as strategies for attempting to provide home infusion therapy when Medicare will not cover patients who appropriately need HPN. Regardless of insurance plan, if there is any possibility that a patient may require HPN post discharge, the planning process should begin immediately so that all members of the healthcare team as well as the patient are aware of what is required to attempt to secure coverage.

- What is needed to try to successfully qualify this patient for HPN under Medicare?
- If the patient has no coverage under Medicare, what options exist for patients to receive PN and other infusion therapies which are medically necessary?

BACKGROUND

Medicare HPN Policy Remains the Same Over 20 Years Later

Medicare is the federal healthcare program enacted by Congress as part of Title 18 of the Social Security Act of 1965. It is the largest health insurance program in

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

<p>Section 1. All Patients must meet 1 and either 2a or 2b in Section 1.</p>	<ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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.
<p>Section 2. In addition to Section 1, patients must meet any one of A – F, OR, All of Section 3. Below</p>	<ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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)
<p>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.</p>	<ol style="list-style-type: none"> 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).
<p>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).</p>	

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the United States. Medicare coverage is divided into Parts A, B, C, and D, each of which provides different benefits.

For over 20 years, parenteral and enteral nutrition (PEN) therapies fall under the prosthetic device benefit under Medicare Part B. The analogy utilized by the Center for Medicare and Medicaid Services (CMS) is that parenteral nutrition (PN) and enteral tube feeding (or actually the devices to administer them), replace an organ or function of an organ that is permanently impaired. If specific criteria related to any one of 7 GI conditions “permanently” (defined as ≥ 3 months) prevents the patient from absorbing nutrients needed to maintain weight and strength commensurate with health status, and it is documented objectively in the manner required, then Medicare may cover HPN accessories and/or supplies. In addition to the necessary supplies, the oversight of HPN is ideally performed by an interdisciplinary team on a weekly basis. This oversight of professional services, clinical assessment, monitoring, or the actual ongoing management of the patient has never been covered under Medicare.

The HPN Policy Under Medicare

Currently, the Parenteral Nutrition Policy A52515,^{2,3} (which has not changed in over 20 years) states:

“Parenteral Nutrition is covered under the Prosthetic Device benefit (Social Security Act § 1861(s)⁸)

Parenteral nutrition is covered for a beneficiary with permanent, severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the beneficiary’s general condition.”

The Medicare concept of permanent impairment of the small intestine is often a challenging one for many clinicians who approach HPN with the hope that it will be temporary and that patients may over time reduce their PN-dependence through bowel adaptation as well as diet and medication management. The policy goes on to read:

"Prosthetic Benefit Requirements

The beneficiary must have a permanent impairment. Permanence does not require a

determination that there is no possibility that the beneficiary’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 beneficiary 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."**

Table 1 provides a checklist outlining the clinical situations (A-H) where Medicare will cover HPN. In addition to meeting the test of permanence (Medicare defines permanence as >90 days), there must be clear objective evidence that the GI tract, specifically the small intestine, is non-functioning. A completed Durable Medical Equipment Medicare Administrative Contractor or DME MAC Information Form (DIF), formerly referred to as a Certificate of Medical Necessity (CMN), a Detailed Written Order (DWO), along with extensive objective documentation from the medical record to support the criteria is the minimum required by the Center for Medicare and Medicaid Services (CMS). The original version of Table 2, published and distributed by the former DMERC (now called DME MAC) Region D over a decade ago, outlines the necessary documentation required for each criteria.

Medicare requires an attempt at tube feeding when there is a “moderate abnormality” (see Table 3) of a condition in Situations A-F (Table 1) and the documentation does not exactly meet criteria for coverage. In this instance, additional information such as documented weight loss, a low albumin, attempts at medication and diet modifications and a tube feeding trial is required. There is currently no exception in the policy allowing for situations where a tube feeding trial may not be clinically appropriate or possible. Criteria outlining the documentation necessary for a failed tube feeding trial is outlined in Table 4.

Table 2. Documentation Required by Medicare (Adapted from DMERC Region D 2006⁹)

<p>Situation A</p> <p>Massive Small Bowel Resection</p>	<p>Situation B</p> <p>Short Bowel Syndrome</p>	<p>Situation C</p> <p>Bowel Rest (Pancreatitis, Enterocutaneous fistula (ECF) or Severe Regional Enteritis/ Crohn’s Disease)</p>
<p>Medical Records Should Document</p> <ul style="list-style-type: none"> ◆ Date of surgery ◆ Details of surgery ◆ How much small bowel is remaining beyond the ligament of Treitz ◆ Estimated length of need for HPN 	<p>Medical Records Should Document</p> <ul style="list-style-type: none"> ◆ Cause of short bowel syndrome ◆ 24 hour I & O documenting oral/enteral intake; stool output and urine output ◆ Electrolyte abnormalities upon admission ◆ Estimated length of need for HPN 	<p>Medical Records Should Document</p> <ul style="list-style-type: none"> ◆ One of the above diagnoses that requires bowel rest ◆ If ECF, statement that tube feeding distal to the fistula is not possible ◆ How long the attending MD anticipates the pt will need bowel rest
<p>Suggested Records</p> <ol style="list-style-type: none"> 1) Admission H&P 2) Operative report 3) Progress notes 4) Discharge summary 	<p>Suggested Records</p> <ol style="list-style-type: none"> 1) Admission H&P 2) Progress notes 3) Discharge summary 4) Operative reports 5) 24 hour Intake & Output records 6) Diagnostic test results <ol style="list-style-type: none"> a. Serum electrolytes b. Other pertinent tests 	<p>Suggested Records</p> <ol style="list-style-type: none"> 1) Admission H&P 2) Progress notes 3) Discharge summary 4) Diagnostic test results

Situation D	Situation E	Situation F	Situation G & H
Complete Mechanical Small Bowel Obstruction	Severe Malabsorption	Severe Motility Disturbance	Other Qualifying Condition and Failed Tube Trial
Medical Records Should Document	Medical Records Should Document	Medical Records Should Document	Medical Records Should Document
<ul style="list-style-type: none"> ◆ Presence of complete small bowel obstruction (radiographic reports) ◆ Surgical options if any ◆ Estimated length of need for HPN 	<ul style="list-style-type: none"> ◆ Cause of malabsorption ◆ 3 month weight history (weight on admission compared to documented weight 3 months ago) ◆ Serum albumin less than normal ◆ 72 hour fecal fat test results documenting fat malabsorption of $\geq 50\%$ of fat intake via calorie counts documenting high fat diet 	<ul style="list-style-type: none"> ◆ Etiology of motility disturbance ◆ 3 month weight history (weight on admission compared to documented weight 3 months ago) ◆ Serum albumin less than normal ◆ Prokinetic medication history ◆ Nuclear isotope or x-ray motility study 	<ul style="list-style-type: none"> ◆ 3 month weight history (weight on admission compared to documented weight 3 months ago) ◆ Serum albumin less than normal ◆ The diagnosed “moderate abnormality” per Medicare policy ◆ Enteral tube feeding trial(s) (see Table 4)
Suggested Records	Suggested Records	Suggested Records	Suggested Records
<ol style="list-style-type: none"> 1) Admission H&P 2) Progress notes 3) Discharge summary 4) Operative reports 	<ol style="list-style-type: none"> 1) Admission H&P 2) Progress notes 3) Discharge summary 4) Diagnostic test results <ol style="list-style-type: none"> a. Serum albumin b. 72 hour fecal fat results c. Other pertinent tests d. Nutrition assessment e. Weight history 	<ol style="list-style-type: none"> 1) Admission H&P 2) Progress notes 3) Discharge summary 4) Diagnostic test results <ol style="list-style-type: none"> a. Serum albumin b. Small bowel motility (the criteria does not specify) c. Nutritional assessment d. Medication records e. Weight history 	<ol style="list-style-type: none"> 1) Admission H&P 2) Progress notes 3) Discharge summary 4) Operative reports 5) Diagnostic test results <ol style="list-style-type: none"> a. Details of enteral trial (see Table 4) b. Nutritional assessment c. Medication records d. Weight history

Table 3. Examples of Moderate Abnormalities Requiring a Failed Enteral Feeding Trial³

- Moderate fat malabsorption - fecal fat exceeds 25% 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
- Diagnosis of malabsorption with objective confirmation by methods other than 72 hour fecal fat test (e.g., Sudan stain of stool, d-xylose test, etc.)
- Gastroparesis which has been demonstrated:
 - a.) Radiographically or scintigraphically as described in F (see Table 2) with the isotope or pellets failing to reach the jejunum in 3-6 hours, OR,
 - b.) By manometric motility studies with results consistent with abnormal gastric emptying, and which is unresponsive to prokinetic medication
- A small bowel motility disturbance which is unresponsive to prokinetic medication, demonstrated with a gastric to right colon transit time between 3-6 hours
- Small bowel resection leaving > 5 feet of small bowel beyond the ligament of Treitz
- Short bowel syndrome which is not as severe (as defined in Section 2, B, Table 1)
- Mild to moderate exacerbation of regional enteritis, or an enterocutaneous fistula
- Partial mechanical small bowel obstruction where surgery is not an option

What Has Changed? The Claims Process and Many, Many Audits

The initial claims submission process is different today than in years past causing confusion among some providers, which could potentially place patients/families at significant financial risk. Qualifying documentation is no longer submitted with the initial claim; in the past, coverage was approved or denied by CMS from the start. Supporting medical records should be obtained by the infusion/PN provider prior to the start of care so they are available for submission when claims are audited, which is a routine occurrence. The initial analysis of whether a patient has coverage falls completely on the infusion provider. If the provider does not fully understand or interpret the policy correctly, physicians and patients may be provided with an incorrect “approval” by the provider/vendor at time of discharge. To make matters more confusing, CMS will pay claims even when a patient does not actually meet criteria--until the provider is audited and then required to submit the initial supporting documentation. This is often months or even years later. CMS can audit a claim up to three years after a claim has been paid, which could potentially end up being as many as five years after an incident of care or shipment was provided.⁴ If documents cannot be produced in an audit, the government recoups all payments and the beneficiary could be at risk for the total amount, which could be tens of thousands of dollars.

The National Medicare Recovery Audit Program was established in 2009. The intent of this program is to identify and correct improper Medicare and Medicaid payments through the detection and collection of overpayments made on claims for health care services provided to Medicare and Medicaid beneficiaries. The frequency and types of audits conducted have increased substantially since 2010. In Fiscal Year 2014, Recovery Auditors collectively identified and corrected 1,117,057 claims that resulted in \$2.57 billion dollars in improper payments being corrected and recouped by Medicare.⁵

After an audit has been conducted and a claim is denied, there are 5 levels of appeal for infusion providers within CMS. Statistics for 2015 from the Office of Medicare Hearing and Appeals (OMHA), give an average time frame of 547 days to reach a Level 3 Administrative Law Judge adjudication, indicating a significant backlog in the current system.⁶ Since audits are a common occurrence, infusion providers should understand and adhere to Medicare PN policy by collecting necessary qualifying documents prior to discharge which may help to protect the patient financially in the long run.

“Are other medically necessary infusion therapies like hydration and anti-infectives covered by Medicare?”

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“How can my patient obtain access to the therapies they need at home if not?”

Challenges with Medicare and Home Infusion Therapies

The Medicare program is the only payer in the United States that fails to recognize the clinical and cost benefits of providing infusion in the home setting. Currently, many infusion therapies are not covered by Medicare under Part B, even when medically necessary (Table 5).

Since Medicare has not kept up with current utilization and nationally accepted standards for use of PN, organizations including the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) and

the National Home Infusion Association (NHIA) have lobbied CMS for years in an attempt to change existing law so that meaningful home infusion therapy for Medicare beneficiaries is available. Current policy for HPN severely limits access to therapy with few patients meeting the government’s criteria, either due to the test of permanence required, or non-qualifying conditions for PN such as malnutrition, GI/nutritional complications due to cancer treatments or bariatric surgery.

An abstract published in 2007 reported that only 16% of Medicare PN referrals received (over a large geographically and medically diverse sample) by a national infusion provider met CMS HPN policy requirements for coverage.⁷ Almost 10 years later,

Table 4. Medicare’s Definition of an Enteral Tube Trial for Situations G and H²

- ◆ A concerted effort must be made to place a tube.
- ◆ For gastroparesis, tube placement must be post-pylorus, preferably in the jejunum.
 - Use of a double lumen tube should be considered.
 - Placement of the tube in the jejunum must be objectively verified by radiographic studies or fluoroscopy.
 - Placement via endoscopy or open surgical procedure would also verify location of the tube, however they are not required.
- ◆ A trial with enteral nutrition must be made, with appropriate attention to dilution, rate, and alternative formulas to address side effects of diarrhea.
- ◆ Examples of a failed tube trial would be:
 - A person with documented placement of a tube in the post-pyloric area that continues to have problems with vomiting and on radiographic recheck the tube has returned to the stomach.
 - After an attempt of sufficient time (5-6 hours) to get a tube into the jejunum, the tube does not progress and remains in the stomach or duodenum.
 - An attempt of enteral tube feeding with a very slow drip was made. It was initially tolerated well, but vomiting occurred when the rate was increased.
 - After placement of the tube in the jejunum and 1-2 days of enteral tube feeding, the person has vomiting and distension.
 - A tube is placed appropriately and remains in place. Enteral nutrition is initiated and the concentration and rate are increased gradually. Over the course of 3-4 weeks, attempts to increase the rate and/or concentration and/or to alter the formula to reach the targeted intake are unsuccessful, with increase in diarrhea, bloating or other limiting symptoms, and the person is unable to meet the needed nutritional goals (stabilize at desired weight or gain weight as needed).

another national infusion provider with similar referral statistics, demonstrated that even fewer Medicare beneficiaries (10.5%) referred for HPN met the restrictive policy requirements, leaving few options for patients without coverage unless they had a secondary major medical insurance policy.⁸

Transitioning from Commercial Payer to Medicare Coverage—What Then?

A significant challenge for HPN patients, providers, and their physicians is when a patient transitions from a commercial payer to Medicare coverage when they meet disability criteria or turn 65 years old. There is no such thing as “grandfathering” of HPN coverage when a patient flips to Medicare from another insurance company, making it incredibly difficult to meet the stringent rules of Medicare coverage when a patient has already been on HPN for months or even years. There are no clear guidelines from CMS on how to “qualify” patients already on HPN who enroll into the Medicare program, leaving physicians and providers to search and scour through old medical records from the time period when the patient first started on PN (if they even exist) and attempt to qualify them retroactively. Many insurance providers only require a statement of “medical necessity” for HPN coverage; therefore testing, objective studies, and length of need documentation may never have been completed at the time of PN initiation months or years before.

Most commercial payers also do not follow a “permanent impairment” deal breaker for HPN coverage, so documentation required by Medicare when PN was initiated, i.e., a statement of how long the attending physician thought the patient would need HPN, may not exist because the insurance coverage the patient had at the time did not require it. Unfortunately, despite the fact that there is almost always medical

Table 5. Home Parenteral Related Infusion Services Not Covered By Medicare

- ◆ Intravenous hydration
- ◆ Catheter care
- ◆ Anti-infective therapies
- ◆ Ethanol locks
- ◆ Nursing
 - Covered under Medicare Part A, but only if patient is homebound

necessity for PN, when a patient switches to Medicare, there will be no coverage for the HPN if there is no “qualifying” situation (A-H), the objective evidence is not available to support the qualifying situation, or there is no documented length of need of 90 days or longer, even in cases where a patient has been on HPN for many years.

Healthcare practitioners caring for HPN patients would be well advised to guide their patients to examine all insurance options available regarding original Medicare, Medicare Advantage or replacement plans before dropping existing insurance coverage when they turn 65 years old. Table 6. outlines less than ideal potential options to investigate when there is no coverage under Medicare.

What about Medicare Part D? Is there any coverage for PN or Other Infusion Therapies Needed?

In the above situation, if a patient does not meet Medicare Part B criteria for HPN when they transition to Medicare, the logical assumption would be that the patient is entitled to HPN coverage under Medicare Part D.

Table 6. Possible Options When a Patient Has No Coverage for HPN Under Medicare

- ◆ Secondary major medical insurance policy may have HPN benefits
- ◆ Skilled nursing facility for completion of therapy if short term (i.e. less than 90 days)
- ◆ Hospital pays the infusion provider a per diem/daily rate for HPN
- ◆ Patient pays for HPN therapy (case manager/physician/patient can research providers for best price)
- ◆ Part D plan may have partial coverage for premixed PN products/individual PN ingredients; there will be a copay for pump/tubing/supplies/services
- ◆ PN is discontinued prior to discharge if appropriate

Table 7. Resources

- ◆ **Centers for Medicare & Medicaid Services**
 - <http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33794&ver=17> (External Infusion Pump Local Coverage Determination)
 - Medicare.gov; the official U.S. government site for Medicare
- ◆ **Medicare National Coverage Determination Manual (NCD): Nutrition Part 3 Section 180.**
 - <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS014961.html>
- ◆ **National Home Infusion Association**
 - www.nhia.org (National Home Infusion Association)
 - www.nhia.org/Members/Medicare_AAD (Audits and Appeals Resource Center)
 - www.nhia.org/resource/legislative/MedicareHomeInfusionSiteofCareAct.cfm
 - www.nhia.org/resource/legislative/WriteYourMemberofCongressMHISOCA.cfm
- ◆ **American Society for Parenteral and Enteral Nutrition: Public Policy**
 - www.nutritioncare.org/Public_Policy/Call_to_Action
- ◆ **The Oley Foundation: Legislative Page**
 - www.oley.org/?page=Legislation

Part D is a prescription drug only benefit that may or may not have limited coverage for certain ingredients in the PN, for example those deemed prescription drugs such as amino acid or lipid. Rarely are all (if any) PN ingredients covered under Part D and each Part D provider has a different drug formulary. Since Part D is a prescription drug only benefit, there is no coverage for pump, supplies, tubing, delivery, or clinical management/professional services, making it nearly impossible for any provider to accept Part D reimbursement. Patients will almost always have a considerable co-pay for these necessary supplies if they choose to receive care at home. If additional PN related infusion therapies such as hydration or anti-infectives are prescribed, the same scenario presents a challenge for the practitioner trying to find providers willing to accept Part D reimbursement when much of the therapy cost is not covered.

Hoping for Change? Medicare Site of Care Act S. 275/H.R. 605

The Medicare Home Infusion Site of Care Act of 2015 S. 275/H.R. 605 was introduced by Senators Johnny Isakson (R-GA), Mark Warner (D-VA) and Congressmen Eliot Engle (D-NY) and Pat Tiberi (R-OH). The goal is for Medicare beneficiaries to have

access to home infusion. This bill would provide a pathway for reimbursement for professional services, supplies and equipment associated with home infusion therapy under Medicare Part B, enabling the Part D coverage of infusion drugs to become more meaningful for Medicare beneficiaries. The bill also requires development of safety standards to ensure the safe and effective provision of infusion therapy, allowing the Medicare program to realize the efficiencies and positive outcomes the private sector has experienced for over 30 years. If passed, many more patients could receive cost-effective, medically necessary infusion treatments such as PN, hydration and anti-infectives in the home setting.

At present, infusion therapy including PN is fully covered by Medicare everywhere but in the home setting: hospitals, skilled nursing facilities (SNFs), hospital outpatient departments, and physician offices. Medicare may pay a portion of certain infusion drugs provided in the home, but due to the lack of reimbursement for the necessary services, supplies and equipment used in the provision of the infusion therapy, most Medicare beneficiaries in reality do not have access to therapy at home since the cost may be prohibitively expensive for the patient, with copays as high as \$30-\$80 or more

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per day. If passed, the Medicare Home Infusion Site of Care Act will provide a much needed mechanism for coverage of all that is necessary to infuse a drug and/or PN safely—clinical professional services, supplies and equipment—which would make the Part D coverage of infusion drugs meaningful and logical.

For more information on how to support the passage of this bill (including templates to write to your state representatives) go to:

- <http://www.nhia.org/resource/legislative/MedicareHomeInfusionSiteofCareAct.cfm>
- www.nhia.org/resource/legislative/WriteYourMemberofCongressMHISOCA.cfm

Selection of HPN/infusion providers who are fluent and compliant with Medicare and federal law may protect beneficiaries from financial hardship down the road. Some providers will accept Medicare PN referrals quickly and without a thorough assessment, then later discontinue care when they learn there is no reimbursement from CMS. If an infusion provider quickly accepts a Medicare PN case without a complete review of the documentation prior to discharge, it should be a red flag to the clinician/referral source. Qualified reputable HPN providers should offer consultative guidance in the way of a “records review” at the time of referral to help physicians navigate the complexity of the policy with the ultimate goal of protecting the patient.

During open enrollment time periods, physicians and PN providers should guide patients to investigate alternative insurance options and/or Medicare Advantage or replacement plans with more meaningful benefits should the patient require PN or other home infusion due to a chronic condition. Lastly, although not ideal, Medicare beneficiaries do have coverage for PN in a skilled nursing facility (with Part A restrictions), so if the HPN did not meet coverage criteria because the length of need was not permanent, the patient may have coverage in the SNF setting.

CONCLUSION

Until new laws are passed and coverage for home infusion/PN becomes more meaningful under Medicare, healthcare providers should carefully assess the need for HPN therapy. Referrals for homecare should be made as early as possible to allow for thorough examination and review of medical documentation and allow for

the possibility that additional testing may be required by Medicare. This will help ensure that the beneficiary will have coverage for HPN and is not at risk for denial of payment should an audit determine that coverage criteria was not met, potentially leaving the patient and family with a significant bill in the future.

All providers involved in the care of patients requiring HPN and related therapies should develop a stronger understanding of the Medicare reimbursement system in order to advocate for the needs of this challenging patient population. Failing to do this may prevent patients from having access to life sustaining nutrition support and could also expose them to significant financial harm. Given these risks, clinicians would be well advised to carefully document the clinical necessity of HPN backed up by objective evidence and testing, along with an estimated length of need for the therapy for all patients going home on PN—as if they needed to meet Medicare criteria. Patients who currently have private insurance may eventually transition to Medicare and supporting documentation will be required for a successful transition and continuation of HPN therapy. For more information regarding the Medicare Home Infusion Site of Care Act as well as additional resources, see Table 7. ■

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