Medicare’s Changing Coverage Criteria for Parenteral and Enteral Nutrition
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About NHIA

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.

Learn more about NHIA and membership at nhia.org/membership.
Long Term Home PN Management Webinar Series

OCTOBER 28, 1 PM ET
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• Developing HPN order
• Patient and caregiver education

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• HPN adjustment
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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
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
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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 (i.e. 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 - i.e. at least 3 months
- Beneficiary’s condition may improve
- Temporary impairments not covered
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 off a covered situation. Keep going down the lane as long as you can answer "Yes" to a criterion. When the answer to the "Yes/No" lane is a "No" move over columns to the right and begin going up that column. Continue checking the medical records against the criteria until you verify whether the patient's condition meets a covered situation or you determine that the patient does not qualify for home TPN.

**Situation A**
- PI has significant liver disease
- PI has undergone a liver transplant
- The surgery occurred within the past 3 months
- The surgery occurred within the past 3 months
- The patient meets Medicare coverage criteria for home TPN therapy under Situation A

**Situation B**
- PI has heart failure
- PI has liver disease
- PI has undergone a liver transplant
- The surgery occurred within the past 3 months
- The surgery occurred within the past 3 months
- The patient meets Medicare coverage criteria for home TPN therapy under Situation B

**Situation C**
- PI has short bowel syndrome
- PI has renal failure for at least 3 mos.
- PI is receiving 23.3 kcal/day IV
- PI has a symptomatic pancreatitis or necrosis of the pancreas
- PI has an arterial insufficiency
- PI has a sustained high level of fluid intake or the fluid intake is not provided
- PI has a sustained high level of fluid intake or the fluid intake is not provided
- The patient meets Medicare coverage criteria for home TPN therapy under Situation C

**Situation D**
- PI has diabetes
- PI has undergone a liver transplant
- The surgery occurred within the past 3 months
- The surgery occurred within the past 3 months
- The patient meets Medicare coverage criteria for home TPN therapy under Situation D

**Situation E**
- PI has a history of heart failure
- PI has severe liver disease
- PI has a history of kidney disease
- PI has a history of GI disease
- PI has a history of chronic obstructive pulmonary disease
- PI has a history of chronic obstructive pulmonary disease
- The patient meets Medicare coverage criteria for home TPN therapy under Situation E

**Situation F**
- PI has a history of heart failure
- PI has severe liver disease
- PI has a history of kidney disease
- PI has a history of GI disease
- PI has a history of chronic obstructive pulmonary disease
- PI has a history of chronic obstructive pulmonary disease
- PI has a history of heart failure
- PI has severe liver disease
- PI has a history of kidney disease
- PI has a history of GI disease
- PI has a history of chronic obstructive pulmonary disease
- PI has a history of chronic obstructive pulmonary disease
- The patient meets Medicare coverage criteria for home TPN therapy under Situation F

**Situation G**
- PI has a history of heart failure
- PI has severe liver disease
- PI has a history of kidney disease
- PI has a history of GI disease
- PI has a history of chronic obstructive pulmonary disease
- PI has a history of chronic obstructive pulmonary disease
- PI has a history of heart failure
- PI has severe liver disease
- PI has a history of kidney disease
- PI has a history of GI disease
- PI has a history of chronic obstructive pulmonary disease
- PI has a history of chronic obstructive pulmonary disease
- The patient meets Medicare coverage criteria for home TPN therapy under Situation G
PN LCD in a checklist format
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
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