Medicare HPN and HEN policies finally changed!

What's new and what does it mean?

Oley Foundation Annual Conference—June 2021
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<td>Review history of CMS coverage for home PN and EN under the Prosthetic Device Benefit</td>
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<td><strong>Describe</strong></td>
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<td><strong>Understand</strong></td>
<td>Understand supporting documentation that is now required upon retirement of current PN and EN policies, based on the National Coverage Determination (NCD), and Billing and Coding Guidance documents</td>
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<td><strong>Learn about</strong></td>
<td>Learn about Oley, ASPEN and NHIA's collaborative advocacy efforts to bring policies up to date with evidence-based medicine</td>
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History of Medicare (or Centers for Medicare and Medicaid Services) Parenteral and Enteral Nutrition (PEN) Coverage

- National Coverage Determination (NCD) was 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 1984!
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 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 short-term tube feeding
Parenteral Nutrition
National Coverage Determination (NCD) 1984

“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—Still the same

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
Lots of studies/tests/labs required to meet criteria so only about **10%** of Medicare PN referrals met this detailed qualification process!
Barriers to home nutrition support for Medicare beneficiaries

- NCD and LCDs for PEN not updated in greater than 35 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 (policy) was 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 HPN

- 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
ASPEN Public Policy Efforts

Worked with Oley and National Home Infusion Association (NHIA) for decades trying to update policies and coverage criteria

Last spring convened a new sub-committee to research and recommend evidence-based updates for HPN

ASPEN/NHIA presented to Medicare Medical Directors July 2020

And?.....
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.”
November 12, 2020

PN and EN LCDs are retired!
New documents and guidance were released

Effective for dates of service 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  (CMS Manual)
New “Billing and Coding” articles: PN & EN

Includes many details that you would find in a Local Coverage Determination (which is coming!)

• References the NCD for “Reasonable and Necessary”
• General Documentation Requirements – SWO, POD, Continued need/use, etc.
• Nutrients – Calorie, protein and lipid ranges spelled out
• Equipment and Supply Coverage
• DME Information Form (DIF)
• Coding Guidelines
• HCPCS Codes
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.”
More patients will now meet criteria for HPN under Medicare!

*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.”
Coverage for HEN under Medicare is about the same as it was

*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.
So, what does this really mean for patients?

- Instead of 10-12% of beneficiaries meeting criteria; 65-70% are now qualify for HPN!
- Will be easier to qualify beneficiaries who flip to Medicare (when they have been on PN with another payer)
- Should be much less time to review records at the time of referral/discharge

- If a patient needs HPN for a shorter period of time ie. less than 90 days, HPN still won’t be covered
- Other therapies like hydration, antibiotics are still not covered under straight Medicare
Continuing the advocacy work...

- What about moving PN/EN out of Prosthetic Device Benefit?
- Coverage for beneficiaries who have a shorter term need for PN or EN?
- Coverage for hydration therapy or antibiotics in the home!

Final PN and EN Local Coverage Determinations coming mid/late summer
Hoping for more positive changes/less paperwork for everyone!


CGS Administrators, LLC and Noridian Healthcare Solutions, LLC, Local Coverage Determination (LCD) Enteral Nutrition (L33783) Effective: 10/1/2015 Revision: 1/1/2020, Retirement Date: ANTICIPATED 11/12/2020

CGS Administrators, LLC and Noridian Healthcare Solutions, LLC, Local Coverage Determination (LCD) Parenteral Nutrition (L33798) Effective: 10/1/2015, Revision: 1/1/2020, Retirement Date: ANTICIPATED 11/12/2020

CGS Administrators, LLC and Noridian Healthcare Solutions, LLC, Local Coverage Article A52493- Enteral Nutrition- Policy Article, Effective 10/01/2015, Revised 1/01/2019, Retirement Date: ANTICIPATED 11/12/2020

CGS Administrators, LLC, and Noridian Healthcare Solutions, LLC, Local Coverage Article: Parenteral Nutrition - Policy Article A52515: Effective 10/01/2015, Revision 1/01/2020

CMS, National Coverage Determination (NCD) for Enteral and Parenteral Nutritional Therapy (180.2) – Effective 7/11/1984