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Medicare Coverage for Home Parenteral Nutrition: Policy Change After Almost Four Decades

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In November 2020, the Durable Medical Equipment Medicare Advisory Contractors retired the policies known as Local Coverage Determinations (LCDs) for home parenteral and enteral nutrition. On September 5, 2021, new LCDs take effect after almost four decades of no change or updates to home nutrition support coverage criteria for Medicare beneficiaries. This article briefly reviews the historical challenges of the retired parenteral nutrition (PN) policy and highlights what the new policy means, specifically for patients requiring PN support at home and the providers that care for them.

INTRODUCTION

"I am sorry, your patient does not meet the Medicare criteria for home parenteral nutrition", was a common refrain whenever physicians and case managers were trying to set up home parenteral nutrition for a Medicare beneficiary.

A number of publications, abstracts, and reports from national home parenteral nutrition (HPN) providers have documented that qualifying patients for HPN coverage under Medicare historically showed a success rate of < 15%, due to an outdated, now retired, parenteral nutrition (PN) policy or Local Coverage Determination (LCD).[1-4]

One of the first abstracts published in 2007 reported that only 16% of 133 Medicare HPN referrals received by a national infusion provider (with a large geographically and medically diverse sample) met the government's HPN policy requirements for coverage.[1] Almost 10 years later, a different national infusion provider with similar referral statistics demonstrated that even fewer Medicare beneficiaries (10.5% of 95) referred for HPN met the restrictive policy requirements, leaving few options for beneficiaries unless they had a secondary major medical insurance policy.[2] A third national infusion provider reported in 2019, that out of an estimated 400 Medicare PN referrals only 13% met criteria for HPN coverage,[3] with many unable to receive care due to lack of documentation and/or required testing, the same reasons reported by a separate PN provider in 2016.[4]

This article provides the clinician with an update of recent changes to Medicare HPN policy and a review of what is required for coverage as of September 5, 2021, when the new LCDs for PN and enteral nutrition (EN) were implemented by the Durable Medical Equipment Medicare Advisory Contractors (DME MACs).[5,6] After the former policies were retired in November 2020 and until the new LCDs were implemented September 5th, coverage was based on the longstanding 1984

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National Coverage Determination (NCD) focused on permanence and "reasonable and necessary" criteria, not the long list of tests and studies previously required. At least one national provider reports improved access to HPN for beneficiaries since the original LCDs retired (63% of 238 Medicare HPN referrals qualified for coverage November 12, 2020 through June 2021).[7] The new PN LCD is based on the premise of the original NCD language and the provisions of the Prosthetic Device Benefit, bringing hope for somewhat better access to HPN moving forward.

Whether a patient has Medicare or any other insurance provider, the recommendation stands that if there is a possibility that a patient may require HPN post discharge, the planning process should start immediately. The healthcare team and patient/beneficiary must be made aware of what is required to secure coverage and assure a safe transition to the home setting.

Background

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

For more than 35 years PN and EN therapies have been covered under the Prosthetic Device Benefit within the Part B Durable Medical Equipment and Prosthetics/Orthotics and Supplies (DMEPOS) benefit.[8]

> "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 analogy utilized by the Centers for Medicare and Medicaid Services or CMS, is that PN and EN via a tube and/or the devices to administer these therapies replace an organ or function of an organ that is permanently impaired, serving as a prosthesis. If an impairment of the gastrointestinal or "alimentary" tract as CMS refers to it, "permanently" (previously defined in the retired LCD as ≥ 3 months) prevents the patient from receiving nutrients into the GI tract (enteral) or absorbing nutrients from the GI tract (parenteral) to maintain weight and strength commensurate with health status; and this is documented and supported with objective data in the medical record, then Medicare may cover home PN or EN along with related accessories and/or supplies.

Highlights and History of Advocacy Efforts

Medicare PN policies have not kept up with clinical paradigms, best practices, and nationally accepted standards for the appropriate utilization of HPN.[9-11] Organizations including the American Society for Parenteral and Enteral Nutrition (ASPEN), the National Home Infusion Association (NHIA), and the Oley Foundation have lobbied CMS and the DME MACs for decades in an attempt to update and/or change the law in support of meaningful home infusion therapy benefits for Medicare beneficiaries.

CMS created the first and only National Coverage Determination (NCD) for PN and EN in 1984, the same year ASPEN organized a key group of members into a Public Policy/Advocacy Committee under the direction of the late Executive Director, Barney Sellers.[12]

In 2008 ASPEN regrouped and reorganized the mission of this Public Policy and Advocacy Committee, with the charge to set a new agenda and develop initiatives related to public policy and advocacy surrounding nutrition support. Efforts regarding HPN reimbursement and access to care at that time were focused on the Medicare Home Infusion Act in its various iterations, by appealing to Congress to pass legislation which would allow Medicare beneficiaries access to home infusion therapy, similar to all other payers.

This was done in partnership with NHIA and the Digestive Disease National Coalition (DDNC). Advocacy efforts to update HPN and HEN policies focusing on the "permanence" aspect of the Prosthetic Device Benefit were unsuccessful.

Current research backed by the European Society for Clinical Nutrition and Metabolism had been published with common indicators for HPN.[13] The consensus in the recommendations included the need for expert care, but not the need

Table 1. Possible Coverage Scenarios Under New PN LCD

If length of need for HPN is documented as "long term and indefinite" in the medical record (documentation should be as specific as possible), the following scenarios would now qualify for HPN, prior to 11/12/20 they would not have been covered.	
Sample GI PN Referral	Beneficiary has a diagnosis of short bowel syndrome and cannot be maintained on oral or enteral nutrition. Patient history and medical record support the lack of adequate functional small bowel to absorb nutrients to maintain weight and strength (i.e., high output, weight loss despite oral nutrient intake and PN is documented as reasonable and necessary).
Sample Oncology PN Referral	Beneficiary has a diagnosis of ovarian cancer and has a partial bowel obstruction which cannot be relieved with surgery or other treatment. Oral and/or enteral feeding is documented as not a possible option and PN is reasonable and necessary.
Sample Surgery PN Referral	Beneficiary has had bariatric surgery in the past, has documented long term GI complications from the surgery that preclude the use of oral or enteral feedings and PN is reasonable and necessary.

for HPN permanence. The "permanence" issue alone has created significant access challenges for decades for those patients who may require shorter courses of home therapy resulting in either lack of coverage for home PN or EN, or longer hospital stays to complete therapy at a much higher cost; with beneficiaries assuming they had home coverage through the Medicare system.[12]

In 2014 ASPEN surveyed physicians, healthcare providers, home infusion vendors and patients about how healthcare reform was affecting their ability to provide or access nutrition care. One major finding was that 72% of home care company respondents reported that they had to discharge patients from service because of insurance issues.[14] As a result of the survey, ASPEN partnered with NHIA to file a "Reconsideration to Policy" with the DME MACs to communicate updated clinical research related to restrictive aspects of the HPN criteria, and to provide recommendations for modifying the PN LCDs. Ongoing challenges for HPN coverage included:

- requiring a fecal fat test to prove malabsorption
- use of an albumin level as a marker of protein status, and
- mandating a tube feeding trial for "moderate abnormalities" including partial small bowel obstruction
- radiologic reports to prove "complete mechanical small bowel obstruction"

The reply from the DME MACs was that they saw no reason to change the coverage criteria in the previous PN LCD.

Five years later, the LCD Reconsideration Process - Medical Policy Article changed, allowing for greater transparency when Reconsiderations are filed.[15] This, together with a change in medical leadership within the DME MACs, prompted a renewed collaboration between NHIA and ASPEN to once again revisit an attempt to update the PN LCD, which has historically prevented 85-90% of Medicare beneficiaries from receiving "reasonable and necessary" HPN. A subcommittee of ASPEN subject matter experts convened, researched current literature to support changes to the PN LCD and a pre-Reconsideration hearing was scheduled for July 2020. A representative from both NHIA and ASPEN met with DME MAC medical directors and presented their recommendations.

As a result of that meeting, on October 8, 2020, the DME MACs released a statement that the existing LCDs for PN and EN were being retired effective November 12, 2020, "due to the evolution of clinical paradigms".[16]

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Table 2. Sample Medicare PN Qualifying Checklist – PN LCD Effective September 5, 2021

Considerations	Yes	No
1. Does the patient require home PN for a long and indefinite duration?		
◆ **Has this been documented clearly in the medical record by the treating practitioner prior to discharge?**		
2. Daily PN is considered reasonable and necessary for a patient with severe pathology of the alimentary (GI) tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition.		
◆ **Does the medical record provide clear documentation that supports this?**		
3. Has the treating practitioner documented in the medical record that enteral nutrition has been considered and ruled out, tried and been found ineffective, or that EN exacerbates gastrointestinal tract dysfunction?		
4. Does the home PN prescription provide 20–35 calories/kg/day?		
◆ **If NO:** has the treating practitioner documented in the medical record the medical necessity for a caloric intake outside this range?		
5. Does the home PN prescription provide 0.8–2.0 gm/kg/day of protein, dextrose concentration above 10%, and lipid use as prescribed in the FDA approved dosing information?		
◆ **If NO:** has the treating practitioner documented the medical necessity for protein orders outside of the range of 0.8–2.0 gm/kg/day, dextrose concentration less than 10%, or lipid use outside of the FDA approved dosing information?		

We Have New Policies for Coverage, but What Really HAS NOT Changed?

When the former PN and EN LCDs were retired in November, the DME MACs issued new Billing and Coding documents for each therapy [17,18] during the interim period of November 2020 through September 2021. These documents provided some of the same information previously included in the retired LCDs (billing codes, guidance for calories, protein, units of fat allowed, etc.). Early in 2021, the DME MACs drafted and posted new proposed PN and EN LCDs[19] and invited live and written commentary from providers. Many groups including ASPEN, NHIA, the Healthcare Nutrition Council, the Oley Foundation, and individual home PN and EN providers submitted comments in April 2021 which contributed to the final version of the new nutrition LCDs.

The original 1984 NCD remains the overarching general policy regarding coverage for HPN and HEN[8] at this time even with the new LCDs rolled out; however, there is current discussion regarding updating or retiring the 1984 NCD which contains some outdated information and language.

Criteria for HPN coverage moving forward remains based on the following two premises:

1. "Test of Permanence": PN and EN LCDs remain under the Prosthetic Device Benefit, so the "permanent impairment" of the gastrointestinal or "alimentary" tract criteria prevails i.e., permanence defined as "long and indefinite". In the new LCD, there is no defined timeframe as there was in the retired LCD where it stated, "ordinarily 3 months or longer". The treating practitioner must document an estimated length of need for PN or EN therapy in the medical record prior to discharge; if the medical judgment and medical record supports that PN therapy

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Table 3. Resources

- **Centers for Medicare & Medicaid Services**
  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**
  www.medicare.gov
- **Medicare National Coverage Determination Manual (NCD): Nutrition Part 3 Section 180**
  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/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

is for temporary or short-term utilization, then PN or EN therapy will not be covered. The prescriber should be as clear as possible documenting the estimated length of need, for example: 2 weeks, 2 months, 4 months, a year, lifetime etc. The length of need must be truthful and in the best judgment of the practitioner – even if it means there will be no coverage. The chart needs to support a prosthesis/permanent impairment of the GI tract, so if the patient only needs PN for 2 more weeks, 4-6 more weeks etc.? This is not a permanent impairment and would not be covered. With the new LCD, there is no specific timeframe stated to meet coverage—only that the chart needs to support the "long and indefinite" language and the permanent impairment.

2. The medical record must provide evidence that PN is "reasonable and necessary" as defined by CMS below:

> "*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".*[20]

There are no specifics for testing or evidence required in the new LCD other than documentation in the medical record must support the above policy statements. Clinicians need to fully document the patient diagnosis, indication and rationale for PN. In other words, clearly tell the story of what the disease process or diagnosis is, how it is affecting nutrient absorption, why does the patient require PN and how long will they need it at home (estimate as accurately as possible) – so that any non-clinician can understand. Medicare requires that therapy be

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Table 4. Frequently Asked Questions (FAQs)

1. **Does the length of need for PN mean combined hospital administered PN plus home PN?**

   No. The "Test of Permanence" criteria is pertaining to the length of need for home PN due to a permanent impairment. The medical record must provide documentation that the need for home PN is long and indefinite. The retired LCD defined this as "ordinarily greater than 3 months"; the new LCD does not provide a specific time frame.

2. **If a short bowel patient needs HPN for 5 days a week instead of 7, would this be covered?**

   The new LCD does not answer this question clearly. The guidance received from the DME MACs thus far suggests that the more detailed the documentation in the medical record to support a long and indefinite need for HPN to maintain weight and strength commensurate with the beneficiary's overall condition or status, the better the chance it will be covered.

3. **If the chart says enteral tube feeding is not possible, is HPN covered?**

   If all other parameters are met and there is a detailed description in the medical record that enteral therapy has been considered, tried and failed, or may exacerbate GI dysfunction, then HPN would be covered.

4. **If my patient has a partial bowel obstruction, would that be covered under the new LCD without a tube feeding trial?**

   Defer to the LCD language and the sample checklist provided. There is no mandated tube feeding trial any longer, however the chart must document that EN has been considered, tried and failed, or may exacerbate GI dysfunction. If the obstruction (partial or complete) is described as a functional impairment that is long term – example, if surgery is not scheduled anytime in the near future, then HPN would be covered.

5. **Does PN have to be started in the hospital?**

   At this time, the 1984 NCD states that PN must be initiated in the hospital. CMS is evaluating the need for the NCD in light of new LCDs launched on September 5, 2021. Guidance from the DME MACs currently is that they understand a number of aspects of the NCD are out of date, so if the documentation overall supports coverage, then starting PN at home should not be an issue.

"reasonable and necessary", and the record must reflect that there is a permanent impairment of the intestinal tract that is not allowing *absorption* of nutrients, this is the CMS definition of reasonable and necessary. For example, there would likely be no coverage of HPN for clinical situations where enteral therapy would be indicated such as upper GI cancers, neurological impairments, esophageal or gastric outlet obstructions. In these scenarios if there is functioning small bowel capable of absorbing nutrients, PN would probably not be covered.

What Has Changed?

1. More (not all) Medicare beneficiaries will have access to HPN (Table 1).
2. The new PN LCD opens with the premise that "When nutritional support other than

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the oral route is necessary, enteral nutrition (EN) is usually initially preferable to parenteral nutrition…" leading to a new documentation requirement from the treating practitioner stating that enteral nutrition has been considered and is not possible.

"For parenteral nutrition to be considered reasonable and necessary, the treating practitioner must document that enteral nutrition has been considered and ruled out, tried and been found ineffective, or that EN exacerbates gastrointestinal tract dysfunction".[20]

From the author: if a tube feeding failed or cannot be used because it is unsafe or inappropriate then documentation in the record should reflect that, so the prescriber should document in detail why enteral is not able to be used vs. just stating that it cannot be tried with no explanation.

Two case examples:

a. "Patient has ovarian cancer with a partial bowel obstruction due to carcinomatosis tumor burden. Enteral tube feeding is not possible at this time due to tumor involvement; it is estimated she will need PN for at least 4 more months."

b. "Patient has been trialed on an enteral formula, but the rate cannot be advanced beyond 30mL/hour without exacerbating nausea and vomiting. The patient will require PN for the next 3 months at least, and most probably, the rest of his/her life.

1. The *treating* practitioner (prescriber who made decision to initiate PN i.e., MD/NP/PA) is required to evaluate the beneficiary within 30 days of initiation of parenteral nutrition vs. prior to the initial certification or required recertification. (This was the language in the retired PN LCD). If the treating practitioner does not see the beneficiary within this timeframe, they must document the reason why and describe what other monitoring methods were used to evaluate the beneficiary's PN needs. There must be documentation in the medical record supporting the clinical diagnosis.[20]
2. The elimination of former Situations A-H in the retired LCD which mandated certain studies that were either outdated or not possible, such as:
   a. Use of albumin as marker of nutritional status (previously needed to be less than 3.4gm/dL)
   b. 72-hour fecal fat testing to prove malabsorption (most institutions do not prescribe 50-100gm fat diets and 72-hour quantitative stool collections to diagnose fat malabsorption)
   c. Mandatory trial of enteral feeding without an allowance for appropriateness or safety if the patient had a moderate abnormality.

Under the "Nutrient" section of the LCD, the protein and lipid ranges increased, which will decrease the amount of documentation required by the prescriber. The treating practitioner must document the medical necessity for protein orders outside the range of 0.8-2.0 gm/kg/day (formerly 0.8-1.5 gm/kg/day); dextrose concentration less than 10%; or lipid use per month in excess of the product-specific FDA-approved dosing recommendations (formerly a maximum of 1500 gm/month).[20] For example, if the dosing recommendation in the prescribing information (PI) for a lipid product says 1.0 gm/kg/day for adults, then a 70 kg patient could be prescribed up to 70 gm* lipid/day, or an 85 kg patient could receive 85 gm* lipid/day—without the prescriber having to document why the monthly total grams exceeds 1500.

*Series editor: = *350mL and 425mL 20% IV lipids respectively.*

When Planning a PN Discharge, What Should Providers be Aware Of?

The selection of HPN infusion providers who are knowledgeable and compliant with Medicare policies and federal laws can protect beneficiaries from financial hardship down the road. Some companies will accept Medicare HPN referrals quickly and without a thorough assessment, then later discontinue care when they learn there is no reimbursement because they do not have necessary documentation to meet coverage criteria, such as a length of need for home PN for a long

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and indefinite timeframe in the medical record or a permanent impairment of the GI tract that is not allowing nutrient absorption. If an infusion provider quickly accepts a Medicare HPN case without a complete review of documentation prior to discharge, it should be a red flag to the prescriber/referral source. Qualified reputable HPN providers should offer consultative guidance in the way of a "records review" or checklist of qualifying questions (Table 2) at the time of referral to help physicians navigate the complexity and changes to policy with the ultimate goal of protecting the patient.

During open enrollment time periods, physicians and HPN providers should guide patients to investigate all insurance options including Medicare Advantage or Replacement plans which may offer more meaningful benefits if a patient requires HPN or other home infusion therapies. Although not ideal, Medicare beneficiaries still have full coverage for PN in a skilled nursing facility (SNF), so if they do not have coverage because of a shorter length of need, the patient will have coverage for PN in the SNF setting.

CONCLUSION

After 35+ years, the restrictive, obsolete, and thankfully retired Medicare nutrition support policies have been somewhat updated. There is collective optimism for the receptiveness of the DME MACs to consider updated nutritional research, evidence-based science, current consensus papers, and clinical paradigms when making policy decisions.

With the NCD still serving as the overarching policy, advocacy efforts to either eliminate or update its language will continue, allowing more beneficiaries who need HPN to qualify for home coverage. Inherent restrictions of the Prosthetic Device Benefit will continue to restrict coverage for Medicare beneficiaries without a "permanent" impairment and until this requirement changes, some beneficiaries will require treatment in a much higher cost care setting or pay for therapy out of pocket.

All providers involved in the care of patients requiring home infusion, particularly HPN, should fully understand Medicare reimbursement regulations to advocate for better access to life sustaining home nutrition support without significant patient financial risk. For additional resources and information, see Table 3 and Table 4. ■

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