Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCNUT003B.0425	**NUTRITIONAL PRODUCTS TOTAL PARENTERAL NUTRITION (TPN)**
Effective Date: 6/1/2025	**Review/Revised Date**: 07/18, 07/19, 07/20, 10/20, 03/21, 03/22, 02/23, 03/24, 03/25 (ZJN)
Original Effective Date: 09/17	**P&T Committee Meeting Date**: 06/17, 08/18, 08/19, 08/20, 12/20, 04/21, 04/22, 04/23, 04/24, 04/25
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:
Medicare Part B – Local Coverage Determination L38953

POLICY CRITERIA:

COVERED USES: All Medically Accepted Indications

REQUIRED MEDICAL INFORMATION:

1. Documentation that the member has a medical condition which does not allow for absorption of sufficient nutrients to maintain weight and strength as defined by one of the following:
    a. A condition involving the small intestine and/or its exocrine glands which significantly impairs the absorption of nutrients, or
    b. A disease of the stomach and/or intestine which is a motility disorder and impairs the ability of nutrients to be transported through and absorbed by the gastrointestinal (GI) system

AND

2. Documentation that the condition is of long and indefinite duration as deemed by the judgment of the attending provider or substantiated in the medical records

AND

3. Documentation that enteral nutrition has been considered and ruled out, tried and been found ineffective, or that enteral nutrition exacerbates gastrointestinal tract dysfunction

AND

4. The treating provider has evaluated the member within 30 days prior to initiation of parenteral nutrition. If the treating provider 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 parenteral nutrition needs.

Reauthorization requires documentation of ongoing medical necessity of total parenteral nutrition.

EXCLUSION CRITERIA:
Parenteral nutritional therapies are not covered under Medicare Part B in situations involving temporary impairments. **Non-Part B uses may be coverable under the Part D benefit.**

AGE RESTRICTIONS: N/A

PRESCRIBER RESTRICTIONS: N/A

COVERAGE DURATION:
Authorization will be approved for a minimum three months, up to 12 months.

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:
Parenteral nutrition (PN) is the provision of nutritional requirements through a central or peripheral venous catheter. The purpose of initiating parenteral nutrition therapy is to prevent or correct specific nutrient deficiencies and the adverse effects of malnutrition when the gastrointestinal tract cannot be used safely or effectively. The PN benefit will include all related supplies, equipment, and nutrients. A skilled assessment of nutritional status will be done at a frequency consistent with the member's diagnosis and overall nutritional condition.

FDA APPROVED INDICATIONS: N/A

POSITION STATEMENT:
- Total parenteral nutrition (TPN) therapy is a covered benefit when determined to be medically necessary to prevent or treat malnutrition and nutritional needs that cannot be met by oral or enteral feedings. Parenteral nutrition will be covered

under the member's medical benefit. For Medicare members, coverage under the Part B benefit is for individuals with permanent dysfunction. Permanence does not require a determination that there is no possibility that the member's condition may improve sometime in the future. If the judgment of the doctor, substantiated in the medical record, the test of permanence is considered met. This is consistent with Center for Medicare and Medicaid Services (CMS) guidelines.

- TPN is not considered medically necessary for conscious patients whose need for parenteral nutrition is solely due to a lack of appetite or cognitive issues.
- Whenever clinically appropriate, attempts should be made to wean the patient off parenteral nutrition in favor of oral or enteral routes.
- The medical policy and criteria are developed based on Medicare and American Society for Parenteral and Enteral Nutrition (ASPEN) guidelines.
- Parenteral nutrition may be covered in patients with the ability to obtain partial nutrition from oral intake or a combination of oral/enteral intake as long as the above criteria are met.
- If coverage requirements for parenteral nutrition are met, medically necessary nutrients, administration supplies, and equipment are covered.
- Parenteral nutrition provided to a patient in a Part A covered stay must be billed by the skilled nursing facility (SNF). No payment from Part B is available when parenteral nutrition services are furnished to a beneficiary in a stay covered by Part A. However, if a beneficiary is in a stay not covered by Part A, parenteral nutrition is eligible for coverage under Part B and may be billed by either the SNF or a supplier.
- When parenteral nutrition is administered in an outpatient facility, the pump used for its administration and IV pole will be denied as not separately payable. The pump and pole are not considered as rentals to a single patient but rather as items of equipment used for multiple patients.
- Dispensing of nutritional therapy is limited to a one-month supply at a time.

Intradialytic Parenteral Nutrition and Intraperitoneal Nutrition[18-19]

- Intradialytic parenteral nutrition (IDPN) and intraperitoneal nutrition (IPN) are both methods of nutritional support for patients with end-stage renal disease (ESRD), but they differ in their administration and clinical indications.
    - Intradialytic parenteral nutrition (IDPN): a type of parenteral nutritional therapy administered to malnourished patients undergoing hemodialysis.
    - Intraperitoneal nutrition (IPN): a type of parenteral nutritional therapy administered to malnourished patients undergoing peritoneal dialysis.
- IDPN involves the infusion of a hyperalimentation formula, composed of amino acids, glucose, and lipids, during dialysis to treat protein-calorie malnutrition. IDPN is indicated for malnourished, non-critically ill hospitalized patients with acute kidney injury or chronic kidney disease (CKD) on hemodialysis, as well as for patients on chronic hemodialysis who require total parenteral nutrition (TPN)

due to inadequate oral intake, resulting in malnutrition. The solutions used for IDPN are similar to those used for TPN, with a typical formula containing 10% amino acids, 40% to 50% glucose, 10% to 20% lipids, or a mixture of carbohydrates and lipids, depending on the patient's needs. These solutions deliver approximately provides 500–1000 kcal and 50–100 g of amino acids in less than 1 L of volume per dialysis treatment. IDPN is administered during routine dialysis sessions, typically three times per week, eliminating the need for additional clinic visits, extended dialysis time, or extra lines.

- IPN is a form of parenteral nutrition injected into the peritoneal cavity during peritoneal dialysis. Unlike IDPN, IPN uses amino acids instead of dextrose as the osmotic agent during dialysis, or a combination of amino acids and glucose. Since IPN involves the administration of an amino acid–containing dialysate, it is also referred to as intraperitoneal amino acid (IPAA) therapy. The amino acids serve a dual purpose: they help cleanse the blood of toxins, aid in fluid removal by acting as an osmotic agent, and provide protein to replace the approximately 5–15 g of amino acids lost per day through the peritoneal membrane.
- Serum albumin concentration is commonly used to assess nutritional status in maintenance dialysis patients, although factors like hydration, inflammation, and liver disease can influence its levels. Low serum albumin is associated with higher mortality risk in dialysis patients. Specifically, in peritoneal dialysis (PD) patients, a baseline serum albumin level below 3.0 g/dL is linked to more than a 3-fold higher risk of all-cause and cardiovascular mortality, and a 3.4-fold higher risk of infection-related mortality compared to levels between 4.0–4.19 g/dL.

<u>Clinical guideline recommendations for IDPN:</u>

National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI)

- The 2020 KDOQI Guidelines recommend that patients may benefit from IDPN therapy if all of the following three criteria are met:
    - Evidence of protein-energy malnutrition and inadequate dietary protein and/or energy intake
    - Inability to administer tolerate adequate oral nutrition, including food supplements or enteral feeding
    - Protein and energy requirements can be met when IDPN is used in conjunction with oral intake or enteral feeding.
- Additionally, the 2020 KDOQI Guidelines recommend the following:
    - IDPN therapy should not be considered a long-term approach to nutritional support. It should be discontinued, and oral nutritional supplementation should be attempted as soon as improvements in nutritional status are observed, and the patient can use the oral or enteral route.

- If IDPN therapy in conjunction with oral intake does not achieve the nutritional requirements of the patient or the gastrointestinal tract is impaired, TPN given on a daily basis should be considered.

American Society for Parenteral and Enteral Nutrition (ASPEN)

- The 2010 Clinical Guideline does not recommend IDPN in malnourished CKD stage 5 hemodialysis patients due to lack of supporting data to reduce mortality (Grade C)
- The 2017 ASPEN Task Force Consensus Recommendations support initiation of IDPN when two of the following criteria is met:
  - Serum albumin concentration less than 3.5 g/dL
  - Evidence of protein malnutrition based on a normalized protein catabolic rate (less than 0.8 g/kg/d)
  - Energy intake less than 25 kcal/kg/d)
  - Weight loss equal to or greater than 10% ideal body weight over 3 months
  - Dysfunctional gastrointestinal tract
  - Inability to administer adequate EN especially if fluid limited
  - Inadequate weight gain over 1 month
- The 2017 ASPEN Task Force Consensus Recommendations suggest discontinuing IDPN if any of the following conditions exist:
  - Reasonable sustained improvement in nutritional parameters
  - Able to sustain weight and return to oral nutritional supplementation
  - Adverse effects are improved
  - Lack of improvement after 3 to 6 months of IDPN should also lead to discontinuation and consider TPN instead

<u>Clinical guideline recommendations for IPN/IPAA:</u>

- There is limited to no evidence for IPN, and limited evidence for IPAA.

National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI)

- IPAA should only be used if spontaneous protein and energy intakes in conjunction with IPAA are able to meet the required protein and energy targets. Otherwise, daily TPN or partial parenteral nutrition (PPN) should be considered.
- In adults with CKD 5D on PD with protein-energy wasting, we suggest not substituting conventional dextrose dialysate with amino acid dialysate as a general strategy to improve nutritional status, although it is reasonable to consider a trial of amino acid dialysate to improve and maintain nutritional status if nutritional requirements cannot be met with existing oral and enteral intake (OPINION).
- The effects of substituting amino acid dialysate for conventional dextrose dialysate on patient survival, hospitalization, other clinical outcomes, and QoL

have not been adequately evaluated. The long-term effect of IPAA therapy remains unclear.

Refeeding Syndrome

In malnourished patients, the aggressive delivery of calories, particularly carbohydrates, can induce refeeding syndrome. Refeeding syndrome involves an intracellular shift of magnesium, potassium, and phosphorus, which can lead to low serum levels of these electrolytes. Symptoms may include fatigue, arrhythmia, edema, muscle weakness, and lethargy. Patients at risk of refeeding syndrome should have their TPN or PPN initiated in an inpatient setting to allow for frequent monitoring of electrolytes and minimize the risk of adverse effects.

Patients at High Risk for Refeeding Syndrome
Anorexia nervosa
Chronic alcoholism
Morbid obesity with rapid weight loss (ex. Gastric bypass surgery)
Protein Calorie Malnutrition
> 10% weight loss over 2-3 months
Chronic malnutrition or starvation
Unfed for 7-10 days or evidence of underfeeding
Prolonged fasting (ex. Observance of Ramadan, NPO status, Clear liquid diet)
Prolonged IV hydration with NPO status
Wasting diseases (ex. Cancer, AIDS)

BILLING GUIDELINES AND CODING:

CODES◊	
Prior Authorization Required	
HCPCS Code	**Description**
B4164	Parenteral nutrition solution: carbohydrates(dextrose), 50% Dextrose or less (500 ml= 1unit), home mix
B4168	Parenteral nutrition solution; amino acid, 3.5%, (500 ml= 1unit), home mix
B4172	Parenteral nutrition solution; amino acid, 5.5% through 7%, (500 ml= 1unit), home mix
B4176	Parenteral nutrition solution; amino acid, 7% through 8.5%, (500 ml= 1unit), home mix
B4178	Parenteral nutrition solution; amino acid, greater than 8.5%, (500 ml= 1unit), home mix
B4180	Parenteral nutrition solution: carbohydrates(dextrose), greater than 50% Dextrose (500 ml= 1unit), home mix
B4185	Parenteral nutrition solution, per 10 grams lipids
B4187	Omegaven, 10 grams lipids

B4189	Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 10 to 51 g of protein, premix
B4193	Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 52 to 73 g of protein, premix
B4197	Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 74 to 100 grams of protein, premix
B4199	Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, over 100 grams of protein, premix
B4216	Parenteral nutrition; additives (vitamins, trace elements, Heparin, electrolytes), home mix, per day
B4220	Parenteral nutrition supply kit; premix, per day
B4222	Parenteral nutrition supply kit; home mix, per day
B4224	Parenteral nutrition administration kit, per day
B5000	Parenteral nutrition solution compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, renal- Aminosyn RF, NephrAmine, RenAmine - premix
B5100	Parenteral nutrition solution compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, hepatic, HepatAmine-premix
B5200	Parenteral nutrition solution compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength,stress-branch chain amino acids-FreAmine-HBC - premix
No Prior Authorization Required	
B9004	Parenteral nutrition infusion pump, portable
B9006	Parenteral nutrition infusion pump, stationary
B9999	NOC for parenteral supplies
E0776	IV Pole

HCPCS MODIFIERS:

BA	Item used in conjunction with parenteral enteral nutrition (PEN) services
EY	No physician or other health care provider order for this item or service
GA	Waiver of liability statement issued as required by payer policy, individual case
GY	Item or service statutorily excluded or doesn't meet the definition of any Medicare benefit category
GZ	Item or service expected to be denied as not reasonable and necessary

KX	Requirements specified in the medical policy have been met

◊ Coding/Administration Notes:
• The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
• HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCE/RESOURCES:

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2. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Enteral and Parenteral Nutritional Therapy (180.2). https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=242&ncdver=1&bc=AAAAQAAAAAAA (accessed March 7, 2024)
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