

# Pharmacy Utilization Management Policy Intradialytic Parenteral Nutrition (IDPN) Therapy

Line of Business: All lines of business P & T Approval Date: February 2, 2024

Effective Date: March 1, 2024

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the IEHP Pharmacy and Therapeutics Subcommittee.

#### **COVERAGE POLICY**

## **Initial Coverage criteria:**

- A. Dependent on hemodialysis; AND
- B. Diagnosis of unspecified severe protein-calorie malnutrition; AND
- C. Evidence of severe protein-calorie malnutrition as shown by serum albumin less than or equal to 3.4 g/dL in the past 4 weeks
- D. Documentation that nutritional counseling has been provided by a renal dietitian; AND
- E. Documentation that oral or enteral nutrition alone, including food supplements or tube feeding, is not sufficient to provide adequate protein nutrition; AND
- F. Documentation showing IDPN is vital for nutritional stability as determined by a nephrology specialist.

#### **Initial Approval Duration:** 3 months

## **Reauthorization Coverage Criteria:**

- A. Continuous dependence on hemodialysis; AND
- B. "1" of the following:
  - 1. Documented improvement in protein nutritional status as shown by positive trends in serum albumin levels; OR
  - 2. Documented clinical stability in protein nutrition.
- C. Cannot exceed 2 reauthorizations after initial approval without re-trial of oral or enteral nutrition.

#### **Reauthorization Approval Duration**

- Improvement: 6 months
- Clinical Stability: 3 months

## Discontinuation of IDPN may be reasonable if 1 (one) of the following criteria is met:

- A. Reasonable sustained improvement in protein and nutrition status as shown by the following:
  - 1. Serum albumin greater than > 4.0 g/dL; AND

- 2. Body mass index (BMI) greater than or equal to 18.5 kg/m2; OR
- B. Lack of improvement in protein and nutrition status after 6 months of IDPN therapy; OR
- C. Successful re-trial of oral or enteral nutrition.

#### **COVERAGE LIMITATION AND EXCLUSIONS**

- A. If beneficiary cannot tolerate any oral or enteral feeding and requires nutritional support, TPN is the appropriate therapy of choice. IDPN is not covered as a single therapy. Evidence that a beneficiary cannot tolerate oral or enteral feeding to maintain nutritional status is shown by ALL of the following:
  - 1. Unable to maintain nutritional status by modifying the nutrient composition of the oral or enteral diet (e.g., lactose free, gluten free, low in long chain triglycerides, substitution with medium chain triglycerides, provision of protein as peptides or amino acids, etc.)
  - 2. Unable to maintain nutritional status by 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.)

#### ADDITIONAL INFORMATION

Intradialytic Parenteral Nutrition (IDPN) is a form of partial parenteral nutrition administered during regularly dialysis sessions. Like Total Parenteral Nutrition (TPN), IDPN can provide infusion of nutrients including amino acids, dextrose, and lipids to aid in improving nutritional status. However, unlike TPN which utilizes infusion through a catheter, IDPN utilizes infusion through venous drip chamber of the dialysis circuit.

#### CLINICAL/REGULATORY RESOURCE

### A. CMS

1. The Centers for Medicare and Medicaid Services (CMS) provides information on authorization requirements for parenteral nutritional therapy. IDPN is included in a section which lists specific requirements regarding policy related to coverage of IDPN.

## B. Medi-Cal

- 1. No references available on IDPN in the Medi-Cal Provider Manual
- C. National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI)
  - 1. 2020 KDOQI Guidelines Update recommends patients may benefit from IDPN therapy if all of the following three criteria are met:
    - a. Evidence of protein-energy malnutrition and inadequate dietary protein and / or energy intake
    - b.Inability to administer tolerate adequate oral nutrition, including food supplements or enteral feeding.
    - c. Protein and energy requirements can be met when IDPN is used in conjunction with oral intake or enteral feeding.
  - 2. 2020 KDOQI Guidelines Update also recommend:

- a. IDPN therapy should not be considered as a long-term approach of nutritional support and should be discontinued, and oral nutritional supplementation should be attempted as soon as improvements in nutrition status are observed and patients can use oral or enteral route
- b.If IDPN therapy is used in conjunction with oral intake does not achieve nutritional requirements of the patient, or the gastrointestinal tract is malfunctioned, then total parenteral nutrition (TPN) given daily should be considered.
- D. American Society for Parenteral and Enteral Nutrition (ASPEN)
  - 2010 Clinical Guideline does not recommend IDPN in malnourished CKD stage V hemodialysis patients due to lack of supporting data to reduce mortality (Grade C)
  - 2. 2017 ASPEN Task Force Consensus Recommendations support initiation of IDPN when the "2" of the following criteria is met:
    - a. Serum albumin concentration less than 3.5 g/dL
    - b.Evidence of protein malnutrition based on a normalized protein catabolic rate (less than 0.8 g/kg/d)
    - c. Energy intake less than 25 kcal/kg/d)
    - d. Weight loss equal to or greater than 10% ideal body weight over 3 months
    - e. Dysfunctional gastrointestinal tract
    - f. Inability to administer adequate EN especially if fluid limited.
    - g.Inadequate weight gain over 1 month
  - 3. 2017 ASPEN Task Force Consensus Recommendations suggest stopping IDPN if any of the following:
    - a. Reasonable sustained improvement in nutritional parameters
    - b. Able to sustain weight and return to oral nutritional supplementation.
    - c. Adverse effects are improved.
    - d.Lack of improvement after 3 to 6 months of IDPN should also lead to discontinuation and consider TPN instead.

#### **DEFINITION OF TERMS**

- 1. End-Stage Renal Disease (ESRD) the last stage of chronic kidney disease where the kidney function has declined to the point that the kidneys can no longer function on their own.
- 2. Intradialytic Parenteral Nutrition (IDPN) A type of partial parenteral nutrition that is administered during hemodialysis via the dialysis tubing to provide nutritional support.
- 3. Parenteral Nutrition Intravenous administration of nutrition which may include protein, carbohydrate, fat, minerals, and electrolytes, vitamins and other trace elements for patients who cannot eat or absorb enough food through tube feeding formula or by mouth to maintain good nutrition.
- 4. Total Parenteral Nutrition (TPN) A type of parenteral nutrition that is administered via a central venous catheter to provide total nutritional support.

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- 4. European Society for Clinical Nutrition and Metabolism (ESPEN). ESPEN Guidelines on Parenteral Nutrition: Acute Renal Failure. Clinical Nutr. 2009; 28: 359-479.
- 5. Marsen TA, Beer J, and Mann H. Intradialytic parenteral nutrition in maintenance hemodialysis patients suffering from protein-energy wasting. Results of a multicenter, open, prospective randomized trial. Clinical Nutr. 2017; 36(1):101-117.
- National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI). KDOQI Clinical Practice Guidelines for Nutrition in Chronic Renal Failure (2000).
   <a href="http://kidneyfoundation.cachefly.net/professionals/KDOQI/guidelines\_nutrition/doqi\_nut\_html">http://kidneyfoundation.cachefly.net/professionals/KDOQI/guidelines\_nutrition/doqi\_nut\_html</a>. Accessed January 12, 2024.
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Change Control		
Date	Change	Author
01/12/2024	Update line of business to reflect all lines of business	SV
	Update reference to reflect currently active CMS LCD	
07/05/2023	Deletion of applicable HCPCS codes and CPT codes	SV
	Minor format updates	
07/11/2022	Updated references	TL
	Removed initial coverage criteria regarding weight	
	and BMI	
04/15/2021	Document Created	JM