Molina Clinical Policy
Intradialytic Parenteral Nutrition (IDPN) / Intraperitoneal Parenteral Nutrition (IPN): Policy No. 421

Last Approval: 10/09/2024
Next Review Due By: October 2025

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members.[1] References included were accurate at the time of policy approval and publication.

OVERVIEW

Protein-energy wasting (PEW) is a syndrome characterized by loss of muscle mass, decreased fat stores, and overall depletion of protein and energy reserves common in patients on hemodialysis for chronic kidney disease (CKD). The underlying pathophysiological mechanisms are multifactorial and include any combination of inadequate nutrition intake, chronic inflammation, hypercatabolism, comorbidities, insulin resistance, the dialysis procedure, and medications. A global meta-analysis of 90 studies on PEW incidence in patients on hemodialysis reported a median prevalence of 43%, making it a frequent syndrome in this patient group (Carrero et al. 2018). CKD patients with PEW have increased morbidity, mortality, and diminished quality of life. The gastrointestinal tract is the preferred route for nutritional intake, however if this is not possible, parenteral nutrition is an option. Intradialytic nutrition is a specialized form of parenteral nutrition administered to malnourished patients with CKD on dialysis. It consists of:

1. **Intradialytic parenteral nutrition (IDPN)**: a type of parenteral nutritional therapy administered to malnourished patients undergoing hemodialysis.
2. **Intraperitoneal nutrition (IPN):** a type of parenteral nutritional therapy administered to malnourished patients undergoing peritoneal dialysis.

IDPN is the infusion of hyperalimentation formula comprised of amino acids, glucose, and lipids, during dialysis to treat protein calorie malnutrition. IDPN is a therapeutic option for hemodialysis patients who are candidates for total parenteral nutrition (TPN) due to inadequate oral intake resulting in malnutrition. IDPN solutions are consistent with those used for TPN. A typical solution contains 10% amino acids, 40% to 50% glucose, 10% to 20% lipids, or a mixture of carbohydrate or lipids depending on patient needs and delivers approximately 800 to 1200 kcals. It is administered via the venous drip chamber during routine dialysis sessions three times per week, thus eliminating the need for additional clinic visits, extended dialysis time, or additional lines. **IPN** is parenteral nutrition injected into the peritoneal cavity during peritoneal dialysis.

Regulatory Status

The FDA does not regulate IDPN as a procedure; however, the FDA does regulate the equipment used for IDPN, which includes hemodialysis blood access devices and infusion pumps.

TPN solutions are compounded by a pharmacy from individual ingredients (such as dextrose, amino acids, and trace elements) into a finished product based on a prescription and do not require FDA approval through the new drug application process.

RELATED POLICIES

Enteral Nutrition: Policy No. 406

COVERAGE POLICY

Intradialytic nutrition, including IDPN or IPN, **may be considered medically necessary** when **ALL** the following criteria are met:

1. Member is candidate for TPN (i.e., nutritional status cannot be adequately maintained on oral or enteral feedings)
2. Member is on chronic dialysis with evidence of protein-energy wasting (PEW)
3. **ALL** the following documentation:
   a. Member cannot be sustained on oral or enteral feedings and requires intravenous nutrient infusion due to severe pathology of the alimentary tract
   b. Physical signs/symptoms, and test results clearly indicating severe pathology of the alimentary tract
   c. Dietary assessment, physical examination, and laboratory values indicative of PEW including but not limited to: biochemical criteria, progressive drop in BMI, reduced total body fat or weight loss, a decrease in muscle mass, low albumin, protein nitrogen appearance, and low protein or energy intakes
      Note: Progressive declines in body mass index (BMI), albumin, and protein nitrogen appearance may be suggestive of PEW. Preferably, each criterion should be documented at least three times, ideally two to four weeks apart (Bansal 2022).

Continuation of Therapy
Continuation of therapy may be authorized when Member has documented evidence of meeting **ALL** the following criteria:

1. Continuous dependence on dialysis
2. Positive clinical response to therapy
3. Member has NOT experienced a drug-related adverse event or toxicity associated with IDPN treatment

Discontinuation of Therapy
Discontinuation of IDPN or IPN may be reasonable if **ONE** of the following criteria is met:

1. Member tolerates adequate oral or enteral nutrition
2. Protein and/or nutrition status does not improve after 6 months on IDPN
3. Reasonable sustained improvement in protein and nutrition status as indicated by a serum albumin greater than **> 4.0 g/dL AND BMI greater than or equal to 18.5 kg/m^2**

Limitations and Exclusions
The following are considered **contraindications/exclusions** based on insufficient evidence:

1. Adverse clinical response (e.g., infections, metabolic decompensation of pre-existing diabetes mellitus)

The following are considered **experimental, investigational, and unproven** based on insufficient evidence:

1. Any indications other than those listed above
2. IDPN administered in addition to regularly planned TPN infusions unless given in lieu of their daily TPN
3. IDPN as an adjunct to hemodialysis in patients who would not otherwise be considered candidates for TPN
4. Acute kidney injury patients who do not have End Stage Kidney Disease
5. Specialized IDPN solutions (e.g., Proplete®) have purportedly been formulated to meet the needs of the hemodialysis patients who are protein malnourished or who consume adequate calories but insufficient protein.

IDPN specialized formulations have not been shown to be clinically superior to standard TPN formulations. There are currently no clinical studies in the published peer-reviewed medical literature that demonstrate the superiority of specialized IDPN preparations. It has not been demonstrated that using specialized solutions results in better outcomes (e.g., serum albumin levels) for dialysis patients in comparison to standard preparations.

NOTE: Coverage for specialized IDPN may be contingent on member's health benefit plan's definition of medical necessity. Medically Necessary/Medical Necessity may be defined as "*not more expensive than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that individual's illness, injury, or disease.*" Because there are different IDPN preparations, and one may be significantly more expensive than the other but not proven to be clinically superior, a more costly specialized IDPN solution may be considered not medically necessary under member's plan benefit.

DURATION OF APPROVAL: Initial authorization: 3 months; Continuation of treatment: 6 months.

PRESCRIBER REQUIREMENTS: Prescribed by, or in consultation with, nephrologist

QUANTITY LIMITATIONS: IDPN or IPN therapy should not be used as a long-term solution, it should be discontinued, and oral or enteral nutritional supplementation should begin when member tolerates (Ikizler et al. 2020).

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Systematic Reviews and Meta-Analyses

Anderson et al. (2019) published a systematic review that assessed the efficacy and adverse effects of IDPN for treating malnutrition in hemodialysis patients. Five RCTs and 6 comparative observational studies were included in the review (4 prospective and 2 retrospective). Clinically relevant improvements in individual indicators of nutrition status, global nutrition status, mortality, morbidity, hospitalization, and QOL were among the outcomes. Primary studies compared IDPN to oral supplements, dietary counseling, or standard care. The studies did not define usual care, which could include dietary counseling or oral supplements based on patient condition and physician recommendation. Except for one large retrospective cohort study (n=24196), the study sample sizes were small (ranging from 12 to 196). Malnutrition criteria varied across studies, with most using serum albumin of 3.5 g/dL or 4.0 g/dL along with at least one other predictor (weight loss, BMI, nutritional score or assessment). No studies compared IDPN to enteral nutrition. It was noted that IDPN did not improve patient mortality, hospitalization, or QOL compared to oral supplements and dietary counseling. Additionally, observational studies reported mixed results for IDPN compared to usual care for mortality, with results differing based on baseline serum albumin levels. The systematic review concluded that "IDPN does not appear to improve patient health or clinically important nutritional outcomes compared to the standard and recommended treatments of oral supplementation or dietary counseling." While the authors agree the limited evidence gives testament to IDPN's safety the authors further noted that "IDPN is recommended by guidelines for malnourished patients on hemodialysis who have not responded to nutritional counseling, oral, and/or enteral treatments. Nevertheless, despite the paucity of data indicating advantage over advised treatments, IDPN is frequently sought or utilized before beginning other forms of treatment."

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Hayes (2023) published a Health Technology Assessment (HTA) report titled *Intradialytic Parenteral Nutrition (IDPN) for End-Stage Renal Disease in Adults* assessed the efficacy and safety of IDPN for malnourished patients with CKD or ESRD receiving hemodialysis. Seven studies met the inclusion criteria for this report: 4 RCTs (Cano et al. 2007; Liu et al. 2016; Marsen et al. 2017; Thabet et al. 2017) and 3 retrospective comparative cohort studies (Capelli et al. 1994; Chertow et al. 1994; Hiroshige et al. 1998). In all studies, IDPN was given 3 times per week during hemodialysis treatments to malnourished ESRD patients with baseline serum albumin values less than 3.5 g/dL. Although IDPN treatment regimens varied between trials, they often comprised the standard components of protein, fat, and carbs. The duration of the treatment varied from 16 weeks to 1 year. IDPN was compared to oral supplements in 3 studies (Capelli et al. 1994; Cano et al. 2007; Liu et al. 2016), dietary/nutritional counseling in 2 studies (Hiroshige et al. 1998; Marsen et al. 2017), and usual/standard care in 2 studies (Chertow et al. 1994; Thabet et al. 2017). No studies

comparing IDPN to enteral tube feeding assistance were identified. The HTA concluded that IDPN is relatively safe and is related to improvements in baseline laboratory markers (serum albumin, serum prealbumin, creatinine), BMI/body weight, and death rates when compared to traditional therapy; however, benefits over traditional therapy were not found. The findings also reflect individual study limitations, heterogeneity in IDPN formulation trials, and unanswered questions about patient selection criteria for IDPN and long-term benefits.

Kittiskulnam et al. (2022) conducted a prospective open label randomized controlled trial comparing 18 participants who received IDPN and standard dietary counseling versus 20 participants in the control group who received intensive dietary counseling. Eligible participants were over 18 years of age, receiving maintenance hemodialysis for at least 3 months, having spontaneous dietary intake of energy ≥ 20 kilocalorie (kcal)/kilogram (kg)/day and protein intake ≥ 0.8 g/kg/day, unable to tolerate sufficient oral intake, and presence of PEW defined as at least two of the following criteria of serum albumin level ≤ 3.5 g/dL16,17, serum prealbumin ≤ 30 mg/dL18, mild to moderate malnutrition evaluated by 7-point subjective global assessment (SGA) in category B, or malnutrition inflammation score ≥ 5 points. The study was comprised of 3 intervention months followed by 3 intervention free months. The primary outcome was serum albumin level increase. The secondary outcomes were prealbumin serum changed, increased muscle mass, increased strength, composite nutritional scoring system, and biomarkers. The average baseline serum albumin level, spontaneous energy, and protein intake were 3.5 ± 0.3 g/dL, 21.3 ± 7.8 kcal/kg/day, and 0.9 ± 0.3 g/kg/day, respectively. After 3 months of IDPN supplementation, the mean serum albumin level increased by 0.3 (95% CI; 0.2–0.4) g/dL from baseline and was significantly higher in the IDPN compared with the control group (3.8 ± 0.2 vs 3.5 ± 0.3 g/dL, respectively, p = 0.01). Body weight was significantly increased from 59.3 ± 12.1 to 61.2 ± 11.9 kg after 3 months of IDPN treatment (p = 0.006) whereas it remained unchanged in the control group (from 55.4 ± 11.2 to 56.1 ± 11.4 kg, p = 0.22). After adjusting for baseline consumption, oral energy intake elevated by 281.2 (95% CI; 120.9—441.4, p = 0.001) kcal/day and protein intake increased by 8.0 (95% CI; 0.4 – 15.5, p = 0.04) g/day at 3 months in the IDPN group. In contrast, spontaneous energy intake was significantly reduced in the control group (from 1,206.8 ± 310.9 to 1,035.2 ± 233.4 kcal/day, p = 0.004). No adverse effects related to IDPN administration were reported.

There is a current clinical trial actively recruiting participants titled "*The Effect of Intradialytic Parenteral Nutrition on Nutritional Status and Quality of Life in Hemodialysis Patients*" [NCT04094038] that has an expected primary completion date of September 2023.

National and Specialty Organizations

American Society for Parenteral and Enteral Nutrition (ASPEN)
ASPEN guidelines state that IDPN alone should not be used as the sole nutrition intervention for malnourished CKD patients. IDPN is a supplemental nutrition intervention that can be used in patients when oral intake and/or EN interventions have failed or are insufficient to meet nutrition goals. Existing data suggest that IDPN is safe in certain patients and can improve weight, appetite, serum albumin levels, and survival in malnourished hemodialysis patients. More research is needed to determine which patient populations would benefit most from this intervention (ASPEN; Worthington et al. 2017).

2017 ASPEN Task Force Consensus Recommendations support initiation of IDPN when the TWO 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

2017 ASPEN Task Force Consensus Recommendations suggest discontinuing IDPN if any of the following conditions exist:

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.

National Kidney Foundation (NKF) / Kidney Disease Outcomes Quality Initiative (KDOQI)
The KDOQI *Clinical Practice Guidelines for Nutrition in Chronic Kidney Disease* (2020) guidelines, recommend that TPN or IDPN may be options to provide nutrients if the enteral route is inadequate. However, feeding through the gastrointestinal route should be preferred for as long as possible.

Global Recommendations

- 7A: Do not use IDPN as the sole source of nutrition intervention in malnourished patients with CKD.
- 7B: Consider IDPN for adult and pediatric patients with CKD who are malnourished and unable to tolerate adequate oral intake or EN.

The KDOQI also recommends that in adults with CKD with PEW, a trial of IDPN should be administered to patients with stage 5 CKD who are on maintenance hemodialysis (recommendation level 2C) to improve and maintain nutritional status if nutritional requirements cannot be met with existing oral and enteral intake (Ikizler et al. 2020).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
90935	Hemodialysis procedure with single evaluation by a physician or other qualified health care professional
90937	Hemodialysis procedure requiring repeated evaluation(s) with or without substantial revision of dialysis prescription
90945	Dialysis procedure other than hemodialysis (e.g., peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies), with single evaluation by a physician or other qualified health care professional
90947	Dialysis procedure other than hemodialysis (e.g., peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies) requiring repeated evaluations by a physician or other qualified health care professional, with or without substantial revision of dialysis prescription
90951	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month
90952	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month
90953	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month
90954	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month
90955	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month
90956	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month
90957	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month
90958	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month

90959	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month
90960	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 4 or more face-to-face visits by a physician or other qualified health care professional per month
90961	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 2-3 face-to-face visits by a physician or other qualified health care professional per month
90962	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 1 face-to-face visit by a physician or other qualified health care professional per month
90963	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents
90964	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents
90965	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents
90966	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older
90967	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients younger than 2 years of age
90968	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 2-11 years of age
90969	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 12-19 years of age
90970	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 20 years of age and older

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
B4164	Parenteral nutrition solution: carbohydrates (dextrose), 50% or less (500 ml = 1 unit) home mix
B4168	Parenteral nutrition solution; amino acid, 3.5%, (500 ml = 1 unit) home mix
B4172	Parenteral nutrition solution; amino acid, 5.5% through 7%, (500 ml = 1 unit) home mix
B4176	Parenteral nutrition solution; amino acid, 7% through 8.5%, (500 ml = 1 unit) home mix
B4178	Parenteral nutrition solution: amino acid, greater than 8.5% (500 ml = 1 unit) home mix
B4180	Parenteral nutrition solution; carbohydrates (dextrose), greater than 50% (500 ml = 1 unit) home mix
B4185	Parenteral nutrition solution, not otherwise specified, 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 grams 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 grams 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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/09/2024 Policy reviewed. No changes to coverage criteria. Summary of medical evidence and references updated.
10/12/2023 Policy reviewed. No changes to coverage criteria. Summary of medical evidence and references updated.
10/12/2022 New Policy. IRO Peer Review 8/22/2022 by a practicing physician board-certified in Nephrology.

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