
Medical Policy



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***Current Policy Effective Date: 1/1/24**
(See policy history boxes for previous effective dates)

Title: Intradialytic Parenteral Nutrition (IDPN)

PROTEIN CALORIE MALNUTRITION

Protein calorie malnutrition occurs in an estimated 25% to 40% of those undergoing dialysis. The cause of malnutrition in patients on dialysis is often multifactorial and may include underdialysis, chronic inflammation, protein loss in the dialysate solution (particularly in peritoneal dialysis), untreated metabolic acidosis and decreased oral intake.

Diagnosis

The clinical evaluation of malnutrition is multifactorial but typically includes measurement of serum albumin. Serum albumin levels correlate with nutritional status but are imperfect measures of nutrition because they can be affected by other disease states. Protein calorie malnutrition is associated with increased morbidity and mortality. For example, the risk of death is increased more than 10-fold in those whose serum albumin levels are less than 2.5 g/dL, and those with a serum albumin near the normal range (ie, 3.5 to 3.9 g/dL) have a mortality rate twice as high as those with albumin greater than 4.0 g/dL.

Treatment

For patients receiving chronic dialysis, the National Kidney Foundation currently recommends a daily protein intake of 1.2 g/kg in patients undergoing hemodialysis and 1.3 g/kg or more in patients undergoing peritoneal dialysis.¹ When malnutrition is present, a stepwise approach to treatment is generally used, beginning with dietary counseling and diet modifications, followed by oral nutrition supplements, and then by enteral nutrition supplements or parenteral nutritional supplements if needed.

Intradialytic parenteral nutrition (IDPN), which refers to the infusion of hyperalimentation fluids at the time of either hemodialysis or peritoneal dialysis, has been investigated as a technique to treat protein calorie malnutrition in an effort to decrease the associated morbidity and mortality. Intradialytic parenteral nutrition solutions are similar to those used for total parenteral nutrition (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. In hemodialysis, the IDPN

infusion is administered through the venous port of the dialysis tubing, typically, 30 minutes after dialysis has begun, and continued throughout the dialysis session.

Regulatory Status

Total parenteral nutrition solutions are compounded by an individual pharmacy from individual ingredients (eg, dextrose, amino acids, trace elements) into a finished medication based on a prescription and are not required to have approval from the U.S. Food and Drug Administration (FDA) through a new drug application process. Compounding pharmacies have historically been subject to regulation by state pharmacy boards, although FDA has increased its regulatory oversight with the Drug Quality and Security Act of 2013.

Peritoneal dialysis solutions are regulated as drugs by the FDA. One amino acid-based peritoneal dialysate, Nutrineal™ PD4, 1.1% Amino Acid Peritoneal Dialysis Solution (Baxter), is available commercially outside of the United States, but has not been FDA approved.

Medical Policy Statement

Intradialytic parenteral nutrition (IDPN) as an adjunct to hemodialysis may be considered established when it is offered as an alternative to a regularly scheduled regimen of total parenteral nutrition (TPN) only in individuals who would be considered candidates for TPN.

IDPN is considered not medically necessary in individuals who would be considered candidates for TPN, but for whom the IDPN is not offered as an alternative to TPN, but in addition to regularly scheduled infusions of TPN.

IDPN as an adjunct to hemodialysis is considered experimental/investigational in individuals who would not otherwise be considered candidates for TPN.

Inclusionary and Exclusionary Guidelines

Inclusions:

- Individuals who meet the criteria for TPN*; **AND**
- Are currently receiving regularly scheduled TPN; **AND**
- When it is given as an alternative to regularly scheduled TPN.

Exclusions:

- For individuals who are not candidates for TPN
- For an individual who is receiving or is a candidate for TPN, but for whom the IDPN is not offered as an alternative to TPN, but in addition to regularly scheduled infusions of TPN

*Individuals who are considered candidates for TPN are those who have a severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition.

This policy only addresses intravenous parenteral nutrition as an adjunct to hemodialysis (not peritoneal dialysis).

Note: Refer to JUMP policy Total Parenteral Nutrition for criteria for TPN.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

B4164-B5200 B9999

Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

For patients who qualify for total parenteral nutrition (TPN) and are concomitantly receiving hemodialysis, it is reasonable to administer intradialytic parenteral nutrition (IDPN) solution, which is similar to a total parenteral nutrition solution. Intradialytic parenteral nutrition is administered via the existing venous port of the dialysis tubing rather than through an alternative intravenous site. This evidence review focuses on studies evaluating whether intradialytic parenteral nutrition as an adjunct to hemodialysis improves outcomes for individuals who may be at risk for malnutrition but who would not otherwise receive parenteral nutrition.

INTRADIALYTIC PARENTERAL NUTRITION

Clinical Context and Therapy Purpose

The purpose of intradialytic parenteral nutrition in individuals who are undergoing hemodialysis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does intradialytic parenteral nutrition improve the net health outcome in individuals who are undergoing hemodialysis?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals who are undergoing hemodialysis.

The cause of malnutrition in individuals on dialysis is often multifactorial and may include underdialysis, chronic inflammation, protein loss in the dialysate solution (particularly in peritoneal dialysis), untreated metabolic acidosis, and decreased oral intake.

Interventions

The therapy being considered is intradialytic parenteral nutrition. Intradialytic parenteral nutrition is the infusion of an intravenous hyperalimentation formula, such as amino acids, glucose, and lipids, during dialysis, to treat protein calorie malnutrition.

Comparators

Relevant comparators are standard of care. When malnutrition is present, a stepwise approach to treatment is generally used, beginning with dietary counseling and diet modifications, followed by oral nutrition supplements, and then by enteral nutrition supplements or parenteral nutrition supplements if needed.

Outcomes

The general outcomes of interest are overall survival, change in disease status, morbid events, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

Systematic Reviews

A systematic review conducted for the U.S. Department of Veterans Affairs Evidence Synthesis Program was published in 2018 (Table 1).²The review addressed the effectiveness and adverse effects of IDPN for the treatment of malnutrition in hemodialysis patients (Table 1). The reviewers included 5 RCTs and 6 comparative observational studies (4 prospective and 2 retrospective). The reviewers also identified 3 systematic reviews but because they did not include a formal quality assessment of individual studies or did not include any relevant primary studies, these were used only to identify additional primary studies. Outcomes included clinically relevant improvements in individual indicators of nutrition status, global nutrition status, mortality, morbidity, hospitalization, and quality of life. Included primary studies compared IDPN to oral supplements, dietary counseling, or usual care. Usual care was not well-defined in the studies and could include dietary counseling or oral supplements based on patient condition and physician recommendation. The study sample sizes were small (range 12 to 196), with the exception of one large retrospective cohort study (n=24196). The criteria for malnutrition varied across the studies, with most using serum albumin of < 3.5 g/dL or < 4.0 g/dL along with at least one other predictor of malnutrition (weight loss, BMI, nutritional score or assessment). No studies compared intradialytic parenteral nutrition to enteral nutrition.

Table 1. Systematic Review Characteristics

Study	Dates	Studies	Participants	N (Range)	Design	Duration
Anderson et al (2018) ²	2009-2017	5 RCTs, 4 prospective cohort, 2 retrospective cohort	Mean age 65 years (37 to 80) Mean 50% male At least 6 months on dialysis prior to inclusion in study Mean serum albumin 3.77 g/dL (range 3.02 to 3.8 g/dL) BMI range 19.2 to 23.4 kg/m ² Race/ethnicity not reported	602 (12 to 196), excluding one large retrospective cohort study (N=24,196)	RCTs and observational studies	12 weeks to 2 years

RCT: randomized controlled trial; BMI: body mass index.

Compared to oral supplements and dietary counseling, IDPN did not improve the patient health outcomes mortality, hospitalization, or quality of life (Table 2). Observational studies found mixed results for intradialytic parenteral nutrition compared to usual care for mortality, with results differing based on baseline serum albumin levels. The effect of intradialytic parenteral nutrition on nutritional indicators also varied across comparisons and studies.

Table 2. Systematic Review Results

Study	IDPN vs Oral Supplement s: Mortality	IDPN vs Oral Supplements: Hospitalization	IDPN vs Oral Supplements: Quality of life	IDPN vs Oral Supplements: Nutritional Indicators	IDPN vs Dietary Counseling: Mortality	IDPN vs Dietary Counseling: Hospitalization	IDPN vs Dietary Counseling: Quality of life	IDPN vs Dietary Counseling: Nutritional Indicators	IDPN vs Usual Care: Mortality	IDPN vs Usual Care: Quality of life	IDPN vs Usual Care: Nutritional indicators
Anderson et al (2018) ²											
Evidence	1 RCT ³	1 RCT ³	1 RCT ³	2 RCTs, ^{3,4} 1 cohort study ⁵	1 RCT ⁶	1 RCT ⁶	1 RCT ⁶	1 RCT ⁶	3 cohort studies ^{5,7}	1 RCT ⁸	2 RCTs, ^{3,8} 3 cohort studies ^{5,7,9}
Total N (range)	186 (NA)	186 (NA)	186 (NA)	238 (20 to 186)	107 (NA)	107 (NA)	107 (NA)	107 (NA)	24,305 (28 to 24,196)	40 (NA)	347 (12 to 186)
Effect	43% vs 39%; P = NS	# days hospitalized/days followup: 0.008 vs 0.06 (P = NS)	No difference in Karnofsky score (data NR)	Mean change: SA (g/dl): 0.18 (P =.048) vs 0.28 (P =.17) Mean change: BMI: -0.10 (P = 0.87) vs -0.10 (P =.69) MAC: -1 (P =.09) vs 0.47 (P =.35) TSF: -0.43 (P = 0.5) vs 0.42 (P =.66)	26.4% (14/53) vs 12.9% (7/54) (P-value NR)	59.0% vs 43.2%, P =.1509	(SF-12) score change from baseline at 16 wks. -2.74 vs 0.34, P=.1175	Positive response to IDPN (≥ 30 mg/L increase in PA) 48.7% vs 31.8% at week 16 (P=.1164) Patients achieving > 15% increase from baseline at week 4, PA (mg/L):41% vs 20.5%, P=.0415 Improved SGA score by one grade: 20.5% vs 13.6%, P=.4037	Survival: RR = 1.34, P <.01 (Cox) Time to death (mo) for nonsurvivors: 16.9 vs 7.5, P <.01 OR death: (SA ≥ 4.0 g/dL & CRE > 8.0 mg/dL) = 2.6 (95% CI 1.34 - 5.04) SA ≤ 3.3 =0.72 (P <.01) SA ≤ 3.0 g/dL = 0.57 (95% CI 0.44 - 0.77) Mortality: 0% vs 27.8%, (P<.02)	No improvement in functional capacity (data NR)	No difference in change in SA or PA (data NR) No difference in change in BMI (data NR) Mean change: SA (g/dL) 0.93 (P =.001) vs -0.14 (P = 0.316) Mean change: BMI 2.8 (P =.001) vs 0.03 (P =.981) Mean change: MIS -8.75 (P =.001) vs 0.25 (P =.716)
Summary	No improvement	No improvement	No improvement	Variable effect with no improvement except serum albumin in a single study	No improvement	No improvement	No improvement	Variable effects on serum prealbumin No improvement in serum albumin or subjective global assessment	Variable effect on mortality; effect differs by baseline serum albumin level	No improvement	Variable effect, with improvement in at least one nutritional indicator

IDPN: intradialytic parenteral nutrition; RCT: randomized controlled trial; N: sample size; NA: not applicable; NS: nonsignificant; NR: not reported; SA: serum albumin; BMI: body mass index; OR: odds ratio; PA: serum prealbumin; SGA: subjective global assessment; RR: relative risk; CI: confidence interval; SF-12: 12-Item Short-Form Health Survey; TSF: tricep skin fold; MAC: mid-arm circumference.

The reviewers 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." They further concluded, "Although IDPN has not been explicitly studied in hemodialysis patients who have failed adequate trials of or are unable to receive dietary counseling, oral, and/or enteral tube feeding due to malfunctioning GI tract or other issues, since evidence - albeit limited - has not raised concerns about IDPN safety, we agree with existing guidelines that it appears reasonable to consider use of IDPN in this population."²

Randomized Controlled Trials

Five RCTs on IDPN were included in the systematic review conducted by Anderson et al (2018)² and are discussed above.

Section Summary

Published systematic reviews, which included randomized controlled trials but could not pool data, have concluded that the current evidence does not demonstrate benefits in patient outcomes with the use of intradialytic parenteral nutrition for those who would not otherwise qualify for total parenteral nutrition.

Summary of Evidence

For individuals who are undergoing hemodialysis who receive intradialytic parenteral nutrition, the evidence includes multiple RCTs, observational studies, and systematic reviews of these studies. Relevant outcomes are overall survival, change in disease status, morbid events, health status measures, quality of life, treatment-related mortality and morbidity. Published systematic reviews, which included RCTs but could not pool data, have concluded that the current evidence does not demonstrate benefits in patient outcomes with the use of IDPN for those who would not otherwise qualify for total parenteral nutrition. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Kidney Foundation

In 2001, the National Kidney Foundation clinical guidelines established target daily protein requirements in patients undergoing chronic dialysis.¹ In 2008, the National Kidney Foundation updated its pediatric nutrition guideline to recommend a trial of intradialytic parenteral nutrition to augment inadequate nutritional intake for malnourished children (body mass index for height and age <5th percentile) receiving maintenance hemodialysis who are unable to meet their nutritional requirements through oral and tube feeding.³

In 2020, in a joint effort with the Academy of Nutrition and Dietetics (Academy), the National Kidney Foundation updated its Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guideline for Nutrition in Chronic Kidney Disease (CKD). The Guideline 4 on Nutritional Supplementation (4.1.3) states that "In adults with CKD with protein-energy wasting, we suggest a trial of Total Parenteral Nutrition (TPN) for CKD 1-5 patients (2C) and intradialytic parenteral nutrition (IDPN) for CKD 5D on maintenance hemodialysis (MHD) patients (2C), to improve and maintain nutritional status if nutritional requirements cannot be met with existing oral and enteral intake."¹⁰ This statement was based on an evidence review of 3 studies published from 1989 to 2007 in individuals who were malnourished.^{7,11,12} Strength of evidence ratings were not provided.

American Society for Parenteral and Enteral Nutrition

In 2010, the American Society for Parenteral and Enteral Nutrition issued guidelines on nutrition support in adults in acute and chronic renal failure. The American Society for Parenteral and Enteral Nutrition assigned a level C recommendation (supported by at least 1 level II investigation) that intradialytic parenteral nutrition should not be used as a nutritional supplement in malnourished chronic kidney disease-V hemodialysis patients. The basis for the recommendation was a large randomized controlled trial that found that mortality rates did not differ between malnourished patients receiving IDPN versus malnourished patients receiving oral supplements without IDPN. An additional concern was that intradialytic parenteral nutrition “is limited by the need to complete the entire nutrient infusion during the hemodialysis” treatment, which may cause adverse effects because of the rapid infusion of glucose and lipids. The American Society for Parenteral and Enteral Nutrition further recommended larger RCTs “in malnourished patients to ensure that a clinical benefit of IDPN does not exist.”¹³

U.S. Preventive Services Task Force

Not applicable.

Ongoing and Unpublished Clinical Trials

One currently unpublished trial that might influence this review is listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT04094038	The Effect of Intradialytic Parenteral Nutrition on Nutritional Status and Quality of Life in Hemodialysis Patients	166	Sep 2023

NCT: national clinical trial

Government Regulations

National:

Medicare Policy/Benefit

The coverage eligibility of IDPN for Medicare beneficiaries is summarized in a Health Care Financing Administration (HCFA) ruling from December 1996, which established that intradialytic nutrition would be considered eligible for coverage only if the patient would otherwise be a candidate for total parenteral nutrition (TPN).^{14,15} This ruling reads in part:

“Medicare coverage policies which apply to parenteral and enteral nutrition therapy items and services apply identically to intradialytic parenteral nutrition therapy items and services, because intradialytic parenteral nutrition therapy is a subset of parenteral and enteral nutrition therapy.

Coverage of parenteral and enteral nutrition therapy is amplified in Medicare Coverage Issues manual section 65-10. Daily parenteral therapy 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.’ Intradialytic parenteral nutrition therapy is administered to end stage renal disease (ESRD) patients while they are receiving dialysis. ESRD patients

sometimes undergo parenteral therapy to replace fluids and nutrients lost during dialysis. ESRD patients must meet all of the parenteral nutrition therapy coverage requirements to receive intradialytic parenteral nutrition therapy. Those patients who do not meet all of the parenteral nutrition therapy coverage requirements are ineligible to receive Medicare coverage of intradialytic parenteral nutrition therapy under the prosthetic device benefit....”

The Health Care Financing Administration ruling clarifies benefits for patients who would be considered candidates for TPN and when the IDPN is designed to be offered in lieu of a regularly scheduled infusion of TPN.

“However, parenteral and enteral nutrition, including intradialytic parenteral nutrition therapy, services and items which are otherwise covered under section 1861(s)(8) can be denied under section 1862(a)(1) for lack of medical necessity: ... Example, if a Medicare beneficiary with ESRD, a dialysis patient who meets all of the requirements for coverage of parenteral nutrition therapy, receives intradialytic parenteral nutrition therapy during dialysis and also receives parenteral nutrition therapy on the other days of the week when the patient is not on dialysis, it may be determined that the patient is receiving an excessive number of lipids. A claim for Medicare payment that is denied because the patient, who qualifies for parenteral nutrition therapy coverage, is receiving an excessive number of lipids would be denied as not reasonable and necessary under section 1862(a)(1)(A) of the Act...

Therefore, the precise statutory basis for the coverage or denial of parenteral and enteral nutrition therapy, including intradialytic parenteral nutrition therapy, services and items is crucial and determinative as to whether or not limitation on liability protections can be applied.”

CMS Memorandum: IDPN/IPN Coverage Under Part D October 5, 2012

The purpose of this memorandum is to clarify Part D coverage of Intradialytic Parenteral Nutrition (IDPN) and Intraperitoneal Nutrition (IPN) provided to Medicare beneficiaries receiving renal dialysis services under the Medicare End Stage Renal Disease (ESRD) benefit. It is important that Part D sponsors understand which costs associated with these therapies are covered under Medicare Part B and which may be covered under Medicare Part D. Chapter 6, Appendix C of the Medicare Prescription Drug Benefit Manual states that Part B coverage for parenteral nutrition is limited to individuals with a non-functioning digestive tract. Therefore, for ESRD patients, IDPN or IPN coverage may be available under Medicare Part D. Medicare Part D coverage of these products is limited to the drug ingredients that meet the definition of a Part D drug, along with dispensing fee, and subject to the requirements in 42 CFR 423.120(d) pertaining to compounded drug products.

While Medicare Part D may cover the Part D drugs in IDPN and IPN, Medicare Part B covers outpatient maintenance dialysis treatments when they are provided to ESRD patients by an approved ESRD facility. Medicare Part B pays for outpatient maintenance dialysis via a prospective payment system (PPS) that combines Medicare payment for dialysis services with payment for ESRD-related drugs and laboratory tests. CMS published a final rule on August 12, 2010 (75 FR 49056) to establish the ESRD PPS. The bundle of services that are reflected in the ESRD PPS payment includes all services that prior to January 1, 2011 were considered to be composite rate services. Those services include: all personal services, equipment and supplies, administrative services, overhead costs, and ESRD-related laboratory tests and

biological. Directed nursing services include registered nurses, licensed practical nurses, technicians, social workers and dietitians. When an ESRD facility furnishes a non-ESRD drug, including IDPN or IPN, the staff time is already included in the ESRD PPS payment and, therefore, such costs should not be included in Part D payments.

IDPN is considered to be a Part D compound because dialysate is not included. There is Part D coverage for amino acids, dextrose, and lipids that meet the definition of Part D drugs. There is no Medicare coverage (under Part B or Part D) for ingredients such as sterile water, since non-covered drugs and other ingredients must be treated as general pharmacy overhead.

Local:

CGS Administrators, LLC – Local Coverage Determination (LCD): Parenteral Nutrition (L33798)

Original Effective Date 10/01/2015, Revision Effective Date 01/01/2020

Retirement Date 11/12/2020

CGS Administrators, LLC – Local Coverage Article: Parenteral Nutrition (A52515)

Original Effective Date 10/01/2015; Revision Effective Date 01/01/2020

Retirement Date 11/12/2020

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Total Parenteral Nutrition
Enteral Nutrition

References

1. Kopple JD. The National Kidney Foundation K/DOQI clinical practice guidelines for dietary protein intake for chronic dialysis patients. *Am J Kidney Dis.* 2001; 38(4 Suppl 1):S68-73. PMID 11576926
2. Anderson J, Peterson K, Bourne D, Boundy E. Evidence Brief: Use of Intradialytic Parenteral Nutrition (IDPN) to Treat Malnutrition in Hemodialysis Patients. VA ESP Project #09-199; 2018; <https://www.ncbi.nlm.nih.gov/books/NBK518608/> Accessed 8/4/23.
3. KDOQI Clinical Practice Guideline for Nutrition in Children with CKD: 2008 update. Executive summary. *Am J Kidney Dis.* 2009; 53(3 Suppl 2):S11-104. PMID 19231749
4. Liu, Y, Xiao, X, Qin, D, et al. Comparison of Intradialytic Parenteral Nutrition with Glucose or Amino Acid Mixtures in Maintenance Hemodialysis Patients. *Nutrients.* 2016 Jun 9;8(6). PMID 27271658.
5. Oguz, Y, Bulucu, F, Vural, A. Oral and parenteral essential amino acid therapy in malnourished hemodialysis patients. *Nephron.* 2001 Sep 11;89(2). PMID 11549907.

6. Capelli JP, Kushner H, Camiscioli TC, et al. Effect of intradialytic parenteral nutrition on mortality rates in end-stage renal disease care. *Am J Kidney Dis.* Jun 1994;23(6):808-816. PMID 8203363.
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8. Thabet, AF, Moeen, SM, Labiqe, MO, et al. Could intradialytic nutrition improve refractory anaemia in patients undergoing haemodialysis?. *J Ren Care.* Sep 2017;43(3). PMID 28636166.
9. Joannidis, M, Rauchenzauner, M, Leiner, B, et al. Effect of intradialytic parenteral nutrition in patients with malnutrition-inflammation complex syndrome on body weight, inflammation, serum lipids and adipocytokines: results from a pilot study. *Eur J Clin Nutr.* June 2008;62(6). PMID 17522619.
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11. Cano NJ, Fouque D, Roth H, et al. Intradialytic parenteral nutrition does not improve survival in malnourished hemodialysis patients: a 2-year multicenter, prospective, randomized study. *J Am Soc Nephrol.* Sep 2007; 18(9): 2583-91. PMID 17656473
12. Toigo G, Situlin R, Tamaro G, et al. Effect of intravenous supplementation of a new essential amino acid formulation in hemodialysis patients. *Kidney Int Suppl.* Nov 1989; 27: S278-81. PMID 2636671
13. Brown RO, Compher C, et al. A.S.P.E.N. clinical guidelines: nutrition support in adult acute and chronic renal failure. *JPEN J Parenter Enteral Nutr.* Jul-Aug 2010;34(4):366-377. PMID 20631382
14. Kopple JD, Foulks CJ, Piraino B et al. Proposed Health Care Financing Administration guidelines for reimbursement of enteral and parenteral nutrition. *Am J Kidney Dis.* Dec 1995; 26(6):995-997. PMID 7503076
15. Department of Health and Human Services, Health Care Financing Administration. HCFA Rulings. Ruling No.96-3. 1996; <https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/downloads/hcfar963.pdf>. Accessed 8/4/23.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 8/4/23, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
10/21/02	10/21/02	11/22/02	Joint policy established
11/1/04	11/1/04	11/1/04	Reviewed, updated references
3/8/06	3/8/06	4/14/06	Routine maintenance
3/1/08	Held	11/27/07	Routine maintenance
5/1/08	2/19/08	5/1/08	Code update
11/1/09	8/18/09	8/18/09	Routine maintenance
11/1/10	8/28/10	8/28/10	Routine maintenance
1/1/13	10/16/12	10/16/12	Routine maintenance; incorporated BCBSA description, rationale, and references.
3/1/14	12/10/13	1/6/14	Routine maintenance
1/1/15	10/21/14	11/20/14	Routine maintenance
11/1/15	8/24/15	9/14/15	Code update <ul style="list-style-type: none"> • Deleted L8499 • Added B4164-B5200, B9999 Updates to Background, Regulatory Status, Rationale and References
11/1/16	8/16/16	8/16/16	Routine maintenance
5/1/17	2/21/17	2/21/17	Routine maintenance
1/1/18	10/19/17	10/19/17	Routine maintenance Rationale and references updated
1/1/19	10/16/18	10/16/18	Routine maintenance
1/1/20	10/15/19		Routine maintenance
1/1/21	10/20/20		Routine maintenance
1/1/22	10/19/21		Routine maintenance
1/1/23	10/18/22		Routine maintenance (ls)
1/1/24	10/17/23		Routine maintenance (jf) Vendor Managed: NA Added ref: 10,11,12

Next Review Date: 4th Qtr, 2024

**BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: INTRADIALYTIC PARENTERAL NUTRITION**

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.