8.01.44	Intradialytic Parenteral Nutrition		
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Section:	8.0 Therapy	**Page:**	Page 1 of 14

Policy Statement

I. Intradialytic parenteral nutrition as an adjunct to hemodialysis may be considered **medically necessary** when it is offered as an alternative to a regularly scheduled regimen of total parenteral nutrition only in individuals who would be considered candidates for total parenteral nutrition (see Policy Guidelines).

II. Intradialytic parenteral nutrition is considered **investigational** in individuals who would be considered a candidate for total parenteral nutrition, but for whom intradialytic parenteral nutrition is not offered as an alternative to total parenteral nutrition, but in addition to regularly scheduled infusions to total parenteral nutrition.

III. Intradialytic parenteral nutrition as an adjunct to hemodialysis is considered **investigational** in individuals who would not otherwise be considered candidates for total parenteral nutrition.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Individuals who are considered candidates for total parenteral nutrition 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 their general condition.

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

Description

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 in an effort to decrease the morbidity and mortality experienced in patients with renal failure.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

Total parenteral nutrition solutions are compounded by an individual pharmacy from individual ingredients (e.g., 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 the FDA increased its regulatory oversight under the Drug Quality and Security Act of 2013.

Peritoneal dialysis solutions are regulated as drugs as defined 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 U. S., but has not been FDA approved.

Rationale

Background

Protein Calorie Malnutrition

Protein calorie malnutrition occurs in an estimated 25% to 40% of patients undergoing dialysis. The cause of malnutrition in patients on dialysis is often multifactorial and may include under dialysis, 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 (i.e., 3.5-3.9 g/dL) have a mortality rate twice as high as those with an albumin level greater than 4.0 g/dL.

Treatment

For patients receiving chronic dialysis, the National Kidney Foundation currently recommends a daily protein of 1.2 g/kg or more 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 nutrition supplements if needed.

Intradialytic parenteral nutrition, which refers to the infusion of hyperalimentation fluids at the time of hemodialysis or peritoneal dialysis, has been investigated as a technique to treat protein calorie malnutrition in an effort to decrease associated morbidity and mortality. Intradialytic parenteral nutrition solutions are similar to those used for total parenteral nutrition. 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 intradialytic parenteral nutrition infusion is administered through the venous port of the dialysis tubing, typically, 30 minutes after dialysis has begun, and continued throughout the dialysis session.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the 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 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 technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one 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 and are concomitantly receiving hemodialysis, it is reasonable to administer intradialytic parenteral nutrition 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

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).[2,] The review addressed the effectiveness and adverse effects of intradialytic parenteral nutrition for the treatment of malnutrition in hemodialysis patients (Table 1). The reviewers included five RCTs and six comparative observational studies (four prospective and two retrospective). The reviewers also identified three 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 intradialytic parenteral nutrition 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/m2 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, intradialytic parenteral nutrition did not improve the patient health outcomes mortality, hospitalization, or quality of life (See 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 Supplements: 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 (≥ 30mg/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	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	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)

Study	IDPN vs Oral Supplements: 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
								grade: 20.5% vs 13.6%, P =.4037	<.01) SA ≤ 3.0 g/dL = 0.57 (95% CI 0.44 - 0.77) Mortality: 0% vs 27.8%, (P <.02)		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 intradialytic parenteral nutrition 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.

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 guidelines 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 nutritional 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 one 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 mortality rates did not differ between malnourished patients receiving intradialytic parenteral nutrition and malnourished patients receiving oral supplements without intradialytic parenteral nutrition. 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 events because of the rapid infusion of glucose and lipids. The American Society for Parenteral and Enteral Nutrition further recommended larger randomized controlled trials "in malnourished patients are needed to ensure that a clinical benefit of IDPN does not exist."[13,]

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The coverage eligibility of intradialytic parenteral nutrition for Medicare beneficiaries was summarized in a 1996 Health Care Financing Administration ruling, which established that

intradialytic nutrition would be considered eligible for coverage only if the patient would otherwise be a candidate for total parenteral nutrition.[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.
>
> ... 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 went on to clarify the benefits for patients who would be considered candidates for total parenteral nutrition and when the intradialytic parenteral nutrition is to be offered in lieu of a regularly scheduled infusion of total parenteral nutrition.

> "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."

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
Ongoing			
NCT04094038	The Effect of Intradialytic Parenteral Nutrition on Nutritional Status and Quality of Life in Hemodialysis Patients	166	Sep 2023

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. Oct 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.hsrd.research.va.gov/publications/esp/idpn-supplemental.pdf. Accessed April 2, 2023.
3. KDOQI Work Group. KDOQI Clinical Practice Guideline for Nutrition in Children with CKD: 2008 update. Executive summary. Am J Kidney Dis. Mar 2009; 53(3 Suppl 2): S11-104. PMID 19231749
4. Liu Y, Xiao X, Qin DP, et al. Comparison of Intradialytic Parenteral Nutrition with Glucose or Amino Acid Mixtures in Maintenance Hemodialysis Patients. Nutrients. Jun 02 2016; 8(6). PMID 27271658
5. Oğuz Y, Bulucu F, Vural A. Oral and parenteral essential amino acid therapy in malnourished hemodialysis patients. Nephron. Oct 2001; 89(2): 224-7. 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): 808-16. PMID 8203363
7. Hiroshige K, Iwamoto M, Kabashima N, et al. Prolonged use of intradialysis parenteral nutrition in elderly malnourished chronic haemodialysis patients. Nephrol Dial Transplant. Aug 1998; 13(8): 2081-7. PMID 9719170
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): 183-191. 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. Jun 2008; 62(6): 789-95. PMID 17522619
10. Ikizler TA, Burrowes JD, Byham-Gray LD, et al; KDOQI Nutrition in CKD Guideline Work Group. KDOQI clinical practice guideline for nutrition in CKD: 2020 update. Am J Kidney Dis. 2020;76(3)(suppl 1):S1-S107
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, McClave S, et al. A.S.P.E.N. clinical guidelines: nutrition support in adult acute and chronic renal failure. JPEN J Parenter Enteral Nutr. 2010; 34(4): 366-77. 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): 995-7. 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 April 2, 2023.

Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Clinical findings (i.e., pertinent symptoms and duration)
  - Activity and functional limitations
  - Reason for procedure, when applicable
  - Prior conservative treatments, duration, and response
  - Treatment plan (i.e., surgical intervention) if applicable

Post Service (in addition to the above, please include the following):

- Procedure report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	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
	90940	Hemodialysis access flow study to determine blood flow in grafts and arteriovenous fistulae by an indicator method
	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,

Type	Code	Description
		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

Type	Code	Description
	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
	90999	Unlisted dialysis procedure, inpatient or outpatient
HCPCS	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 g lipids
	B4187	Omegaven, 10 g 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

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
07/01/2017	BCBSA Medical Policy adoption
07/01/2018	Policy revision without position change
08/01/2019	Policy revision without position change
07/01/2023	Policy reactivated. Previously archived from 07/01/2020 to 06/30/2023.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly 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 the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	**AFTER** Blue font: Verbiage Changes/Additions
Reactivated Policy **Policy Statement:** N/A	**Intradialytic Parenteral Nutrition 8.01.44** **Policy Statement:** I. Intradialytic parenteral nutrition as an adjunct to hemodialysis may be considered **medically necessary** when it is offered as an alternative to a regularly scheduled regimen of total parenteral nutrition only in individuals who would be considered candidates for total parenteral nutrition (see Policy Guidelines). II. Intradialytic parenteral nutrition is considered **investigational** in individuals who would be considered a candidate for total parenteral nutrition, but for whom intradialytic parenteral nutrition is not offered as an alternative to total parenteral nutrition, but in addition to regularly scheduled infusions to total parenteral nutrition. III. Intradialytic parenteral nutrition as an adjunct to hemodialysis is considered **investigational** in individuals who would not otherwise be considered candidates for total parenteral nutrition.