8.01.44	Intradialytic Parenteral Nutrition		
Original Policy Date:	July 1, 2017	**Effective Date:**	July 1, 2018
Section:	8.0 Therapy	**Page:**	Page 1 of 11

Policy Statement

Intradialytic parenteral nutrition (IDPN) 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 (TPN) only in patients who would be considered candidates for TPN (see Policy Guidelines).

IDPN is considered **not medically necessary** in patients who would be considered a candidate for TPN, but for whom IDPN is not offered as an alternative to TPN, but in addition to regularly scheduled infusions to TPN.

IDPN as an adjunct to hemodialysis is considered **investigational** in patients who would not otherwise be considered candidates for TPN.

Policy Guidelines

Patients 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 a patient's general condition.

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

Description

Intradialytic parenteral nutrition (IDPN) 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 United States, 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 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 (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 intake 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 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 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 (IDPN) solution, which is similar to a total parenteral nutrition solution. IPDN 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 IDPN 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

Systematic Reviews

Hotta (1993) published a review for the Agency for Healthcare Research that concluded existing studies of IDPN had reported equivocal results and the data did not validate its efficacy.[2] Subsequently, Foulks (1999) conducted on an evidenced-based evaluation of IDPN.[3] The analysis concluded that the overall quality of the literature was poor; although 3 RCTs were identified, one was excluded because it was a crossover study and assessed the feasibility of using the IDPN technique while the other two had methodologic flaws or used types of IDPN not routinely used or unavailable in the United States. The remaining literature consisted of case series, which cannot control for known and unknown prognostic factors that can affect study outcomes. According to Foulks's analysis, most case series had methodologic flaws, including heterogeneity in study designs, patient selection criteria, types of IDPN used, and adequacy of dialysis. Dukkipati et al (2010) conducted a systematic review of IDPN for the treatment of malnutrition in hemodialysis patients.[4] Reviewers identified 3 RCTs and found the data insufficient to conduct a meta-analysis or to demonstrate a net benefit in health outcomes with the use of IDPN. They concluded that further clinical trials on IDPN would be needed and should measure survival, quality of life, and nutritional status. Sigrist et al (2010) reported results from a systematic review of IDPN for patients with chronic kidney disease.[5] Reviewers evaluated RCTs and systematic reviews of RCTs that specifically enrolled malnourished patients on hemodialysis who had been randomized to IDPN (including full IDPN or amino acids plus carbohydrates only) or to any form of enteral or oral nutrition. Three studies met reviewers' inclusion criteria, only one of which reported mortality as an outcome. The data were insufficient to conduct a meta-analysis, and reviewers concluded that the evidence was insufficient to demonstrate either a net benefit or a net harm associated with the providing IDPN to malnourished hemodialysis patients.

Randomized Controlled Trials

Marsen et al (2017) reported on the results of an RCT assessing 107 patients on maintenance hemodialysis suffering from protein-energy wasting syndrome.[6] Patients were randomized to IDPN 3 times weekly plus standardized nutrition counseling or standardized nutrition counseling only. Patients were included if they were moderately or severely malnourished (Subjective Global Assessment score B or C) and had 2 or more of the following markers: albumin levels less than 35 g/L, prealbumin levels less than 250 mg/L, and phase angle alpha levels less than 4.5. The trial assessed intermediate outcomes (change in serum prealbumin from baseline to week 16). The proportion of patients that showed at least a 15% or more increase in prealbumin levels compared with baseline was higher in the IDPN group (41.0%) than in the control group at 16 weeks (20.5%; $p<0.05$), with sustained response thereafter. Quality of life scores, as measured by 12-Item Short-Form Health Survey, did not differ statistically between treatment arms.
Cano et al (2007) reported on the results of an RCT of 186 malnourished hemodialysis patients from 38 treatment centers in France. Patients were randomized to IDPN plus oral

supplementation or to oral supplementation alone (1 year of treatment with 2 years of follow-up).[7] Malnutrition was defined as the presence of 2 or more of the following markers: body mass index less than 20 kg/m^2, body weight loss within 6 months greater than 10%, serum albumin levels less than 35 g/L, and serum prealbumin levels less than 300 mg/L. Based on intention-to-treat analysis, no differences were found in 2-year survival, hospitalizations, Karnofsky Performance Status score, body mass index, and serum albumin and prealbumin levels between treatment groups. The trial was powered to detect a 10% reduction in mortality with 78% power (5% α error). Meeting the stated nutritional goals (orally or parenterally) might have improved outcomes; an editorialist suggested that both groups achieved about a 15% improvement in survival compared with historical controls.[8]

Nonrandomized Comparative Studies

Multiple nonrandomized studies published before the 2017 Marsen RCT reported on predictors of outcomes for patients treated with IDPN.[9-16] The largest study, by Chertow et al (1994), was a retrospective case series that compared morbidity rates in 1679 IDPN-treated patients with those of 22,517 untreated patients.[9] This series reported on patients with a serum albumin level of less than 3.4 g/dL who experienced a significant decrease in the odds ratio for death at 1 year compared with those who not treated using IDPN. The odds ratio for death increased for IDPN-treated patients who had an albumin level of greater than 3.4 mg/dL. Predictors of IDPN response were examined by Dezfuli et al (2009) in a study of 196 hypoalbuminemic patients receiving maintenance hemodialysis who underwent IDPN.[12] The study suggested that IDPN treatment could improve hypoalbuminemia in patients receiving maintenance hemodialysis and that the likelihood and magnitude of response to IDPN in these patients was associated with the baseline severity of hypoalbuminemia. Two other uncontrolled studies have also suggested improved outcomes associated with IDPN.[14,15] Because of the numerous biases inherent in any uncontrolled trial, these studies cannot validate whether IDPN is associated with lowered mortality rates. The observed treatment effect could have been related to a selection bias in which very ill patients (i.e., those expected to die) were not offered IDPN. In addition, IDPN administration might have been associated with an increased attentiveness to factors such as dialysis parameters, counseling, and nutritional advice These studies suggested that being selected for IDPN may be associated with reduced mortality rate, but analysis of the direct contribution of IDPN requires controlled trials.

Summary of Evidence

For individuals who are undergoing hemodialysis who receive IDPN, the evidence includes multiple RCTs and systematic reviews. Relevant outcomes are overall survival, change in disease status, morbid events, health status measures, quality of life, treatment-related mortality and morbidity. Findings from a well-conducted, adequately powered RCT designed to evaluate the effects of 1 year of IDPN plus oral supplements failed to show any incremental reductions in mortality or hospitalization rates at 2 years compared with oral supplements alone. Other smaller RCTs have assessed the impact of IDPN on nutritional or inflammation outcomes, rather than the more important outcomes of morbidity, mortality, and quality of life. Limitations of these smaller RCTs include inadequate power to demonstrate benefits and heterogeneity in the trial patient populations resulting from variation in diagnostic criteria for protein-energy wasting, comorbid conditions, dialysis practices, and composition and doses of IDPN solutions. Published systematic reviews, which included RCTs but could not pool data, have also 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 TPN. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information
Practice Guidelines and Position Statements

National Kidney Foundation

National Kidney Foundation clinical guidelines (2001) established target daily protein requirements in patients undergoing chronic dialysis.[1] In 2008, the Foundation updated its

pediatric nutrition guidelines to recommend a trial of intradialytic parenteral nutrition (IDPN) 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.[17]

American Society for Parenteral and Enteral Nutrition

The American Society for Parenteral and Enteral Nutrition (ASPEN) issued guidelines (2010) on nutritional support in adults in acute and chronic renal failure. ASPEN assigned a level C recommendation (supported by at least 1 level II investigation) that IDPN 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 IDPN and malnourished patients receiving oral supplements without IDPN. An additional concern was that IDPN "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. ASPEN further recommended larger randomized controlled trials "in malnourished patients are needed to ensure that a clinical benefit of IDPN does not exist."[18]

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The coverage eligibility of IDPN 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.[19,20] 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 IDPN 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

A search of ClinicalTrials.gov in April 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

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Documentation for Clinical Review

Please provide the following documentation (if/when requested):

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

Post Service

- 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. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

MN/IE

The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

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),

Type	Code	Description
		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

Type	Code	Description
	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	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, per 10 grams lipids
	B4189	Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 10 to 51 g of protein, premix
	B4193	Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 52 to 73 g of protein, premix
	B4197	Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements and vitamins, including preparation, any strength, 74 to 100 grams of protein - premix
	B4199	Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements and vitamins,

Type	Code	Description
		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 - Amirosyn 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
ICD-10 Procedure	3E0336Z	Introduction of Nutritional Substance into Peripheral Vein, Percutaneous Approach
	3E0436Z	Introduction of Nutritional Substance into Central Vein, Percutaneous Approach
	3E0536Z	Introduction of Nutritional Substance into Peripheral Artery, Percutaneous Approach
	3E0636Z	Introduction of Nutritional Substance into Central Artery, Percutaneous Approach
	3E1M39Z	Irrigation of Peritoneal Cavity using Dialysate, Percutaneous Approach

Policy History

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

Effective Date	Action	Reason
07/01/2017	BCBSA Medical Policy adoption	Medical Policy Committee
07/01/2018	Policy revision without position change	Medical Policy Committee

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

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 (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. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

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.