

7.01.72	Percutaneous Intradiscal Electrothermal Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty	
Section 7.0 Surgery	Effective Date September 30, 2014	
Subsection	Original Policy Date June 6, 1999	Next Review Date September 2015

Description

Intradiscal annuloplasty therapies use energy sources to thermally treat discogenic low back pain arising from annular tears. Thermal annuloplasty techniques are designed to decrease pain arising from the annulus and enhance its structural integrity.

Related Policies

- Automated Percutaneous and Endoscopic Discectomy, Laser Discectomy and Nucleoplasty

Policy

Percutaneous annuloplasty (e.g., intradiscal electrothermal annuloplasty, percutaneous intradiscal radiofrequency thermocoagulation, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain is considered **investigational**.

Policy Guidelines

Intradiscal electrothermal therapy may be requested through a pain management clinic.

Coding

Fluoroscopy CPT codes are considered inclusive of CPT code 22526 (percutaneous intradiscal electrothermal annuloplasty (IDET™) unilateral or bilateral including fluoroscopic guidance; single level) and 22527 (1 or more additional levels (List separately in addition to code for primary procedure)).

Discography

- Discography may be performed at several levels to determine the location of the pathogenic disc.

The following CPT codes have been used to describe the initial discography procedure:

- 72295: Discography, lumbar, radiological supervision and interpretation
- 62290: Injection procedure for discography, each level: lumbar

- 72285: Discography, cervical or thoracic, radiological supervision and interpretation
- 62291: Injection procedure for discography, each level: cervical or thoracic

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)) prohibit 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.

Rationale

Background

It has been proposed that heat-induced denaturation of collagen fibers in the annular lamellae may stabilize the disc and potentially seal annular fissures and that pain reduction may occur through the thermal coagulation of nociceptors in the outer annulus.

With the intradiscal electrothermal annuloplasty procedure (IDET™, Oratec SpineCath System), a navigable catheter with an embedded thermal resistive coil is inserted posterolaterally into the disc annulus or nucleus. The catheter is then snaked through the disc circuitously to return posteriorly. Using indirect radiofrequency (RF) energy, electrothermal heat is generated within the thermal resistive coil at a temperature of 90 degrees centigrade; the disc material is heated for up to 20 minutes. Proposed advantages of indirect electrothermal delivery of RF energy with IDET™ include precise temperature feedback and control and the ability to provide electrothermocoagulation to a broader tissue segment than would be allowed with a direct RF needle.

Another procedure, referred to as percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), uses direct application of RF energy. With PIRFT, the RF probe is placed into the center of the disc, and the device is activated for only 90 seconds at a temperature of 70 degrees centigrade. The procedure is not designed to coagulate, burn, or ablate tissue. The Radionics RF Disc Catheter System has been specifically designed for this purpose.

A more recently developed annuloplasty procedure, referred to as intradiscal biacuplasty (Baylis Medical, Inc., Montreal, Canada) involves the use of 2 cooled RF electrodes placed on the posterolateral sides of the intervertebral annulus fibrosus. It is believed that by cooling the probes, a larger area may be treated than could occur with a regular needle probe.

Annuloplasty using a laser-assisted spinal endoscopy kit to coagulate the disc granulation tissue (percutaneous endoscopic laser annuloplasty) has also been described.

Regulatory Status

IDET™, Oratec Nucleotomy Catheter, received marketing clearance through FDA's 510(k) process in 2002. The predicate device was the SpineCATH® Intradiscal Catheter, which received FDA clearance for marketing in 1999. Radionics (Burlington, MA - a division of Tyco Healthcare group) RF (Radiofrequency) Disc Catheter System received marketing clearance through FDA's 510(k) process in 2000. Valleylab (Boulder, CO - another division of Tyco Healthcare) is marketing the DiscTRODE™ RF catheter electrode system for use with the RFG-3CPlus™ RF lesion generator in the U.S. FDA product code: GEI.

The Baylis Pain Management Cooled Probe received marketing clearance through FDA's 510(k) process in 2005. It is intended for use "in conjunction with the Radio Frequency Generator to create radiofrequency lesions in nervous tissue."

Note: This policy does not address DISC Nucleoplasty™, a technique based on a device offered by ArthroCare (Austin, TX). With the ArthroCare system, a bipolar RF device is used to provide lower energy treatment (Coblation®) to the intervertebral disc, which is designed to provide tissue removal with minimal thermal damage to collateral tissue. DISC Nucleoplasty is closer in concept to a laser discectomy in that tissue is removed or ablated in an effort to provide decompression of a bulging disc. DISC Nucleoplasty and laser discectomy are considered separately in the Blue Shield of California Medical Policy: Automated Percutaneous and Endoscopic Discectomy, Laser Discectomy and Nucleoplasty

This policy is based in part on TEC Assessments from 2002 and 2003. (1, 2) As with any therapy for pain, a placebo effect is anticipated, and thus randomized placebo-controlled trials are necessary to investigate the extent of the placebo effect and to determine whether any improvement with annuloplasty exceeds that associated with a placebo. Therefore, evidence reviewed for this policy focuses on randomized controlled trials (RCTs).

Systematic Reviews. A 2013 review of the evidence for American Society of Interventional Pain Physicians guidelines found limited to fair evidence for intradiscal electrothermal annuloplasty (IDET) and biacuplasty and limited evidence for percutaneous intradiscal radiofrequency thermocoagulation (PIRFT). (3) Based on the evidence of 1 positive randomized trial performed by Pauza et al. (2004) and 4 positive observational studies that met the inclusion criteria, and negative evidence from another randomized trial that they considered to be flawed, performed by Freeman et al. (2005), and an observational study, the review concluded that evidence for IDET is fair. They identified 1 randomized trial by Kapural and Mekhail (2007) for biacuplasty that showed modest benefits. The single study evaluating PIRFT performed by Kvarstein et al. (2009) (sections that follow further describe all of these studies), showed no benefit from the procedure.

In 2007, a systematic review of IDET and PIRFT was published that followed the criteria recommended by the Cochrane Back Review Group. (4) Four randomized and 2 nonrandomized studies, totaling 283 patients, were included in the review (key studies are described next). A 2012 systematic review by some of the same authors identified 3 RCTs and 1 observational study that met their criteria on thermal annular procedures. (5) No new controlled trials were identified. The included evidence was found to be fair for IDET and poor for discTRODE and biacuplasty procedures regarding whether they are effective in relieving discogenic low back pain. Of the 2 randomized studies that evaluated IDET, (6, 7) 1 showed weak evidence of effectiveness, and the other, which reported no improvement in either the active or sham treatment group, was rejected for

methodologic shortcomings. The single randomized trial with the discTRODE device that was included in the review was considered to be a high-quality study that showed lack of efficacy. (8) There were no high-quality studies that evaluated the efficacy of biacuplasty, although it was noted that this procedure is being investigated in 2 ongoing RCTs.

A number of other systematic reviews that focused on related issues have come to various and different conclusions about the efficacy of these procedures. (9-11) Freeman and Mehdiian (2008) reported that the evidence for IDET was mixed and that the evidence showed that PIRFT was ineffective for discogenic back pain. (9) Levin (2009) concluded that IDET was modestly effective for discogenic pain in carefully selected patients. (10) Helm et al. (2009) concluded that the literature was limited, but supported that IDET led to significant benefit in approximately half of appropriately chosen patients and that there was minimal evidence for the efficacy of intradiscal biacuplasty. (11)

An industry-funded meta-analysis and systematic review were published that support the use of IDET. (12, 13) However, the quality of the studies included in these reviews was poor; 14 of the 18 studies reviewed did not have appropriate controls.

Percutaneous Intradiscal Electrothermal Annuloplasty (IDET™)

Randomized Controlled Trials (RCTs). Pauza et al. (2004) published the results of a RCT, (6) which was the focus of discussion in the 2003 TEC Assessment. The study included 64 patients with low back pain of greater than 6 months' duration who were randomly assigned to receive either percutaneous Intradiscal electrothermal annuloplasty (IDET™) or a sham procedure. Visual analog scale (VAS) pain was reduced by an average of 2.4 cm in the IDET group, compared with 1.1 cm in the sham group, a significant difference between groups ($p=0.045$). The mean change in the Oswestry Disability Scale (ODS) was also significantly greater for the IDET group compared with the sham group. The improvement on the Short Form (SF)-36 Bodily Pain subscale was nearly significantly higher for the IDET group. The study also reported the percentage with a change in VAS of more than 2.0 cm, which is greater than the minimally clinically significant improvement of 1.8 to 1.9. When the VAS is dichotomized in this way, a relative risk of 1.5 is observed with a 95% confidence interval (CI) of 0.82 to 2.74. In summary, the Pauza et al. (2004) trial is well- designed with respect to randomization, clear description of intervention, and use of valid and reliable outcomes measures. However, this single-center trial does not permit conclusions about the relative effects of IDET and placebo, and it is unclear whether IDET achieves clinically and statistically significant improvements in measures of pain, disability, and quality of life.

An industry-sponsored double-blinded, sham-controlled trial RCT was published by Freeman et al. (2005). (7) This trial enrolled patients with chronic discogenic low back pain, marked functional disability, magnetic resonance imaging evidence of degenerative disc disease, and failure of conservative management. Both the active IDET and sham groups had an intradiscal catheter that was navigated to cover at least 75% of the posterior annulus. Planned enrollment based on power analysis was for 75 patients; however, the trial was stopped early due to slower than expected recruitment after 57 patients (38 IDET, 19 placebo) had been enrolled. Follow-up was for 6 months, and the outcome measure was successful treatment response, as defined by all of the following: 1) no neurologic deficit; 2) an increase on the Low Back Outcome Score (LBOS) of at least 7 points; and 3) improvements in the SF-36 physical functioning and bodily pain scales of at least 1 standard deviation. No subject in either group achieved a successful treatment response, and IDET™ was no more effective than sham

stimulation on any of the outcomes. Outcomes were similar between the IDET and sham groups on the LBOS (38.31 vs. 37.45), ODI (39.77 vs. 41.58), SF-36 subscales (35.10 vs. 30.40), the Zung Depression Index (41.39 vs. 40.82), and the Modified Somatic Perception Questionnaire (8.67 vs. 8.67, IDET vs. sham, all respectively). None of the subgroup analyses showed statistically or clinically significant differences in the study outcomes. There were no serious adverse events reported in either group.

Non-randomized Trials. In a controlled study by Kapural et al. (2005) comparison of 21 electrothermal (IDET) and 21 radiofrequency (RF) procedures found significant improvements in most IDET patients but not in matched RF-treated patients at 1-year follow-up; the study did not have a placebo-control group. (14)

Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT)

There is relatively minimal published data on percutaneous intradiscal radiofrequency thermocoagulation (PIRFT). Barendse et al. (2001) reported on a double-blind trial that randomly assigned 28 patients with chronic low back pain to undergo PIRFT or to a sham control group. (15) The primary outcome was the percentage of success at 8 weeks, as measured by changes in pain level, impairment, ODS, and analgesics taken. At the end of 8 weeks, there were 2 treatment successes in the sham group compared with 1 in the treatment group. The authors concluded that PIRFT was not better than the placebo procedure in reducing pain and disability.

Kvarstein et al. (2009) published 12-month follow-up from an RCT of intra-annular RF thermal disc therapy using the discTRODE™ probe from Radionics. (8) Recruitment was discontinued when blinded interim analysis of the first 20 patients showed no trend toward overall effect or difference in pain intensity between active and sham treatment at 6 months. At 12 months, there was a reduction from baseline pain but no significant difference between the 2 groups. Two patients from each group reported an increase in pain. Although this controlled study did not find evidence for a benefit of PIRFT, it may not have been powered to detect a small or moderate effect of the procedure.

Biacuplasty

Randomized Controlled Trials (RCTs). Kapural et al. (2013) have published several articles on the use of transdiscal RF annuloplasty using 2 transdiscal probes (biacuplasty); including a 2013 industry-sponsored small Phase I double-blind RCT (NCT00750191). (16) Of 1894 patients who were screened, 1771 (94%) did not meet inclusion criteria. Sixty-four subjects were consented and enrolled in the study. Outcome measures were the SF-36 physical functioning subscore (0-100), the numerical rating scale (NRS) for pain (0-10), and the ODI (0-100). There were no significant differences between the groups at 1 month or 3 months. At 6 months, the biacuplasty group showed a significantly greater change from baseline for the SF-36 (15.0 vs. 2.63), NRS (-2.19 vs. -0.64), and ODI (-7.43 vs. 0.53). Mean SF-36 and NRS scores were considered to be clinically significant, but mean ODI scores did not achieve the minimally important difference of 10 points. With clinical success defined post-hoc as a 15-point increase in physical function together with a greater than 2 point decrease in pain, 30% of biacuplasty patients and 3% of sham-treated patients were considered successful. There was no significant difference in opioid use between the 2 groups.

Observational Studies. Kapural et al. (2007) published a case report of biacuplasty, which they reported to be the first publication with this procedure. (17) Aside from several publications from the group of Kapural et al. (2007), 1 report from Turkey was identified with a case series of 15 patients treated with biacuplasty. (18)

Section Summary

One Randomized Controlled Trial (RCT) has been published on the use of biacuplasty to treat chronic low back pain. In this report, only 6% of the subjects screened met the strict inclusion/exclusion criteria for the study. Significant differences in outcomes were observed at 6 months, but not at 1 month or 3 months, and the definition of successful treatment appears to be post-hoc. Additional study in a broader population of patients is needed to determine with greater certainty the effect of this treatment on health outcomes.

Ongoing Clinical Trials

A search of online site ClinicalTrials.gov in June 2014 identified 1 industry-sponsored study on biacuplasty.

- NCT01263054 is a manufacturer-sponsored Phase IV randomized, multicenter, open-label clinical trial comparing disc biacuplasty with the TransDiscal system versus medical management for discogenic lumbar back pain. The study was scheduled to begin in December 2010 with an estimated enrollment of 136 subjects. Study completion is expected in December 2014 with a total of 60 subjects.

Summary

There is limited evidence on the efficacy of intradiscal thermal annuloplasty, consisting of a small number of randomized controlled trials and case series. The 2 RCTs on intradiscal electrothermal annuloplasty report different results, with 1 reporting benefit for IDET and the other reporting no benefit. There is a lack of evidence to support a role for radiofrequency annuloplasty with a single probe. One recent RCT on biacuplasty suggests that this procedure may provide modest benefit in a proportion of highly selected patients; confirmation of these results in a broader population is needed. Overall, evidence is insufficient to conclude that these procedures improve health outcomes. Therefore, annuloplasty (i.e., IDET™, PIRFT, biacuplasty) is considered investigational.

Practice Guidelines and Position Statements

A 2013 review of the evidence for American Society of Interventional Pain Physicians guidelines found limited to fair evidence for IDET and biacuplasty and limited evidence for PIRFT. (3) This updates 2007 guidelines that concluded that the evidence is moderate for management of chronic discogenic low back pain with IDET™. (19) Complications include catheter breakage, nerve root injuries, post-IDET disc herniation, cauda equina syndrome, infection, epidural abscess, and spinal cord damage. The evidence for radiofrequency posterior annuloplasty (PIRFT) was reported to be limited, with complications similar to IDET. (19)

The United Kingdom's National Institute for Health and Clinical Excellence (NICE) guidance, published in 2004, indicates that the current evidence on safety and efficacy of PIRFT for lower back pain does not appear adequate to support its use. (20)

The NICE guidance on electrothermal annuloplasty was updated in 2009. (21) NICE considers evidence on the safety and efficacy of percutaneous intradiscal electrothermal therapy for low back pain to be inconsistent. NICE recommends that this procedure only be used with special arrangements for clinical governance, consent, and audit or research.

U.S. Preventative Services Task Force Recommendations

Annuloplasty is not a preventive service.

Medicare National Coverage

The Centers for Medicare and Medicaid Services has determined that thermal intradiscal procedures, including IDET and PIRFT are not reasonable and necessary for the treatment of low back pain. Therefore, thermal intradiscal procedures, which include procedures that employ the use of a RF energy source or electrothermal energy to apply or create heat and/or disruption within the disc for the treatment of low back pain, are noncovered. (22)

References

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Intradiscal electrothermal therapy for chronic low back pain. TEC Assessments 2002; Volume 17, Tab 11.
2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Percutaneous intradiscal radiofrequency thermocoagulation for chronic discogenic low back pain. TEC Assessments 2003; Volume 18, Tab 19.
3. Blue Cross Blue Shield Association. Medical Policy Reference Manual, No. 7.01.72 (July 2014).
4. Manchikanti L, Abdi S, Atluri S et al. An Update of Comprehensive Evidence-Based Guidelines for Interventional Techniques in Chronic Spinal Pain. Part II: Guidance and Recommendations. Pain Physician 2013;16(2 Suppl):S49-S283.
5. Urrutia G, Kovacs F, Nishishinya MB et al. Percutaneous thermocoagulation intradiscal techniques for discogenic low back pain. Spine (Phila Pa 1976) 2007; 32(10):1146-54.
6. Helm S, Deer TR, Manchikanti L et al. Effectiveness of thermal annular procedures in treating discogenic low back pain. Pain Physician 2012; 15(3):E279-E304.
7. Pauza KJ, Howell S, Dreyfuss P et al. A randomized, placebo-controlled trial of intradiscal electrothermal therapy for the treatment of discogenic low back pain. Spine J 2004; 4(1):27-35.
8. Freeman BJ, Fraser RD, Cain CM et al. A randomized, double-blind, controlled trial: intradiscal electrothermal therapy versus placebo for the treatment of chronic discogenic low back pain. Spine (Phila Pa 1976) 2005; 30(21):2369-77; discussion 78.
9. Kvarstein G, Mawe L, Indahl A et al. A randomized double-blind controlled trial of intra-annular radiofrequency thermal disc therapy--a 12-month follow-up. Pain 2009;145(3):279-86.
10. Freeman BJ, Mehdian R. Intradiscal electrothermal therapy, percutaneous discectomy, and nucleoplasty: what is the current evidence? Curr Pain Headache Rep 2008;12(1):14-21.
11. Levin JH. Prospective, double-blind, randomized placebo-controlled trials in interventional spine: what the highest quality literature tells us. Spine J 2009; 9(8):690-703.
12. Helm S, Hayek SM, Benyamin RM et al. Systematic review of the effectiveness of thermal annular procedures in treating discogenic low back pain. Pain Physician 2009;12(1):207-32.
13. Andersson GB, Mekhail NA, Block JE. Treatment of intractable discogenic low back pain. A systematic review of spinal fusion and intradiscal electrothermal therapy (IDET). Pain Physician 2006;9(3):237-48.

14. Appleby D, Andersson G, Totta M. Meta-analysis of the efficacy and safety of intradiscal electrothermal therapy (IDET). *Pain Med* 2006;7(4):308-16.
15. Kapural L, Hayek S, Malak O et al. Intradiscal thermal annuloplasty versus intradiscal radiofrequency ablation for the treatment of discogenic pain: a prospective matched control trial. *Pain Med* 2005;6(6):425-31.
16. Barendse GA, van Den Berg SG, Kessels AH et al. Randomized controlled trial of percutaneous intradiscal radiofrequency thermocoagulation for chronic discogenic back pain: lack of effect from a 90-second 70 C lesion. *Spine (Phila Pa 1976)* 2001;26(3):287-92.
17. Kapural L, Vrooman B, Sarwar S et al. A randomized, placebo-controlled trial of transdiscal radiofrequency, biacuplasty for treatment of discogenic lower back pain. *Pain Med* 2013;14(3):362-73.
18. Kapural L, Mekhail N. Novel intradiscal biacuplasty (IDB) for the treatment of lumbar discogenic pain. *Pain Pract* 2007;7(2):130-4.
19. Karaman H, Tufek A, Kavak GO et al. 6-month results of TransDiscal Biacuplasty on patients with discogenic low back pain: preliminary findings. *Int J Med Sci* 2010;8(1):1-8.
20. Boswell MV, Trescot AM, Datta S et al. Interventional techniques: evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician* 2007;10(1):7-111.
21. National Institute for Health and Clinical Excellence. IPG83 Percutaneous intradiscal radiofrequency thermocoagulation for lower back pain. 2004. Available online at: <http://guidance.nice.org.uk/IPG83>. Last accessed May, 2014.
22. National Institute for Health and Clinical Excellence. IPG319 Percutaneous intradiscal electrothermal therapy for low back pain: guidance. 2009. Available online at: <http://guidance.nice.org.uk/IPG319/Guidance/pdf/English>. Last accessed May, 2014.
23. Centers for Medicare and Medicaid Services. NCD for Thermal Intradiscal Procedures (TIPs) (150.11). 2008. Available online at: <http://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=150.11&bc=gAAAAAAAAAAAA&>. Last accessed May, 2014.

Documentation Required for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

IE

The following services are considered investigational and therefore not covered for any indication.

Type	Code	Description
CPT®	<i>See Policy Guidelines</i>	
	22526	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level
	22527	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; 1 or more additional levels (List separately in addition to code for primary procedure)
HCPC	None	
ICD-9 Procedure	80.59	Other destruction of intervertebral disc (use for IDET)
ICD-10 Procedure	<i>For dates of service on or after 10/01/2015</i>	
	0R530ZZ	Destruction, upper joints, open, cervical and thoracic disc code list
	0R550ZZ	Destruction, upper joints, open, cervical and thoracic disc code list
	0R590ZZ	Destruction, upper joints, open, cervical and thoracic disc code list
	0R5B0ZZ	Destruction, upper joints, open, cervical and thoracic disc code list
	0S520ZZ	Destruction, lower joints, open, lumbar and lumbosacral disc code list
	0S540ZZ	Destruction, lower joints, open, lumbar and lumbosacral disc code list
ICD-9 Diagnosis	All Diagnoses	
ICD-10 Diagnosis	<i>For dates of service on or after 10/01/2015</i>	
	All Diagnoses	

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
6/6/1999	BCBSA Medical Policy adoption 7.01.72	Medical Policy Committee
6/25/2001	Policy Revision Addendum added for clarification	Medical Policy Committee
11/8/2002	Administrative Review policy unchanged	Administrative Review of BCBSA TEC Assessment
9/1/2003	Policy Title Revision, Medically Necessary criteria added adopted October 2003 CTAF	Medical Policy Committee

	IDET (Radionics RF)	
12/1/2003	Policy Title Revision, Medically Necessary criteria added adopted October 2003 CTAF IDET (Oratec)	Medical Policy Committee
3/10/2005	Policy title change from Review of BCBSA TEC February 2004 Vol. 18, No. 19	Administrative Review
1/25/2008	Policy Revision Disclaimer statement added to Medical Policy	Administrative Review
7/7/2008	Policy Title Revision, Medically Necessary criteria added BCBSA policy statement 7.01.72. Applicable rationale and references added. Coding updated.	Medical Policy Committee
1/15/2010	Coding Update	Administrative Review
7/1/2011	Policy title change from Percutaneous Intradiscal Electrothermal (IDET™) Annuloplasty and Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT) without position change	Medical Policy Committee
9/30/2014	Policy title change from Intradiscal Electrothermal Annuloplasty (IDET™), Percutaneous Intradiscal Radiofrequency Annuloplasty (PIRFT), and Intradiscal Biacuplasty (IDB) 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

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

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 also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.