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1998 ANNIVERSARY 2008

Aug 10, 2008

Dr. Steve Phurrough, MD, MPA
Centers for Medicare & Medicaid Services
Director, Coverage and Analysis Group
Mailstop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244

Re: Proposed National Coverage Memorandum for Thermal Intradiscal Procedures (TIPs) – CAG-00387N

Dear Dr. Phurrough,

I am writing this letter in response to the proposed National Coverage Memorandum for Thermal Intradiscal Procedures (TIPs) CAG-00387N that was issued by CMS on July 15, 2008. The proposed memorandum focused mainly on discussions regarding clinical evidence related to IDET. However, the non-coverage memorandum covers all Thermal Intradiscal Procedures (TIPs), including disc Biacuplasty using the TransDiscal system.

There are technological and clinical differences between disc Biacuplasty and other TIPs, and as such, the National Coverage Determination should not include disc Biacuplasty. Disc Biacuplasty offers a new and promising technological approach to treatment of chronic low back pain. The TransDiscal system used for disc Biacuplasty works with Cooled-RF technology in a bipolar manner to ablate nociceptors and aberrant neural growth in the posterior annulus of the disc, thereby relieving the discogenic pain. The Cooled-RF technology allows the TransDiscal probes to achieve therapeutic temperature profiles ablating nerves in clinically relevant regions such as the posterior annulus of the disc. Studies have shown that IDET, which uses electrothermal energy, is unable to achieve such therapeutic temperatures.

Disc Biacuplasty also differs from IDET in the procedural technique, offering a far less invasive technique compared to IDET. The IDET procedure is performed using thermal energy that is transferred through a resistant coil placed inside the disc. It is inherently risky as it involves invasion of more disc material, increasing the likelihood of complications. The proposed decision memorandum also describes 'severe' complications such as discitis, epidural abscess, bacterial meningitis, cauda equine syndrome, and vertebral osteonecrosis have been reported for IDET. In contrast, disc Biacuplasty is performed using cooled-RF through two Cooled-RF electrodes positioned in

a bipolar manner in the postero-lateral corners of the disc annulus. This unique positioning minimizes invasion of the disc material, thereby potentially reducing procedural complications. The proposed decision memorandum for TIPs describes the increased safety of disc Biacuplasty procedure compared to IDET as seen in the various studies.

The clinical evidence for disc Biacuplasty also differs from IDET. The clinical evidence of IDET has already been reviewed in the proposed decision memorandum. On the other hand, the clinical evidence for disc Biacuplasty is still being developed systematically. Current clinical evidence for Disc Biacuplasty includes pilot studies conducted by Dr. Kapural, Cleveland Clinic Foundation and Dr. Whyte, Louisiana Pain Physicians. These have shown positive patient outcomes. Two double-blinded randomized placebo-controlled trials (RCTs) are currently underway for Disc Biacuplasty. These trials will generate high level of clinical evidence for the effectiveness of disc Biacuplasty. With the new clinical evidence, CMS will be better equipped to accurately assess and determine coverage for Disc Biacuplasty. Lumping disc Biacuplasty with other TIPs will impede the development of this critical evidence, which will negate the possibility of assessing the true potential of the unique cooled-RF technology for treating chronic discogenic pain. Therefore, it would be in the interest of Medicare beneficiaries, and the medical community, to consider Disc Biacuplasty separately from all other TIPs and exclude it from the noncoverage determination.

Disc Biacuplasty is a promising procedure that is fundamentally different from all other TIPs. Its novel Cooled-RF technology has the potential to offer better health outcomes for patients with chronic discogenic low back pain. Clinical evidence for Disc Biacuplasty in form of placebo controlled RCTs is likely to be developed within a year. Grouping Disc Biacuplasty with other TIPS in a noncoverage decision would only impede the development of this new clinical evidence for Disc Biacuplasty. Therefore, I respectfully request that CMS exclude Disc Biacuplasty from the NCD for TIPs and leave the assessment of disc biacuplasty coverage to the discretion of local carriers.

Thank you.

Sincerely,

Andrea M. Trescot, MD
Director, Pain Fellowship Program, University of Florida
Diplomate American Board of Anesthesiology
Special Qualifications in Pain Management
Special Qualifications in Critical Care
Diplomate American Board of Pain Medicine
Diplomate American Academy of Pain Management
Fellow, Interventional Pain Practice
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WELLPOINT

August 14, 2008

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: CAG-00387N
Comment on Proposed Coverage for Thermal Intradiscal Procedures

Dear Sirs:

On behalf of WellPoint, Inc., I would like to thank you for the opportunity to provide comment on the proposed coverage decision memorandum for Thermal Intradiscal Procedures (CAG-00387N). We would agree that the social and economic impact of chronic low back pain is large and that the rapid adoption of new technologies without evidence of clinically meaningful benefit is of serious concern to patients, clinicians, and third party payers. We would like to congratulate the CMS on a very thoughtful and comprehensive review of the topic.

In April 2008, the WellPoint Medical Policy & Technology Assessment Committee reviewed the published medical literature, the results of external technology assessments and the opinions of specialty societies and experts in the field with regard to the clinical outcome benefits of percutaneous intradiscal electrothermal and radiofrequency coagulation procedures. This committee reached the same general conclusions as outlined in CAG-00387N following its review of the subject and did not identify relevant publications not already cited in the very thorough review by the CMS.

The WellPoint Medical Policy & Technology Assessment Committee concluded that published evidence to date is dominated by case series of patients with varying lengths of follow-up and that the few randomized sham controlled clinical trials which have been published provide conflicting results. This committee felt that the quality of many of the published studies was disappointing. With few exceptions, published studies have lacked long term follow-up to establish a durable outcome benefit, used non-standardized outcome measures and lacked adequate controls with a placebo comparator. We would agree that the published evidence to date is inadequate to establish a meaningful and durable outcome benefit for these thermal intradiscal therapies.

We hope this feedback is useful to CMS.

Sincerely,

Carol Brodie, RN, MSN, JD
Director, Clinical Research and Policy Development
Office of Medical Policy & Technology Assessment
WellPoint, Inc.

Baylis MEDICAL

August 14, 2008

Steve Phurrough, MD, MPA
Centers for Medicare and Medicaid Services
Coverage and Analysis Group
Mail Stop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: **CAG-00387N:**
Comment on Proposed Coverage For Thermal Intradiscal Therapy

Dear Dr. Phurrough:

Please find enclosed a document in response to the proposed decision memorandum issued by Centers for Medicare and Medicaid Services for Thermal Intradiscal Procedures (TIPs) (document CAG-00387N).

This document presents our position that disc biacuplasty should be removed from the above NCD for the reasons outlined herein.

Baylis Medical requests a meeting with CMS once the comment period closes and the CAG staff has reviewed the comments. At this meeting, we will provide further information to CMS on the ongoing disc biacuplasty RCTs, which will generate the clinical evidence that CMS should used in assessing the coverage decision for disc biacuplasty. We would be happy to schedule this meeting at your convenience.

Please contact me at (905) 602-4875; ext 222 if you have any questions concerning the enclosed document.

Sincerely,

Kris Shah
Vice President

***Enclosure:***

Document: **Response to Proposed Decision Memorandum on Thermal Intradiscal Procedures (CAG-00387N)**

**Baylis Medical Company Inc.**
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# Response to Proposed Decision Memorandum on Thermal Intradiscal Procedures (CAG-00387N)

To: The Centers for Medicare and Medicaid Services
From: Kris Shah, Baylis Medical Company
Subject: Response to Proposed Decision Memo for TIPs (CAG-00387N)
Date: August 14, 2008

## Executive Summary

This letter is submitted on behalf of Baylis Medical Company (Baylis) in response to the proposed decision memorandum issued by the Centers for Medicare and Medicaid Services for Thermal Intradiscal Procedures (TIPs) (document CAG-00387N) – the proposed decision. We respectfully request that the Coverage and Analysis Group remove disc biacuplasty from this NCD.

The evidence considered in CAG-00387N was by and large a review of the literature pertaining to IDET. IDET entails use of an electrical heating coil that is difficult to place and provides limited thermal energy in the immediate vicinity of the coil by way of conduction heating. In contrast disc biacuplasty utilizes two water cooled RF electrodes that allow for a wider and precisely directed zone of neuroablation by way of ionic heating. The efficacy of RF neuroablation using ionic heating is very well documented in several other clinical applications.

Early study of disc biacuplasty is very encouraging and the body of evidence is growing with two randomized controlled trials underway at this time. Inclusion of disc biacuplasty in CAG-00387N is inappropriate and will negatively impact clinical trial recruitment. Moreover, the results from these ongoing randomized controlled trials (RCTs) should be used in the evaluation of coverage for this procedure.

Establishing a national noncoverage decision for disc biacuplasty now, (based on IDET information), would strip the local Medicare contractors of the discretion to consider the upcoming RCT information. This would force another national coverage analysis to be opened to reconsider this proposed national noncoverage policy. During such a lengthy and burdensome process Medicare beneficiaries would not have access to disc biacuplasty.

Leaving the coverage assessment of disc biacuplasty to the local contractors' discretion will facilitate the continued development of clinical evidence and Baylis respectfully asks that CMS take such action. We note that the agency could do so by finding that disc biacuplasty is not properly part of this analysis based on its review of the literature, the procedure, and the technology. Alternatively, CMS is requested to facilitate the development of the clinical evidence by permitting coverage for disc biacuplasty under its policy on coverage with evidence development.

## I. *Introduction to Disc Biacuplasty*

Disc biacuplasty is a minimally invasive procedure for treating chronic axial discogenic (disc mediated) back pain. Disc biacuplasty is performed by inserting two internally cooled radiofrequency electrodes into the postero-lateral aspects of the symptomatic intervertebral disc. The bipolar RF application combined with internal water cooling allows tissue to be heated within an ideal range for ablating nociceptors

Evidence to demonstrate the capability of disc biacuplasty has been built, beginning with animal and cadaver studies, and leading to case series and prospective pilot studies. These clinical studies have shown positive outcomes encouraging further investigation with randomized controlled trials (RCTs). Currently two randomized, double-blinded, placebo-controlled trials are underway which include the Medicare population. These RCTs will generate clinical evidence of the highest level that should be used in the coverage assessment for disc biacuplasty. These studies are discussed in more detail in Section III below.

## II. *Disc Biacuplasty is distinct from IDET and other TIPs*

According to the proposed decision, "*CMS believes that the various techniques utilized for TIPs use the same function – the use of heat, seeking the same desired outcome – relief of pain. Some techniques have greater representation in the published literature; however, the similarities of function and desired outcome are sufficient to support generalizing the available published evidence across all techniques used in TIPs.*" Baylis respectfully disagrees with this statement. There are important clinical differences between disc biacuplasty and other TIPs.

Disc biacuplasty is distinct from IDET and other TIPs due to its ability to create a therapeutic temperature profile, i.e. to heat the appropriate region of the disc to appropriate temperatures for ablating sensitized annular nociceptors and aberrant neural growth present in patients with chronic discogenic pain. Also, disc biacuplasty utilizes cooled RF, which is recognized to be distinct from non cooled RF in other areas of medicine due to its effect and capabilities. Furthermore, the American Medical Association (AMA) and national professional societies consider disc biacuplasty to be distinct from IDET. These differences are described in detail below:

## A. *Ability to create a therapeutic temperature profile*

Thermal energy has been used to ablate nerves in various medical treatments for the past four decades (Borggrefe 1990, Friedman 1984, Prithvi Raj 2002, Shealy 1975). It is known that appropriate thermal energy applied to a nerve will deactivate the signal transmission. Histological studies have shown that temperatures as low as between 42°C and 50°C for 2 minutes are cytotoxic to nerves (Smith 1981).

Recent investigation has led to a greater understanding of the pathophysiology of the intervertebral disc, and pathogenesis of discogenic pain (Burke 2002, Coppes 1997, Freemont 1997, Peng 2006) In particular, the extent of disc innervation has been shown (Bogduk 1981), and that painful discs are associated with an increase in fissuring and innervation extending to the inner third of the posterior annulus fibrosus (Coppes 1997, Freemont 1997). The location of a fissure does not correlate with the location of nerve growth (Slipman 2001). Thus, in order to confidently and consistently ablate all neural structures associated with the chronic pain, the complete posterior and posterolateral disc must be treated.

The region of tissue required to be heated in the disc is large relative to tissue volumes heated in procedures such as zygapophoseal joint denervation. Other TIPs, such as those represented by the evidence assessed in the proposed decision memo, may have shown poor results because they are technically limited, unable to meet this challenge.

The IDET procedure was the subject of all of the external technology assessments cited in the proposed decision, and seven of the items in the internal technology assessment. IDET uses a flexible catheter containing an electrically resistive heating coil (Cohen 2003). Heat is transmitted through the disc by thermal conduction. The procedure is challenging as it requires the flexible catheter to be skillfully maneuvered along the perimeter of the annulus. When a disc contains fissures or hardened portions of nucleus pulposus, which is frequent with painful discs, it is difficult to place the heating portion across the entire posterior region of the annulus fibrosus (see Figure 1) (Cohen, 2003). Improper catheter positioning can result in heating of imprecise disc areas leading to poor therapeutic outcomes.

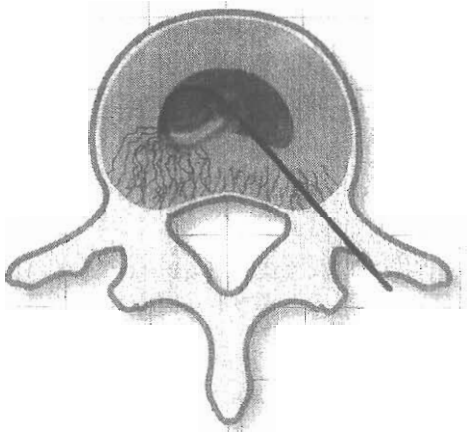


*Figure 1: IDET procedure*

PIRFT is the subject of two external technology assessments and three items in the internal technology assessment. Similarly, this procedure is limited in its ability to heat clinically relevant regions of the annulus fibrosus. In the PIRFT procedure, which uses standard RF energy in a monopolar fashion, a single electrode is placed in the nucleus pulposus of the disc (see Figure 2). The volume of tissue heated using this technology is a function of the power delivered. However, the region of tissue heated is limited to a small volume because when the tissue contacting the electrode rises above 90°C the electrical resistance of the tissue increases impeding even flow of electrical current (Cosman 1988). Just below this limit, temperature decreases to body temperature within a short distance of 1/electrode radius^4 (Organ 1976). The heat that is generated at the centre of the disc does not get properly dissipated to the posterior annulus thereby limiting positive clinical outcomes (Troussier 1995).

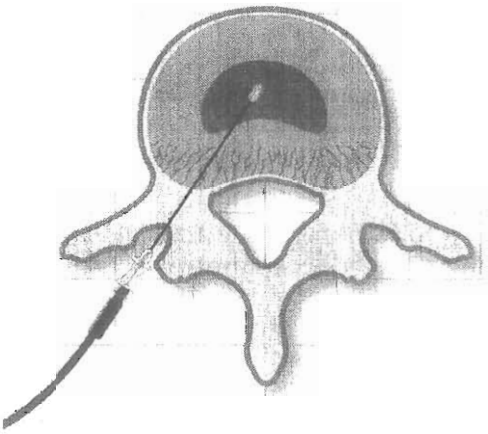


*Figure 2: PIRFT procedure*

In contrast, disc biacuplasty, which was not represented by any of the evidence assessed in the proposed decision memo, employs bipolar, cooled RF technology. In this procedure, two cooled RF electrodes are positioned in a bipolar manner in the posterolateral corners of the annulus of the disc (see Figure 3). Positioning the rigid probes in this location is consistently repeatable. The electrodes are internally cooled using continuous flow of water within the probe shaft thereby limiting the rate of heating at the electrode surface. This overcomes the volume limit of non cooled RF. Significantly greater energy is delivered to the tissue surrounding the electrodes, resulting in a larger lesion that spans the posterior annulus of the disc. The cooling approach coupled with RF energy used in the disc biacuplasty procedure achieves the therapeutic temperature profile, which is required to ablate the nociceptor nerve fibers. Evidence of the capability of disc biacuplasty to attain appropriate temperatures is discussed in Section III (Petersohn 2008, Kapural 2008). Thus, disc biacuplasty procedure with the use of cooled RF technology is able to reach temperatures that are of clinical relevance.

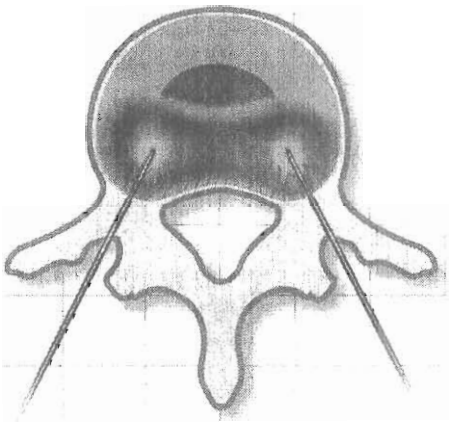


*Figure 3: Disc biacuplasty procedure*

### B. American Medical Association's (AMA) CPT Coding Differentiation for TIPs

In 2007, the AMA created specific CPT codes to differentiate between IDET and other percutaneous intradiscal annuloplasty procedures. The CPT codes 22526 and 22527 with the description *"percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; (single level or one or more additional levels)"* were created for IDET. Meanwhile, the code 0062T with the description

"*percutaneous intradiscal annuloplasty, any method except electrothermal, unilateral or bilateral including fluoroscopic guidance*" was created for all other non-IDET procedures.

AMA is using this specific CPT coding to distinguish the IDET procedure, which uses electrothermal energy through a resistive heating coil to treat symptomatic annular tears, from all other non-electrothermal annuloplasty procedures.

For reasons outlined in this document, disc biacuplasty is not accurately described by any existing CPT codes. Hence, current practice is to bill it with the unlisted procedure code for the nervous system or spine (64999 or 22899). This differentiation in CPT coding clearly indicates that there are significant differences between the TIPs.

Given the procedural differences that exist between IDET, other non-IDET TIPs and disc biacuplasty, we urge CMS to consider the evidence for disc biacuplasty separately from this national coverage analysis.

### C. *Recommendations by National Professional Societies*

The proposed decision memo for Thermal Intradiscal Procedures CAG-00387N includes the following comments from different National Professional Societies:

*"CMS also received separate comments from NASS, the American Academy of Pain Management (AAPM) and the International Spine Interventional Society (ISIS).....The comments from these societies were based on review of the literature which specifically addressed IDET. The commenters felt it was important to distinguish IDET or resistance coil heating methods and other intradiscal thermal technologies".*

*"NASS pointed that the evidence for these distinct technologies differs. AAPM and ISIS pointed out that other emerging technologies, radiofrequency intradiscal thermal procedures are differentiated under CPT Category III codes".*

The above comments show that the National Professional Societies recognize that differences exist between IDET and other emerging technologies based on procedural method and availability of clinical evidence. Given these differences, grouping all non-IDET emerging technologies with IDET under one coverage determination is not consistent with the medical evidence.

### D. *Cooled-RF Technology Facilitates Larger Lesions than Standard RF*

Standard RF is effective in heating a small volume of tissue. However, as previously shown, standard RF is incapable of heating a large volume of tissue necessary to effectively treat a lumbar disc.

Cooled RF used in disc biacuplasty overcomes the limitations posed by standard-RF. In disc biacuplasty, a continuous flow of water within the shaft of the RF electrode provides a cooling effect. The internal cooling of the electrodes facilitates significantly greater energy to be delivered to the tissue surrounding the electrode. Studies have shown that internally cooling the tip of the electrode prevents charring of the tissue adjacent to the electrode tip (Watanabe 2002). The internal-cooling of the electrodes allows for increased power deposition at the procedural site thus producing larger lesions (Lorentzen 1996). The volume of the lesion size is further aided by the bipolar placement of the two cooled RF electrodes in the posterior annulus fibrosus of the disc. These aspects of disc biacuplasty allow larger and appropriate volumes of tissue to be treated so as to ablate nociceptors contributing to discogenic pain.

The ability of cooled radiofrequency (RF) technique to create controlled anatomy specific and therapeutic lesion size is already recognized as a clear differentiator in several areas of medicine. For instance, a standard-RF system is accepted for the treatment of right-sided cardiac arrhythmias, where as cooled RF system is required to treat left-sided cardiac arrhythmias such as atrial fibrillation where a larger amount of cardiac tissue requires ablation (Wittkampf 1998).

Another example is seen in RF used in cancer treatment. Standard-RF systems are utilized to treat inoperable brain tumors, where as cooled RF systems are required to treat liver tumors where larger amount of tissue requires ablation (Goldberg 1996).

### E. *CMS' differentiation between Standard RF and Cooled RF*

CMS itself has previously issued a C code (C2630) for a cool-tip catheter used in cardiac electrophysiology, diagnostic/ablation under the transitional pass-through process under the Hospital Outpatient Prospective Payment mechanism. C code distinguishes this device from other RF catheters and identifies it under a new device category for payment purposes. This shows that CMS has already recognized the differences between the applications of cooled RF and non cooled, (standard), RF devices.

In light of the important clinical differences identified above, we urge CMS to consider disc biacuplasty separately from all other TIPs discussed in the

proposed decision memorandum. We also propose that CMS be consistent within its own decision making parameters. If CMS considers cooled RF different for cardiac applications, CMS should also consider cooled RF different for pain management applications.

## III. *The Clinical Evidence for Disc Biacuplasty Warrants Leaving Coverage to the Discretion of Medicare Contractors*

For the reasons discussed in Section II above, the clinical evidence for disc biacuplasty should be considered separately than the evidence for all other TIPs because CMS' assumption that the information from other TIPs is applicable to disc biacuplasty is not correct. Indeed, because of this assumption, CMS did not consider the clinical evidence submitted on disc biacuplasty. As a result, CMS could take the position that the failure to address the evidence for disc biacuplasty in the proposed decision means that the service is not part of the current national coverage analysis and thus would not be part of the final decision. Below, we address the clinical evidence, which we believe supports a continuation of the current policy of leaving coverage to the discretion of Medicare contractors.

### A. *Preclinical Evidence*

Preclinical studies conducted by Dr. Kapural and Dr. Petersohn show that disc biacuplasty achieves suitable temperatures to ablate nociceptors while showing no evidence of damage to neural tissue in safety zones surrounding the disc.

***Petersohn J.D., Conquergood L.R., Leung M. Acute Histologic Effects and Thermal Distribution Profile of Disc Biacuplasty Using a Novel Water-Cooled Bipolar Electrode System in an in vivo Porcine Model. Pain Medicine 2008;9(1):26–32.***

In Dr. Petersohn's animal study, seven porcine lumbar discs were equipped with thermocouples and treated with disc biacuplasty. Intradiscal and peridiscal temperatures were monitored and recorded during the procedure, and discs were observed for histological signs of heat induced damage. The generator was set to a maximum electrode temperature of 45°C and discs were treated for up to 20 minutes; the electrode temperature of 45°C refers to the surface of the electrodes which are internally cooled whereas the tissue temperature is significantly hotter.

Temperatures in the inner posterior disc annulus reached values of 65°C, while temperatures in designated safety zones next to and at the peripheries of the disc remained near physiological levels. There was no

histological evidence of thermal damage to the dorsal root ganglia or spinal nerve roots compared to control discs. The nucleus pulposus of treated discs did show increased coarseness in the fibrillar matrix and loss of cellular detail, which is an indication of collagen restructuring. This study indicates that disc biacuplasty can achieve temperatures in the posterior disc annulus that are higher than temperatures required for neuroablation (45°C) and that induce thermal transition of collagen (>62°C).

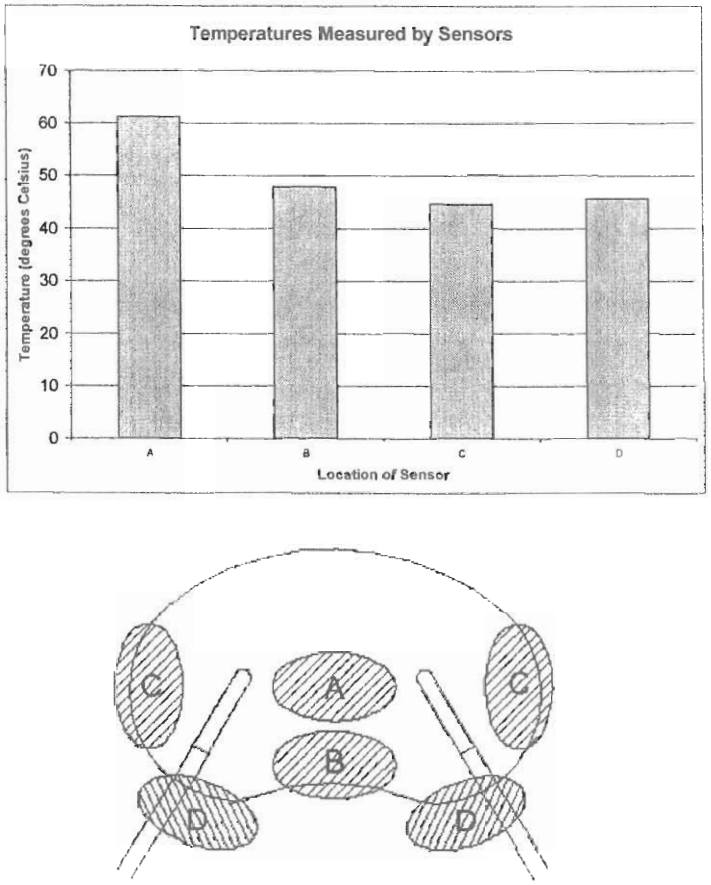



*Figure 4: Biacuplasty in a porcine model achieved suitable temperatures to induce transition of collagen and thermoneurolysis while showing no evidence of damage to neural tissues in safety zones surrounding the disc (Petersohn J et al. Pain Medicine 2008; 9: 26-32)*

***Kapural L, Mekhail N, Hicks D, Kapural M, Sloan S, Moghal N, Ross J, and Petrinec D. Histological changes and temperature distribution studies of a novel bipolar radiofrequency heating system in degenerated and nondegenerated human cadaver lumbar discs. Pain Med 2008;9(1):68-75.***

Dr. Kapural designed and performed this study to determine precise thermal profiles within the discs during disc biacuplasty. Eight lumbar discs from 2 human cadavers were treated with disc biacuplasty. These were compared with four similar discs that served as controls and remained untreated. In addition to disc temperature measurements, critical temperatures were also monitored in the epidural space and near nerve roots around the disc.

Temperatures in the posterior annulus of all discs treated with disc biacuplasty were greater than 50°C (which is more than the temperature required for nerve ablation), but temperatures in the nearby nerve root and epidural space did not exceed the safe temperature of 43°C. Important additional in-depth histopathological analysis of all the intervertebral discs studied showed that the collagen matrix of the disc annulus and surrounding structures were not altered by the disc biacuplasty procedure.

Dr. Kapural concluded that performing the disc biacuplasty procedure using the TransDiscal™ System yields thermal profiles that are consistent with those suggested for clinical safety and efficacy.

Please refer to Figure 5 on the following page for the schematic and fluoroscopic view of the electrodes and thermocouples placement within the human cadaver and the temperature graph.

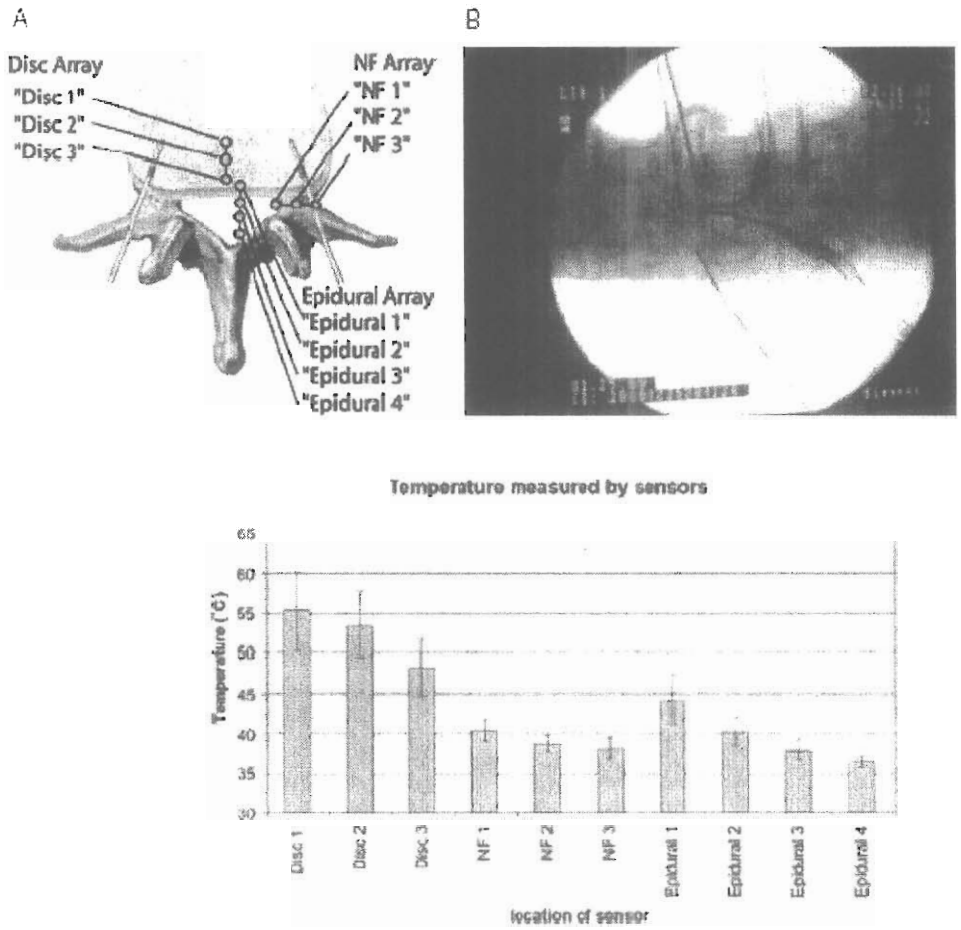



*Figure 5: Schematic (A) and fluoroscopic (B) view of the electrodes and thermocouples placement within the human cadaver discs. (A) Schematic of transected lumbar intervertebral disc with two bipolar radiofrequency electrodes positioned appropriately. (B) Anterior-posterior fluoroscopic view of the lumbar spine with properly positioned bipolar system and thermocouples in place to begin temperature recordings. (C) The average temperatures measured by sensors on strategically placed temperature arrays across the cadaver intervertebral disc. Note that the sensor labeled Epidural 1 was actually placed inside the disc. NF = neural foramina (Kapural et al. Pain Medicine; 9(1): 68-75).*

## B. *Prospective Clinical Evidence*

Currently available clinical evidence for disc biacuplasty is supported by two prospective clinical study outcomes and case series. Clinical investigation consisting of non-randomized pilot studies has shown positive results.

***Kapural L., Ng A., Mekhail N. A Novel Radiofrequency Annuloplasty (Intervertebral Disc Biacuplasty) for the treatment of Lumbar Discogenic Pain: 6-months results of the pilot study. Pain Medicine 2008;9(1):60-67.***

This pilot study, conducted by Dr. Kapural at the Cleveland Clinic, consisted of 15 patients suffering from chronic lumbar discogenic pain that were treated with disc biacuplasty and followed for 6 months. Outcome measures used were Visual Analogue Scale (VAS) for pain intensity, ODI for change in disability, SF-36 for change in physical functionality and change in opioid use.

Dr Kapural's results showed clinically and statistically significant improvements in his patients' pain and functional capacity at 1 month follow up, which were sustained for at least 6 months following treatment. 92% of patients who met the inclusion criteria for disc biacuplasty experienced clinically meaningful improvements in pain severity, functional status and reduction of opioid use. Improvements in pain and disability, and the reduction in use of pain medication suggest that the procedure is effective in providing pain relief. These data are even more compelling when compared to the current standards of care such as fusion or disc replacement surgery and chronic narcotic management and other methods of palliative care. These improvements were sustained for at least 6 months following the disc biacuplasty treatment.

The author states that "Median visual analog scale pain scores were reduced from 7 (95% confidence interval [CI] 6, 8) to 4 (2, 5) cm at 1 month, and remained at 3 (2, 5) cm at 6 months. The Oswestry improved from 23.3 (SD 7.0) to 16.5 (6.8) points at 1 month and remained similar after 6 months. The SF-36 Physical Functioning scores improved from 51 (18) to 70 (16) points after 6 months, while the SF-36 Bodily Pain score improved from 38 (15) to 54 (23) points. Daily opioid use did not change significantly from baseline: from 40 (95% CI 40, 120) before IDB to 5 (0, 40) mg of morphine sulfate equivalent 6 months after IDB. No procedure-related complications were detected."

From the results, the authors conclude that the patients experience clinically and statistically significant improvements in pain and physical functioning following treatment with disc biacuplasty.

***Kapural L., Ng A., Mekhail N. Intervertebral Disk Cooled Bipolar Radiofrequency (Intradiskal Biacuplasty) for the Treatment of Lumbar Diskogenic Pain: A 12-Month Follow-Up of the Pilot Study. Pain Medicine 2008; 9(4):407-408***

The 12-month results of the pilot study indicate that improvements in pain and functionality seen at 6 months following intervertebral disc biacuplasty are sustained for at least 12 months following treatment. The daily opioid use continued to decrease among majority of the patients after the 6 month follow-up. The median opioid use decreased from 40 (40, 120) mg before intervertebral disc biacuplasty to 0 (0, 20) mg at 12 months after the procedure. The majority of patients continued to experience >50% pain relief from the procedure, which further supports the potential viability of disc biacuplasty as an effective minimally invasive long-term treatment for discogenic pain.

***Whyte W. 12-month Prospective Study of Disc Biacuplasty. Under review for publication***

Dr. Whyte also conducted a prospective study with 10 patients to determine long term (12 month) efficacy of disc biacuplasty, which is under review for publication. In Dr. Whyte's prospective study, results showed clinically meaningful improvements in pain severity for 80% of patients at 6 and 12-month follow-up. 50% patients received clinically meaningful improvement in disability index at 6 and 12-month follow-up. Furthermore, 53% of patients achieved ≥50% pain relief (Visual Analog Score) at 6 months post procedure. The result dropped slightly (46%) at 1 year evaluation (Dr. Whyte's unpublished results). The results from Dr. Whyte's study mimic the results seen in Dr. Kapural's study at Cleveland Clinic Foundation mentioned above.

***Kapural L, Mekhail N. Novel Intradiscal Biacuplasty (IDB) for the Treatment of Lumbar Discogenic Pain. Pain Practice 2007;7(2):130-134***

A case study was presented by Dr. Kapural and Dr. Mekhail. The results are stated by the authors as follows: There were no intra and postoperative complications, and significant improvements in patient functional capacity, and pain scores were noted. Visual analog scale pain score decreased from 5 to 1 cm at 6 month follow up, Oswestry disability scores improved from 14 (28% or moderate disability) to 6 points (12% or minimal disability) and SF-36-PF (physical function) score changed from 67 to 82.

## C. *Randomized Controlled Trial (RCT)*

Evidence from clinical studies that would offer reliable outcomes for the clinical effectiveness of disc biacuplasty are currently in progress in the form of two randomized double-blinded placebo controlled trials. The inherent strengths of these two randomized controlled trials (RCT) add weight to the evidence that will be generated by them. It is well recognized by CMS and the medical community that RCTs serve as the gold standard for assessment of clinical effectiveness. The outcomes from these two RCTs will provide valuable clinical evidence to add to the currently available literature on disc biacuplasty. This would in turn provide CMS with relevant clinical evidence to assess if disc biacuplasty is medically necessary and is clinically effective in improving health outcomes of patients suffering from chronic low back pain of discogenic origin.

The first RCT is currently being conducted by Dr. L. Kapural at the Cleveland Clinic Foundation. The second RCT is being conducted by Dr. R. Burnham at Lacombe Hospital in Alberta, Canada. The 6 months follow-up for all patients to be enrolled in both the RCTs is expected by 2009.

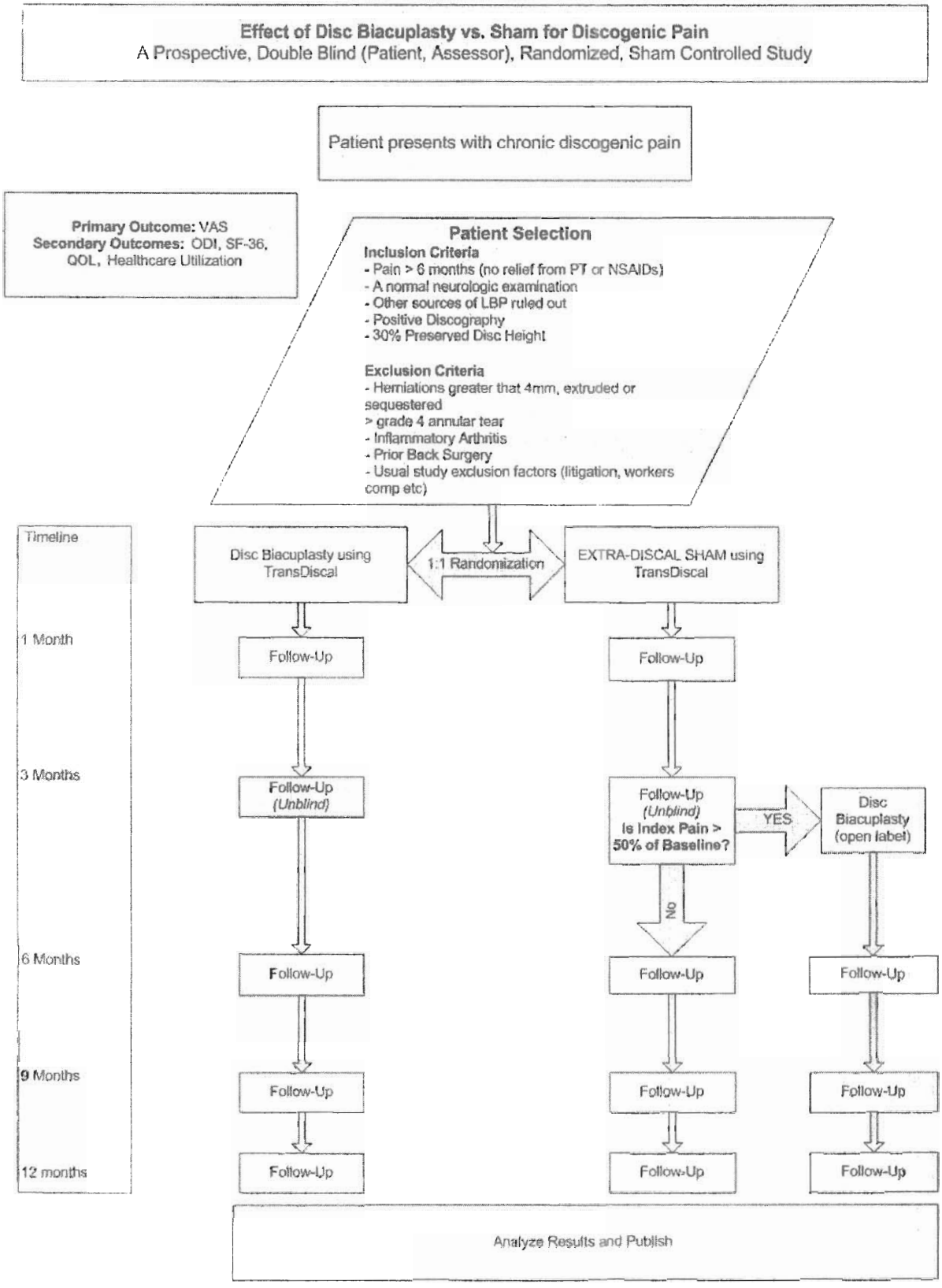
The study designs of these two RCTs have built-in attributes that will strengthen the clinical evidence for disc biacuplasty. The following are some of the strong attributes of the ongoing two disc biacuplasty RCTs:

- Patients are randomized into control and treatment groups using a computer generated random numbers. The person generating this randomization is a separate person from the assessor or physician and will have no participation in determining eligibility, administering the intervention or assessing outcome.
- Selection criteria include the Medicare age population.
- Both the patient and the assessor responsible for the patient's follow-up and clinical assessment are blinded (double blinding) thereby minimizing bias.
- A sham control group is being used to control for placebo effect.
- The sample size is large enough to detect statistically and clinically significant differences in primary outcome measures between the two groups with a power of 90% and a confidence interval of 95%.
- Follow-ups are at 1, 3, 6, 9 and 12 months post-procedure.
- Thorough documentation and control of co-interventions (i.e. medications) or provision of care apart from the intervention under evaluation will be done to minimize the effect of confounding factors.
- Visual analog scale (VAS) for pain intensity is the primary outcome measure for pain status change post disc biacuplasty. Secondary outcomes measures include SF-36, which measures general health status; Oswestry Disability Index 2.0 which evaluates functional

status change; physical assessment and Healthcare Utilization questionnaire, which measures the "use or need" for other care (PT, drugs, rehab, other surgery, pain clinic etc).

- The number of patients who complete follow-up for the entire duration of the study and the number of patients who leave or are excluded from the study before it ends will be documented, along with the reason for termination or exclusion, and all patients' results will be included in analysis to minimize attrition bias.
- Adverse events and serious adverse events have been specifically defined in the protocol and will be tracked as indicated in the clinical investigation plan. Furthermore, each serious and unanticipated adverse event will be investigated and will be reported to the appropriate regulatory agencies as per the relevant regulations.
- The primary study clinical endpoint is 6 months, after which the effect of the intervention will be assessed to determine if treatment should be offered to the control group if they have not experienced relief from pain.
- The RCT protocols have been approved by the Research Ethics Board (REB) or Institutional Review Board (IRB) of the institutions where the studies are being conducted. The studies are being conducted in compliance with the clinical investigation plan, ICH Guidelines for Good Clinical Practice (GCP) and FDA and Health Canada relevant regulations.

The flow chart presented on the following page outlines the study design for the RCT underway at the Cleveland Clinic Foundation by Dr. L Kapural.


Effect of Disc Biacuplasty vs. Sham for Discogenic Pain
A Prospective, Double Blind (Patient, Assessor), Randomized, Sham Controlled Study
Patient presents with chronic discogenic pain
Primary Outcome: VAS
Secondary Outcomes: ODI, SF-36, QOL, Healthcare Utilization
Patient Selection
Inclusion Criteria
- Pain > 6 months (no relief from PT or NSAIDs)
- A normal neurologic examination
- Other sources of LBP ruled out
- Positive Discography
- 30% Preserved Disc Height
Exclusion Criteria
- Herniations greater that 4mm, extruded or sequestered
> grade 4 annular tear
- Inflammatory Arthritis
- Prior Back Surgery
- Usual study exclusion factors (litigation, workers comp etc)
Timeline
1 Month
3 Months
6 Months
9 Months
12 months
Disc Biacuplasty using TransDiscal
1:1 Randomization
EXTRA-DISCAL SHAM using TransDiscal
Follow-Up
Follow-Up (Unblind)
Follow-Up (Unblind) Is Index Pain > 50% of Baseline?
YES
NO
Disc Biacuplasty (open label)
Analyze Results and Publish

## IV. Coverage With Evidence Development

While Baylis believes that the clinical evidence discussed in Section III above warrants the agency continuing to leave the question of coverage of disc biacuplasty to the discretion of Medicare contractors, if the agency does not agree, we ask that the agency consider applying its coverage with evidence development (CED) policy. As noted in CMS' CED guidance document, the purpose of CED is to generate data on an item or service so that Medicare can generate clinical information that will improve the evidence base on an item or service.[1] As noted in Section III(C) above, there are two RCTs on disc biacuplasty that are nearing completion and that would surely improve the evidence base on this procedure. Accordingly, covering disc biacuplasty under CED would be consistent with CMS policy and thus should be considered as an alternative to continuing to cover disc biacuplasty at the discretion of Medicare contractors.

## V. Conclusion

Disc biacuplasty is distinct from IDET and other TIPs due to its ability to create a therapeutic temperature profile, i.e. to heat the appropriate region of the disc to appropriate temperatures for ablating sensitized annular nociceptors and aberrant neural growth present in patients with chronic discogenic pain. Importantly, disc biacuplasty utilizes cooled RF, which is recognized to be distinct from non cooled RF in other areas of medicine due to its effect and capabilities. CMS itself recognizes this distinction in other decisions it has taken. As a result, we believe that the proposed decision improperly considered that the data on other TIPS is applicable to disc biacuplasty.

Most importantly, CMS' decision on disc biacuplasty should be derived from evidence based medicine that is applicable to this procedure and technology. Such evidence is presently being compiled and will be available shortly.

As the agency finalizes this national coverage analysis, Baylis believes that CMS should either make a determination that disc biacuplasty is not part of the analysis and that coverage should be left to the discretion of Medicare contractors based on its review of the clinical evidence. Alternatively, CMS could provide for coverage of disc biacuplasty under its CED policy.

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[1] *See* https://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=8.

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