

# POSITION PAPER ON INTRADISCAL ELECTROTHERMAL (IDET) TREATMENT FOR LOW BACK PAIN

## I. Purpose:

The purpose of this document is to review the available literature concerning the use of Intradiscal Electrothermal (IDET) treatment for low back pain focusing on the procedure, outcomes, indications, complications, and criteria to be considered for authorization of the study. This information should assist MCOs and providers in authorization decisions for this service.

## II. Overview:

Low back pain is frequently listed as the number one cause of workers' compensation claims, costs, and disability. Specific diagnoses are frequently difficult to determine and multiple types of treatment are frequently provided including passive modalities, chiropractic manipulation, exercise therapy, injections, oral medications, and surgeries. In 1998 Drs. Jeffrey and Joel Saal<sup>1</sup> described treatment of internal disc disruption (IDD) using IDET. Since that time, the procedure has become widespread with several hundred physicians having been trained to perform the procedure and several thousand patients having undergone the procedure by December 1999 according to statements from the catheter manufacturer Oratec.<sup>2</sup> According to the manufacturer, patients have experienced significant pain reduction and improvement in quality of life including return to work. The stated cost is \$8,000 in comparison to \$45,000 for spinal fusion.

The procedure consists of sedating the patient and inserting a 17 gauge trocar into the target disc that is causing the symptoms experienced by the patient. The trocar is passed through the annulus into the inner annulus using fluoroscopic guidance. A flexible electrode is then passed into the nucleus and advanced. Once the electrode is satisfactorily placed, it is gradually heated to 90° C. over 13 minutes. This should generate an intradiscal temperature of 60 to 65° C. This temperature is believed to be optimal for destroying collagen hydrogen bonds causing them to contract and thicken. It is also theorized that the temperatures are high enough to destroy nociceptors in the posterior annulus.<sup>3</sup>

## II. Outcomes:

Two studies have recently been published in Spine describing 12 month follow up of patients treated by IDET. These are summarized as follows:

Saal and Saal described 12 month follow-up of 62 of their own patients treated with IDET.<sup>4</sup> Inclusion criteria for the study included patients with unremitting, persistent low back pain for at least 6 months duration; no satisfactory improvement with nonoperative care program; normal neurologic examination; negative straight leg raising (SLR) findings; MRI scan that did not demonstrate a neural compressive lesion; and discogram

reproducing concordant pain at low pressurization ( $\leq 1.25$  ml dye volume at the disc) and adjacent controls not reproducing the pain. Excluded were inflammatory arthritides, nonspinal conditions that could mimic spinal pain, and prior surgery at the symptomatic levels. Outcomes were measured using the visual analog scale (VAS) and the Short Form (SF)-36 Health Status Questionnaire. Positive improvement in the VAS was a 2-point change and positive improvement in the SF-36 was a 7-point change from the pre-treatment baseline. Of the 62 participants 39 were private pay and 23 received workers' compensation. 51% of the private payers were working and none of the 23 work comp patients were working at the time of IDET. 30 patients were treated at one level and 32 received treatment at more than one level. SF-36 Physical Function subscale scores improved in 44 of the 62 patient (71%) and 44 of 62 patients showed improvement on the VAS. Twelve of 62 (19%) did not show improvement on any scale. 97% of patients with private payers and 83% of workers compensation patients returned to work. Patients with decreased disc height and those with multiple disc levels had a less favorable outcome. No patients developed neurologic deficit, new radicular pain, adverse event or complications in the study period.

Karasek and Bogduk<sup>5</sup> described evaluating 110 patients to yield a cohort of 53 patients with IDD. 36 patients underwent IDET and 17 patients (whose insurance carrier refused to authorize treatment) were given traditional rehabilitation and served as the control group. Reportedly all patients showed no evidence on examination or imaging of disc prolapse, neurologic disease, tumor, or infection. All had positive discograms. Outcomes were measured using a visual analog scale (VAS), use of analgesics, and return to work. Of the 17 control patients, one improved significantly, three obtained modest improvement, four no improvement, and nine showed deterioration. Only one of five not working at the beginning returned to work and three of the ten working initially stopped working. Of the 36 who received IDET, 4 obtained no relief. Among those who responded, the median VAS declined by 3 at three months. Return to work was associated with improvement in the VAS. There were several concerns with the study including the placebo effect and nocebo effect in the control group (Patient attitude by being denied IDET). These factors would tend to amplify results. Results were better than anticipated and authors attributed this to patient selection and technique. All patients had preserved disc heights and no one had severe degenerative disc disease. Responses noted at three months were not always maintained as 50% deteriorated and 50% retained relief of pain. It is estimated that 60% of patients clearly benefited. "Until it has been shown that others can achieve results equivalent to or better than those of the current study, IDET should not be considered ready for wholesale use in the public".

Two articles from The Back Letter<sup>6,7</sup> describing presentations and discussions at the annual meeting of the International Society for the Study of the Lumbar Spine (ISSLS) reported that prominent international back specialists raised concerns over the use of IDET, lack of longterm outcomes, and the lack of clinical investigations supporting the procedure. A multicenter study of 65 patients who underwent IDET at 120 disc levels found "eight outright treatment failures" with four undergoing interbody fusion surgery and four adverse outcomes involving lower extremity pain possibly due to catheter position. According to Dr. Gunnar Andersson, lead investigator, the results "do not prove that IDET is an effective treatment."

### **III. Patient Selection**

According to the above studies and the information from Oratec, the following patient criteria would be appropriate for the IDET procedure if it were authorized:

- Unremitting, persistent low back pain of 6 months duration
- No satisfactory improvement with nonoperative treatment
- Normal neurologic examination
- Negative straight leg examination
- MRI showing no evidence of neural compression lesion
- Discogram performed appropriately reproducing pain at low pressure ( $\leq$  to 1.25 ml dye volume) at one or more levels with adjacent control levels not reproducing pain.

Indications include an internally disrupted disc with an annular fissure or a contained disc herniation. Patients with compressive pathology due to stenosis or frankly herniated disc or sequestered discs are not candidates.

Patients with discogenic pain following previous discectomy or with  $>50\%$  collapse of the disc may be difficult to treat due to difficulty reaching the posterior wall with the catheter.

### **IV. Potential Benefits/Issues/Recommendations**

#### **A. Benefits**

- Less Invasive versus spinal fusion
- Less Costly versus spinal fusion
- Less Risk versus spinal fusion
- Less Disability if preliminary studies accurate
- Good Short Term Benefits
- May Obtain Better Outcomes Long-term

#### **B. Issues**

- No long-term ( $> 1$  year outcomes) outcomes
- Mixed or less than positive results from multicenter studies
- Most Studies by select physician groups (Bias and Patient Selection Bias?)
- Studies not applied to general population and mass physicians
- Appears to be used more and more with time
- Selection criteria will probably be important
- Other Treatment Alternatives for this group of patients
- Specific allowed condition for authorization of IDET
- Diagnostic criteria for the allowed condition

**C. Recommendations**

- If authorized, should adhere to patient selection criteria described above
- Appropriate allowed conditions typically would be lumbar strain or lumbosacral sprain strain or allowance of degenerative disc disease of the appropriate level. This is due to the requirement of normal MRI, no neurologic findings, and positive discogram. There is no ICD-9 currently recognized specifically for internal disc disruption.
- Consider second opinion prior to authorizing
- Utilize the specific CPT Code (AMA Suggested 62287 *Aspiration procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method, single or multiple levels, lumbar.*)
- BWC should consider a measurement of outcomes in terms of return to work, medical costs, permanent partial disability costs, and narcotic usage.

**Date of Creation: December 26, 2000**

## **Update of Current Literature May 2004**

A literature review of articles pertaining to IDET was performed focusing on articles dealing with outcomes. These articles are summarized below along with revision of patient selection criteria based on the more recent articles.

### **V. Review of Articles Published Since the Creation of Original IDET Position Paper**

A literature review and discussion of the pathophysiology, diagnosis, and treatment of internal disc disruption was published by Biyani et. al. This review included reported outcome measures for the IDET procedure including outcomes reported at national meetings. The authors concluded “IDET offers a technically facile procedure with a low complication rate and is an attractive alternative to more invasive procedures to manage discogenic lumbar pain. However, the magnitude of the benefits, its length of duration, and its comparability with other treatment methods are unknown. Based on the available literature and only short-term clinical follow-up trials, IDET should be viewed with guarded optimism and reserved for a select group of patients with chronic discogenic low back pain who have failed to improve after comprehensive nonoperative treatment and would otherwise be candidates for spinal fusion.”<sup>8</sup>

A prospective case series was performed by Lutz et. al. to determine the efficacy of IDET in treating individuals with discogenic pain of more than 6 months duration in spite of conservative treatment and who had positive discograms. Their study group total 33 patients of whom 15 (45%) were classified as workers’ compensation or no-fault cases. The mean duration for follow-up was 15 months (range, 8 – 24 months). The pre and post VAS scores improved by  $\geq 3$  in 23 (69.6%) of the 33 patients. They reported 25 (77%) of the 33 patients reported they would undergo the same procedure performed for the same outcome. They reported no statistical difference between the workers’ compensation versus the no-fault cases. They also report that 8 patients who were not working returned to work after IDET was performed. Five patients had increased pain that responded to epidural steroid injection and one patient had a progressive disk extrusion that required surgery. Complete or nearly complete relief of pain was observed in 24% of patients who were described as having relatively preserved disk heights with discrete annular tears.<sup>9</sup>

Cohen et. al. reported the outcomes and complication rate of 79 patients who underwent IDET procedure between 1999 and 2002.<sup>10</sup> Sixty-five patients were treated at Walter Reed Army Medical Center and fourteen were treated at Massachusetts General Hospital. Primary outcome measurement was a 50% pain relief on the six-month Visual Analog Scale following the IDET procedure as compared to the pre-procedure pain level on the Visual Analog Scale. Complications were determined by patient self-report and diagnostic studies performed on a case by case basis. Eight patients reported a complication. Three patients described paresthesias or increased leg pain that resolved within one month. One patient developed foot drop that resolved in 6 weeks. Two patients developed disc herniations and ultimately underwent surgery. It is unknown whether the herniations were related to the IDET procedure. One patient developed a severe headache that resolved within a week and one patient developed worsening leg pain contralateral to the IDET catheter insertion site that failed to resolve. On analysis of risk factors, only obesity (body weight more than 20% above ideal body weight) was found to be statistically

significant. Of the 69 non-obese patients, 54% reported a good outcome (50% pain relief at 6-months) while only one of the 10 obese patients reported a good outcome. Both patients who developed disc herniations were obese. Other common risk factors such as diabetes, smoking, or leg pain were not found to be statistically significant in relation to the outcome of 50% pain reduction. The authors hypothesized that the relatively low percentage of positive outcomes in this study may be reflective of stricter positive outcome criteria and less stringent inclusion criteria than other studies. The authors concluded that IDET was safe and relatively effective treatment but obesity of the patient should be considered a relative contraindication to the procedure.

Freedman et. al. reported on use of IDET to treat soldiers who had chronic discogenic lumbar pain that failed to respond to nonoperative therapy. Their population consisted of 36 active duty soldiers who underwent a single IDET procedure between 1999 and 2001. All 36 responded to outcome questions at 6 months and 31 of the 36 were contacted at more than 24 months. Successful outcome was defined as a 50% reduction in pain from the pre-IDET pain. Forty-seven percent of the 36 soldiers reported 50% reduction in pain at 6 months but the number decreased to only 16% (5 of 31) at final follow-up at greater than 24 months post procedure. Sixteen of the 31 soldiers reached at greater than 24 months post procedure reported a two-point or greater decrease in pain according to the Visual Analog Scale. Nineteen percent reported their back pain was worse since receiving IDET. Twenty-one of the 31 responded that they would undergo IDET again knowing their current outcome. However, only 16% indicated they were somewhat or very satisfied with their outcome. Seven of 15 patients on narcotic medications before IDET were able to decrease narcotic medications and of these, five stopped using narcotics completely. Twelve of the 31 had been medically discharged from the military because of low back pain. Seven of the 31 went on to spinal surgery. Five complications were noted – two had increased or new nondermatomal leg pain, one developed L5 nerve injury with foot drop, one had increased disc herniation, and one developed decreased sphincter tone with fecal incontinence. Reportedly these developed within two months and resolved completely.<sup>11</sup>

Davis et. al. reported on 60 patients referred by spine specialists who underwent IDET and were followed at one and two year intervals by questionnaires. Inclusion criteria included internally disrupted disc with an annular fissure; contained disc herniation; discogenic pain diagnosed by low volume provocative discogram, preserved disc height > 50%; chronic symptoms > 6 months; and failed aggressive nonoperative care including NSAIDs, physical therapy, bracing and injections. Exclusion criteria were stenosis; frank disc herniation or sequestered disc; evidence of neural compression on MRI; previous lumbar surgery; overlying psychological issues; segmental instability; and severe loss of disc height > 50%. Of the 60 patients, eight could not be located and eight refused to participate primarily due to pending workers' compensation claims. Of the remaining 44 patients, six underwent lumbar surgery (5 fusions, 1 discectomy) within 12 months of the IDET procedure and were excluded from analysis. A second attempt to get further information at two years after the IDET procedure revealed that four additional patients had undergone a lumbar surgical procedure between 12 and 24 months post-IDET. Of the 38 patients who completed the questionnaires, 37 (97%) continued to have pain. Fifteen (39%) described less pain than prior to IDET, 11 (29%) described same amount of pain, and 11 (29%) described more pain than prior to IDET. Five (13%) of the patient reported no medication use, 12 (32%) less medication use, 10 (26%) same amount of medication, and 11 (29%) more medication use when compared to prior to IDET procedure. Sixteen (42%) were employed prior to IDET and 11 (29%) were employed after IDET. Fourteen (37%) were satisfied with their IDET outcome, 19 (50%) were dissatisfied, and 5 (13%) were undecided with regard to their satisfaction with the procedure. Among complications, one individual was diagnosed with discitis requiring a fusion. Another developed a L4-L5 Grade 1 anterolisthesis requiring decompression and fusion.<sup>12</sup>

A case series of 142 individuals covered by a single workers' compensation insurer who underwent IDET performed by 97 different providers between December 1, 1998 and February 29, 2000 was reported by Webster relying on claim files and administrative bill payment data. Outcomes assessed included use of narcotic medications 6 months or more after IDET, additional low back injections or surgical procedures performed after IDET, and improved work status at 24 months after IDET. One hundred of the patients (70%) had at least one narcotic prescription more than 6 months after IDET and 78 (55%) had a least two narcotic prescriptions. Fifty-three (37%) of the individuals in the study underwent at least one lumbar injection after IDET. Thirty-two individuals (23%) went on to have a lumbar surgical procedure after IDET with 23 (16%) undergoing a lumbar fusion. Of the 104 (73%) of individual not working before IDET, 28 (20%) returned to work and 76 (54%) remained off work after IDET. Of the 35 individuals who were working before IDET, 27 remained at work after IDET. In analyzing factors that may impact the outcomes, narcotic use before IDET and having discography and IDET performed by the same provider (provider self-referral) were associated with poor results in all outcomes measured. Negative factors for return to work included provider self-referral, male gender, litigation, narcotic use 3 months before IDET, and older age.<sup>13</sup>

## **VI. Discussion**

The more recent medical literature has not found outcomes as good as those previously reported regardless of the measure used in the study. It must be realized that there are no randomized clinical controlled trials regarding this procedure. Earlier reported outcomes were of shorter duration, in patients with perhaps more stringent adherence to selection criteria, and were generally reported by physicians performing the procedure. More recent outcomes have included multiple physicians performing the procedure and included independently assessed patient satisfaction with their outcomes. Outcomes may also be affected by a condition which is primarily manifest as pain, which has failed nonsurgical treatment for more than six months, and for which there are very limited alternative treatment options. Therefore, it can be argued that poor to modest outcomes should be acceptable. On the otherhand, given the outcomes to date at best the procedure can only be considered a less invasive option than lumbar fusion in the treatment of chronic discogenic lumbar pain. Adherence to strict patient selection for performing this procedure may improve the outcomes. Additional outcomes studies are needed.

Inclusion criteria required for consideration of IDET from most authors and published research studies.

- Persistent low back pain of > 6 months duration
- Normal neurologic examination
- No satisfactory improvement with aggressive nonoperative treatment (Many would consider at least one epidural steroid injection that failed to relieve symptoms.)
- Negative straight leg examination and no signs of radiculopathy
- MRI showing no evidence of neural compression lesion or frank herniation
- Discogram performed appropriately reproducing pain at low pressure ( $\leq$  to 1.25 ml dye volume) at one or more levels with adjacent control levels not reproducing pain.
- Disc height  $\geq$  50% of normal
- No prior surgery at symptomatic level
- No evidence of lumbar canal stenosis
- No Psychological Issues or Barriers to Recovery

Factors that may be associated with a poor outcome include obesity, older age, litigation, narcotic use 3 months before the procedure, and discography and IDET performed by the same physician. These and other factors require additional study.

**Date of Last Revision:            May 11, 2004**

## **Update of Current Literature December 2005**

A literature review of articles pertaining to IDET was performed focusing on articles dealing with outcomes since the May 2004 Update. These articles are summarized below along with information regarding payment for this procedure by major insurers.

### **VII. Review of Outcome Studies Published Since May 2004**

There have been two randomized controlled trials performed and published in a peer-reviewed medical journal in the past year.

#### **A. Randomized Clinical Trial by Pauza et. al.**

The first randomized, placebo-controlled prospective trial was published by Pauza et. al.<sup>14</sup> Primary eligibility criteria included: age between 18 and 65 years; low back greater than leg pain present for more than 6 months duration; failure to improve after at least 6 weeks nonoperative care including anti-inflammatory and analgesic medications, physical therapy, and/or home directed lumbar exercise program; low back pain exacerbated by sitting or standing and relieved by lying down; a score less than 20 on the Beck depression scale; no surgical interventions within the previous 3 months; and less than 20% disc height narrowing on lateral plain film radiographs. Exclusion criteria were: previous lumbar spine surgery; abnormal neurological examination other than ankle reflex changes; radicular pain by history or examination; structural deformities such as spondylolisthesis at the painful segmental level, vertebral canal stenosis, or scoliosis; intervertebral disc herniations greater than 4 mm; sequestered intervertebral disc herniations; concomitant cervical or thoracic pain greater than 2/10 on a VAS; uncontrolled or acute medical illnesses; chronic severe conditions such as rheumatoid arthritis, ambulatory dysfunction, pregnancy, or allergy to contrast media or drugs to be used; or workers' compensation, injury litigation, disability remuneration; or unwillingness to consent to the study.

Patients meeting study criteria underwent discography and were considered to have discogenic pain if provocation of the disc reproduced their accustomed pain and no pain was reported when adjacent discs were stimulated. CT scans were obtained after discography and patients were required to have a posterior tear of the annulus fibrosus to be included in the study. Those patients admitted to the study were randomly assigned to undergo IDET or sham IDET. Those receiving the procedure had the flexible electrode passed into the disc and a circumferential posterior placement within the annulus fibrosus confirmed by lateral radiograph. The electrode was then heated to 90° C. using standard protocol. Those receiving the sham procedure had the introducer needle firmly positioned against the outer aspect of the annulus fibrosus but no electrode was inserted. The patients were exposed to a fluoroscope monitor that showed the passage of an electrode and the generator was used to create noise for 16.5 minutes simulating performing the actual procedure. After the procedure both groups were given monitored postoperative rehabilitation program.

Outcomes were assessed prior and six months after treatment using the 10-point visual analog scale (VAS) for pain, the Short Form (SF) – 36, and the Oswestry Disability Scale. A total of

37 patients were randomized to receive IDET and 27 to receive sham therapy. Reportedly there were no relevant statistical differences between the groups prior to treatment and baseline outcome measures were similar. Scores for most of the subscales of the SF-36 were high indicating “the patients were reasonably healthy apart from having pain and slight to moderate disability in physical functioning”. Of the 37 receiving IDET, one was excluded due to unacceptable catheter placement and one died unrelated to the procedure. Two were removed from the study due to new injury and another sustained a fractured leg unrelated to the procedure. Thirty-two patients were involved in the analysis. Of the 27 individuals receiving sham therapy, one was non-compliant with follow up, one was found to have a concurrent illness, and one individual had an undisclosed compensation claim. Therefore, 24 individuals receiving sham therapy was included in the analysis. When questioned after treatment 78% of individuals receiving IDET thought they received active treatment and 74% of those receiving the sham treatment believed they received active treatment.

When outcomes were measured at six months, both groups had significant improvements in pain scores with the IDET group being significantly greater than the sham group. The IDET group also had significantly better outcomes on the Oswestry Disability Scale. There were no significant changes on the SF-36 as both groups improved. When stratifying the outcomes to the baseline scores, the authors concluded that IDET was significantly more effective for patients with pain scores less than 70 at inception and for patients with poor function or greater disability at inception and IDET had no significant effect than sham treatment for patients with low disability or who already had good physical function. Of the patients treated with IDET, 40% achieved greater than 50% relief of pain at six months versus 33% in the sham treatment group. Twenty-two percent of patients receiving IDET had the same or worse pain after six months versus 54% of patient in the sham treatment group. The authors concluded that IDET is a “worthwhile intervention for some highly select patients”.

## **B. Randomized Clinical Trial by Freeman**

Another prospective, randomized, double-blind, placebo-controlled clinical trial of the use of IDET to treat chronic discogenic low back pain was reported by Freeman et. al.<sup>15</sup> Inclusion criteria included:

1. Candidate for IDET procedure at one or two levels;
2. Symptoms of degenerative lumbar disc disease of at least 3 months duration;
3. Failure to improve with a minimum of 6 weeks of conservation treatment including pain medication and physical therapy;
4. Present with marked functional limitation;
5. Sitting intolerance greater than standing intolerance;
6. Present with predominant low back pain with or without referred leg pain;
7. Negative straight leg raise and normal neurologic examination;
8. The presence of degenerative disc disease on magnetic resonance scan with global disc degeneration or posterior or posterolateral annular tear evident;
9. The presence of one- or two-level symptomatic disc degeneration as determined by provocative lumbar discography at L3-L4, L4-L5, L5-S1 and with an adjacent asymptomatic control disc;
10. At the target level, the discogram and subsequent computed tomography scan should demonstrate contrast spreading to the outer annulus or beyond the confines of the disc;
11. Minimum age 18 years;
12. Must be willing to comply with follow-up as per the protocol.

Exclusion criteria included:

1. Evidence of a large contained or sequestered herniation (small contained herniation is allowed);
2. Loss of more than 50% disc height at the target level;
3. Severely disrupted disc (sufficient annular tissue is required for safe catheter placement);
4. Neurogenic claudication due to spinal stenosis;
5. Three or more symptomatic lumbar disc levels;
6. Previous back surgery at any level of the lumbar spine;
7. Spondylolisthesis at a symptomatic disc level;
8. Psychological disorders that may impact treatment outcome (e.g., severe depression, drug addiction);
9. Medical condition that could interfere with follow-up care or evaluation;
10. Current injury litigation;
11. Pregnant women (risk of exposure to radiation);
12. Failure to understand informed consent form;
13. Participation in other studies of any kind.

Outcome measures were recorded at baseline and 6 months post procedure using the Visual Analogue Score for back pain (VAS), the Low Back Pain Outcome Score (LBOS), the Oswestry Disability Index (ODI), the Short-Form 36 General Health questionnaire (SF-36), the Zung Depression Index (ZDI), the Modified Somatic Perception Questionnaire (MSPQ), sitting tolerance, work tolerance, medication, and the presence of any neurologic deficit. Successful outcomes was defined as demonstrating no neurologic deficit resulting from the procedure, improvement in the LBOS of 7 or more points, and in improvement of the SF-36 subscales of bodily pain and physical functioning of greater than 1 standard deviation from the mean.

The study used a 2:1 IDET:placebo randomization resulting in 38 patients randomized to receive IDET and 19 to receive placebo (sham IDET). The IDET procedure involved placing the intradiscal catheter in the disc to cover at least 75% of the posterior annulus or at least 75% of the annular tear defined on the postdiscography CT scan. Once placed the technician opened an envelop to ascertain randomization and either connected the catheter to the generator (active IDET group) or did not (sham IDET). The generator was then switched on and the procedure followed the standard heating protocol. Both the patient and the surgeon were blinded as to whether the patient actually received active IDET. All subjects then followed a common rehabilitation program.

According to the authors, the IDET and placebo group were well-matched based on baseline LBOS, ODI, SF-36, ZDI, and MSPQ scores. Two subjects (both of whom had received IDET) were removed from analysis. One was due to a technical failure of the procedure and another withdrew at three months and underwent spinal fusion. Based on the outcome criteria for success, no one in either group met the criteria. Neither group had any neurologic deficits. No one demonstrated an improvement in the LBOS score of more than 7 points. In regard to the SF-36 subscales, 9 (25%) individuals who received IDET and 4 (21.1%) individuals who received placebo IDET showed an improvement in physical functioning and body pain index. Only 3 (8.3%) of the IDET and 3 (15.8%) of the placebo IDET showed an improvement in physical functioning and body pain index more than one standard deviation above their baseline values. Secondary outcome measures showed no statistical improvement and comparison among the surgeons who performed the study showed no significant differences. The only adverse events was transient radiculopathy lasting less than 6 weeks

occurred in four individuals who underwent IDET and in one who underwent placebo IDET. The authors concluded that IDET is no more effective than placebo for the treatment of chronic discogenic low back pain.

**VIII. Coverage by Other Insurers/Payment Systems**

The Regence Group in their Medical Policy effective June 1, 2005 stated “Intradiscal electrothermal annuloplasty or percutaneous intradiscal radiofrequency thermocoagulation is considered investigational as a treatment of chronic discogenic back pain.”

Aetna has the following statement regarding IDET:

“Aetna considers *any* of the following injections or procedures experimental and investigational for the treatment of back pain

1. Intradiscal electrothermal annuloplasty (IEA), also known as SpineCATH intradiscal electrothermal therapy (IDET), for relief of discogenic pain

The Work Loss Data Institute *Official Disability Guidelines* states the following:

<p>IDET (intradiscal electrothermal anuloplasty)</p>	<p>Not recommended. Early studies of IDET (intradiscal electrothermal anuloplasty) showed some advantages over discectomy, but IDET is operator dependent and should not be considered ready for wholesale use by the public, and more current studies are less positive. These early studies may exaggerate the efficacy of IDET, since some who initially improve later deteriorate. In addition, studies of IDET have relied on discography, a technique not well supported by the medical evidence. (<a href="#">Spruit, 2002</a>) (<a href="#">Saal, 2000</a>) (<a href="#">Saal2, 2000</a>) (<a href="#">Saal, 2002</a>) (<a href="#">Bogduk, 2002</a>) (<a href="#">Endres, 2002</a>) (<a href="#">Heary, 2001</a>) (<a href="#">Saal2, 2002</a>) (<a href="#">Pauza, 2004</a>) (<a href="#">Webster, 2004</a>) (<a href="#">Davis, 2004</a>) (<a href="#">Cohen, 2005</a>) A recent study found a significant decline in early success rates of IDET, declining from 47% at 6 months to only 16% at the latest follow-up, 24 months. (<a href="#">Freedman, 2003</a>) Another recent study indicates that obesity should be considered a relative contraindication to performing IDET, since the obese patients in the study were more likely to have a complication from intradiscal electrothermal therapy than they were to obtain pain relief. (<a href="#">Cohen, 2003</a>) Note: IDET is not generally covered by non workers’ comp health plans. (<a href="#">Blue Cross Blue Shield, 2004</a>) (<a href="#">Wellmark, 2004</a>) (<a href="#">Unicare, 2004</a>) (<a href="#">Cigna, 2004</a>) (<a href="#">Medicare, 2004</a>) (<a href="#">Regence BlueCross BlueShield, 2005</a>) Or some workers’ comp jurisdictions. (<a href="#">Washington, 2003</a>) "The department does not cover intradiscal heating techniques. We have found no substantial scientific evidence documenting the long-term safety and efficacy of intradiscal heating, particularly in the injured worker population." However, the procedure is recommended by practice guidelines written by the American Society Of Interventional Pain Physicians. (<a href="#">Boswell, 2005</a>)</p> <p><b>While not recommended, Patient selection criteria if IDET is to be performed anyway:</b></p> <ul style="list-style-type: none"> <li>•Unremitting, persistent low back pain of at least 6 months continuous duration</li> <li>•Lack of satisfactory improvement with a comprehensively applied non-operative care program, including: back education, activity modification, progressive intensive exercise, at least one fluoroscopically guided epidural corticosteroid injection, a trial of manual physical therapy, and</li> </ul>
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	<p>oral anti-inflammatory medication</p> <ul style="list-style-type: none"> <li>•Normal neurologic exam</li> <li>•Negative straight leg raise (SLR)</li> <li>•And MRI which did not demonstrate a neural compressive lesion</li> </ul> <p>•If the patient fails to improve with aggressive non-operative care and additional criteria for study inclusion were met, discography is undertaken. The discogram has to reproduce concordant pain at low pressurization (i.e. at less than or equal to 1.25 cc dye volume) at one or more levels with adjacent control levels not demonstrating pain reproduction. Concordant pain reproduction was defined as reproduction of the patient's typical low back pain symptoms. (<a href="#">Saal, 2000</a>)</p>
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## IX. Recommendations

Based on the result of more recent medical studies showing the lack of effectiveness of IDET in comparison to placebo in the only two randomized clinical trials available, IDET does not appear to be medically necessary, appropriate, and cost effective in terms of treatment results.

### December 2006 Update

**CPT code Assignment effective, 01/01/2007.**

The American Medical Association (AMA) has identified two new CPT codes for the IDET Procedure. CPT codes 22526 and 22527 will become effective 01/01/2007. Refer to CPT 2007 for the descriptions of these codes.

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- <sup>1</sup> Saal JS and Saal JA: “Management of Chronic Discogenic Low Back Pain with a Thermal Intradiscal Catheter” Spine 25:382-388, 2000.
- <sup>2</sup> Information From Oratec, Venture Capital Journal Vol 40(6), page 65, June 2000.
- <sup>3</sup> Wetzel, FR, Yuan H, et. al.: “Initial Results from a Prospective MultiCenter Study of Intradiscal Electrothermal Therapy (IDET)” unpublished, obtained from Oratec, dated March 30, 2000.
- <sup>4</sup> Saal, JA and Saal JS: “Intradiscal Electrothermal Treatment for Chronic Discogenic Low Back Pain – A Prospective Outcome Study with Minimum 1-Year Follow-Up” Spine 25:2622-2627, 2000.
- <sup>5</sup> Karasek, M and Bogduk N: “Twelve-Month Follow-Up of a Controlled Trial of Intradiscal Thermal Anuloplasty for Back Pain Due to Internal Disc Disruption”: Spine 25:2601-2607, 2000.
- <sup>6</sup> “IDET: Is There Any Indication That Intradiscal Thermal Therapy Works?” The Back Letter 15(6):64,65, 2000.
- <sup>7</sup> “Sharp Criticism of Intradiscal Thermal Therapy Research” The Back Letter 15(6):61-64, 2000.
- <sup>8</sup> Biyani A, Andersson G, et. al: “Intradiscal Electrothermal Therapy – A Treatment Option in Patients With Internal Disc Disruption” Spine 28:S8-S14, 2003.
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