



CLAIMS EVAL

*Utilization Review and
Peer Review Services*

DATE OF REVIEW: 7-7-09

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

IDET L3-L4, L5-S1

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION

American Board of Orthopaedic Surgery-Board Certified

REVIEW OUTCOME

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- 4-3-09 MRI of the lumbar spine.
- 4-28-09 Mental Health Evaluation.
- 5-27-09 and 6-4-09, MD., office visits.
- 5-19-09 MD., performed a Designated Doctor Evaluation.
- 6-4-09 MD., performed a Utilization Review.
- 6-18-09, MD., performed a Utilization Review.

PATIENT CLINICAL HISTORY [SUMMARY]:

An MRI of the lumbar spine dated 4-3-08 shows mild disc bulging and facet hypertrophy in the lower lumbar spine. No disc herniation or central spinal stenosis. Mild bilateral neuroforaminal stenosis at L4-L5. Minimal narrowing of neural foraminal at L3-L4 bilaterally and at L5-S1 on the right.

A Mental Health Evaluation dated 4-28-09 notes that in concurrence with Dr., the surgeon, who recently evaluated the claimant, the discography/surgery for lower back is recommended. At this time, the claimant appears to be ready to undertake treatment and the eventual rehabilitation required to successful surgery procedure. Testing of the Anxiety scale, BDI-II, FABQ and MMPI-2, all reveal positive progress. Thus it is recommended that the claimant go forward with treatment and be authorized for discography/low back surgery.

On 5-27-09, MD., evaluated the claimant. The claimant presents for review of his response to the lumbar discogram and post CT L2-L3 to L5-S1 performed on 5-15-09. At L2-L3, there was pressure with No pain. At L3-L4, there was no pain provoked. At L5-S1, there was concordant low back pain recorded. The claimant reported that his low back pain was definitely replicated during the procedure along with right leg pain "shooting from the low back to all 5 toes", very little left leg pain. Dr noted lateral stenosis at S1 right > left. The claimant continues with low back pain and left leg pain rated as 9/10 described as sharp pulsing with numbness and tingling from the buttocks to all 5 toes. The claimant's medications include Venlafaxine. He discontinued taking Hydrocodone, Naproxen and Skelaxin. On exam, the claimant has restricted range of motion. Lateral bending reveals paraspinal spasms on the right. Extension and rotation is positive bilateral, left greater than right with pain in the low back,. There is tenderness that is moderate on the left and mild on the right over his paraspinal muscles and worse at the lower lumbar levels. DTR are equal and reactive at the knees and intact at the ankles. SLR is positive on the left for left leg pain. Lessague is positive on the left for left leg pain. Motor strength is 5/5 of the hip flexors, 3/5 of the left

EHL, and 4/5 of the left dorsi evertors. Dermatomal pattern is numb throughout the entire left leg from the proximal thigh to all 5 toes. The evaluator recommended IDET L3-L4 and L5-S1.

Follow-up with Dr. dated 6-4-09 notes the evaluator was able to talk to Dr. regarding the proposed IDET procedure. The evaluator noted he emphasized the rationale for the procedure which is the claimant is thought to be a good candidate for fusion procedure, but is not prudent to fuse levels not adjacent to one another as his discogram found primary discogenic pain at L3-L4 and L5-S1. The claimant may need a fusion in the future, but IDET affords the claimant the greatest opportunity to have his primary pain generator addressed and hopefully will restore function at the least cost and time for him.

On 5-19-09, MD., performed a Designated Doctor Evaluation. He certified the claimant had not reached MMI and estimated 9-19-09 as the date of MMI. The evaluator recommended the claimant undergo discogram, which had been performed, however, he did not have the report. The evaluator recommended referring the claimant back to Dr. for further evaluation.

On 6-4-09, MD., performed a Utilization Review. It was his opinion that based on the clinical information provided, the request for a 2 level IDET L3-L4 and L5-S1 is not recommended as medically necessary. Per ODG Guidelines, IDET is not recommended as medically necessary given the lack of strong scientific evidence of efficacy of this procedure.

On 6-18-09, MD., performed a Utilization Review. An attempted peer to peer was not successful. The claimant is over a year post injury and has persistent low back and lower extremity symptomatology. While he has had an appropriate conservative course of care, IDET procedures have not been proven by quality, long-term clinical trials to be effective. Studies have not shown clear evidence of benefit and studies noted it was no more effective than placebo. In addition, an EMG/NCS findings of mild chronic left L5 radiculopathy. Thus based on the lack of supportive literature, the proposed IDET procedure cannot be recommended as medically necessary.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION.

MEDICAL RECORDS REFLECT A CLAIMANT WITH LOW BACK PAIN. THE CLAIMANT HAS BEEN TREATED WITH MEDICATIONS, PT. HE UNDERWENT A LUMBAR DISCOGRAM WHICH DEMONSTRATED CONCORDANT PAIN AT L5-S1 LEVEL. THERE HAS BEEN A REQUEST FOR IDET AT L3-L4 AND L5-S1. CURRENT EVIDENCE BASED MEDICINE REFLECTS THAT IDET IS NOT RECOMMENDED. RANDOMIZED TRIALS HAVE NOT FOUND IDET TO BE

EFFECTIVE. BASED ON THE CLAIMANT'S HISTORY OF EXAM FINDINGS, THE REQUESTED IDET IS NOT CERTIFIED.

ODG-TWC, last update 6-25-09 Lumbar Spine - IDET: Not recommended. Also known as intradiscal electrothermal annuloplasty. *Proposed indications:* The procedure is suggested for discogenic pain that is non-radicular and that has not responded to conservative treatment as an alternative to a fusion procedure. *Mechanism of discogenic pain:* The exact mechanism of discogenic pain remains unknown but is presumed to relate to internal disc disruption. It is hypothesized that painful discs are the result of repetitive injury and subsequent repair. Radial annular tears are thought to allow the matrix substance of the nucleus pulposus to migrate and induce nerve ingrowth into the demyelinated regions. (Kloth, 2008) *Mechanism of action of the procedure:* Involves inserting an intradiscal catheter radiologically into the outer posterior or posterolateral annulus across a previously identified tear. The precise mechanism of action of the procedure remains uncertain. The proposed goals of the treatment are to remove unwanted tissue, create a seal to limit expression of the matrix components, shrink collagen tissue, and destroy nociceptors. (Derby, 2008)

Current literature:

Randomized-controlled trials: There are two RCTs that have evaluated IDET. In the first by Pauza et al, the researchers initially sent out 4,523 inquiries for the study. Of this number 3,163 declined and 1,100 did not meet the criteria. Ultimately 64 patients participated (of the remaining 260 patients that were screened with discography). Inclusion criteria included pain of at least six months that had not responded to conservative care. Disc height narrowing was restricted to 20%. The Beck Depression Index score could not be less than 20. Exclusion included radicular pain, previous lumbar surgery, disc herniation > 4 mm, and structural deformities. No patient was involved in workers' compensation or litigation, nor could they have disability remuneration. The difference in VAS score at six months for the IDET group was 2.4 (6.6 to 4.2). For the sham group this was 1.1 (6.5 to 5.4). This was statistically significant at 0.045. Differences in the Oswestry Disability Scale and SF-36 were not significant. The conclusion was that the apparent efficacy appeared to be related to "non-specific" factors associated with treatment that could not be related to placebo. (Pauza-Spine, 2004) A second RCT was performed by Freeman et al. Similar inclusion criteria were utilized except that a 50% loss of disc height was allowed. Exclusion criteria included "Psychological disorder that may impact treatment outcome (e.g. severe depression, drug addiction)." This study did not include an adequate number of subjects for the power analysis. The technique used in the study has also been questioned. No patient in either group met the predefined criteria for successful outcome at 6 months and the authors concluded that IDET was no more effective than placebo. A criticism of the study was the lack of placebo response in the sham group. (Freeman-Spine, 2005)

Systematic reviews and meta-analysis: A systematic review was conducted by a manufacturer of an IDET device in 2006 that found that IDET provided sufficiently similar symptom amelioration to fusion procedures, although none of the studies were

head-to-head comparisons. (Andersson, 2006) A meta-analysis (also sponsored by the same manufacturer) found that the pooled results of 17 articles (not including the Freeman study) found a positive trend for relative efficacy and safety. (Appleby, 2006) These studies used only one randomized controlled trial (the Pauza trial). Freeman also performed a review in 2006. (Freeman, 2006) They reported that initial reports were impressive with improvements in subjective outcome measures in highly selective cases. They recommended caution in recommending the treatment and felt current evidence did not provide clear evidence for benefit.

Other studies and associated issues: Numerous non-controlled studies have found positive results with the use of IDET although the treatment appears to have limited success for workers' compensation patients. Webster et al. found that continued work absence post IDET was associated with provider self-referral, male gender, litigation, narcotic use prior to the procedure, and older age. (Webster-Spine, 2004) This was an insurance sponsored study. Decreased success in workers' compensation patients was also found by Mekhail. (Mekhail, 2004) A recent study examining this procedure specifically in the workers' compensation population included patients with pain of no greater than six months duration that was not attributed to radiculopathy, pseudoradiculopathy, or facet disease. These patients had not responded to conservative treatment. Discography was performed on all patients. Approximately 70% of the patients performed heavy labor and approximately 80% of these patients were off-work. Variables that affected outcome included age, BMI, VAS score at the time of the presentation and the initial Oswestry score. Six percent of patients in the heavy lifting group resumed full duty and 16% resumed work with restrictions (it was not clear if these patients had been working before). Opioid use decreased from 51% of patients to 13% of patients. In a post-hoc analysis the authors stated that there were certain demographic predictors of a positive response that included younger age, a BMI between 20 and 30, and relatively recent onset of symptoms (≤ 6 months). (Nunley, 2008) (Saal-Spine, 2000) (Saal2-Spine, 2000) (Saal-Spine, 2002) (Bogduk-Spine, 2002) (Davis-Spine, 2004) (Cohen, 2005) (Kapural, 2004) There is good evidence that prolotherapy and percutaneous intradiscal radiofrequency thermocoagulation are not effective. (Chou3, 2009)

Recommendations from Cochrane and other Professional Societies: (1) A 2005 Cochrane review concluded that the effectiveness of IDET remained unproven. (Gibson-Cochrane, 2005) (2) The American Pain Society has a published bulletin that states that there is currently insufficient literature to support this procedure. (Chou, 2008) (Stanos, 2007); (3) CMS (Centers for Medicare and Medicaid Services) recently issued a national non-coverage determination for intradiscal electrothermal therapy (IDET), concluding that the totality of the evidence is sufficient to determine that IDET does not improve health outcomes for patients with low back pain. (CMS, 2008); (4) The American Society of Interventional Pain Physicians stated the procedure received moderate evidence for managing chronic low back pain. (Boswell, 2007); (5) The European Guidelines for the Management of chronic non-specific pain stated that there was conflicting evidence that the procedure was more effective than sham treatment and the procedure was not recommended. (Airaksinen, 2006); (6) The North American

Spine Society (NASS) recently stated that they felt the procedure provided only modest improvement but was less destructive, cheaper, and safer than other invasive procedures. Functional improvement was less than that of pain relief. They suggested that the procedure was most effective for patients with less functional impairment, relatively well-maintained disc heights, and discogenic pain caused by annular tears or protrusions less than 3-4 mm. They felt there was little expectation that IDET would return the claimant to work involving significant manual labor. They went on to state, "like spinal fusion or arthroplasty, even a technically satisfying procedure will not prevent a significant number of patients reporting that they have worsening of pain from a variety of different factors." (Derby, 2008)

Areas of uncertainty concerning this procedure: (1) The procedure appears to be operator dependent; (2) Diagnostic criteria in most studies includes the use of discography, a technique not well supported by medical evidence; (3) As noted above, the role of involvement in workers' compensation and/or litigation appears to have a negative effect on outcome; (4) Provider self-referral may be an issue; (5) There is little evidence as to how to adequately pre-assess a patient in terms of psychiatric comorbidity although the Pauza group attempted this, and groups such as NASS now recommend that the patients be excluded from treatment with conditions such as somatization disorder or other psych conditions correlated with higher false-positive rates on discography or poorer clinical outcomes from other interventions; (6) There is virtually no research of the role of medications including opioids and other poly-pharmaceutical regimens on the outcome of IDET.

Potential Adverse Events: Possible complications include discitis, epidural abscess, vertebral osteomyelitis, and bacterial meningitis. Potential neural complications include cauda equine syndrome, nerve root damage and acute disc herniation. Patients may develop an allergic reaction to the dye. Vascular complications may include retroperitoneal bleeding or intramuscular hematoma. (CMS, 2008)

IDET is Not Recommended by the ODG.

Patient selection criteria for IDET if provider & payor agree to perform anyway:

- Unremitting, persistent low back pain of at least 6 months continuous duration;
- Other potential structural causes of chronic low back pain have been excluded;
- There is no evidence of primary radicular pain or radiculopathy;
- A MRI has been performed demonstrating disc pathology of the posterior annulus at no more than two levels without evidence of a neural compressive disorder or prior surgery at that level;
- No more than two discs are involved and reduction of disc height is no more than 50%;
- There is evidence of lack of satisfactory improvement with a comprehensively applied non-operative care program, including: back education, activity modification, progressive intensive exercise, a trial of manual physical therapy, and oral anti-inflammatory medication;
- If a patient fails to improve with aggressive treatment psychiatric screening should be undertaken. This includes independent neuropsychiatric screening using a validated

instrument (with the gold standard being the MMPI-2). The psych screen should include an evaluation for potential dependence/addiction if medications known for dependence are in use (such as opioids or benzodiazepines). See Psychological evaluations, IDDS & SCS (intrathecal drug delivery systems & spinal cord stimulators);

- If the patient fails to improve with aggressive non-operative care and the above criteria are met, discography is undertaken. The discogram has to reproduce concordant pain at low pressurization (i.e. at less than 50 psi above opening pressure) at one or more levels with adjacent control levels not demonstrating pain reproduction. Concordant pain reproduction is defined as reproduction of the patient's typical low back pain symptoms.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN
- INTERQUAL CRITERIA
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- MILLIMAN CARE GUIDELINES
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- TEXAS TACADA GUIDELINES

- TMF SCREENING CRITERIA MANUAL**
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE
(PROVIDE A DESCRIPTION)**
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME
FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**