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IRO REVIEWER REPORT

DATE OF REVIEW: 05/27/07

IRO CASE NO.:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Items in Dispute: L3-L4, L4-L5 lumbar discogram followed by Plasma disc decompression at L3-L4, L4-L5 utilizing the Perc DLG Spine Wand from Discocare.

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

Texas License and currently on TDI DWC ADL.
Board Certified Neurosurgeon

REVIEW OUTCOME:

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

Denial Upheld

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

1. 01/19/07-05/09/07 –Orthopedic & Sports Medicine.
2. 01/30/07-02/20/07 –Imaging & Diagnostics.
3. 02/26/07 –Surgery Center Partners.
4. 03/20/07 – Medical necessity letter from Dr.
5. 03/19/07-03/27/07 — Denial letters.
6. 05/04/07 – TDI IRO information.

INJURED EMPLOYEE CLINICAL HISTORY (SUMMARY):

The employee was when he reported to have injured his low back.

The employee was evaluated by Dr. on XX/XX/XX. The employee was reported to have low back pain with radiation into the right posterior thigh. The employee was referred for

physical therapy, which was reported to have made his pain worse. Upon examination, the employee had slightly limited flexion, negative straight leg raise, normal lower extremity motor strength, normal sensory, and normal reflexes. Radiographs were essentially unremarkable.

The employee was referred for MR imagery of the lumbar spine on 01/30/07. This study reported early bilateral facet arthropathy at L5-S1. At L4-L5, there was a minimal annular bulge that contacted the ventral aspect of the thecal sac and the exiting L5 nerve root sleeves, which did not appear to be significantly deformed. The neural foramina was patent. At L3-L4, there was narrowing of the intervertebral disc space with an annular bulge that flattened the ventral aspect of the thecal sac and early bilateral facet arthropathy.

The employee was referred for epidural steroid injections and had no response to the initial injection, and these were discontinued.

The employee was referred for an MRI of the thoracic spine on 02/22/07, which was reported as normal.

The employee was later recommended to undergo lumbar discography. This study was not approved through utilization review.

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

Dr. requested a two level lumbar discogram at levels L3-L4 and L4-L5 to be followed by Plasma Disc decompression at L3-L4 and L4-L5 which was not considered medically necessary. Discography was not recommended by current evidence based guidelines if pursued, the *Official Disability Guidelines* requires the employee have a detailed psychosocial assessment which does not appear to have been performed. Plasma Disc decompression was not supported by the *Official Disability Guidelines* and was considered experimental/investigational due to the lack of comprehensive clinical studies. The current available data does not indicate this procedure to be superior to more conventional forms of operative intervention.

Citations:

Official Disability Guidelines:

Discography – Not recommended. In the past, discography has been used as part of the preoperative evaluation of patients for consideration of surgical intervention for lower back pain. However, the conclusions of recent, high quality studies on discography have significantly questioned the use of discography results as a preoperative indication for either IDET or spinal fusion. These studies have suggested that reproduction of the patient's specific back complaints on injection of one or more discs (concordance of symptoms) is of limited diagnostic value. (Pain production was found to be common in non-back pain patients; pain reproduction was found to be inaccurate in many patients with chronic back pain and abnormal psychosocial testing, and in this latter patient type, the test itself was sometimes found to produce significant symptoms in non-back pain controls more than a year after testing). Also, the findings of discography have not been shown to consistently correlate well with the findings of a High Intensity Zone (HIZ) on MRI. (Carragee-Spine, 2000) (Carragee 2-Spine, 2000) (Carragee 3-Spine, 2000) (Carragee 4-Spine, 2000) (Bigos, 1999) (ACR, 2000) (Resnick, 2002) (Madan, 2002) (Carragee – Spine, 2004) (Carragee 2, 2004) (Pneumaticos, 2006) (Airaksinen, 2006).

Positive discography was not highly predictive in identifying outcomes from spinal fusion. A recent study found only a 27% success from spinal fusion in patients with low back pain and a positive single level low pressure provocative discogram, versus a 72% success in patients having a well-accepted single level lumbar pathology of unstable spondylolisthesis. (Carragee, 2006) Discography involves the injection of a water soluble imaging material directly into the nucleus pulposus of the disc. Information is then recorded about the pressure in the disc at the initiation and completion of injection, about the amount of dye accepted, about the configuration and distribution of the dye in the disc, about the quality and intensity of the patient's pain experience and about the pressure at which that pain experience is produced. Both routine x-ray imaging during the injection and post injection CT examination of the injected discs are usually performed as part of the study. There are two diagnostic objectives" (1) to evaluate radiographically the extent of disc damage on discogram and (2) to characterize the pain response (if any) on disc injection to see if it compares with the typical pain symptoms the patient has been experiencing. Criteria exists to grade the degree of disc degeneration from one (normal disc) to severe. A symptomatic degenerative disc is considered one that disperses injected contrast in an abnormal, degenerative pattern, extending to the outer margins of the annulus and at the same time reproduces the patient's lower back complaints (concordance) at a low injection pressure. See also Functional Anesthetic Discography (FAD)

While not recommended above, if a decision is made to use discography anyway, the following criteria should apply:

- Back pain of at least three months duration.
- Failure of recommended conservative treatment.
- An MRI demonstrating one or more degenerated discs as well as one or more normal appearing discs to allow for an internal control injection (injection of a normal disc to validate the procedure by a lack of a pain response to that injection).
- Satisfactory results from detailed psychosocial assessment (discography in subjects with emotional and chronic pain problems has been linked to reports of significant back pain for prolonged periods after injection, and therefore should be avoided).
- Intended as a screen for surgery; i.e., the surgeon feels that lumbar spine fusion is appropriate but is looking for this to determine if it is not indicated (although discography is not highly predictive). (Carragee, 2006)
- Briefed on potential risks and benefits from discography and surgery.
- Single level testing. (Colorado, 2001)

Nucleoplasty: Not recommended. Nucleoplasty is a percutaneous method of decompressing herniated vertebral discs that uses radiofrequency energy {Coblation (ArthroCare Corp. Sunnyvale, CA)}for ablating soft tissue, and thermal energy for coagulating soft tissue, combining both approaches for partial disc removal. Nucleoplasty is designed to avoid the substantial thermal injury risks of Intradiscal Electrothermal Annuloplasty (IDET), because nucleoplasty produces lower temperatures within the disc annulus. Given the extremely low level of evidence available for nucleoplasty (Coblation Nucleoplasty), and the lack of clinical trials, it is recommended that this procedure be regarded as experimental at this time. (Chen, 2003) (Manchikanti, 2003) (Aetna, 2004) (Medicare, 2004) (Cohen, 2005) (Blue Cross Blue Shield, 2005)

An assessment by the National Institute for Clinical Excellence (2004) concluded: "Current evidence on the safety and efficacy of percutaneous disc decompression using coblation for

lower back pain does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research.... The lack of data makes it difficult to draw conclusions regarding the efficacy of the procedure. The lack of long-term and comparative data also makes it difficult to distinguish between the treatment effect and the natural history of the disease, as well as determine whether the benefits of this procedure are sustained beyond 12 months.”

Bhagia et al (2006) reported the short-term side effects and complications after percutaneous disc decompression utilizing coblation technology (nucleoplasty). Following institutional review board approval, consecutive patients who were to undergo percutaneous disc decompression using nucleoplasty were prospectively enrolled. Patients were questioned preoperatively, postoperatively, and 24 hours, 72 hours, 1 week, and 2 weeks post procedure by an independent reviewer regarding seventeen symptom complications, which include bowel or bladder symptoms, muscle spasm, new pain, numbness/tingling or weakness, fevers/chills, rash/pruritus, headaches, nausea/vomiting, bleeding, and needle insertion site soreness. Statistical analysis was performed using Wilcoxon’s signed rank test. A total of 53 patients enrolled, of whom four patients dropped out. Two patients had increased symptoms and opted for surgery. Two patients could not be contacted. The most common side effects at twenty-four hours post procedure was soreness at the needle insertion site (76%), new numbness and tingling (26%), increased intensity of pre-procedure back pain (15%), and new areas of back pain (15%). At two weeks, no patient has soreness at the needle insertion site or new areas of back pain; however, new numbness and tingling was present in 15% of patients. Two patients (4%) had increased intensity of pre-procedure back pain. There were statistically significant reductions in visual analog scale (VAS) score for back pain and leg pain ($p < 0.05$). The authors concluded that based on this preliminary data, nucleoplasty seemed to be associated with short-term increased pain at the needle insertion site and increased pre-procedure back pain and tingling numbness but without other side effects.

If the IMED’s decision is contrary to: (1) the DWC’s policies or guidelines adopted under Labor Code §413.011, IMED must indicate in the decision the specific basis for its divergence in the review of medical necessity of non-network health care or (2) the network’s treatment guidelines, IMED must indicate in the decision the specific basis for its divergence in the review of medical necessity of network health care.

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

- A. *Spine*
- B. *The Spine Journal*
- C. *Official Disability Guidelines*