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Notice of Independent Review Decision

DATE OF REVIEW: 08/13/10

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

The item in dispute is the prospective medical necessity of an outpatient low pressure lumbar discogram at L4/5 and L5/S1 with control level at L3/4.

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

The reviewer is a Medical Doctor who is board certified in Orthopedic Surgery. The reviewer has been practicing for greater than 10 years.

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)

The reviewer agrees with the previous adverse determination regarding the medical necessity of an outpatient low pressure lumbar discogram at L4/5 and L5/S1 with control level at L3/4.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Records were received and reviewed from the following parties:, MD, and attorney.

These records consist of the following (duplicate records are only listed from one source): Records reviewed from Dr.: 4/20/07 through 12/31/09 history and physical reports, 4/20/07 to 10/16/09 discharge summaries, 6/15/06 through 12/31/09 operative reports, 4/20/07 to 11/9/07 admission notes, 7/6/10 preauth request form, 7/20/10 denial letter, study by, results of surgery for diskogenic LBP Spine, 2009, abstract by (systemic review of discography) Pain Phys 2009, abstract by et al (system review of lumbar provocation...) Pain Phys 2008, abstract by (system review of discography....) Pain Phys 2007, TMB bulletin, study by Pneumatics, et al Journ Amer Acad Ortho Surg 2006, abstract by Kor

Med Sci 2006, abstract by Lettice et al Spine 2005, abstract by, Spine 2002, study by Tomecek et al Neurosurg Focus 2002, study by Derby et al Spine 1999, study by et al Journ Bone Joint Surg 1990, 7/12/10 denial letter, 7/8/10 telephonic conference report, 6/8/10 x-ray lumbar report, 1/15/10 thoracic x-ray report, 4/12/07 to 12/28/09 lab panel reports, 10/29/09 thoracic and lumbar x-ray reports, 10/26/09 script for radiographs, 10/7/09 chest x-ray report, 4/12/07 to 10/7/09 EKG reports, 8/19/08 FCE report, 2/18/08 script by, MD, 11/9/07 surgical pathology report, undated script for CBC, 10/11/07 lumbar MRI report, 12/23/08 lumbar MRI report, 5/9/05 lumbar MRI report, 4/19/05 lumbar radiographic report, addendum dated 7/5/10 by Dr., 7/16/10 letter by, 6/8/10 to 6/24/10 reports by Dr. , 4/14/10 script by MD, office notes by Dr. from 6/5/06 to 2/8/10, 11/3/07 to 11/30/09 telephone message notes, 8/27/09 psychological eval report, 4/6/09 letter by Dr., 2/17/09 letter by the patient, 2/3/09 script by Dr., 5/21/08 to 1/27/09 notes by, MD, 12/15/08 report by, MD, 12/15/08 lumbar ROM sheet, 8/19/08 DD report by MD, 4/30/08 script by Dr., 4/16/08 office note by MD, 3/4/08 letter by PC, undated note from Pain Management Clinic, 11/6/07 note by DO, 10/24/07 note by MD, 5/12/06 to 4/12/07 notes by MD, 6/17/05 to 8/12/05 notes by MD and 6/20/05 letter by, MD.

: 7/28/10 IRO response, copy of ODG discography criteria, 7/6/10 and 7/14/10 copy of 134.600 letter, 7/26/10 email from, undated case summary by, 7/20/10 denial letter, 1/20/09 denial letter, 1/20/09 email from, 1/13/09 preauth request, 10/3/08 email by, 11/13/07 letter by MD, 12/15/06 DD report by MD, 2/3/09 amended report by Dr., 10/13/09 script by Dr., 10/13/09 precert request, patient charge sheet and copy of ambulatory surgical center license.

attorney: All records received were duplicative of the above records.

A copy of the ODG was provided by the Carrier/URA for this review.

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant was noted to have been involved in a motor vehicle accident. The vehicle in which the claimant was a passenger was broadsided on the driver's side. The claimant had a history of having undergone prior lumbar surgical intervention. Since the motor vehicle accident, the claimant has complained of persistent back pain. An MRI scan from 10-11-07 (post-operative) was noted to reveal a large L5-S1 disc protrusion resulting in neuroforaminal stenosis along with postoperative changes reflecting an L5 laminectomy. Degenerative disc disease was also noted at L3-4 and L 4-5. A second discectomy was performed in November-07, due to persistent findings. The claimant continued to have persistent abnormalities (subjectively and objectively) and was therefore treated with medications, injections and a spinal cord stimulator. The spinal MRI from 12-23-08 was reported as not having been significantly different than the 2005 dated MRI (regarding the region proximal to L5-S1) as per Dr.. The 12-24-08 dated MRI report revealed central bulges with impingement at L5-S1 greater than at L4-5 and other levels.

In records from 6-2010, Dr. rendered diagnoses of failed laminectomy X 2 along with mechanical low back pain. The additional diagnoses included an L5-S1 HNP, left-sided radiculopathy along with SI joint pain. The claimant was noted to have weakness of the left EHL and peroneals, compatible with L5 radiculopathy. The possibility of a discogram as a pre-op. adjunctive diagnostic was proposed. Denial letters denoted that discograms are not indicated and/or potentially harmful.

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

The claimant has not met criteria for fusion, based on the lack of flexion-extension studies documenting significant instability. Even in cases where discograms are considered potentially applicable, fusion criteria must be first met, which is not the case in this instance. In addition, the most recent studies related to discograms have not reflected reliable pre-operative pain generators. Discograms for any specific type of surgical spinal intervention have therefore not been determined as being reasonable and/or necessary as per applicable guidelines.

The ODG indicates discograms are not recommended. In the past, discography has been used as part of the pre-operative 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 finding of a High Intensity Zone (HIZ) on MRI. Discography may be justified if the decision has already been made to do a spinal fusion, and a negative discogram could rule out the need for fusion (but a positive discogram in itself would not allow fusion).

Discography may be supported if the decision has already been made to do a spinal fusion, and a negative discogram could rule out the need for fusion on that disc (but a positive discogram in itself would not justify fusion). Discography may help distinguish asymptomatic discs among morphologically abnormal discs in patients without psychosocial issues. Precise prospective categorization of discographic diagnoses may predict outcomes from treatment, surgical or otherwise. 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. The prevalence of positive discogram may be increased in subjects with chronic low back pain who have had prior surgery at the level tested for lumbar disc herniation. Invasive diagnostics such as provocative discography have not been proven to be accurate for diagnosing various spinal conditions, and their ability to effectively guide therapeutic choices and improve ultimate patient outcomes is uncertain. Although discography, especially combined with CT scanning, may be more accurate than other radiologic studies in detecting degenerative disc disease, its ability to improve surgical outcomes has yet to be proven. It is routinely used before IDET, yet only occasionally used before spinal fusion. Provocative discography is not recommended because its diagnostic accuracy remains uncertain, false-positives can occur in persons without low back pain, and its use has not been shown to improve clinical outcomes. This recent RCT concluded that, compared with discography, injection of a small amount of bupivacaine into the painful disc was a better tool for the diagnosis of discogenic LBP. Discography may cause disc degeneration. Even modern discography techniques using small gauge needle and limited pressurization resulted in accelerated disc degeneration (35% in the discography group compared to 14% in the control group), disc herniation, loss of disc height and signal and the development of reactive endplate changes compared to match-controls. These findings are of concern for several reasons. Discography as a diagnostic test is controversial and in view of these findings the utility of this test should be reviewed. Furthermore, discography in current practice will often include injecting discs with a low probability of being symptomatic in an effort to validate other disc injections, a so-called control disc. Although this strategy has never been confirmed to increase test validity or utility, injecting normal discs even with small gauge needles appears to increase the rate of degeneration in these discs over time. The phenomenon of accelerated adjacent segment degeneration adjacent to fusion levels may be, in part, explained by previous disc puncture if discography was used in segments adjacent to the fusion. Similarly, intradiscal therapeutic strategies (injecting steroids, sclerosing agents, growth factors, etc.) have been proposed as a method to treat, arrest or prevent symptomatic disc disease. This study suggests that the injection procedure itself is not completely innocuous and a recalculation of these demonstrated risks versus hypothetical benefits should be considered. 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 exist to grade the degree of disc degeneration from none (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. Discography is not a sensitive test for radiculopathy and has no role in its confirmation. It is, rather, a confirmatory test in the workup of axial back pain and its validity is intimately tied to its indications and performance. As stated, it is the end of a diagnostic workup in a patient who has failed all reasonable conservative care and remains highly symptomatic. Its validity is enhanced (and only achieves potential meaningfulness) in the context of an MRI showing both dark discs and bright, normal discs -- both of which need testing as an internal validity measure. And the discogram needs to be performed according to contemporary diagnostic criteria -- namely, a positive response should be low pressure, concordant at equal to or greater than a VAS of 7/10 and demonstrate degenerative changes (dark disc) on MRI and the discogram with negative findings of at least one normal disc on MRI and discogram.

Discography is Not Recommended in ODG.

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

- o Back pain of at least 3 months duration
- o Failure of recommended conservative treatment including active physical therapy
- o 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)
- o 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)
- o 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) NOTE: In a situation where the selection criteria and other surgical indications for fusion are conditionally met, discography can be considered in preparation for the surgical procedure. However, all of the qualifying conditions must be met prior to proceeding to discography as discography should be viewed as a non-diagnostic but confirmatory study for selecting operative levels for the proposed surgical procedure. Discography should not be ordered for a patient who does not meet surgical criteria.
- o Briefed on potential risks and benefits from discography and surgery
- o Single level testing (with control)
- o Due to high rates of positive discogram after surgery for lumbar disc herniation, this should be potential reason for non-certification

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)