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Notice of Independent Review Decision

DATE OF REVIEW: 06/29/2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Lumbar Discography (*Spelling corrected from Lumber to Lumbar in Amended Letter Number Two, July 2, 2010 . Copies of this letter were sent to all involved parties on this date as specified.*)

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

Certified by the American Board of Orthopaedic Surgery

REVIEW OUTCOME

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

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

Injury date	Claim #	Review Type	ICD-9 DSMV	HCPCS/ NDC	Upheld/ Overturned
		Prospective	724.2	72295	Upheld
		Prospective	724.2	62290	Upheld

INFORMATION PROVIDED TO THE IRO FOR REVIEW

1. MRI lumbar spine dated 03/31/10.
2. MRI bilateral hips dated 03/31/10.
3. CT myelogram lumbar spine dated 04/29/10.
4. Provider clinical note dated 05/07/10.
5. Previous utilization review determination dated 05/14/10.
6. Utilization review determination dated 05/24/10.

PATIENT CLINICAL HISTORY:

Notice of Independent Review Decision

June 30, 2010 Original Notice

Amended Notice July 01, 2010

Amended Notice Number Two, July 02, 2010

Copies of all notices sent to all involved parties on each date as specified above

Page 2

The patient is a male who is reported to have sustained work related injuries to his low back on xx/xx/xx. The record contains an MRI of the lumbar spine dated 03/31/10 which reports L1-2, L2-3, and L3-4 to be unremarkable. At L4-5 there is trace annular bulge present, and in lateral aspect of right neural foramen there is questionable soft tissue versus disc herniation identified. At L5-S1 there is a moderate posterior disc flattening and disc desiccation present. There is reported retrolisthesis of L5 relative to S1. There is a broad based very slightly left paracentral protrusion measuring 2 mm which mildly encroaches on the ventral epidural fat without central spinal canal stenosis, moderate bilateral neural foraminal stenosis is identified. MRI of the bilateral hips was performed on this same date which is reported to be normal. CT myelogram of the lumbar spine was performed on 04/29/10. The myelogram reports a mild 2 mm concentric disc bulge at L5-S1 with no central canal stenosis or nerve root impingement. The remaining lumbar levels are normal. There is no focal disc protrusion or herniation. There is no evidence of nerve root impingement or filling defects.

On 05/07/10 the claimant was seen by provider. It is reported there are no changes in symptoms since last visit. Despite imaging studies the patient is opined to have herniated disc at L5-S1. The provider reports he is evaluating the patient's pain which is primarily right sided but nondermatomal. He subsequently recommended lumbar discography or gad-enhanced MRI.

On 05/17/10, the request was reviewed. The physician reviewer reports this request is reported to have not been supported by ODG. The rationale is not readily identifiable.

On 05/24/10 the request was reviewed by another physician reviewer. This physician again reports that the request is not medically necessary and the rationale is not readily evident in the peer reviewed report.

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

The submitted clinical records indicate that the claimant sustained an injury to the low back on xx/xx/xx. The record does not contain any other clinical data establishing that the claimant has failed all conservative treatment and is a surgical candidate. The limited clinical record suggests that the patient has low back pain with radiation into the lower extremity which is non dermatomal in nature. The claimant subsequently underwent diagnostic studies which included an MRI lumbar spine which suggested neural foraminal stenosis at the L4-5 level and evidence of a centralized disc protrusion at L5-S1. The claimant was then referred for CT myelogram which showed no evidence of filling defects, notes a sub-millimeter disc protrusion at L5-S1 with no evidence of impingement. The single clinical note submitted by provider dated 05/07/10 does not include any physical examination or other data from which to establish the medical necessity for the performance of lumbar discography. Current evidence based guidelines, while not supporting the performance of lumbar discography, allow for its performance if the patient has failed all conservative care and is considered surgical candidate and the intent of lumbar discography is to rule out pathology rather than to be utilized as indication for operative

Notice of Independent Review Decision

June 30, 2010 Original Notice

Amended Notice July 01, 2010

Amended Notice Number Two, July 02, 2010

Copies of all notices sent to all involved parties on each date as specified above

Page 3

intervention. The record does not establish that the patient has any instability or has been referred for a pre operative psychiatric evaluation to address any potentially confounding issues which may skew the results of controversial test. As such, there is clearly insufficient clinical information to support the medical necessity for the performance of discography and as such, the previous determination is upheld.

Reference:

ACOEM Chapter 12

Discography is a diagnostic test that attempts to determine if chronic spinal pain is coming from (caused by) disc pathology. In this test, a needle is inserted into the middle (nucleus) of a disc and x-ray dye is injected. Images are then made, usual both by plain x-ray and by computed tomography (CT). Images are able to classify a disc as normal or as having varying degrees of degeneration.¹³⁹ Discography is usually used in patients with chronic spinal pain without significant leg pain, as MRI and/or CT xylography provide adequate anatomic information for surgical decisions on decompress surgery in patients with significant radiculopathy. This procedure is fairly painful and sedation is required.

Discography proponents believe that discs with more severe degrees of degeneration are more likely to be painful. Proponents analyze and place more importance on the pain response of the sedated patient. If a patient does not experience pain on injection, that disc is considered as unlikely to be the source of chronic spinal pain. If a patient experiences pain that is mild or that is clearly different in location or character to his or her chronic pain, that disc is considered as unlikely to be the source of chronic spinal pain. However, if the patient experiences significant pain that is identical in location and character to the patient's chronic pain ("concordant pain"), proponents believe that discography has identified the pain-generating structure responsible for chronic spinal pain. It also follows that changes on MRI (e.g., Modic changes) should be more severe in those with positive discography; however, that has not been shown. More recent studies have added measurement of the injection pressure (pressure in the disc at the time of pain production) as a test criterion. Those discs with pain provoked at less than 15 psi are categorized as chemically sensitive, 15 to 50 psi are mechanically sensitive, and those over 50 psi are classified as not clinically significant. Chemical sensitivity supposedly suggests the disc is degenerate, but not necessarily the pain-generating structure. High injection pressures may produce pain even in radiographically normal discs. Thus, discography proponents seek concordant pain response at injection pressures of 15 to 25 psi as a criterion for declaring the disc to be the pain-generating structure.

The technique of discography is not standardized. There is no universally accepted definition of what constitutes a concordant painful response. There are no published intra-rater or inter-rater reliability studies on discography. The discussion of discography is crucial to the subsequent discussion of IDET, spinal fusion for "degenerative disc disease," and artificial disc replacement, as many North American surgeons (but not European surgeons) use discography results in surgical planning. If discography can accurately identify a disc as the pain-generating structure, then surgical procedures on that disc make sense and should lead to patient improvement. If

Notice of Independent Review Decision

June 30, 2010 Original Notice

Amended Notice July 01, 2010

Amended Notice Number Two, July 02, 2010

Copies of all notices sent to all involved parties on each date as specified above

Page 4

discography can produce pain, but cannot accurately identify that disc as the pain generating structure, then surgery on that disc is presumably unlikely to be helpful.

Recommendation: Discography for Assessing Acute, Subacute, or Chronic Low Back Pain or Radicular Pain Syndromes

Discography, whether performed as a solitary test or when paired with imaging (e.g., MRI), is not recommended for acute, subacute, chronic LBP or radicular pain syndromes.

Strength of Evidence – Moderately Not Recommended, Evidence (B)

Rationale for Recommendation

Discography has been evaluated in quality studies. Currently, the estimated positive predictive value appears to be at or below 50%, which means the test is not helpful. These studies have failed to find that it reliably indicates what particular disc is the source of the patient's pain. Validity of those findings through improved operative successes is not present. There are a number of studies comparing lumbar discography to other imaging studies such as MRI and CT myelography. These studies can describe how likely a given finding on imaging is to be associated with pain on injection, but cannot determine whether the pain response is a true-positive or a false-positive response. Thus, these studies are not capable of guiding surgical therapy. Studies on imaging have shown that most imaging findings do not correlate with an individual's pain status. There are a number of studies that have looked at the rate of positive or painful responses in individuals without back pain. If the asymptomatic population has a high rate of painful responses to disc injection, a similar pain response, and the inevitable age-related degeneration on imaging studies can easily be interpreted as a positive discogram (false-positive) in patients being evaluated for significant back pain. Since these are experimental subjects who do not have back pain, the pain cannot be concordant with pain they do not have; however, the intensity of the pain response is such that it could easily be misinterpreted as a painful response (false-positive).

Discography, like all invasive procedures, has complications. The 0.1 to 0.2% rate of discitis (disc space infection) is low. Temporary complications include headache, nausea, and worsened back pain. Uncommon, but serious reported complications include meningitis, epidural abscess, arachnoiditis, intrathecal hematoma, intradural injection of contrast, retroperitoneal hematoma, cauda equina syndrome, and acute disc herniation.

Discography results in a patient exposure to radiation of 1.5 to 4.0 rads. Discography is also expensive.

Evidence for the Use of Lumbar Discography

There are no quality studies regarding the use of lumbar discography. (There are two reviews, one guideline, and nine other studies in the Appendix.)

Notice of Independent Review Decision

June 30, 2010 Original Notice

Amended Notice July 01, 2010

Amended Notice Number Two, July 02, 2010

Copies of all notices sent to all involved parties on each date as specified above

Page 5

The 2010 Official Disability Guidelines, 15th edition, The Work Loss Data Institute. Online edition.

Discography

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). (Carragee-Spine, 2000) (Carragee2-Spine, 2000) (Carragee3-Spine, 2000) (Carragee4-Spine, 2000) (Bigos, 1999) (ACR, 2000) (Resnick, 2002) (Madan, 2002) (Carragee-Spine, 2004) (Carragee2, 2004) (Maghout-Juratli, 2006) (Pneumaticos, 2006) (Airaksinen, 2006) (Manchikanti, 2009) 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. (Derby, 2005) (Derby2, 2005) (Derby, 1999) 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) 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. (Heggeness, 1997) 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. (Chou, 2008) 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. (Cohen, 2005) 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. (Chou2, 2009) 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. (Ohtori, 2009) Discography may cause disc degeneration. Even

Notice of Independent Review Decision

June 30, 2010 Original Notice

Amended Notice July 01, 2010

Amended Notice Number Two, July 02, 2010

Copies of all notices sent to all involved parties on each date as specified above

Page 6

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. (Carragee, 2009) 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. See also Functional anesthetic discography (FAD).

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

Notice of Independent Review Decision

June 30, 2010 Original Notice

Amended Notice July 01, 2010

Amended Notice Number Two, July 02, 2010

Copies of all notices sent to all involved parties on each date as specified above

Page 7

- 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) (Carragee, 2006) 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) (Colorado, 2001)
- o Due to high rates of positive discogram after surgery for lumbar disc herniation, this should be potential reason for non-certification

Notice of Independent Review Decision

June 30, 2010 Original Notice

Amended Notice July 01, 2010

Amended Notice Number Two, July 02, 2010

Copies of all notices sent to all involved parties on each date as specified above

Page 8

**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

Notice of Independent Review Decision

June 30, 2010 Original Notice

Amended Notice July 01, 2010

Amended Notice Number Two, July 02, 2010

Copies of all notices sent to all involved parties on each date as specified above

Page 9

- 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)**