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Notice of Independent Review Decision

DATE OF REVIEW: 10/30/09

IRO CASE #:

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

This case was reviewed by a Pain Management (Board Certified), Licensed in Texas and Board Certified. The reviewer has signed a certification statement stating that no known conflicts of interest exist between the reviewer and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent (URA), any of the treating doctors or other health care providers who provided care to the injured employee, or the URA or insurance carrier health care providers who reviewed the case for a decision regarding medical necessity before referral to the IRO. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

MRI lumbar spine
Discogram/Post CT scan L4-5, L5-S1

REVIEW OUTCOME

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

Upheld (Agree)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- o Submitted medical records were reviewed in their entirety.
- o Treatment guidelines were provided to the IRO.
- o 09-24-03 Radiology Services Report read by Dr.
- o 11-09-04 Discogram report from Dr.
- o 02-08-07 MRI lumbar spine read by Dr.
- o 03-26-08 Progress Noted from Dr.
- o 10-20-08 New Patient History and PE from Dr.
- o 10-20-08 Chart Note from Dr.
- o 11-11-08 Radiology Report from Dr.
- o 12-22-08 Return Office Visit from Dr.
- o 03-24-09 History and Physical from Dr.
- o 05-05-09 Return Office Visit from Dr.
- o 08-25-09 Return Office Visit from Dr.
- o 08-27-09 Initial Adverse Determination Letter
- o 09-08-09 Appeal Resolution Letter
- o 09-10-09 Request for IRO from the provider
- o 10-13-09 Confirmation receipt of IRO
- o 10-14-09 Notice of Case Assignment of IRO

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records and prior reviews the patient is a female employee who sustained an industrial injury to the low back on xx/xx/xx when lifting boxes. The patient is 5 feet and 147 pounds and

smokes one pack of cigarettes daily. Her health history includes COPD, hypertension and hyperlipidemia.

Lumbar MRI of September 22, 2003 was provided with an impression of minimal concentric disc bulge at L4-5 without spinal stenosis or foraminal stenosis.

Lumbar discogram performed on November 9, 2004 was interpreted as negative discogram L3-4 and L5-S1 with concordant pain at L4-5.

Repeat lumbar MRI of February 8, 2007 was given impression of unremarkable MRI of the lumbar spine without gadolinium contrast.

According to a reevaluation report of March 26, 2008 the patient has no muscle weakness or muscle spasm. There is moderate tenderness with palpation. Motor strength is 5/5. Straight leg raise is positive on the right. Diagnosis includes back pain, tremor, mechanical low back pain syndrome, chronic pain syndrome, facet joint pain, sacroiliitis and myofasciitis.

On October 20, 2008 the patient is seen in pain management (new provider) and reporting axial low back pain (70%) and left-sided lower extremity radicular pain (30%). She is using hydrocodone 5 mg twice daily and Soma. Her health history includes hypertension, pneumonia and asthma. She smokes one pack of cigarettes daily and is on metoprolol, Cymbalta, Lipitor, Ambien and nebulta. Lower extremity motor and sensation are grossly intact. A urine study was negative for opioids but did show benzodiazepine which would be reviewed with the patient.

Repeat lumbar MRI of November 11, 2008 revealed a minimal broad-based posterior disc protrusion at L4-5 and a small central focal disc protrusion at L5-S1 that contacts the thecal sac without compressing the exiting nerve roots. Otherwise unremarkable.

On December 22, 2008 the patient reportedly has a long course of conservative treatment and would like to consider surgery. She states Skelaxin 800 mg twice daily is not effective in relieving her pain. Upper and lower extremity motor strength and sensation are grossly intact. She will initiate Zanaflex.

A surgical consultation was provided on March 24, 2009. She reports PT magnified her symptoms. She attempted a pain management program several years prior but was unable to continue due pain. She has had 3 epidural injections with brief relief. She will be referred for a surgical evaluation. Lumbar MRI of November 2008 shows a minimal broad-based posterior disc protrusion at L4-5 and a small central focal disc protrusion at L5-S1 that contacts the thecal sac without compressing the exiting nerve roots. A discogram of January 2005 shows concordant pain at L4-5. She has normal gait. She is able to heel and toe walk. No muscle spasms are noted. There is decreased sensation in the left foot, especially the medial aspect. Straight leg raising elicits low back pain, bilaterally. Range of motion is very limited. Lumbar radiographs taken this visit show a mild L5-S1 anterolisthesis and a mild L4-5 retrolisthesis. Both of these correct somewhat on motion films. There is instability at L4-5 and L5-S1. She could consider fusion L4-S1.

The patient returned to her pain management provider on May 5, 2009. The patient decided to try epidural injections and hold off on a possible surgery. She wants a second surgical opinion and will be referred in that regard. On return visit of August 25, 2009 it was noted that a second surgical opinion consultation had been realized with recommendation for updated imaging and repeat discogram.

Request for repeat MRI and discogram with post CT scan was considered in review on August 27, 2009 and recommended for certification of an updated MRI and non-certification for discography. A peer discussion was attempted but not realized. A psyche evaluation of December 2008 was noted which indicated a BDI (depression) of 16 and BAI (anxiety) of 16. A clinic note of March 2009 states the patient has had 3 epidural injections with short-term relief. She was unable to complete a pain management program. Decreased sensation was noted in the left foot. A clinic note of 8/17/09 notes physical exam findings of left lower extremity weakness with decreased sensation in the L5 distribution. Repeat MRIs are supported when there is indication of progression of neurologic deficit. Discography is not recommended in the guidelines. A repeat MRI may be appropriate for the patient as the prior studies are over 1 year old and new studies are being requested for surgical consideration. The efficacy of discography as a preoperative indication for either IDET or spinal fusion is not supported in the literature. The prior discogram is stated to show concordant disc pain at L4-5. MRI studies do not show any pathology outside of the L4-5, L5-S1 levels that would require additional studies. Also, the patient's psychological exam was focused towards chronic pain management program and not discography.

Request for reconsideration repeat MRI and discogram with post CT scan was considered in review on September 8, 2009 with recommendation for non-certification of both repeat MRI and discogram. Rationale states, although the previous MRI results were over 10 months old, there is no evidence presented that the patient's symptomatology has worsened to justify a repeat MRI. Guidelines do not recommend use of a discogram for patients with low back pain of any etiology. It has been found to have limited value, even if used pre-operatively to evaluate for surgery.

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

The patient has been treated for a low back injury of over xx years prior. She is middle-aged female with COPD, hypertension and a history of heavy smoking. The patient is using Cymbalta which is a medication indicated for Major Depressive Disorder.

MRI of 2003 revealed a minimal concentric disc bulge at L4-5 without spinal stenosis or foraminal stenosis. Lumbar discogram performed on November 9, 2004 was interpreted as negative discogram L3-4 and L5-S1 with concordant pain at L4-5. Repeat

MRI of 2007 revealed an unremarkable MRI examination. The most recent MRI of November 2008 has shown a minimal broad-based posterior disc protrusion at L4-5 and a small central focal disc protrusion at L5-S1 that contacts the thecal sac without compressing the exiting nerve roots, otherwise unremarkable. Radiographs taken March 24, 2009 show a mild L5-S1 anterolisthesis and a mild L4-5 retrolisthesis. Both of these are reported to "correct somewhat on motion films". The provider opines instability at L4-5 and L5-S1 and recommends the patient consider fusion surgery L4-S1. Electrodiagnostic studies have not been reported.

The patient appears have some minimal criteria for a surgery with 2 prior MRI scans showing little surgical pathology present. There is no documentation of progressive neurologic deficits or increasing symptomatology that would indicate a medical necessity for a repeat MRI.

The plan for a fusion appears to be based on a discogram of xx years prior and radiographs of March 2009 which interpret mild L5-S1 anterolisthesis and mild L4-5 retrolisthesis which correct somewhat on motion films. Instability would need to be substantiated with quantitative vertebral translation of at least 4 mm. The clinical findings do not establish the criteria that would indicate a medical necessity for a fusion surgery. Per guidelines, 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. Additionally, it is noted that the patient is a heavy smoker, which renders her a less than optimal candidate for fusion surgery. Given the criteria for a fusion surgery have not been met and the patient has not completed a psychological assessment in regard to discography, and the lack of support in guidelines for this intervention, it cannot be recommended for the patient to under go this invasive intervention.

Therefore, my recommendation is to agree with the prior non-certification for repeat MRI and discogram/post CT scan L4-5, L5-S1.

The IRO's decision is consistent with the following guidelines:

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

X 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

The Official Disability Guidelines -Lumbar (10-12-2009) 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). 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. (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 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
- 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.

ODG - Lumbar (10-12-2009) CT Myelography

Not recommended except for indications below for CT. CT Myelography OK if MRI unavailable, contraindicated (e.g. metallic foreign body), or inconclusive. (Slebus, 1988) (Bigos, 1999) (ACR, 2000) (Airaksinen, 2006) (Chou, 2007) Magnetic resonance imaging has largely replaced computed tomography scanning in the noninvasive evaluation of patients with painful myelopathy because of superior soft tissue resolution and multiplanar capability. Invasive evaluation by means of myelography and computed tomography myelography may be supplemental when visualization of neural structures is required for surgical planning or other specific problem solving. (Seidenwurm, 2000) The new ACP/APS guideline as compared to the old AHCPR guideline is more forceful about the need to avoid specialized diagnostic imaging such as computed tomography (CT) without a clear rationale for doing so. (Shekelle, 2008) A new meta-analysis of randomized trials finds no benefit to routine lumbar imaging (radiography, MRI, or CT) for low back pain without indications of serious underlying conditions, and recommends that clinicians should refrain from routine, immediate lumbar imaging in these patients. (Chou-Lancet, 2009)

Indications for imaging -- Computed tomography:

- Thoracic spine trauma: equivocal or positive plain films, no neurological deficit
- Thoracic spine trauma: with neurological deficit
- Lumbar spine trauma: trauma, neurological deficit
- Lumbar spine trauma: seat belt (chance) fracture
- Myelopathy (neurological deficit related to the spinal cord), traumatic
- Myelopathy, infectious disease patient
- Evaluate pars defect not identified on plain x-rays
- Evaluate successful fusion if plain x-rays do not confirm fusion (Laasonen, 1989)

ODG - Lumbar - (10-12-2009) MRI:

Recommended for indications below. MRI's are test of choice for patients with prior back surgery. Repeat MRI's are indicated only if there has been progression of neurologic deficit. Magnetic resonance imaging has also become the mainstay in the evaluation of myelopathy. An important limitation of magnetic resonance imaging in the diagnosis of myelopathy is its high sensitivity. The ease with which the study depicts expansion and compression of the spinal cord in the myelopathic patient may lead to false positive examinations and inappropriately aggressive therapy if findings are interpreted incorrectly. There is controversy over whether they result in higher costs compared to X-rays including all the treatment that continues after the more sensitive MRI reveals the usual insignificant disc bulges and herniations. In addition, the sensitivities of the only significant MRI parameters, disc height narrowing and anular tears, are poor, and these findings alone are of limited clinical importance. (Videman, 2003) Imaging studies are used most practically as confirmation studies once a working diagnosis is determined. MRI, although excellent at defining tumor, infection, and nerve compression, can be too sensitive with regard to degenerative disease findings and commonly displays pathology that is not responsible for the patient's symptoms. With low back pain, clinical judgment begins and ends with an understanding of a patient's life and circumstances as much as with their specific spinal pathology. (Carragee, 2004) Diagnostic imaging of the spine is associated with a high rate of abnormal findings in asymptomatic individuals. Herniated disk is found on magnetic resonance imaging in 9% to 76% of asymptomatic patients; bulging disks, in 20% to 81%; and degenerative disks, in 46% to 93%. (Kinkade, 2007) Baseline MRI findings do not predict future low back pain. (Borenstein, 2001) MRI findings may be preexisting. Many MRI findings (loss of disc signal, facet arthrosis, and end plate signal changes) may represent progressive age changes not associated with acute events. (Carragee, 2006) MRI abnormalities do not predict poor outcomes after conservative care for chronic low back pain patients. (Kleinstück, 2006) The new ACP/APS guideline as compared to the old AHCPR guideline is more forceful about the need to avoid specialized diagnostic imaging such as magnetic resonance imaging (MRI) without a clear rationale for doing so. (Shekelle, 2008) A new meta-analysis of randomized trials finds no benefit to routine lumbar imaging (radiography, MRI, or CT) for low back pain without indications of serious underlying conditions, and recommends that clinicians should refrain from routine, immediate lumbar imaging in these patients. (Chou-Lancet, 2009) Despite guidelines recommending parsimonious imaging, use of lumbar MRI increased by 307% during a recent 12-year interval. When judged against guidelines, one-third to two-thirds of spinal computed tomography imaging and MRI may be inappropriate. (Deyo, 2009) As an alternative to MRI, a pain assessment tool named Standardized Evaluation of Pain (StEP), with six interview questions and ten physical tests, identified patients with radicular pain with high sensitivity (92%) and specificity (97%). The diagnostic accuracy of StEP exceeded that of a dedicated screening tool for neuropathic pain and spinal magnetic resonance

imaging. (Scholz, 2009) There is support for MRI, depending on symptoms and signs, to rule out serious pathology such as tumor, infection, fracture, and cauda equina syndrome. Patients with severe or progressive neurologic deficits from lumbar disc herniation, or subjects with lumbar radiculopathy who do not respond to initial appropriate conservative care, are also candidates for lumbar MRI to evaluate potential for spinal interventions including injections or surgery. See also ACR Appropriateness Criteria™. See also Standing MRI.

Indications for imaging -- Magnetic resonance imaging:

- Thoracic spine trauma: with neurological deficit
- Lumbar spine trauma: trauma, neurological deficit
- Lumbar spine trauma: seat belt (chance) fracture (If focal, radicular findings or other neurologic deficit)
- Uncomplicated low back pain, suspicion of cancer, infection
- Uncomplicated low back pain, with radiculopathy, after at least 1 month conservative therapy, sooner if severe or progressive neurologic deficit. (For unequivocal evidence of radiculopathy, see AMA Guides, 5th Edition, page 382-383.) (Andersson, 2000)
- Uncomplicated low back pain, prior lumbar surgery
- Uncomplicated low back pain, cauda equina syndrome
- Myelopathy (neurological deficit related to the spinal cord), traumatic
- Myelopathy, painful
- Myelopathy, sudden onset
- Myelopathy, stepwise progressive
- Myelopathy, slowly progressive
- Myelopathy, infectious disease patient
- Myelopathy, oncology patient