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NOTICE OF INDEPENDENT REVIEW DECISION

DATE OF REVIEW:

Jul/20/2009

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Bilateral facet joint injections at L4-5 and L5-S1 OR facet rhizotomy L5-S1

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

MD, Board Certified in Physical Medicine and Rehabilitation
Subspecialty Board Certified in Pain Management

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)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

ODG Guidelines and Treatment Guidelines
Adverse Determination Letters, 5/6/09, 6/8/09 (Revised)
Email from Managed Care, 7/6/09
Medical Associates, MD, 4/6/09, 4/27/09, 4/1/09,
2/4/09, 1/19/09 (pp. 2-3)
MRI of Lumbar Spine, 4/1/09

PATIENT CLINICAL HISTORY SUMMARY

This xx year old man was injured in xx/xx. On 4/6/09, Dr. described "classical facet joint mediated pain. He had a superb response to facet joint blocks, and was referred to Dr. in consideration of facet joint rhizotomy. It was reviewed he had undergone facet joint blocks for facet joint mediated pain in February 2008 with superb benefit." He later had left SI joint pain and injection with pain relief. Dr. found him to have pain on the left lumbar facet region with erect standing, extension and with ipsilateral left and right lateral bending. He noted an MRI that showed L4/5 annular bulge and minimal retrolisthesis. There was a pars defect at L5 without slippage. The radiologist wrote that at the L4-5 level "the facet joints are intact." He

further wrote "I feel one can ordinarily progress directly to a facet rhizotomy, rather than another facet joint injection, as the patient has not been injected on the left side and the patient's pain is bilateral, we will go forward at this stage with bilateral facet joint injections..."

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

The diagnostic criteria for facet pain in the ODG is limited to local pain in the absence of evidence of radiculopathy, which appears to be present in this case. The current request is for repeat facet injections. However, the ODG does not allow a series of repeat facet injections. Two bilateral (or 4) levels were requested.

In addition, radiofrequency neurotomy is not an established procedure in the ODG. When approved, the ODG places limits on the frequency based on the prior results. Criteria 2 requires that there be at least 12 weeks of benefit and more than 50% reduction in pain. In the medical records, Dr. commented that Dr. had written erroneously that there was one week of relief, and then corrected this to several weeks of relief "with near complete relief of his pain." No specific duration of the pain relief was provided.

Repeat facet injections would not be justified, nor would 4 levels of RF rhizotomy as per the ODG. The request does not meet the guidelines. The reviewer finds that medical necessity does not exist for Bilateral facet joint injections at L4-5 and L5-S1 OR facet rhizotomy L5-S1.

Facet joint pain, signs & symptoms

Recommend diagnostic criteria below. Diagnostic blocks are required as there are no findings on history, physical or imaging studies that consistently aid in making this diagnosis. Controlled comparative blocks have been suggested due to the high false-positive rates (17% to 47% in the lumbar spine), but the use of this technique has not been shown to be cost-effective or to prevent a false-positive response to a facet neurotomy. (Bogduk, 2005) (Cohen 2007) (Bogduk, 2000) (Cohen2, 2007) (Manchukonda 2007) (Dreyfuss 2000) (Manchikanti 2003) The most commonly involved lumbar joints are L4-5 and L5-S1. (Dreyfus, 2003) In the lumbar region, the majority of patients have involvement in no more than two levels. (Manchikanti, 2004)

Mechanism of injury: The cause of this condition is largely unknown, but suggested etiologies have included microtrauma, degenerative changes, and inflammation of the synovial capsule. The overwhelming majority of cases are thought to be the result of repetitive strain and/or low-grade trauma accumulated over the course of a lifetime. Less frequently, acute trauma is thought to be the mechanism, resulting in tearing of the joint capsule or stretching beyond physiologic limits. Osteoarthritis of the facet joints is commonly found in association with degenerative joint disease. (Cohen 2007)

Symptoms: There is no reliable pain referral pattern, but it is suggested that pain from upper facet joints tends to extend to the flank, hip and upper lateral thighs, while the lower joint mediated pain tends to penetrate deeper into the thigh (generally lateral and posterior). Infrequently, pain may radiate into the lateral leg or even more rarely into the foot. In the presence of osteophytes, synovial cysts or facet hypertrophy, radiculopathy may also be present. (Cohen 2007) In 1998, Revel et al. suggested that the presence of the following were helpful in identifying patients with this condition: (1) age > 65; (2) pain relieved when supine; (3) no increase in pain with coughing, hyperextension, forward flexion, rising from flexion or extension/rotation. (Revel, 1998) Recent research has corroborated that pain on extension and/or rotation (facet loading) is a predictor of poor results from neurotomy. (Cohen2, 2007) The condition has been described as both acute and chronic. (Resnick, 2005)

Radiographic findings: There is no support in the literature for the routine use of imaging studies to diagnose lumbar facet mediated pain. Studies have been conflicting in regards to CT and/or MRI evidence of lumbar facet disease and response to diagnostic blocks or neurotomy. (Cohen 2007) See also Facet joint diagnostic blocks (injections); & Segmental rigidity (diagnosis)

Suggested indicators of pain related to facet joint pathology (acknowledging the contradictory findings in current research)

- (1) Tenderness to palpation in the paravertebral areas (over the facet region);
- (2) A normal sensory examination;
- (3) Absence of radicular findings, although pain may radiate below the knee;
- (4) Normal straight leg raising exam

Indicators 2-4 may be present if there is evidence of hypertrophy encroaching on the neural foramen

Facet joint injections, multiple series

Not recommended.

Diagnostic blocks: One set of medial branch blocks is recommended prior to a neurotomy. Intra-articular blocks are not recommended as the diagnostic procedure. Confirmatory blocks, while recommended for research studies, do not appear to be cost effective or to prevent the incidence of a false positive response to the neurotomy procedure itself. See Facet joint diagnostic blocks (injections).

Therapeutic injections: With respect to facet joint intra-articular therapeutic injections, no more than one therapeutic intra-articular block is suggested. If successful (pain relief of at least 50% for a duration of at least 6 weeks), the recommendation is to proceed to a medial branch diagnostic block and subsequent neurotomy (if the medial branch block is positive). See Facet joint intra-articular injections (therapeutic blocks). There is no peer-reviewed literature to support a "series" of therapeutic facet blocks.

Facet joint diagnostic blocks (injections)

Recommend no more than one set of medial branch diagnostic blocks prior to facet neurotomy, if neurotomy is chosen as an option for treatment (a procedure that is still considered "under study"). Diagnostic blocks may be performed with the anticipation that if successful, treatment may proceed to facet neurotomy at the diagnosed levels. Current research indicates that a minimum of one diagnostic block be performed prior to a neurotomy, and that this be a medial branch block (MBB). Although it is suggested that MBBs and intra-articular blocks appear to provide comparable diagnostic information, the results of placebo-controlled trials of neurotomy found better predictive effect with diagnostic MBBs. In addition, the same nerves are tested with the MBB as are treated with the neurotomy. The use of a confirmatory block has been strongly suggested due to the high rate of false positives with single blocks (range of 25% to 40%) but this does not appear to be cost effective or to prevent the incidence of false positive response to the neurotomy procedure itself. (Cohen, 2007) (Bogduk, 2000) (Cohen2, 2007) (Manchukonda, 2007) (Dreyfuss, 2000) (Manchikanti2, 2003)

Etiology of false positive blocks: Placebo response (18-32%), use of sedation, liberal use of local anesthetic, and spread of injectate to other pain generators. The concomitant use of sedative during the block can also interfere with an accurate diagnosis. (Cohen, 2007)

MBB procedure: The technique for medial branch blocks in the lumbar region requires a block of 2 medial branch nerves (MBN). The recommendation is the following: (1) L1-L2 (T12 and L1 MBN); (2) L2-L3 (L1 and L2 MBN); (3) L3-L4 (L2 and L3 MBN); (4) L4-L5 (L3 and L4 MBN); (5) L5-S1: the L4 and L5 MBN are blocked, and it is recommended that S1 nerve be blocked at the superior articular process. Blocking two joints such as L3-4 and L4-5 will require blocks of three nerves (L2, L3 and L4). Blocking L4-5 and L5-S1 will require blocks of L3, L4, L5 with the option of blocking S1. (Clemans, 2005) The volume of injectate for diagnostic medial branch blocks must be kept to a minimum (a trace amount of contrast with no more than 0.5 cc of injectate), as increased volume may anesthetize other potential areas of pain generation and confound the ability of the block to accurately diagnose facet pathology. Specifically, the concern is that the lateral and intermediate branches will be blocked; nerves that innervate the paraspinal muscles and fascia, ligaments, sacroiliac joints and skin. (Cohen, 2007) Intraarticular blocks also have limitations due to the fact that they can be technically challenging, and if the joint capsule ruptures, injectate may diffuse to the epidural space, intervertebral foramen, ligamentum flavum and paraspinal musculature. (Cohen, 2007) (Washington, 2005) (Manchikanti, 2003) (Dreyfuss, 2003) (BlueCross BlueShield, 2004) (Pneumatics, 2006) (Boswell, 2007) (Boswell2, 2007) A recent meta-analysis concluded that there is insufficient evidence to evaluate validity or utility of diagnostic selective nerve root block, intra-articular facet joint block, medial branch block, or sacroiliac joint block as diagnostic procedures for low back pain with or without radiculopathy. (Chou2, 2009) See also Facet joint pain, signs & symptoms; Facet joint radiofrequency neurotomy; Facet joint medial branch blocks (therapeutic injections); & Facet joint intra-articular injections (therapeutic blocks). Also see Neck Chapter and Pain Chapter

Criteria for the use of diagnostic blocks for facet “mediated” pain

Clinical presentation should be consistent with facet joint pain, signs & symptoms

1. One set of diagnostic medial branch blocks is required with a response of $\geq 70\%$. The pain response should be approximately 2 hours for Lidocaine
2. Limited to patients with low-back pain that is non-radicular and at no more than two levels bilaterally
3. There is documentation of failure of conservative treatment (including home exercise, PT and NSAIDs) prior to the procedure for at least 4-6 weeks
4. No more than 2 facet joint levels are injected in one session (see above for medial branch block levels)
5. Recommended volume of no more than 0.5 cc of injectate is given to each joint
6. No pain medication from home should be taken for at least 4 hours prior to the diagnostic block and for 4 to 6 hours afterward
7. Opioids should not be given as a “sedative” during the procedure
8. The use of IV sedation (including other agents such as midazolam) may be grounds to negate the results of a diagnostic block, and should only be given in cases of extreme anxiety
9. The patient should document pain relief with an instrument such as a VAS scale, emphasizing the importance of recording the maximum pain relief and maximum duration of pain. The patient should also keep medication use and activity logs to support subjective reports of better pain control
10. Diagnostic facet blocks should not be performed in patients in whom a surgical procedure is anticipated. (Resnick, 2005)

11. Diagnostic facet blocks should not be performed in patients who have had a previous fusion procedure at the planned injection level

Facet joint radiofrequency neurotomy

Under study. Conflicting evidence is available as to the efficacy of this procedure and approval of treatment should be made on a case-by-case basis (only 3 RCTs with one suggesting pain benefit without functional gains, potential benefit if used to reduce narcotics). Studies have not demonstrated improved function. Also called Facet rhizotomy, Radiofrequency medial branch neurotomy, or Radiofrequency ablation (RFA), this is a type of injection procedure in which a heat lesion is created on specific nerves to interrupt pain signals to the brain, with a medial branch neurotomy affecting the nerves carrying pain from the facet joints

Current research: Multiple placebo-controlled trials have been completed on this topic, but these studies all had potential clinical methodologic flaws including the use of non-controlled diagnostic blocks and potential discrepancies in technique of lesioning from that which is currently recommended. (Hooten, 2005) (van Kleef, 1999) (Boswell, 2005) (Leclaire, 2001) (Van Kleef, 1999) (Gallagher, 1994) (van Wijk, 2005) A recent small RCT found that the percutaneous radiofrequency neurotomy treatment group showed statistically significant improvement not only in back and leg pain but also back and hip movement as well as the sacro-iliac joint test. There was significant improvement in quality of life variables, global perception of improvement, and generalized pain. But RF neurotomy was not a total treatment, and it provided relief for only one component of the patients' pain. (Nath, 2008) Observational Trials: One observational trial found 60% of patients received 90% relief at 12 months and 87% had 60% pain relief. The authors used confirmatory blocks with 80% pain relief. (Dreyfuss, 2000) Clinical audits have reported pain relief in almost 70% of patients at 6 months. (Gofeld, 2007)

Systematic reviews: When compiled into systematic reviews, the evidence has been found to be conflicting for a short-term effect (Niemisto-Cochrane, 2003) (Niemesto-Cochrane, 2006) and moderate to strong for a long-term effect when compared to a placebo. (Geurts, 2001) (Boswell, 2005) The latter systematic review failed to distinguish results between lumbar and cervical patients. A critical nonsystematic review by Slipman et al. reported "sparse evidence" to support use in the lumbar region (Slipman, 2003) and the ICSI did not feel the current scientific evidence allowed for a conclusion on the subject. (ICSI, 2005) Boswell et al have recently published a systematic review that included several new observational studies that came to the conclusion that the evidence for neurotomy was moderate (Level III) for long-term relief of cervical and lumbar facet joint pain. This conclusion was based on the standard techniques used in the United States. (Boswell2, 2007) Interventional strategies, such as prolotherapy, botulinum toxin injections, radiofrequency denervation, and intradiskal electrothermal therapy, are not supported by convincing, consistent evidence of benefit from randomized trials. (Chou, 2008)

Technique: There are several techniques. (Gofeld2, 2007) The North American technique uses tangential insertion of a curve-tipped cannula parallel to the nerves. There is a long learning curve and results vary among operators. The European technique relies on radiologic appearance. Potential technical flaws include inadequate exposure of the tip to the target nerve and generation of a lesion that is too small to ablate the nerve. There is also an Australian technique.

Factors associated with failed treatment: These include increased pain with hyperextension and axial rotation (facet loading), longer duration of pain and disability, significant opioid dependence, and history of back surgery

Factors associated with success: Pain above the knee (upper leg or groin); paraspinal tenderness. (Cohen2, 2007)

Duration of pain relief: One retrospective analysis has determined that the mean duration of relief is approximately 10-12 months (range 4-19 months). Subsequent procedures may not be as successful (possibly secondary to technical failure or progression of spinal degeneration). (Schofferman, 2004) In a more recent study 68.4% of patients reported good to excellent pain relief at 6 months and showed consistent results with the above findings. (Gofeld, 2007)

Complications: Potential side effects include painful cutaneous dysesthesias, increased pain due to neuritis or neurogenic inflammation, and cutaneous hyperesthesia. Neuritis is the most frequent complication (5% incidence). (Boswell, 2005) (Boswell2, 2007) (Cohen, 2007) The clinician must be aware of the risk of developing a deafferentation centralized pain syndrome as a complication of this and other neuroablative procedures. This procedure is commonly used to provide a window of pain relief allowing for participation in active therapy. (Washington, 2005) (Manchikanti , 2003) See also Facet joint diagnostic blocks (injections); Facet joint pain, signs & symptoms; Facet joint medial branch blocks (therapeutic injections); Facet joint intra-articular injections (therapeutic blocks). Also see Neck Chapter and Pain Chapter

Criteria for use of facet joint radiofrequency neurotomy

(1) Treatment requires a diagnosis of facet joint pain using a medial branch block as described above. See Facet joint diagnostic blocks (injections)

(2) While repeat neurotomies may be required, they should not occur at an interval of less than 6 months from the first procedure. A neurotomy should not be repeated unless duration of relief from the first procedure is documented for at least 12 weeks at $\geq 50\%$ relief. The current literature does not support that the procedure is successful without sustained pain relief (generally of at least 6 months duration). No more than 3 procedures should be performed in a year's period.

(3) Approval of repeat neurotomies depends on variables such as evidence of adequate diagnostic blocks, documented improvement in VAS score, and documented improvement in function.

(4) No more than two joint levels are to be performed at one time

(5) If different regions require neural blockade, these should be performed at intervals of no sooner than one week, and preferably 2 weeks for most blocks

(6) There should be evidence of a formal plan of additional evidence-based conservative care in addition to facet joint therapy.

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

- ACOEM-AMERICA 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)