

# Becket Systems

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## NOTICE OF INDEPENDENT REVIEW DECISION

**DATE OF REVIEW:**

Jul/12/2010

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:**

Left L2/3 L3/4 and L4/5 Facet Joint Steroid Injection

**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  
Subspecialty Board Certified in Electrodiagnostic Medicine

**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**

**PATIENT CLINICAL HISTORY SUMMARY**

This is a man reportedly injured in xx/xx. He had a fusion at L2/3 and L4/5 in 1993. A lumbar MRI in 2006 showed a pseudoarthrosis at the L4/5 interbody fusion. He has sleep apnea and cardiac problems. He had bilateral radiofrequency rhizotomy in 11/07 with good results for 18 months. . He had a favorable response to a right L3/4 MBB block in right L4/5 facet block in 9/15/09. He has relief following a right sided RF at L3/4/5 done on 3/31/10 for right sided back pain. That improved, but he now has recurrence of the left sided pain. Dr. would like to try the RF on the left side. It appears the intent is the initial local block prior to the RF procedure itself.

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

The request is for local blocks before any RF is to be performed. ODG permits this procedure when there is an RF being considered. However, this request is for three levels, and the ODG permits no more than 2 levels to be injected at a time. In addition, the ODG does not justify the procedure at a level of a prior fusion. The solid fusion is at L2/3. Records indicate the fusion failed and there is a pseudoarthrosis at L4/5. Following the ODG, the requested procedure is not justified as there are more than 2 levels requested, and one level involves the solid fusion. The request does not conform to the evidence-based guidelines. The reviewer finds that the previous adverse determinations should be upheld. The reviewer finds there is not medical necessity for Left L2/3 L3/4 and L4/5 Facet Joint Steroid Injection.

#### 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) (Datta, 2009)

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. [Exclusion Criteria that would require UR physician review: Previous fusion at the targeted level. (Franklin, 2008)]

#### Facet joint intra-articular injections (therapeutic blocks)

Under study. Current evidence is conflicting as to this procedure and at this time 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). If a therapeutic facet joint block is undertaken, it is suggested that it be used in consort with other evidence based conservative care (activity, exercise, etc.) to facilitate functional improvement. (Dreyfuss, 2003) (Colorado, 2001) (Manchikanti, 2003) (Boswell, 2005) See Segmental rigidity (diagnosis). In spite of the overwhelming lack of evidence for the long-term effectiveness of intra-articular steroid facet joint injections, this remains a popular treatment modality. Intra-articular facet joint injections have been popularly utilized as a therapeutic procedure, but are not currently recommended as a treatment modality in most evidence-based reviews as their benefit remains controversial. The therapeutic facet joint injections described here are injections of a steroid (combined with an anesthetic agent) into the facet joint under fluoroscopic guidance to provide temporary pain relief. (Dreyfuss, 2003) (Nelemans-Cochrane, 2000) (Carette, 1991) (Nelemans, 2001) (Slipman, 2003) (van Tulder, 2006) (Colorado, 2001) (ICSI, 2004) (Bogduk, 2005) (Resnick, 2005) (Airaksinen, 2006) An updated Cochrane review of injection therapies (ESIs, facets, trigger points) for low back pain concluded that there is no strong evidence for or against the use of any type of injection therapy, but it cannot be ruled out that specific subgroups of patients may respond to a specific type of injection therapy. (Staal-Cochrane, 2009)

Systematic reviews endorsing therapeutic intra-articular facet blocks:

Pain Physician, 2005: In 2005 there were two positive systematic reviews published in Pain Physician that stated that the evidence was moderate for short-term and limited for long-term improvement using this intervention. (Boswell, 2005) (Boswell, 2005) These results were based, in part, on five observational studies. These non-controlled studies were confounded by variables such as lack of confirmation of diagnosis by dual blocks and recording of subjective pain relief, or with measures that fell under verbal rating and/or pain relief labels (measures that have been reported to have problems with validity). (Edwards, 2005)

Pain Physician, 2007: Pain Physician again published a systematic review on this subject in 2007 and added one additional randomized trial comparing intra-articular injections with sodium hyaluronate to blocks with triamcinolone acetonide. The diagnosis of facet osteoarthritis was made radiographically. (Fuchs, 2005) Two randomized trials were not included, in part, as they failed to include controlled diagnostic blocks. These latter articles were negative toward the use of therapeutic facet blocks. (Lilius, 1989) (Marks, 1992) An observational non-controlled study that had positive results was included that made the diagnosis of lumbar facet syndrome based on clinical assessment of "pseudoradicular" lumbar pain, including evidence of an increase of pain in the morning and with excessive stress and exercise (no diagnostic blocks were performed). (Schulte, 2006) With the inclusion of these two articles the conclusion was changed so that the evidence for lumbar intra-articular injections was "moderate" for both short-and long-term improvement of low back pain. (Boswell2, 2007)

Complications: These included suppression of the hypothalamic-pituitary-adrenal axis for up to 4 weeks due to steroids with resultant elevated glucose levels for less than a week. (Ward, 2002) There have been rare cases of infection (septic arthritis, epidural abscess and meningitis). (Cohen, 2007) Complications from needle placement include dural puncture, spinal cord trauma, intraarterial and intravenous injection, spinal anesthesia, neural trauma, pneumothorax, and hematoma formation. (Boswell2, 2007)

Single photon emission computed tomography: (bone scintigraphy, SPECT scan): Not recommended although recent research is promising. This technique is recommended based on the ability of radionuclide bone scintigraphy to detect areas of increased function, depicting synovial areas of inflammation as well as degenerative changes. Thirteen of 15 patients had a > 1 standard deviation pain score improvement at 1 month versus 7 of 32 patients with a negative or no scan. The benefit of the injection lasted for approximately 3 months and did not persist to 6 months. (Pneumaticos2, 2006) See also Facet joint diagnostic blocks (injections); Facet joint pain, signs & symptoms; Facet joint radiofrequency neurotomy; Facet joint medial branch blocks (therapeutic injections); & Segmental rigidity (diagnosis). Also see Neck Chapter and Pain Chapter

Criteria for use of therapeutic intra-articular and medial branch blocks, are as follows

1. No more than one therapeutic intra-articular block is recommended.
2. There should be no evidence of radicular pain, spinal stenosis, or previous fusion
3. If successful (initial pain relief of 70%, plus 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).
4. No more than 2 joint levels may be blocked at any one time
5. There should be evidence of a formal plan of additional evidence-based activity and exercise in addition to facet joint injection 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)