

Notice of Independent Review Decision AMENDED

DATE OF REVIEW: 03/15/2012

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

bilateral facet injections L3 and L4, flouroscopy and sedation 64493 64494 77003
99144

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

The physician performing this review is Board Certified, American Board of Physical Medicine & Rehabilitation. He is certified in pain management. He is a member of the Texas Medical Board. He has a private practice of Physical Medicine & Rehabilitation, Electrodiagnostic Medicine & Pain Management in Texas. He has published in medical journals. He is a member of his state and national medical societies.

REVIEW OUTCOME

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

- | | |
|---|----------------------------------|
| <input checked="" type="checkbox"/> Upheld | (Agree) |
| <input type="checkbox"/> Overturned | (Disagree) |
| <input type="checkbox"/> Partially Overturned | (Agree in part/Disagree in part) |

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

Upon independent review, I find that the previous adverse determination should be upheld:

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Records Received: 16 page fax 2/24/12 Texas Department of Insurance IRO request, 69 page fax 2/28/12 URA response to disputed services including administrative and medical records. Dates of documents range from 02/04/08 to 2/24/12.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient reportedly was originally injured xx/xx/xx. He has had persisting lower back pain with some radiation into the right leg. Dr. indicates that he has a permanent lifting restriction. He has undergone an L4 to the sacrum fusion. The patient was initially seen by Dr. 10/03/11 in reference to pain management. The pain has been described as aching, sharp, stiff, but only limited radiation into the right leg. Pain was noted to be aggravated by bending, sitting, or standing for

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long periods. It also interfered with sleep. The patient has been diagnosed with post-laminectomy syndrome. The patient has been noted to have positive straight leg raise on the right side. He has decreased pin sensitivity in an S1 nerve root distribution. The patient in Dr. list of diagnoses is noted to have lumbago and lumbar post laminectomy. There is no diagnosis within Dr. Pak's records of a facet disorder.

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

Upon independent review, I find that the previous adverse determination should be upheld because they do not meet the ODG criteria.

Facet Joint Injection

ODG Criteria

Facet joint diagnostic blocks (injections)	<p>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)</p> <p>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)</p> <p>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)</p> <p>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) (Pneumaticos, 2006) (Boswell, 2007)</p>
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	<p>(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) This study suggests that proceeding to radiofrequency denervation without a diagnostic block is the most cost-effective treatment paradigm, but does not result in the best pain outcomes. (Cohen, 2010) 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.</p> <p>Criteria for the use of diagnostic blocks for facet “mediated” pain: Clinical presentation should be consistent with facet joint pain, signs & symptoms.</p> <ol style="list-style-type: none"> 1. One set of diagnostic medial branch blocks is required with a response of $\geq 70\%$. The pain response should last at least 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 injections, lumbar	<p>See Facet joint injections, multiple series; Facet joint diagnostic blocks (injections); Facet joint intra-articular injections (therapeutic blocks); Facet joint medial branch blocks (therapeutic injections); Facet joint pain, signs & symptoms; & Facet joint radiofrequency neurotomy. Also see Neck Chapter and Pain Chapter.</p>
Facet joint injections, multiple series	<p>Not recommended.</p> <p>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).</p> <p>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 fact blocks.</p>
Facet joint intra-	<p>Under study. Current evidence is conflicting as to this procedure and at this time no</p>

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articular injections (therapeutic blocks)	<p>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)</p> <p>Systematic reviews endorsing therapeutic intra-articular facet blocks:</p> <p>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)</p> <p>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)</p> <p>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)</p> <p>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</p>
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	<p>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. (Pneumatics2, 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.</p> <p>Criteria for use of therapeutic intra-articular and medial branch blocks, are as follows:</p> <ol style="list-style-type: none"> 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.
<p>Facet joint medial branch blocks (therapeutic injections)</p>	<p>Not recommended except as a diagnostic tool. Minimal evidence for treatment. Pain Physician 2005: In 2005 Pain Physician published an article that stated that there was moderate evidence for the use of lumbar medial branch blocks for the treatment of chronic lumbar spinal pain. (Boswell, 2005) This was supported by one study. (Manchikanti, 2001) Patients either received a local anesthetic or a local anesthetic with methyl prednisolone. All blocks included Sarapin. Sixty percent of the patients overall underwent seven or more procedures over the 2½ year study period (8.4 ± 0.31 over 13 to 32 months). There were more procedures recorded for the group that received corticosteroids than those that did not (301 vs. 210, respectively). [“Moderate evidence” is a definition of the quality of evidence to support a treatment outcome according to Pain Physician.] The average relief per procedure was 11.9 ± 3.7 weeks.</p> <p>Pain Physician 2007: This review included an additional randomized controlled trial. (Manchikanti2, 2007) Controlled blocks with local anesthetic were used for the diagnosis (80% reduction of pain required). Four study groups were assigned with 15 patients in each group: (1) bupivacaine only; (2) bupivacaine plus Sarapin; (3) bupivacaine plus steroid; and (4) bupivacaine, steroid and Sarapin. There was no placebo group. Doses of 1-2ml were utilized. The average number of treatments was 3.7 and there was no significant difference in number of procedures noted between the steroid and non-steroid group. Long-term improvement was only thought to be possible with repeat interventions. All groups were significantly improved from baseline (a final Numeric Rating Scale score in a range from 3.5 to 3.9 for each group). Significant improvement occurred in the Oswestry score from baseline in all groups, but there was also no significant difference between the groups. There was no significant difference in opioid intake or employment status. There was no explanation posited of why there was no difference in results between the steroid and non-steroid groups. This study was considered positive for both short- and long-term relief, although, as noted, repeated injections were required for a long-term effect. Based on the inclusion of this study the overall conclusion was changed to suggest that the evidence for therapeutic medial branch blocks was moderate for both short- and long-term pain relief. (Boswell2, 2007) Psychiatric comorbidity is associated with substantially diminished pain relief after a medial branch block injection performed with steroid at one-month follow-up. These findings illustrate the importance of assessing comorbid psychopathology as part of a spine care evaluation. (Wasan, 2009) The use of the blocks for diagnostic purposes is discussed in Facet joint diagnostic blocks (injections). See also Facet joint intra-articular injections (therapeutic blocks).</p>

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Facet joint pain, signs & symptoms	<p>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)</p> <p>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)</p> <p>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)</p> <p>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) Degenerative changes in facets identified by CT do not correlate with pain and are part of the natural degenerative process. (Kalichman, 2008) See also Facet joint diagnostic blocks (injections); & Segmental rigidity (diagnosis).</p> <p>Suggested indicators of pain related to facet joint pathology (acknowledging the contradictory findings in current research):</p> <ol style="list-style-type: none">(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. <p>Indictors 2-4 may be present if there is evidence of hypertrophy encroaching on the neural foramen.</p>
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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)