

DECISION AND ORDER

This case is decided pursuant to Chapter 410 of the Texas Workers' Compensation Act and Rules of the Division of Workers' Compensation adopted thereunder.

ISSUE

A contested case hearing was held on April 2, 2008, to decide the following disputed issue:

1. Is the preponderance of the evidence contrary to the IRO decision upholding Carrier's denial of the request to preauthorize radiofrequency neurotomy bilaterally at L4-5 and L5-S1 and an epidural steroid injection on the right at L5-S1?

PARTIES PRESENT

Claimant appeared and was assisted by an (Ombudsman). Carrier appeared and was represented by an (Attorney).

BACKGROUND INFORMATION

Claimant sustained a compensable lumbar injury while employed as a certified nursing assistant at ___ in (City), Texas. Dr. H, one of the claimant's medical providers, requested pre-authorization of radiofrequency neurotomy bilaterally at L4-L5 and L5-S1 and an epidural steroidal injection at L5-S1 on the right. Carrier denied the pre-authorization. Claimant requested reconsideration of the request and pre-authorization was once again denied. Claimant requested that the matter be referred to an independent review organization (IRO) by the Texas Department of Insurance (TDI) and TDI assigned C-IRO to review the case. The IRO concurred with Carrier's denial of the request.

In the initial review of the request, the utilization review agent, Dr. M stated:

This claimant is a 45 year old who reports low back and right lower extremity pain to the heel. She did have previous neurotomies which gave her prolonged relief. About 2 months ago however, she started developing increased low back pain and right lower extremity weakness/tingling and pain. This has progressively worsened. Then about 2 weeks after pain return, she experienced a fall onto her buttocks. She reports increased urgency and frequency of urination since increased pain. Physical examination shows tenderness over the lumbar spine and sacroiliac joint. Provider states that this claimant had good long term relief with medal (sic) branch neurotomies. Provider recommends repeat neurotomies with possible ESI to help with radicular symptoms. He additionally recommends urology referral. Dr. R was not aware if the claimant has had facet blocks in the past or if the results were beneficial. He informed me that he is not the one who will be performing the

procedure. Based on the information discussed, the requested procedure is not supported.

The second utilization review agent was Dr. H. In his report, dated October 18, 2007, he stated:

The claimant has a history of prior neurotomies which reportedly provided prolonged relief. The claimant had an increase in symptoms about 2 months ago and now complains of low back and right lower extremity pain. Pain has progressively worsened and now the claimant complains of urgency with urination. Objective exam reveals decreased range of motion and mild tenderness to palpation at the SI joints bilaterally and weakness of the right lower extremity with poor heel/toe walking. Recommendation is made by the provider for RFN, epidural steroidal injection and urological consult as well as an EMG/NCS to evaluate the right lower extremity weakness.

Documentation does not indicate that the claimant has had a good response to diagnostic medial branch blocks or facet injections that would support the medical necessity of this request. Without review of the specific results for the prior neurotomies or injections the medical necessity of a radiofrequency neurotomy and epidural steroidal injections (sic) is not established.

C-IRO assigned the case to an M.D. physician reviewer. The physician reviewer practices neurology, is a fellowship trained pain specialist, and is board certified in Neurology and Pain Medicine. In the IRO report dated December 17, 2007, the physician reviewer concurred that the radiofrequency neurotomy at L4-5 and L5-S1 and the epidural steroid injection at L5-S1 should be denied. The physician reviewer noted that Claimant had responded well to medial branch neurotomies in the past and that an updated request for a radiofrequency neurotomy of the facet joints and a right-sided epidural steroid injection had been submitted. In explaining his concurrence with the prior denials, the physician reviewer stated:

The reviewer agrees with the previous reviewers that there is no sufficient evidence submitted to suggest that a radiofrequency neurolysis of the lower lumbar facet joints will help with the claimant's current symptomatology. Indeed, her current symptomatology appears to be more radicular and may consist of troublesome and more advanced condition due to the reported weakness in the leg as well as possibly some bladder symptomatology. It is unclear to this reviewer whether an updated MRI scan of the lumbar spine has been performed to rule out any significant lumbar stenosis/compression. Due to the concern of adding to potential compression of the nerve roots, the reviewer also agrees that the requested epidural steroid injections would not be expected to help with symptomatology that has advanced to this degree, again causing weakness in the leg and possibly bladder involvement.

In reaching the foregoing conclusion, the IRO physician reviewer cited his medical judgment, clinical experience and expertise in accordance with accepted medical standards and the ODG - Official Disability Guidelines & Treatment Guidelines.

An employee who sustains a compensable injury is entitled to all health care reasonably required by

the nature of the injury as and when needed (Texas Labor Code §408.021). "Health care reasonably required" is defined as health care that is clinically appropriate and considered effective for the injured employee's injury and provided in accordance with best practices consistent with evidence based medicine or, if evidence based medicine is not available, generally accepted standards of medical practice recognized in the medical community (Texas Labor Code §401.011(22-a)). "Evidence based medicine" means the use of the current best qualified scientific and medical evidence formulated from credible scientific studies, including peer-reviewed medical literature and other current scientifically based texts and treatment and practice guidelines (Texas Labor Code §401.011 (18-a)).

The ODG gives the following procedure summary for facet joint radiofrequency neurotomy:

Under study. Conflicting evidence is available as to the efficacy of this procedure (emphasis added) and approval of treatment should be made on a case-by-case basis. 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) *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) (Niemisto-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)

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 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.** (Emphasis added.)

(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.** (Emphasis added.)

The ODG addresses epidural steroid injections for both diagnostic and pain relief. When an epidural steroid injection is used as a diagnostic tool, the ODG provides the following guidance:

Recommended as indicated below. Diagnostic epidural steroid transforaminal injections are also referred to as selective nerve root blocks, and they were originally developed as a diagnostic technique to determine the level of radicular pain. In

studies evaluating the predictive value of selective nerve root blocks, only 5% of appropriate patients did not receive relief of pain with injections. No more than 2 levels of blocks should be performed on one day. The response to the local anesthetic is considered an important finding in determining nerve root pathology. (CMS, 2004) (Benzon, 2005) When used as a diagnostic technique a small volume of local is used (<1.0 ml) as greater volumes of injectate may spread to adjacent levels. **When used for diagnostic purposes the following indications have been recommended** (Emphasis added.):

- 1) To determine the level of radicular pain, in cases where **diagnostic imaging is ambiguous** (emphasis added), including the examples below:
- 2) To help to evaluate a pain generator when **physical signs and symptoms differ from that found on imaging studies** (emphasis added);
- 3) To help to determine pain generators when **there is evidence of multi-level nerve root compression** (emphasis added);
- 4) To help to determine pain generators when **clinical findings are consistent with radiculopathy in a dermatomal distribution but imaging studies are minimal** (emphasis added);
- 5) To help to identify the origin of pain in patients who have had previous spinal surgery.

When an epidural steroid injection is used for therapeutic reasons, the ODG provides the following guidance:

Recommended as a possible option for short-term treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy) **with use in conjunction with active rehab efforts**. (Emphasis added.) See specific criteria for use below. Radiculopathy symptoms are generally due to herniated nucleus pulposus or spinal stenosis, although ESIs have not been found to be as beneficial a treatment for the latter condition.

Short-term symptoms: The American Academy of Neurology recently concluded that epidural steroid injections may lead to an improvement in radicular pain between 2 and 6 weeks following the injection, but they do not affect impairment of function or the need for surgery and do not provide long-term pain relief beyond 3 months. (Armon, 2007) Epidural steroid injection can offer short-term pain relief and use should be in conjunction with other rehab efforts, including continuing a home exercise program. There is little information on improved function or return to work. There is no high-level evidence to support the use of epidural injections of steroids, local anesthetics, and/or opioids as a treatment for acute low back pain without radiculopathy. (Benzon, 1986) (ISIS, 1999) (DePalma, 2005) (Molloy, 2005) (Wilson-MacDonald, 2005)

Use for chronic pain: Chronic duration of symptoms (> 6 months) has also been found to decrease success rates with a threefold decrease found in patients with symptom duration > 24 months. The ideal time of either when to initiate treatment or when treatment is no longer thought to be effective has not been determined. (Hopwood, 1993) (Cyteval, 2006) Indications for repeating ESIs in patients with

chronic pain at a level previously injected (> 24 months) include a symptom-free interval or indication of a new clinical presentation at the level.

Transforaminal approach: Some groups suggest that there may be a preference for a transforaminal approach as the technique allows for delivery of medication at the target tissue site, and an advantage for transforaminal injections in herniated nucleus pulposus over translaminar or caudal injections has been suggested in the best available studies. (Riew, 2000) (Vad, 2002) (Young, 2007) This approach may be particularly helpful in patients with large disc herniations, foraminal stenosis, and lateral disc herniations. (Colorado, 2001) (ICSI, 2004) (McLain, 2005) (Wilson-MacDonald, 2005)

Fluoroscopic guidance: Fluoroscopic guidance with use of contrast is recommended for all approaches as needle misplacement may be a cause of treatment failure. (Manchikanti, 1999) (Colorado, 2001) (ICSI, 2004) (Molloy, 2005) (Young, 2007)

Factors that decrease success: Decreased success rates have been found in patients who are unemployed due to pain, who smoke, have had previous back surgery, have pain that is not decreased by medication, and/or evidence of substance abuse, disability or litigation. (Jamison, 1991) (Abram, 1999) Research reporting effectiveness of ESIs in the past has been contradictory, but these discrepancies are felt to have been, in part, secondary to numerous methodological flaws in the early studies, including the lack of imaging and contrast administration. Success rates also may depend on the technical skill of the interventionalist. (Carette, 1997) (Bigos, 1999) (Rozenberg, 1999) (Botwin, 2002) (Manchikanti, 2003) (CMS, 2004) (Delpont, 2004) (Khot, 2004) (Buttermann, 2004) (Buttermann2, 2004) (Samanta, 2004) (Cigna, 2004) (Benzon, 2005) (Dashfield, 2005) (Arden, 2005) (Price, 2005) (Resnick, 2005) (Abdi, 2007) (Boswell, 2007) Also see Epidural steroid injections, “series of three” and Epidural steroid injections, diagnostic. ESIs may be helpful with radicular symptoms not responsive to 2 to 6 weeks of conservative therapy. (Kinkade, 2007) As noted above, injections are recommended if they can facilitate a return to functionality (via activity & exercise). If post-injection physical therapy visits are required for instruction in these active self-performed exercise programs, these visits should be included within the overall recommendations under Physical therapy, or at least not require more than 2 additional visits to reinforce the home exercise program.

Criteria for the use of Epidural steroid injections:

Note: The purpose of ESI is to reduce pain and inflammation, restoring range of motion and thereby facilitating progress in more active treatment programs, and avoiding surgery, but this treatment alone offers no significant long-term functional benefit.

(1) **Radiculopathy must be documented. Objective findings on examination need to be present.** (Emphasis added.) For unequivocal evidence of radiculopathy, see AMA Guides, 5th Edition, page 382-383. (Andersson, 2000)

(2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants).

(3) Injections should be performed using fluoroscopy (live x-ray) and injection of contrast for guidance.

(4) At the time of initial use of an ESI (formally referred to as the “diagnostic phase” as initial injections indicate whether success will be obtained with this treatment

intervention), a maximum of two injections should be performed. A second block is not recommended if there is inadequate response to the first block. A second block is also not indicated if the first block is accurately placed unless: (a) there is a question of the pain generator; (b) there was possibility of inaccurate placement; or (c) there is evidence of multilevel pathology. In these cases a different level or approach might be proposed. There should be an interval of at least one to two weeks between injections. To be considered successful after this initial use of a block/blocks there should be documentation of at least 50-70% relief of pain from baseline and evidence of improved function for at least six to eight weeks after delivery.

(5) No more than two nerve root levels should be injected using transforaminal blocks.

(6) No more than one interlaminar level should be injected at one session.

(7) In the therapeutic phase (the phase after the initial block/blocks were given and found to produce pain relief), repeat blocks should only be offered if there is at least 50-70% pain relief for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year. (CMS, 2004) (Boswell, 2007)

(8) Repeat injections should be based on continued objective documented pain relief, decreased need for pain medications, and functional response.

(9) Current research does not support a routine use of a "series-of-three" injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections for the initial phase and rarely more than 2 for therapeutic treatment.

(10) It is currently not recommended to perform epidural blocks on the same day of treatment as facet blocks or sacroiliac blocks or lumbar sympathetic blocks as this may lead to improper diagnosis or unnecessary treatment.

(11) Cervical and lumbar epidural steroid injection should not be performed on the same day.

In a letter dated March 28, 2008, Dr. H responded to the denial of the requested procedure, stating:

In the past, [claimant] has had previous lumbar medial branch neurotomies which had given her long-term pain relief, however, pain had started to return in her low back and it was felt necessary at that time to repeat lumbar medial branch neurotomies. Lumbar medial branch neurotomies in this patient have already proved to be successful and was giving long-term duration of benefit, which is expected with this procedure. This is a procedure that is not experimental or new, it is a procedure that has been around for several years and is standard of care in the community and supported by the North American Spine Society as well as taught in the majority, if not all, of the university pain fellowship programs across the country and also the World Pain Organization, the American Academy of Pain Management, the American Society of Interventional Pain Physicians, and International Spine Injection Society all support this procedure as a procedure that has scientific basis and is evidence-based. Therefore, I feel that this is a reasonable request. Also, the patient has radicular pain going along the right L5 distribution for which I have recommended selective epidural steroid injections. This can be used for both diagnostic as well as for therapeutic purposes, also a standard of care throughout the pain practicing community and major of medical institutions and teaching institutions across the nation. There are nothing new in the world of medicine and

are commonplace in the practical treatment of pain. Therefore, I think to deny this patient these procedures with a pretense that these were not accepted procedures is disingenuous.

In reviewing the IRO decision, it is clear that the physician reviewer's determination is not based upon a lack of pain relief from earlier radiofrequency neurotomies or because he believes that radiofrequency neurotomy and/or epidural steroid injections are not accepted within the medical community as valid treatment options. The physician reviewer points out that there is insufficient clinical and diagnostic support for the procedures at this time.

In determining the weight to be given to expert testimony, a trier of fact must first determine if the expert is qualified to offer it. The trier of fact must then determine whether the opinion is relevant to the issues at bar and whether it is based upon a solid foundation. An expert's bald assurance of validity is not enough. *See Black vs. Food Lion, Inc.*, 171 F.3rd 308 (5th Cir. 1999); *E.I. Du Pont De Nemours and Company, Inc. v. Robinson*, 923 S.W.2d 549 (Tex. 1995). Evidence is considered in terms of (1) general acceptance of the theory and technique by the relevant scientific community; (2) the expert's qualifications; (3) the existence of literature supporting or rejecting the theory; (4) the technique's potential rate of error; (5) the availability of other experts to test and evaluate the technique; and (7) the experience and skill of the person who applied the technique on the occasion in question. *Kelly v. State*, 792 S.W.2d 579 (Tex.App.-Fort Worth 1990). A medical doctor is not automatically qualified as an expert on every medical question and an unsupported opinion has little, if any, weight. *Black v. Food Lion, Inc.*, 171 F.3rd 308 (5th Cir. 1999). Health care providers are directed to provide treatment in accordance with the current edition of the Official Disability Guidelines (ODG), and such treatment is presumed to be reasonably required. (28 Tex. Admin. Code § 137.100 (Rule 137.100)).

Dr. H fails to address the requisites for the procedures set forth in the ODG or the concerns raised by the utilization review agents and the IRO physician reviewer. The procedures proposed may generally be neither experimental nor new and may generally be consistent with the standard of care in the community, but Dr. H fails to provide information from which it can be determined that the proposed care is appropriate and necessary for this injured worker under these circumstances.

According to the ODG, radiofrequency neurotomy is commonly used to provide a window of pain relief allowing for participation in active therapy but it is under study and approval is based on the particular facts of each case. The ODG states that approval of repeat neurotomies depends on variables such as evidence of adequate diagnostic blocks, documented improvement in VAS score, and documented improvement in function. Dr. H has provided no information regarding those variables in his rebuttal of the IRO decision nor does his rebuttal indicate that active rehabilitation is contemplated after the proposed neurolysis. It is uncontroverted that epidural steroid injections are an accepted treatment option within the medical community, but the ODGs set forth parameters for ESIs including objectively documented radiculopathy and the failure of the patient to respond to conservative measures such as exercises, NSAIDs and muscle relaxants. Dr. H fails to document either condition precedent to the use of ESIs.

Without evidence of consideration of the ODG criteria for the use of ESIs and radiofrequency neurotomy, Claimant has failed to prove that the procedures requested are clinically appropriate and considered effective for her injury and provided in accordance with best practices consistent with

evidence based medicine. The preponderance of the evidence is not contrary to the IRO recommendation. Even though all the evidence presented was not discussed, it was considered. The Findings of Fact and Conclusions of Law are based on all of the evidence presented.

FINDINGS OF FACT

1. The parties stipulated to the following facts:
 - A. Venue is proper in the (City) Field Office of the Texas Department of Insurance, Division of Workers' Compensation.
 - B. On ____, Claimant sustained a compensable injury while employed by (Employer).
 - C. Claimant requested preauthorization for radiofrequency neurotomy bilaterally at L4-5 and L5-S1 and an epidural steroid injection on the right at L5-S1, which was denied by Carrier.
 - D. C-IRO was selected by the Division as the independent review organization (IRO) to review Carrier's denial of the preauthorization request.
 - E. On December 19, 2007, the IRO issued its decision upholding Carrier's denial of Claimant's preauthorization request.
2. Carrier delivered to Claimant a single document stating the true corporate name of Carrier, and the name and street address of Carrier's registered agent, which document was admitted into evidence as Hearing Officer's Exhibit Number 2.
3. The IRO decision is consistent with the provisions of the ODG regarding the appropriate use of radiofrequency neurotomy for facet mediated pain and the appropriate use of epidural steroid injections.
4. Claimant failed to prove that the criteria set forth in the ODG had been met prior to the request for preauthorization of the radiofrequency neurotomy at L4-5 and L5-S1 and the administration of an epidural steroid injection at L5-S1.

CONCLUSIONS OF LAW

1. The Texas Department of Insurance, Division of Workers' Compensation, has jurisdiction to hear this case.
2. Venue is proper in the (City) Field Office.
3. The preponderance of the evidence is not contrary to the IRO decision upholding Carrier's denial of the request to preauthorize radiofrequency neurotomy bilaterally at L4-5 and L5-S1 and an epidural steroid injection on the right at L5-S1.

DECISION

The preponderance of the evidence is not contrary to the IRO decision upholding Carrier's denial of the request to preauthorize radiofrequency neurotomy bilaterally at L4-5 and L5-S1 and an epidural steroid injection on the right at L5-S1.

ORDER

Carrier is not liable for the benefits at issue in this hearing. Claimant remains entitled to medical benefits for the compensable injury in accordance with §408.021.

The true corporate name of the insurance carrier is **(SELF-INSURED)** and the name and address of its registered agent for service of process is

**KN
(ADDRESS)
(CITY), TEXAS (ZIP CODE)**

Signed this 4th day of April, 2008.

KENNETH A. HUCHTON
Hearing Officer