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Notice of Independent Review Decision

DATE OF REVIEW: OCTOBER 9, 2012

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Medical necessity of proposed Bilateral Lumbar Radiofrequency Ablation (64622, 64623, 77003) at levels L2, L3 and L5

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

This case was reviewed by a Medical Doctor licensed by the Texas State Board of Medical Examiners. The reviewer specializes in Physical Medicine and Rehabilitation and is engaged in the full time practice of medicine.

REVIEW OUTCOME

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

☐ Upheld (Agree)

XX Overturned (Disagree)

☐ Partially Overturned (Agree in part/Disagree in part)

Primary Diagnosis	Service being Denied	Billing Modifier	Type of Review	Units	Date(s) of Service	Amount Billed	Date of Injury	DWC Claim#	IRO Decision
847.2	64622		Prosp	1					Overturn
847.2	64623		Prosp	1					Overturn
847.2	77003		Prosp	1					Overturn

INFORMATION PROVIDED TO THE IRO FOR REVIEW

TDI-HWCN-Request for an IRO-19 pages

Respondent records- a total of 52 pages of records received to include but not limited to: 7.19.12, 8.27.12, 9.20.12; provider list; report, Medical Center 2.7.12,4.30.12; records, Family Care 9.28.09-6.4.12; Pain Team record 7.16.12; Prescription History; ODG Facet Joint Radiofrequency

Requestor records- a total of 12 pages of records received to include but not limited to:
TDI letter 9.18.12; Dr. report 5.21.12-8.31.12; Medical Center 4.30.12

PATIENT CLINICAL HISTORY [SUMMARY]:

Clinical History:
Patient is a male who sustained a work related injury on xx/xx/xx(no details of injury was provided at this time).
Patient was seen as a follow up by Dr. for the work related injury that was sustained on xx/xx/xx. The patient came in ambulatory with no assistance for pain in lower back and has stimulator that has been helping for pain in the legs. On examination of lower extremities, there was adequate range of motion noted to the hip, knee and ankle, with extension there was an increase of pain noted to the across waist. The assessment was Lumbar Strain; the radiating pain is controlled with stimulator, axial pain still persisted. Lumbar imaging was prescribed on this day.
The Imaging study shows MRI of L spine: L5-S1 bulge and 4 mm L3-4 disc herniation with foraminal stenosis. The patient underwent postoperative physical therapy. The patient was not seen from 2009 and states that he was incarcerated .He stated that he had pain for last two years.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION. IF THERE WAS ANY DIVERGENCE FROM DWC'S POLICIES/GUIDLEINES OR THE NETWORK'S TREATMENT GUIDELINES, THEN INDICATE BELOW WITH EXPLANATION.

APPROVE THE PROCEDURE FOR RADIOFREQUENCY ABLATION AT L2,L3 AND L5 LEVELS.

Medical necessity in this case is deemed necessary as the patient continues to have constant pain inspite of having a spinal stimulator, medial branch block and conservative care. This recommendation is based on the current evidence guidelines, as available.

REVIEW OF THE LITERATURE ON DIAGNOSTIC AND THERAPEUTIC BLOCKS – RADIOFREQUENCY – ODG GUIDELINES.
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 ≥ 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, decreased medications 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.

Ref: *Official Disability Guidelines, (ODG), 2009*

Facet joint diagnostic blocks	Recommended prior to facet neurotomy (a procedure that is considered "under study"). Diagnostic blocks are 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 MBB. 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 27% to 63%) but this does not appear to be cost effective or to prevent the incidence of false positive response to the neurotomy procedure itself. *Technique:* The described technique of blocking the medial branch nerves in the C3-C7 region (C3-4, C4-5, C5-6, and C6-7) is to block the named medial branch nerves (two injections). Authors have described blocking C2-3 by blocking the 3rd occipital nerve. Another technique of blocking C2-3 is to block at three injection points (vertically over the joint line, immediately above the inferior articular facet at C2 and immediately below the superior articular facet at C3). (Barnsley, 1993) 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. (Washington, 2005) (Manchikanti , 2003) (Dreyfuss, 2003) See the Low Back Chapter for further references. Criteria for the use of diagnostic blocks for facet nerve 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 ≥ 70%. The pain response should be approximately 2 hours for Lidocaine. 2. Limited to patients with cervical 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 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 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. 11. Diagnostic facet blocks should not be performed in patients who have had a previous fusion procedure at the planned injection level. 12. It is currently not recommended to perform facet blocks on the same day of treatment as epidural steroid injections or stellate ganglion blocks or sympathetic blocks or trigger point injections as this may lead to improper diagnosis or unnecessary treatment.
Facet joint therapeutic steroid injections	Not recommended. There is one randomized controlled study evaluating the use of therapeutic intra-articular corticosteroid injections. The results showed that there was no significant difference between groups of patients (with a diagnosis of facet pain secondary to whiplash) that received

	corticosteroid vs. local anesthetic intra-articular blocks (median time to return of pain to 50%, 3 days and 3.5 days, respectively). (Barnsley, 1994) There is only one prospective, non-randomized study evaluating the use of medial branch blocks for chronic cervical pain (diagnosed with comparative, controlled blocks that were performed under "light sedation"). The trial did not differentiate the results between patients that received local anesthetic from those that received steroids, and all patients received Sarapin with in their injectate. (Nelemans-Cochrane, 2000) (Manchikanti, 2004) (Manchikanti, 2003) (Boswell, 2007) While not recommended, criteria for use of therapeutic intra-articular and medial branch blocks, if used anyway: Clinical presentation should be consistent with facet joint pain, signs & symptoms. 1. There should be no evidence of radicular pain, spinal stenosis, or previous fusion. 2. 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). 3. When performing therapeutic blocks, no more than 2 levels may be blocked at any one time. 4. If prolonged evidence of effectiveness is obtained after at least one therapeutic block, there should be consideration of performing a radiofrequency neurotomy. 5. There should be evidence of a formal plan of rehabilitation in addition to facet joint injection therapy. 6. No more than one therapeutic intra-articular block is recommended.

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

XX DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES

XX MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

XX ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES