Becket Systems

An Independent Review Organization
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Notice of Independent Review Decision

Description of the service or services in dispute:

Left L3, L4, and L5 Rhizotomy under fluoroscopic guidance
64635 – Destruction by neurolytic agent
64636 – Destruction by neurolytic agent
77003 - Fluoroscopic Guidance

Description of the qualifications for each physician or other health care provider who reviewed the decision:

Board Certified Anesthesiologist

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

☐ Overturned (Disagree)

☑ Upheld (Agree)

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

Patient Clinical History (Summary)

XX is a XX who was diagnosed with low back pain (M54.5), displacement of cervical intervertebral disc without myelopathy (M50.20), lumbago (M54.5), lumbar herniated nucleus pulposus without myelopathy (M51.26), thoracic spine pain (M54.6), and bulging lumbar disc (M51.26). XX sustained an injury on XX when XX was rear-ended by an 18-wheeler truck which had not slowed down for a multi-vehicular stop on a highway.

On XX, XX was seen by XX, MD for back pain and leg numbness. XX stated XX low back pain was unchanged from the prior visit, rated at 6/10 without medications and 2/10 with medications. XX described the pain had burning quality, which did not radiate. On cervical spine examination, Spurling's test was positive. Thoracic spine was tender to touch. The lumbar spine range of motion was mildly reduced and painful. Facet loading caused pain on the left side.

The magnetic resonance imaging (MRI) of the lumbar spine dated XX documented an acute disc herniation at L4-L5. The base was the widest impression consistent with a disc protrusion.

An Appeal letter was written by XX MS, PA-C on XX. XX had been treated for a work-related injury to the lumbar region of XX back. XX was initially treated with facet medial branch block (MBB) on XX. XX did receive at least 80% pain relief and increased function, and was subsequently approved for, and underwent a lumbar rhizotomy procedure on the right side on XX. XX was seen for follow up on XX and reported 100% relief with 0/10 pain on the right side of XX lumbar region. XX noted that the pain relief on the right did uncover pain on XX left side, which XX reported was 4/10 and severe enough to impair XX activity. Dr. XX ordered the facet medial branch block (MBB) for the left side at the visit. The procedure was approved following a peer to peer conversation with Dr. XX, who did also confirm a rhizotomy could then be performed if the MBB was diagnostically successful The patient did undergo the left-sided MBB on XX, reported at least 80% relief immediately following the procedure. At the subsequent follow up office visit on XX, XX again reported XX relief was initially at least 80%, but XX was experiencing the low back pain recurring on the left and rated the pain as 6/10. When XX took XX pain medication, XX pain would subside to around 2/10, but the fact that XX needed to take the pain medication interfered with XX ability to perform XX normal occupational duties. XX was a XX and XX was not able to get XX "medical card" while taking the pain medication. Without the pain medication, XX was not able to tolerate XX occupational duties. The denial of the requested procedure did request clarification as to how the procedure might affect the patient's clinical outcomes.

This was clear. At this point in time, because XX needed to take the pain medication to remain at work, XX could not get cleared to XX and XX ability to earn XX normal wage was severely impaired. Having experienced such complete relief of XX back pain following the first rhizotomy on XX right side, XX was certain the rhizotomy on XX left side will give XX similar results, and XX will be able to return to work without taking pain medication. XX desperately wanted and needed to be off pain medication so XX could get XX medical card and be cleared to XX and return to XX previous wage-earning ability. Reasonable medical judgment suggested the left L3 L4 L5 rhizotomy was medically necessary and the adverse determination would be reviewed and reversed.

The treatment to date included medications (XX, XX, XX, and XX), medial branch block (80% pain relief), lumbar rhizotomy (100% relief), and physical therapy.

Per a utilization review decision letter dated XX, the requested service was denied by XX MD.

Per a utilization review decision letter dated XX, the requested service was denied by XX, MD. Rationale: "Based on the clinical information submitted for this review and using the evidence-based, peer-reviewed guidelines referenced above, this request is non-certified. A clear and measurable objective comparison could not still be established in the records to fully validate efficacy from injection received to support the request. In addition, the guidelines indicated that studies have not demonstrated improved function with facet rhizotomy. Clarification is needed regarding the request and how it might affect the patient's clinical outcomes. Prior non-certification is upheld".

Analysis and Explanation of the Decision include Clinical Basis, Findings and Conclusions used to support the decision.

This patient underwent a right sided lumbar medial branch block with a subsequent RFA – the response was unequivocal and produced 100% pain relief. On the right side, these procedures were duplicated. However, the response was equivocal. The patient archived some pain relief initially, but later developed burning dysesthesias and a recurrence of the left-sided back pain. The pain score was recorded as 2/10, however this was recorded while the patient took pain medication. In order to achieve pain control, the patient has continued to oral pain medication.

The ODG is clear in its directive that a repeat RFA is only indicated if 50% pain relief or more was archived for at least XX. This has not been met. In addition, the ODG does not support repeating the RFA within XX of the original intervention. This reviewer is of the opinion the right-sided RFA was not really effective. A repeat intervention is therefore not indicated. Given the documentation available, the requested service(s) is considered not medically necessary.

A description and the source of the screening criteria or other clinical basis used to make the decision:

- ☐ ACOEM-America College of Occupational and Environmental Medicine
- ☐ AHRQ-Agency for Healthcare Research and Quality Guidelines
- ☐ DWC-Division of Workers Compensation
- ☐ Policies and Guidelines European Guidelines for Management of Chronic Low Back Pain
- ☐ Interqual Criteria
- ☑ Medical Judgment, Clinical Experience, and expertise in accordance with accepted medical standards
- ☐ Mercy Center Consensus Conference Guidelines
- ☐ Milliman Care Guidelines
- ☑ ODG-Official Disability Guidelines and Treatment Guidelines

  Low Back Chapter:

  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).

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 over the course of a year.

(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.

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 sacroiliac 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) Among the top 5 tests and therapies that are of questionable usefulness in the field of pain medicine, as prepared by the American Society of Anesthesiologists (ASA) and the American Pain Society (APS) is to avoid irreversible interventions for noncancer pain, such as peripheral chemical neurolytic blocks or peripheral radiofrequency ablation, because such interventions may be costly and carry significant long-term risks of weakness, numbness, or increased pain. (ASA, 2014)

Systematic reviews: When compiled into systematic reviews, the evidence has been found to be conflicting for a short-term effect (Niemistö, 2003) (Niemisto, 2003) 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 intradiscal electrothermal therapy, are not supported by convincing, consistent evidence of benefit from randomized trials. (Chou, 2008)

Technique: There are several techniques. (Gofeld, 2008) 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. (Cohen, 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)

- ☐ Pressley Reed, the Medical Disability Advisor
- ☐ Texas Guidelines for Chiropractic Quality Assurance and 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)

Appeal Information

You have the right to appeal this IRO decision by requesting a Texas Department of Insurance, Division of Workers' Compensation (Division) Contested Case Hearing (CCH). A Division CCH can be requested by filing a written appeal with the Division's Chief Clerk no later than 20 days after the date the IRO decision is sent to the appealing party and must be filed in the form and manner required by the Division.

Request for or a Division CCH must be in writing and sent to:
Chief Clerk of Proceedings Texas Department of Insurance
Division of Workers' Compensation P. O. Box 17787
Austin, Texas, 78744

For questions regarding the appeals process, please contact the Chief Clerk of Proceedings at 512-804-4075 or 512- 804-4010. You may also contact the Division Field Office nearest you at 1-800-252-7031.