

Clear Resolutions Inc.

An Independent Review Organization

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Review Outcome

Description of the service or services in dispute:

Bilateral radiofrequency thermocoagulation (RFTC) of L4, L5 and S1 during two-day sessions / Partial was approved. (Note: "Since it's a nerve ablation if there is a complication it would only involve one side doing one a time. If both sides are performed and there is complication at the same, there could be a potential problem with issues such as inability to walk.")

64635 – Destroy lumbar/sacral facet joint

64636 – Destroy lumbosacral facet joint additionally

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

Board Certified PM&R

Board Certified Pain Medicine

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 Xx with the diagnosis of sprain of ligaments of lumbar spine, initial encounter (S33.5XXA). XX stated while working as a XX and stopped on the XX, another XX collided with XX on XX. Immediately, XX had noticed a sharp increase of low back pain with radiating pain to XX bilateral legs, mostly XX right leg where XX never had pain before. The patient had been admitted previously for low back pain and left leg pain, which had led to surgery in XX. Afterwards, XX had completely recovered but noted earlier this year that XX left leg started to have some minor pain. After the accident on XX the low back pain worsened significantly as well as the left leg pain; however, XX developed pain from the lower back to the right lower leg that XX never had before.

On XX, XX, DC evaluated XX for a chief complaint of low back pain and bilateral leg pain. Per note, XX underwent a lumbar discectomy and laminectomy by XX. XX had undergone postoperative physical therapy. XX had continued to have some pain in XX lower back and pain to XX left leg but XX right leg pain had improved significantly. XX had undergone a new MRI of the lumbar spine ordered by the surgeon. XX reviewed the MRI and noted XX should try an injection to treat for the localized low back pain. XX had received a medial branch block with XX, which successfully decreased XX low back pain. XX continued to express depression with altering XX career since XX no longer could perform XX duties as a XX. XX was referred for a chronic pain management program and was approved. XX had also been recommended for a lumbar radiofrequency thermocoagulation (RFTC) since the medial branch block helped with the low back pain. On examination, XX carriage and gait were antalgic. Surgical scars were noted in the lumbar region. XX had trouble sitting for the duration of the examination due to pain. Minors sign was positive for pain when rising from the seated position. There was mild tenderness to palpation in the lumbar spine with hypertonicity noted in the musculature. Kemp's test was positive for local lumbar complaints. XX test was positive for lumbosacral pain. Lumbar range of motion was restricted in all planes. XX had been approved for the radiofrequency thermocoagulation (RFTC) procedure in the lower back by XX since the facet joint injection helped with XX localized back pain after spinal surgery.

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On XX, an MRI of the lumbar spine showed discogenic disease at L4-L5 and L5-S1; moderate neuroforaminal stenosis and mid spinal canal stenosis at L4-L5; and mild neuroforaminal stenosis at L5-S1.

Prior treatment included medications, injections, surgery, postoperative physical therapy (PT), and a home exercise program. XX underwent diagnostic medial branch block targeting the bilateral L4, L5, and S1 segments from which XX had a decrease of pain from 8/10 to 2/10 bilaterally intraoperatively. XX received lumbar epidural steroid injection (LESI) with improved low back and leg pain by 40-50 percent. XX medications included XX 300 mg-XX 30 mg tablet, XX 10 mg tablet, XX 5 mg tablet, XX 100 mg capsule, XX 300 mg capsule, XX, XX 4 mg tablets in a dose pack, XX 500 mg tablet. XX was currently not on oral medications. The patient had taken XX 20 mg, XX 15 mg, XX 500 mg, XX 5 mg, and XX 100 mg as prescribed and was deriving some benefit.

An Adverse Determination Letter dated XX indicated the requested services were not authorized. Rationale: "Presently, based upon the medical documentation available for review, Official Disability Guidelines would not support a medical necessity for this specific request. As documented in the summary, recent treatment did include treatment in the form of lumbar medial branch blocks. There was documentation of a decrease in pain symptoms with this form of treatment. However, the submitted clinical documentation does not provide any data to indicate whether there was a decrease in utilization of prescription medication with a previous attempt at treatment in the form of lumbar medial branch blocks. Additionally, past MRI testing of the lumbar spine revealed findings consistent with the presence of a compressive lesion upon a neural element in the lumbar spine. With such documentation, presently, the above-noted reference would not support a medical necessity for this specific request. "

Per a preauthorization determination letter dated XX the requested service was partially preauthorized and modified to bilateral radiofrequency thermocoagulation (RFTC) of L4, L5 and S1 during a one (1) single session only. Rationale: "A successful peer-to-peer call with XX on behalf of XX was made at XX. During the peer conversation with XX, the case was discussed with regard to the provided medical records and the guidelines. XX indicated 70 to 80% relief following the bilateral medial branch blocks. The patient has signs and symptoms that are consistent with lumbar facet pain and has failed physical therapy. The patient has had prior lumbar surgery but is not fused at any levels. Official Disability Guidelines support radiofrequency neurotomy as a treatment option for low back pain refractory to conservative management. However, on the peer-to-peer, there is no indication for separating treatment of the two sides into two sessions identified. XX agreed to the modification of the request to bilateral radiofrequency thermocoagulation (RFTC) of L4, L5, and S1 during a one (1) single session only as certified."

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

Based on the clinical information provided, the request for Bilateral radiofrequency thermocoagulation (RFTC) of L4, L5 and S1 during XX sessions / Partial was approved. (Note: "Since it's a nerve ablation if there is a complication it would only involve one side doing one a time. If both sides are performed and there is complication at the same, there could be a potential problem with issues such as inability to walk."), 64635 – Destroy lumbar/sacral facet joint, 64636 – Destroy lumbosacral facet joint additionally is recommended as medically necessary, and the previous determinations are overturned.

The patient underwent diagnostic medial branch blocks with 70-80% pain relief. The patient has signs and symptoms that are consistent with lumbar facet pain and has failed physical therapy. The patient has had prior lumbar surgery but is not fused at any levels. Official Disability Guidelines support radiofrequency neurotomy as a treatment option for low back pain refractory to conservative management. If there is a complication, it will only involve one side if the procedure is done on different sides on different days. If both sides are performed and there is complication bilaterally, there could be a potential problem with issues such as inability to walk. Therefore, medical necessity is established in accordance with current evidence based guidelines.

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

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- ☐ 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

Radiofrequency Neurotomy 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).*

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 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

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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

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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.