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IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Lumbar Radiofrequency Neurolysis Ablation L4-L5, L5-S1 levels on the Left Medical Branch of the Dorsal Ramus x1.

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

Board Certified PM&R and Board Certified Pain Medicine.

REVIEW OUTCOME:

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

Overturned (Disagree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a female who reported an injury to her low back as a result of pulling furniture on XX/XX/XX. The MRI of the lumbar spine revealed mild disc desiccation at L1-2 with a left sided paracentral 2mm disc protrusion creating effacement of the thecal sac without significant nerve root compromise. A 2-3mm disc protrusion and herniation was identified at L2-3 creating effacement of the thecal sac without nerve root compromise. All other levels presented with no abnormalities. The clinical note indicates the patient complaining of ongoing low back pain. The patient described the pain as constant and burning. Radiation of pain was identified to the left lower extremity, specifically the upper thigh. Radiation of pain was also identified at the left buttocks at that time. Left lower extremity strength deficits were identified. The patient had undergone

approximately 5 physical therapy sessions to date. The patient reported no significant improvement. Upon exam, the patient was able to demonstrate 5/5 strength throughout both lower extremities. Moderate limitations were identified with lumbar flexion and lateral bending. Tenderness was identified upon palpation at the left side of the sciatic notch. Reflex deficits were identified at the right lower extremity at both the patellar and Achilles regions. The clinical note indicates the patient rating the low back pain as 7/10. The pain was primarily located at the left side of the low back and sacroiliac region on the left. Radiating pain continued into the left thigh and calf. The clinical note indicates the patient having undergone a medial branch block in the lumbar region. The patient had undergone a left sided L4-5 and L5-S1 medial branch block with anesthesia. The note indicates the patient tolerating the procedure well with no complications. The clinical note indicates the patient continuing with low back pain. The patient reported an ability to stand for up to 30 minutes. The patient reported 0-3/10 pain at that time. The note indicates the patient able to demonstrate 90 percent range of motion throughout the lumbar region. The patient was recommended for an L4-5 and L5-S1 radiofrequency ablation on the left at that time. The utilization review dated XX/XX/XX resulted in a denial as insufficient information had been submitted regarding the patient's response to the diagnostic medial branch block at the left of L4-5 and L5-S1.

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

The documentation indicates the patient complaining of ongoing low back pain. A radiofrequency ablation in the lumbar region is indicated provided the patient meets specific criteria to include a positive response to a diagnostic medial branch block manifested by a 70 percent reduction in pain. The most recent clinical note indicates the patient had been rating her low back pain as 7-9/10 prior to the medial branch block. The patient subsequently rated her pain as 0-3/10 following the medial branch block. There is also indication the patient had demonstrated an increase in tolerance for standing, sitting and walking following the medial branch block. Given the recently submitted clinical information regarding the patient's positive response to the diagnostic medial branch block at the L4-5 and L5-S1 levels a radiofrequency neurolysis and ablation at L4-5 and L5-S1 is indicated as medically reasonable. As such, it is the opinion of this reviewer that the request for a radiofrequency ablation at L4-5 and L5-S1 on the left is recommended as medically appropriate.

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

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

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

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). 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) 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 (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) 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 $\geq 50\%$ 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, 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.