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Date notice sent to all parties:

May 12, 2016

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

SI joint injection and lateral branch block SA, S1, S2

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

Board Certified Orthopedic Surgeon

REVIEW OUTCOME:

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

X Upheld (Agree)

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 male whose date of injury is XX/XX/XX. The patient was injured when a X backed into his X. MRI of the lumbar spine dated XX/XX/XX revealed 3 mm broad based disc herniation at L4-5 along with facet hypertrophic changes contributing to moderate bilateral neural foraminal stenosis and mild central canal stenosis; additional 3 mm posterior disc herniation at L5-S1. Note dated XX/XX/XX indicates that the patient presents for an evaluation of his cervical spine and lumbar spine. He has completed physical therapy. He reports his neck pain resolved with therapy. Note dated XX/XX/XX indicates that he underwent an epidural steroid injection on XX/XX/XX and reported approximately 60% relief of his symptoms. Note dated XX/XX/XX indicates that the patient was recommended to undergo a repeat epidural steroid injection at L4-5. Office visit note dated XX/XX/XX indicates that he continues to have moderate left leg and low back pain. He had a second epidural steroid injection on XX/XX/XX and reports only 20-25% relief of leg pain. Current medications are blood pressure medication and muscle relaxer. On

physical examination there is tenderness to palpation of the left lumbar paraspinal muscles. Lumbar range of motion is decreased. Straight leg raising is positive on the left. Strength is 5/5 throughout the lower extremities. Deep tendon reflexes are 2+ and symmetrical. Sensation is intact to light touch throughout the bilateral lower extremities. The patient was referred for possible facet joint injections. Physical examination on XX/XX/XX indicates that there is tenderness to palpation over the left SI joint. Straight leg raising is positive on the left. Patrick's maneuver is positive on the left. The patient was recommended to undergo left SI joint injection and left LBB SA-S2.

The initial request for SI joint injection and lateral branch block SA, S1, S2 was non-certified on XX/XX/XX noting that the Official Disability Guidelines note that sacroiliac intra-articular joint diagnostic and therapeutic injections are not recommended. Therapeutic sacroiliac joint injections are not recommended for non-inflammatory sacroiliac pathology based on insufficient evidence. The therapeutic sacroiliac joint injections are recommended on case by case basis for cases of inflammatory spondyloarthritis. The documentation does not provide evidence that the patient suffers from inflammatory spondyloarthritis in order to support the request for the injections. In regard to the request for lateral branch block SA, S1, S2, the referenced guidelines indicate sacral lateral branch nerve injections are not recommended due to the questionable nature of the efficacy of diagnosis by these injections. The denial was upheld on appeal dated XX/XX/XX noting that there have been no additional medical records submitted to further support the request. The issues raised by the prior review have not been addressed and still remain true. ODG states that sacroiliac injections are not recommended for non-inflammatory sacroiliac pathology but are recommended on a case by case basis for sacroiliitis. Although the patient has been diagnosed with sacroiliitis, he presents only with positive Faber. Guidelines do not overwhelmingly recommend SI joint injections. In regards to lateral branch blocks, no additional medical records were submitted to further support the request. The rationale for the requested procedure has not been provided. It is unclear if the provider intends to proceed with a sacroiliac neurotomy or if this is meant to be therapeutic. ODG does not recommend sacral lateral branch nerve blocks as a diagnostic test prior to a neurotomy.

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 SI joint injection and lateral branch block SA, S1, S2 is not recommended as medically necessary. There is no documentation of any recent active treatment. The Official Disability Guidelines note that diagnostic sacroiliac joint injections are not recommended. Diagnostic intra-articular injections are not recommended (a change as of August 2015) as there is no further definitive treatment that can be recommended based on any diagnostic information potentially rendered. There is no documentation of inflammatory spondyloarthritis in order to support the request for the injection. In regards to lateral branch block SA, S1, S2, the Official Disability Guidelines note

that the efficacy of diagnosis by these injections has been questioned. Sacral lateral blocks have been shown to have poor face value. There is no clear rationale provided to support the requested injections at this time. Therefore, medical necessity is not 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:

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

X ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

ODG Hip and Pelvis Chapter 2016

Sacroiliac injections, diagnostic

Not recommended, including sacroiliac intra-articular joint and sacroiliac complex diagnostic injections/blocks (for example, in anticipation of radiofrequency neurotomy). Diagnostic intra-articular injections are not recommended (a change as of August 2015) as there is no further definitive treatment that can be recommended based on any diagnostic information potentially rendered (as sacroiliac therapeutic intra-articular injections are not recommended for non-inflammatory pathology). Consideration can be made if the injection is required for one of the generally recommended indications for sacroiliac fusion. See Sacroiliac fusion. Also Not recommended: Sacral lateral branch nerve blocks and/ or dorsal rami blocks in anticipation of sacroiliac radiofrequency neurotomy. See Diagnostic blocks in anticipation of SI neurotomy below. See also Sacroiliac problems, diagnosis; Sacroiliac injections, therapeutic; Sacroiliac radiofrequency neurotomy.

Diagnostic injections (also referred to as diagnostic blocks): There are two basic types of SI joint diagnostic injections. Studies evaluating diagnostic blocks in anticipation for radiofrequency neurotomy have utilized a combination of both intra-articular and nerve blocks as well as nerve blocks alone. Most studies on SI joint fusion have used intra-articular blocks for diagnoses. In the case of the latter, there are no studies to evaluate the predictive value of this injection in terms of results of the surgical treatment.

(1) Intra-articular injections: In the past, intra-articular injections were those most commonly recommended for diagnosis of sacroiliac joint pain. These do not address the interosseous or dorsal sacroiliac ligaments. When performed, local anesthetic can escape the intra-articular region and anesthetize nearby structures. The latter can result in inaccurate blocks. Other causes of inaccurate blocks

include use of sedative medications (to the point of limiting the patient's response to the procedure) and failure to achieve infiltration throughout the entire SI joint complex. A negative test is not able to exclude extra-articular causes of pain. (Berthelot, 2006)

(2) Sacral lateral branch nerve injections and/or medial dorsal rami injections (L4-5): These injections are thought to be of diagnostic value in addressing posterior SI joint pain and pain mediating from the posterior ligaments stabilizing the SI joint. They have therefore been suggested for use in eliciting an etiology of extra-articular sources of sacroiliac complex pain. They are suggested, in particular, in anticipation of radiofrequency neurotomy procedures. The efficacy of diagnosis by these injections has been questioned, in part, due to the variability of the innervation of the SI complex area. (See Innervation below.) Recent authors indicate the only diagnostic injection that shows validity for the diagnosis of sacral lateral branch pain is the multisite, multi-depth technique. Sacral lateral blocks have been shown to have poor face value. They also do not protect normal volunteers from experiment sacroiliac pain (produced by using intra-articular injections). (Dreyfuss, 2008) (Dreyfuss, 2009) (Yin, 2003) (Manchikanti, 2013) (King, 2015) (Bogduk, 2015)

Diagnostic blocks in anticipation of SI neurotomy: The best way to screen in anticipation for a neurotomy has not been established. Discussion continues as to whether or not lateral branch blocks are necessary, or if intra-vs. peri-articular injections are indicated. There is no "gold standard" diagnostic test or procedure suggested to select the patients who will most benefit from this procedure (regardless of the technique). Published studies have used no confirmatory/prognostic test before proceeding to a definitive neurotomy. Studies have shown no prediction of success of neurotomy based on either prognostic intra-articular or lateral branch blocks, and the use of multiple SI joint local anesthetic blocks, near-complete pain relief from diagnostic blocks or prognostic lateral branch blocks is currently not recommended. (Cohen, 2009) In a 2012 poster presentation, Cheng et al. indicated that sacroiliac joint intra-articular steroid injections (used as a diagnostic indicator) did not directly predict pain relief with neurotomy, and as noted above, they do not protect normal volunteers from experiment-induced sacroiliac pain. (Dreyfuss, 2008) (Cheng, 2012) (Cheng, 2013) See Sacroiliac radiofrequency neurotomy.

Innervation: Exact innervation of the joint and complex remains unclear. The anterior portion of the joint is thought to be innervated by branches of the lumbosacral trunk with no clear cut evidence of the involved nerves. Anterior innervation may also be supplied by the obturator nerve and superior gluteal nerve. The posterior portion

is thought to be innervated by the posterior rami of L4-S3, although the actual innervation also remains unclear. Other research supports innervation by the S1 and S3 sacral dorsal rami. Myelinated and unmyelinated fibers along with encapsulated endings have been found in the joint. (Vallejo, 2006) (King, 2015) (Cox, 2014) (Roberts, 2014) (Vleeming, 2012) (Aydin, 2010) (Cohen, 2013) (Simopoulos, 2012) (Vanelderden, 2010) (Cohen, 2005) (Berthelot, 2006)

Factors that can affect sensitivity and specificity of diagnostic blocks: Placebo effect; Referred pain; Central sensitization; Expectation bias; Symptomatic blockade; Systemic absorption; Psychological issues. (Cohen, 2005)

Research addressing the use of diagnostic SI joint blocks: (1) In a literature review by Berthelot et al., SI blocks were found to be insufficiently sensitive or specific to be used as a diagnostic gold standard. Reasons given were discordance in results of two consecutive SI joint blocks and leakage of injection fluid into adjacent tissues. It is also mentioned that pain formerly believed to have a source within the SI joint could be secondary to extraarticular structures (including numerous surrounding ligaments). (Berthelot, 2006) (2) A systematic review commissioned by the American Pain Society (APS) and conducted at the Oregon Evidence-Based Practice Center states that there is insufficient evidence to evaluate validity or utility of diagnostic sacroiliac joint blocks, and that there is insufficient evidence to adequately evaluate benefits of sacroiliac joint steroid injection. (Chou, 2009) (3) The European Guidelines for the Diagnosis and Treatment of Pelvic Girdle Pain found there was insufficient evidence to use local SIJ injections as a diagnostic tool for pelvic girdle pain. Local SIJ injections as a diagnostic tool for pelvic girdle pain were not recommended. (Vleeming, 2008) (4) A review undertaken as a contribution to a multi-society Appropriate Use Criteria Task Force project convened by the International Spine Intervention Society addressed the validity of fluoroscopically guided diagnostic SI joint injections to diagnosis SI joint pain and predict a subsequent therapeutic response. The authors indicated it was not clear if image-guided intra-articular diagnostic injections of a local anesthetic predicted a positive response to a therapeutic agent. (Kennedy, 2015)

Sacroiliac injections, therapeutic

Not recommended (neither therapeutic sacroiliac intra-articular nor periarticular injections) for non-inflammatory sacroiliac pathology, based on insufficient evidence. Recommended on a case-by-case basis injections for inflammatory spondyloarthropathy (sacroiliitis). This is a condition that is generally considered rheumatologic in origin

(classified as ankylosing spondylitis, psoriatic arthritis, reactive arthritis, arthritis associated with inflammatory bowel disease, and undifferentiated spondyloarthropathy). Instead of injections for non-inflammatory sacroiliac pathology, conservative treatment is recommended. Current research is minimal in terms of trials of any sort that support the use of therapeutic sacroiliac intra-articular or periarticular injections for non-inflammatory pathology. Below are current reviews on the topic and articles cited. There is some evidence of success of treatment with injections for inflammatory spondyloarthropathy, although most rheumatologists now utilize biologic treatments (anti-TNF and/or disease modifying antirheumatic drugs) for treatment. Also see Sacroiliac problems, diagnosis; Sacroiliac injections, diagnostic.

Current research and reviews available:

Chou et al., 2009: This is a systematic review commissioned by the American Pain Society (APS) and conducted at the Oregon Evidence-Based Practice Center that states that there is insufficient evidence to evaluate validity or utility of therapeutic sacroiliac joint blocks. (Chou, 2009)

Vanelderen et al., 2010: These authors indicate that SI joint intra-articular injections may provide good pain relief for periods of up to 1 year, but give no reference to support this. They indicate periarticular sources of pain should be considered for treatment in addition to intra-articular injections. They describe in detail the Luukkainen et al. randomized trial of 24 patients who received periarticular injections with one month follow up (see below). (Luukkainen, 2002) They also cite Maugars et al.; a double-blind study evaluating SI joint injections for patients with spondyloarthropathy. The authors recommend intra-articular injections of local corticosteroid. (Vanelderen, 2010) (Luukkainen, 2002) (Maugars, 1996)

Hansen et al., 2012: Evidence was considered limited (or poor) for short-term and long-term relief from intra-articular steroid injections or periarticular injections. (Hansen, 2012)

Manchikanti et al., 2013: Evidence was considered limited for SI joint and periarticular injections. (Manchikanti, 2013)

Cohen et al., 2013: Cohen, et al. indicated that evidence for intra-articular injections was weak. They indicated there was moderate evidence supporting intra-articular injections for spondyloarthropathy and anecdotal evidence for beneficial effect in non-spondyloarthropathy pain. The authors listed a prospective study by Fischer et al., that found a mean duration of benefit of 12 months for

juvenile patients with spondyloarthritis who failed to respond to NSAIDs (a German language study). They also listed a study by Hanley et al., that examined 13 patients with inflammatory spondyloarthritis and MRI evidence of sacroiliitis (the authors of this study indicated the injections were ineffective). The Maugars study was also cited. (Cohen, 2013) (Fischer, 2003) (Hanley, 2000) (Maugars, 1996)

Itz et al, 2015: This is the Dutch Multidisciplinary Guideline for Invasive Treatment for Pain Syndromes of the Lumbosacral Spine. This group recommended intra-articular SI joint injections as “only study related” (because no literature is available, or case reports are insufficient to indicate effectiveness or safety to give a clear recommendation for practice). The two studies cited for support are those by Luukkainen, et al. and Maugars, et al. (Itz, 2015) (Luukkainen, 2002) (Maugars, 1996)

Chou et al., 2015: This is a report from the Agency for Healthcare Research and Quality. The evidence was considered insufficient to evaluate sacroiliac joint corticosteroid injections. The one study cited was Luukkainen et al. (Chou, 2015) (Luukkainen, 2002)

Kennedy et al., 2015: A review was undertaken as a contribution to a multi-society Appropriate Use Criteria Task Force project convened by the International Spine Intervention Society to assess effectiveness of intra-articular steroid injections in treating SI joint pain. Two randomized controlled trials were cited to support moderate strength recommendation for this treatment. The first was Maugars et al., 1996, and the second (Kim et al., 2010) was a study comparing intra-articular prolotherapy versus steroid injection. The authors of the Kim et al., study found that prolotherapy was a more successful therapy. Several observational studies were also cited. (Maugars, 1996) (Kim, 2010)

Other case series of intra-articular blocks for non-inflammatory pathology:

Lillang et al., 2009: This is a prospective case series of 39 patients who underwent dual diagnostic intra-articular blocks. Twenty-six

(66.7%) experienced pain relief of greater than 50% for 5 weeks.

Thirteen patients (33.3%) responded for a shorter term period (mean 4.4 ± 1.8 weeks). Risk factors for shorter term response included history of lumbosacral spinal fusion. (Lillang, 2009)

Research on periarticular or combined periarticular/intra-articular

injections:

Luukkainen et al., 2002: This study, which is double-blind and controlled, is commonly cited to support periarticular injections. Twenty-four patients were treated with periarticular injections (13 with steroid and local and 11 with saline and local). Follow up was at 1 month with improvement in the steroid group. (Luukkainen, 2002)

Borowsky et al., 2008: This was a retrospective review of 2 large case series. Patients receiving intra-articular injections alone had a positive response (defined as a 50% drop in VAS pain score or a report that activities of daily living had “greatly improved”) at 3 months of 12.5% versus 31.25% for the combined injections. The authors suggested that significant extra-articular sources of sacroiliac region pain existed and that intra-articular diagnostic blocks underestimated the prevalence of sacroiliac region pain. (Borowsky, 2008)

Research on intra-articular injections for inflammatory spondyloarthritis (in adults):

Hanly et al., 2000: This is a study of 19 patients with symptoms of inflammatory low back pain. Thirteen had radiographic evidence of sacroiliitis. All patients received bilateral SI joint injections with steroid. Transient improvement was most pronounced at 1-3 months after injection. This did not reach statistical significance by 6 months. The author’s conclusion was that the injections were ineffective in the management of patients with inflammatory spondyloarthritis. (Hanly, 2000)

Maugers, 1996: This is a double blind study of 10 patients (13 injections) with painful sacroiliitis. In 5/6 joints injected in the treatment group the patients had relief of > 70% compared to 0/7 in the placebo group at one month. Re-injection with corticosteroid occurred at one month with inclusion of 6/7 of the placebo group. Results of this combined group showed 58% success at 6 months. (Maugers, 1996)

Bollow et al., 1996: Sixty-six patients with inflammatory back pain were treated with CT-guided corticosteroid injections. Statistically significant abatement of subjective complaints occurred in 92.5% at 1.7 ± 1.1 weeks with improvement lasting for 10 ± 5 months. (Bollow, 1996)