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Description of the service or services in dispute:
In-office left sacroiliac joint injection under fluoroscopy with monitored sedation.
27096 – Introduction or Removal Procedures on the Pelvis and Hip Joint
01936 – Anesthesia for percutaneous image guided procedures on the spine and spinal cord
J3490 – Unclassified drugs or just "Drugs unclassified injection" for short, used in Medical care

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

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)
XXXX with a diagnosis of sprain of ligaments of the lumbar spine, subsequent encounter (S33.5XXD). XXXX had a history of pain syndrome since XXXX on XXXX buttocks on XXXX. XXXX was unable to work since then.

On XXXX, XXXX was seen by XXXX for a follow –up of sacroiliac pain, which had restarted from the previous week. XXXX described an aching pain in XXXX lower back and left buttock and to XXXX left hip. The pain did radiate some to the left knee. XXXX also had some pain, which had started from XXXX left knee and radiated down XXXX left foot. The pain was described as a burning type of pain. The pain rated at the severity of 9/10. On musculoskeletal examination, there was left S1 and greater trochanteric (GT) bursa tenderness and paraspinal tenderness, the left worse than the right of the midline of the lumbar spine. The facet loading test and Gaenslen's test were positive. Faber's test was positive on the left. The neurological examination showed clonus on the left lower extremity.

The treatment to date included medications (XX, XX and XX), sacroiliac joint injections (85% pain relief), lumbar epidural steroid injection, which made the pain worse, physical therapy, a cane and chronic pain management program.

An x-ray of the lumbosacral spine dated XXXX showed instability at L4-L5. There was also multilevel degenerative bone and disc changes. An MRI of the lumbar spine was reviewed and showed multilevel lumbar disc and facet degenerative changes and L4-L5 degenerative grade 1 spondylolisthesis. A canal and foraminal compromise at the same level had the potential for irritation of descending and exiting nerves, more so if there was instability related to the facet arthropathy. At L5-S1, there was right posterior lateral disc herniation that contacted the descending right S1 nerve without mass defect, which had a low potential for right S1 nerve irritation. There was discogenic marrow edema at L5-S1, which

indicated a more likely discogenic pain generator. An MRI of the bilateral hips and pelvis dated XXXX revealed mild degenerative changes in both hips. XXXX stated XXXX had undergone an EMG/nerve conduction study, which was negative.

Per a utilization review decision letter dated XXXX, the requested service was denied by XXXX with the following rationale: "The guidelines do not recommended therapeutic sacroiliac joint injections for non-inflammatory sacroiliac pathology, based on insufficient evidence. There is no documentation of the claimant having inflammatory sacroiliitis as required by the guidelines. Also, after the prior injections, there is no objective documentation of a decreased need for pain medication, to support the reported improvement. The request for a left sacroiliac joint injection under fluoroscopy with monitored sedation is not certified."

Per a utilization review decision letter dated XXXX, the prior decision was upheld by XXXX. XXXX documented the rationale as follows. "The Official Disability Guidelines specify treatment therapeutic sacroiliac injections are recommended on a case-by-case basis as injections for inflammatory spondyloarthropathy. The patient reported that the prior sacroiliac joint injection provided an 85% reduction in pain and requested a repeat injection. A prior determination was found not medically necessary due to lack of documentation regarding physical examination evidence of inflammatory sacroiliitis and no documentation of the decreased need for pain medication to support reported improvement from the prior injection. There remained a lack of physical examination evidence of pain related to sacroiliac joint pathology as recommended by the evidence-based guidelines. The guidelines recommended documentation of at least three positive examination findings to suggest the diagnosis. Additionally, there remained a lack of documentation regarding objective functional improvement and a decreased need for pain medication following the prior injection to support a repeat injection. Based on the information provided for the review, the request is not medically necessary".

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

Both utilization reviews conducted on XXXX provided a through and accurate analysis of the facts in this case. There was one exception, in that the provider did report positive Faber's, Gaenslen's and local tenderness tests which suggest sacroiliac dysfunction. The ODG in 2015 significantly changed its rules with respect to sacroiliac injections in that the pathophysiology of the sacroiliac dysfunction needs to clearly be stated. The evidentiary basis for approval of sacroiliac injections is now the presence of an inflammatory or rheumatic mechanism. This is based on extensive research analysis.

In addition, there is no rationale to go outside the guidelines in this case since there are no exceptional factors. I agree with the prior adverse determinations. 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
Integrated Treatment/Disability Duration Guidelines Low Back - Lumbar and Thoracic (Acute and Chronic) (updated 05/04/18)

Integrated Treatment/Disability Duration Guidelines - Hip and Pelvis (Acute and Chronic) (updated 05/15/18)

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. See 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 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) (Vanelderen, 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 Bertholet 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)

<u>Sacroiliac injections, therapeutic</u>

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 as 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.

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 spondyloarthropathy 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 spondyloarthropathy 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 Luukainen 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 spondyloarthropathy (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 spondyloarthropathy. (Hanly, 2000)

Maugars, 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. (Maugars, 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)

- ☐ 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.