Core 400 LLC

An Independent Review Organization
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Review Outcome

Description of the service or services in dispute:

Bilateral facet injection therapy at L4-L5 and L5-S1 under fluoroscopy with intravenous sedation.
Due to anxiety and ASA III status, will need anesthesia.

64493 – Bilateral injection (s), first level one unit, diagnostic or therapeutic agent, paravertebral agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral
64494 – Bilateral injection (s), second level one unit, diagnostic or therapeutic agent, paravertebral agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral
77003 – Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid)

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

Board Certified Anesthesiology

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

- ☐ Upheld (Agree)
- ☑ Overturned (Disagree)
- ☐ Partially Overturned (Agree in part / Disagree in part)

Patient Clinical History (Summary)

XX is a XX who was diagnosed with intervertebral disc displacement of the lumbar region. On XX, the patient XX onto the XX at work resulting in injury to the lower back.

A CT of the lumbar spine on XX (for left hip and low back pain) revealed no evidence of acute osseous abnormality. There were multilevel degenerative changes at the L3-L4 and L4-L5 levels where the combined effects of the discogenic disease, ligamentum flavum thickening, and facet arthropathy produced moderate circumferential central canal narrowing. Partial sacralization of L5 with transitional lumbosacral anatomy was noted. An MRI of the lumbar spine done XX demonstrated left intraforaminal disc protrusion / herniation at L1-L2, which nearly impinged the exiting left L1 nerve root; mild L2-L3 narrowing and desiccation without bulging or herniation; subligamentous protrusion / herniation at L3-L4 compressing the anterior thecal sac without creating stenosis or impingement of the neural elements; benign interosseous hemangiomata noted within the L3 vertebral body; transverse stenosis of the spinal canal and stenosis of the neural foramina at L4-L5 created by spondylotic annular bulging, superimposed subligamentous disc herniation and moderate facet joint hypertrophy compressing the thecal sac and intrathecal nerve roots; impingement of the exiting right L4 nerve root; a benign intraosseous hemangioma of the L4 vertebral body. There was transitional partially sacralized L5-S1 segment noted. The annulus was narrowed and desiccated with posterior annular protrusion / osteophytic complex and facet joint hypertrophy impinging the descending S1 nerve roots. Stenosis of the spinal canal was noted without impingement of the thecal sac.

On XX, XX DO performed lumbar epidural XX /local anesthetic block under fluoroscopy, and administered an injection of contrast for performance of epidurogram and an injection of XX with local anesthetic solution. The postoperative diagnoses were lumbar strain /

sprain syndrome and herniated discs at L4-L5 and L5-S1 with bilateral lumbar radiculopathy following work injury. Per office visit of XX, the patient had near complete resolution of XX leg pain below the level of the knee following a single epidural block. The remainder of the pain was across XX axial back. On examination XX had facet tenderness at L4-L5 and L5-S1. Dr. XX believed the physical findings were consistent with lumbar facet syndrome. On XX, XX visited Dr. XX for having pain. XX continued with severe axial back, buttock, and lateral thigh pain. The associated symptoms included tenderness over L4-L5 and L5-S1. The pain was aggravated with side bending and extension. Dr. XX suggested intra-articular facet injection therapy. However, XX stated the peer-reviewed doctor did not appreciate that XX had severe systemic disease of American Society of Anesthesiologists (ASA) III type in the prone position with multiple needle injections to get appropriate sedation for the painful procedure. That treatment included appropriate sedation and anesthesia. XX was fearful of needles. XX would have extreme anxiety and would not undergo the procedure if XX did not receive the appropriate sedation. As a result of the wrongful denial of the care, they were having to resubmit XX consideration for the procedure. Any further delay in the treatment denial of rightful and reasonable necessary care would only lead to more costly pain complaint with increased pain and suffering. Dr.XX stated XX would hold the reviewer who denied XX care responsible for the decision-making and hold them to the convention of care as practiced in the state of XX

XX, DO completed a utilization review on documenting that the request for bilateral facet injection therapy at L4-L5 and L5-S1 under fluoroscopy with intravenous sedation was not certified. Rationale: “Facet joint intra-articular injections (therapeutic blocks) under study. Current evidence supporting this procedure is conflicting and at this time, no more than one therapeutic intra-articular block is suggested. If this treatment is successful (pain relief of at least 50 percent for a duration of at least XX), the recommendation is to proceed to a medial branch diagnostic block and subsequent neurotomy (if the medial branch block is positive). If therapeutic facet joint block is undertaken, it is suggested that it be used in concert with other evidence-based conservative care (activity, exercise, etc.) to facilitate functional improvement. Review of the submitted information indicates this XX was injured on XX. According to the follow-up note dated XX the patient was pleased to report near complete resolution of the leg pain, complaints below the level of the knee following single lumbar epidural block. The patient was diagnosed with other intervertebral disc displacement, lumbar region, low back pain, radiculopathy, lumbar region. The patient has facet findings on examination and MRI (magnetic resonance imaging) but the injection is denied as sedation is not supported with this according to the ODG evidence-based guidelines nor does the patient have significant anxiety per GAD-7 (generalized anxiety disorder) score of 5/21. There was no MD contact to modify so the request is denied. Based on the clinical information submitted for this review and using the evidence-based, peer-reviewed guidelines referenced above, the requested bilateral facet injection therapy at L4-L5 and L5-S1 under fluoroscopy with IV sedation is not medically necessary and is non-certified.”

Per a utilization review by XX, MD on XX, the appeal for bilateral facet injection therapy at L4-L5 and L5-S1 under fluoroscopy with intravenous sedation request on XX was denied as the proposed treatment plan was not consistent with the clinical review criteria. Rationale: “There was a previous adverse determination dated XX whereby the request for the appeal bilateral facet injection therapy at the L4-L5 and L5-S1 under fluoroscopy with intravenous sedation was non-certified. The reviewer noted that the patient had facet findings on examination and MRI (magnetic resonance imaging) but the injection was denied as sedation was not supported according to the ODG evidence-based guidelines nor did the patient have significant anxiety per GAD-7 (generalized anxiety disorder) score of 5/21. There was no medical doctor contact to modify, so the request was denied. Based on the clinical in1ormation submitted for the review and using the ev1dence-hased, peer-reviewed guidelines referenced above, the requested bilateral facet injection therapy at the L4-L5 and L5-S1 under fluoroscopy with intravenous sedation was not medically necessary and was non-certified.”

Treatment to date included medications (XX, XX, XX, and XX), physical therapy, and lumbar epidural injection on XX (with near complete resolution of the leg complaints below the level of the knee; the remainder of XX pain was across XX axial back pain).

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

Two prior reviews on this patient identified the facet joint as the pain generator in this patient, but both reviewers had issues with the sedation requested in this patient. They cited the GAD-7 as 5/21 which is evidence of low anxiety.

The issue of sedation can be quite convoluted w.r.t facet joint procedures, because diagnostic procedures generally should not include XX as part of the sedative, since this might interfere with the response. However, for non-diagnostic procedures, the sedative standard is less restrictive.

Needle phobia or anxiety is a particular syndrome that patients manifest when confronted with a needle. So, it is a situational or focused anxiety. It has nothing to do with generalized anxiety disorder. So, this reviewer's opinion is that the patient is eligible to receive the procedure with sedation, because the provider has documented the presence of needle anxiety clearly in the patient's notes.

The requested services are 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

ODG Treatment Integrated Treatment/Disability Duration Guidelines; Low Back (updated XX)

Facet joint intra-articular injections (therapeutic blocks)

Under study. Current evidence supporting this procedure is conflicting, and at this time, no more than one therapeutic intra-articular block is suggested. If this treatment is successful (pain relief of at least 50% for a duration of at least 6 weeks), the recommendation is to proceed to a medial branch diagnostic block and subsequent neurotomy (if the medial branch block is positive). If a therapeutic facet joint block is undertaken, it is suggested that it be used in concert with other evidence-based conservative care (activity, exercise, etc.) to facilitate functional improvement. (Dreyfuss, 2003) (Colorado, 2001) (Manchikanti, 2003) (Boswell, 2005)

See Facet joint diagnostic blocks (injections); Facet joint pain, signs and symptoms; Facet joint radiofrequency neurotomy; Facet joint medial branch blocks (therapeutic injections); and Segmental rigidity (diagnosis). See also the Neck Chapter and Pain Chapter.

Criteria for use of therapeutic intra-articular and medial branch blocks, are as follows:

1. No more than one therapeutic intra-articular block is recommended.
2. There should be no evidence of radicular pain, spinal stenosis, or previous fusion.

3. If successful (initial pain relief of 70%, plus pain relief of at least 50% for a duration of at least 6 weeks), the recommendation is to proceed to a medial branch diagnostic block and subsequent neurotomy (if the medial branch block is positive).

4. No more than 2 joint levels may be blocked at any one time.

5. There should be evidence of a formal plan of additional evidence-based activity and exercise in addition to facet joint injection therapy.

In spite of the overwhelming lack of evidence for the long-term effectiveness of intra-articular steroid facet joint injections, they remain a popular treatment modality. Intra-articular facet joint injections have been popularly utilized as a therapeutic procedure, but are not currently recommended as a treatment modality in most evidence-based reviews, as their benefit remains controversial. The therapeutic facet joint injections described here are injections of a steroid (combined with an anesthetic agent) into the facet joint under fluoroscopic guidance to provide temporary pain relief. (Dreyfuss, 2003) (Nelemans, 2000) (Carette, 1991) (Nelemans, 2001) (Slipman, 2003) (van Tulder, 2006) (Colorado, 2001) (ICSI, 2004) (Bogduk, 2005) (Resnick, 2005) (Airaksinen, 2006) An updated Cochrane review of injection therapies (ESIs, facets, trigger points) for low back pain concluded that there is no strong evidence for or against the use of any type of injection therapy, but it cannot be ruled out that specific subgroups of patients may respond to a specific type of injection therapy. (Staal, 2009)

Systematic reviews endorsing therapeutic intra-articular facet blocks:

Pain Physician, 2005: In 2005, there were two positive systematic reviews published in Pain Physician that stated that the evidence was moderate for short-term and limited for long-term improvement using this intervention. (Boswell, 2005) (Boswell, 2005) These results were based, in part, on five observational studies. These non-controlled studies were confounded by variables such as lack of confirmation of diagnosis by dual blocks and recording of subjective pain relief, or with measures that fell under verbal rating and/or pain relief labels (measures that have been reported to have problems with validity). (Edwards, 2005)

Pain Physician, 2007: Pain Physician again published a systematic review on this subject in 2007 and added one additional randomized trial comparing intra-articular injections with sodium hyaluronate to blocks with triamcinolone acetonide. The diagnosis of facet osteoarthritis was made radiographically. (Fuchs, 2005) Two randomized trials were not included, in part because they failed to include controlled diagnostic blocks. These latter articles were negative toward the use of therapeutic facet blocks. (Lilius, 1989) (Marks, 1992) An observational non-controlled study with positive results was included that made the diagnosis of lumbar facet syndrome based on clinical assessment of “pseudoradicular” lumbar pain, including evidence of an increase of pain in the morning and with excessive stress and exercise (no diagnostic blocks were performed). (Schulte, 2006) With the inclusion of these two articles, the conclusion was changed so that the evidence for lumbar intra-articular injections was “moderate” for both short-and long-term improvement of low back pain. (Boswell2, 2007)

Complications: These included suppression of the hypothalamic-pituitary-adrenal axis for up to 4 weeks due to steroids with resultant elevated glucose levels for less than a week. (Ward, 2002) There have been rare cases of infection (septic arthritis, epidural abscess and meningitis). (Cohen, 2007) Complications from needle placement include dural puncture, spinal cord trauma, intra-arterial and intravenous injection, spinal anesthesia, neural trauma, pneumothorax, and hematoma formation. (Boswell2, 2007)

Single photon emission computed tomography: (bone scintigraphy, SPECT scan): Not recommended, although recent research is promising. This technique is recommended based on the ability of radionuclide bone scintigraphy to detect areas of increased function, depicting synovial areas of inflammation as well as degenerative changes. Thirteen of 15

patients had a > 1 standard deviation pain score improvement at 1 month versus 7 of 32 patients with a negative or no scan. The benefit of the injection lasted for approximately 3 months and did not persist to 6 months. (Pneumaticos2, 2006)

☐ 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)

The GAD-7 questionnaire; Nerys Williams

Occupational Medicine, Volume 64, Issue 3, 1 April 2014, Pages 224, https://doi.org/10.1093/occmed/kqt161

☐ 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.