

Core 400 LLC

An Independent Review Organization
2407 S. Congress Avenue, Suite E #308
Austin, TX 78704
Phone: (512) 772-2865
Fax: (512) 551-0630
Email: manager@core400.com

09/14/18

Description of the service or services in dispute:

XX

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:

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

Patient Clinical History (Summary)

XXXX who was diagnosed with sprain of ligaments of the XX XX (XX.XX). XXXX sustained an injury on XXXX when XXXX. XXXX and felt pain in the XX and XX shoulder.

Per an office visit dated XXXX evaluated XXXX for chronic persistent XX XX, shoulder, and XX pain all following a work-related injury of XXXX. Examination revealed increased XX XX XX and XX XX throughout the XX XX XX regions. The trigger points in the XX region on the XX with XX signs elicited from XX-XX down to XX-XX with reproduction of XXXX XX XX pain. Palpation of the XX XX revealed exquisite tenderness over the XX joint. XXXX had mild tenderness with internal and external rotation. XXXX definitely had positive drop arm test with weakness due to rotator cuff partial tear. Trigger points in the XX XX region were noted.

The treatment to date included medications and physical therapy.

An MRI of the XX XX dated XXXX showed XX% thickness partial tearing of the XX and XX tendons. XX joint XX and XX / XX XX were noted. There was mild XX joint capsule XX appreciated, which could act as a source for rotator cuff XX.

An MRI of the XX XX was completed on XXXX revealing a XX XX XX XX XX / XX at XX-XX. At the XX-XX level, there was a broad XX.XX XX XX XX / XX with mild XX XX XX and mild XX XX XX XX.

Per a peer review dated XXXX, and a utilization review determination letter dated XXXX, the request for a XX XX blockade at XX-XX interspace utilizing a XX approach under XX with intravenous (IV) sedation was non-certified. Rationale: "ODG XX and XX XX (updated XX/XX/XX) - Online Version, Epidural steroid injection (ESI). Not recommended based on recent evidence, given the serious risks of this procedure in the XX region and the lack of quality evidence for sustained benefit. Excessive sedation should be avoided. The injured worker is a XXXX individual who sustained an injury on XXXX. The injured worker was diagnosed with a XX of XX of the XX XX (initial encounter) and pain in the XX XX. The XX magnetic resonance imaging (MRI) reveals only mild pathology that is insufficient to justify an exception to the guidelines. Furthermore, a plan for monitored anesthesia care is noted but monitored anesthesia care is seldom if ever required for this procedure and there is no specific indication for its use is noted. Per ODG guidelines, this procedure is "Not recommended based on recent evidence, given the serious risks of this procedure in the cervical region and the lack of quality evidence for sustained benefit." Therefore, the request is not medically necessary."

Per a note dated XXXX documented XXXX continued with moderate-to-severe XX pain radiating to the XX XX, XX XX area associated with a "continued" what felt like a "crick" in XXXX neck, pain which was sharp and shooting in sensation. XXXX had pain with flexion. XX maneuvers were moderately provoking. XXXX documented that the peer doctor who reviewed the case passed judgments contrary to standard prudent medical decision making. XXXX had failed conservative rehabilitative medical treatment options. XXXX continued with moderate-to-severe XX pain requiring XX support medicine XXXX in conjunction with nonsteroidal anti-inflammatory drugs (NSAIDs), which was known to have side effects and complications as well as a XX XX at night. XXXX was trying to hold off on XX XX. XXXX had recommended injection therapies, specifically XX epidural blockade utilizing a soft XX-XX to treat XXXX disorder. Unfortunately, the peer physician had denied it. XXXX did not agree with the peer reviewer's opinion and noted XXXX continued to have weakness in XXXX XX shoulder and shooting pains preventing XXXX from good sound sleep at night. Per an addendum, XXXX documented that XXXX Center for Epidemiologic Studies Depression Scale (CESD) showing mild increasing anxiety due

to the denial was XX/XX, and XXXX anxiety levels were XX/XX on XXXX XX-XX test. On XXXX filled a form for reconsideration of the adverse determination.

Per a peer review dated XXXX utilization review determination letter and the original non-certification determination was upheld. Rationale: "There was an adverse determination on XXXX whereby the request for a XX epidural blockade at the XX-XX interspace utilizing a XX approach under XX with sedation is not certified. ODG XX and XX XX (updated XX/XX/XX) - Online Version Epidural steroid injection (ESI) Not recommended based on recent evidence, given the serious risks of this procedure in the XX region and the lack of quality evidence for sustained benefit. ODG does not address the request for the XX approach. Peer-reviewed literature referenced. <https://www.ncbi.nlm.nih.gov/pubmed/10834791> XX XX epidural catheter placement for continuous XX XX XX and sympathetic block. XX XX Pain Med. XX May-Jun, XX(XX-XX). XX XX, XX JC. Conclusions: This case report shows results typical of this series of 30 patients. In this series, the XX XX XX epidural XX was an effective technique to produce continuous XX XX and sympathetic block. Key Words: Analgesia (epidural), Autonomic nerve block, Reflex sympathetic dystrophy, Postoperative pain. The injured worker is a XXXX individual who sustained an injury on XXXX. The injured worker was diagnosed with a sprain of ligaments of the XX XX, initial encounter and pain in the XX XX. The (Magnetic resonance imaging) MRI showed a XX at XX/XX. The exam of XXXX XX/XX (which is the only one) is devoid of XX findings although the MD writes that the injured worker sometimes has numbness in the XX XX XX. The injured worker has "XX XX" with a XX of XX/XX. The injured worker has no noted past medical or XX history. The injured worker is not a candidate for the ESI in general as there is no clinical evidence of XX. The injured worker is not a candidate for sedation as sedation is not supported with this injection nor does the injured worker have any XX medical or XX issues to support that. Therefore, the request is not medically necessary."

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

This patient is under consideration for a XX epidural steroid injection. The request has undergone two utilization reviews which would not support the request citing deficiencies relative to the Official Disability Guidelines. When the patient first seen by the provider, the evaluation heavily emphasized a XX XX problem with a XX XX pain problem. Trigger points were in the therapeutic plan. An MRI then found some XX XX which then changed the therapeutic plan to a XX epidural steroid injection. The patient's most recent medical notes do not clearly delineate the diagnosis of XX XX. There are some descriptions of shoulder pain and some sensory loss in the XX, but the diagnostic criteria of XX pain, sensory loss, and motor weakness, which by definition is the

requirement under the ODG, are just XX in this patient's case report. The technique employed by the provider, that is, placing the XX in the XX XX at XX and then threading the XX up to desired level is an accepted technique. Many patients are extremely fearful of this approach, particularly the thought of having needles placed in their XX XX. Sedation is needed during the procedure simply for them not to move when the needle enters the XX. The presence of XX prior to procedure does not have any relevance to the occurrence of XX during the procedure. In summary, the provider's technical approach and request for sedation are acceptable. But, the provider needs to make a better case for a XX in this patient. The diagnosis needs to be clearly stated as well as the confirmatory symptoms to support medical necessity.

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

XX and XX XX Chapter: Epidural steroid injection (ESI)

Not recommended based on recent evidence, given the serious risks of this procedure in the XX region and the lack of quality evidence for sustained benefit. This treatment had been recommended as an option for treatment of XX pain (defined as pain in XX XX with corroborative findings of XX), with specific criteria for use below.

See Autologous blood-derived products. See also the XX XX Chapter, where ESIs are recommended as a possible option for short-term treatment of radicular pain in conjunction with active rehab efforts, but they are not recommended for spinal stenosis or for nonspecific low back pain.

While not recommended, XX ESIs may be supported using Appendix D, Documenting Exceptions to the Guidelines, in which case:

Criteria for the use of Epidural steroid injections, therapeutic:

Note: The purpose of ESI is to reduce pain and inflammation, thereby facilitating progress in more active treatment programs, and avoiding surgery, but this treatment alone offers no significant long-term functional benefit.

(1) XX must be documented by physical examination and corroborated by imaging studies and/or electrodiagnostic testing.

(2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants).

(3) Injections should be performed using fluoroscopy (live X-ray) for guidance

(4) No more than two nerve root levels should be injected using transforaminal blocks.

(5) No more than one interlaminar level should be injected at one session.

(6) In the therapeutic phase, repeat blocks should only be offered if there is at least 50% pain relief for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year.

(7) Repeat injections should be based on continued objective documented pain and function response.

(8) Current research does not support a "series-of-three" injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections.

(9) It is currently not recommended to perform epidural blocks on the same day of treatment as facet blocks or stellate ganglion blocks or sympathetic blocks or trigger point injections as this may lead to improper diagnosis or unnecessary treatment.

(10) XX and XX epidural steroid injection should not be performed on the same day;

(11) Additional criteria based on evidence of risk:

(i) ESIs are not recommended higher than the XX-XX level;

(ii) XX XX ESI is not recommended;

(iii) Particulate steroids should not be used. (Benzon, 2015)

(12) Excessive sedation should be avoided.

Criteria for the use of Epidural steroid injections, diagnostic:

If used for diagnostic purposes, a maximum of two injections should be performed. A second block is not recommended if there is inadequate response to the first block. Diagnostic blocks should be at an interval of at least one to two weeks between injections.

To determine the level of radicular pain, in cases where diagnostic imaging is ambiguous, including the examples below:

(1) To help to evaluate a pain generator when physical signs and symptoms differ from that found on imaging studies;

(2) To help to determine pain generators when there is evidence of multi-level nerve root compression;

(3) To help to determine pain generators when clinical findings are suggestive of radiculopathy (e.g., dermatomal distribution), and imaging studies have suggestive cause for symptoms but are inconclusive;

(4) To help to identify the origin of pain in patients who have had previous spinal surgery.

In a previous Cochrane review, there was only one study that reported improvement in pain and function at four weeks and at one year in individuals with radiating chronic neck pain. (Peloso-Cochrane, 2006) (Peloso, 2005) Other reviews have reported moderate short-term and long-term evidence of success in managing cervical radiculopathy with interlaminar ESIs. (Stav, 1993) (Castagnera, 1994) Some have also reported moderate evidence of management of XX nerve root pain using a transforaminal approach. (Bush, 1996) (Cyteval, 2004) A previous retrospective review of interlaminar XX ESIs found that approximately two-thirds of patients with symptomatic XX XX from disc herniation were able to avoid surgery for up to 1 year with treatment. Success rate was improved with earlier injection (< 100 days from diagnosis). (Lin, 2006) There have been case reports of XX XX and XX XX as well as XX XX XX after XX XX XX. (Beckman, 2006) (Ludwig, 2005) Quadriplegia with a XX ESI at XX-XX has also been noted (Bose, 2005) and the American Society of Anesthesiologists Closed Claims Project database revealed 9 deaths or cases of brain injury after XX ESI (1970-1999). (Fitzgibbon, 2004) These reports were in contrast to a retrospective review of 1,036 injections that showed that there were no catastrophic complications with the procedure. (Ma, 2005) The American Academy of Neurology concluded that epidural steroid injections may lead to an improvement in XX XX pain between 2 and 6 weeks following the injection, but they do not affect impairment of function or the need for surgery and do not provide long-term pain relief beyond 3 months, and there is insufficient evidence to make any recommendation for the use of epidural steroid injections to treat XX XX pain. (Armon, 2007) In other studies, there was evidence for short-term symptomatic improvement of radicular symptoms with epidural or selective root injections with corticosteroids, but these treatments did not appear to decrease the rate of open surgery. (Haldeman, 2008) (Benyamin, 2009) Some experts have

said epidural steroid injections should be reserved for those who may otherwise undergo open surgery for nerve root compromise. (Bigos, 1999) There is limited evidence of the effectiveness of epidural injection of methyl prednisolone and lidocaine for chronic MND with radicular findings. (Peloso-Cochrane, 2006) The FDA has warned that injection of corticosteroids into the epidural space of the XX may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death. (FDA, 2014)

Sedation: The use of sedation during ESI remains controversial. Excessive sedation should be avoided because it prevents the patient from reporting pain and from participating in neurologic evaluation after receiving a test dose of local anesthetic. However, some experts have promoted the use of mild sedation to prevent complications due to sudden movements (Malhotra, 2009) A multidisciplinary collaboration led by the FDA recommended that sedation for ESI remain light enough to allow the patient to communicate during the procedure. (Rathmell, 2015) For a more extensive discussion, see the Pain Chapter. See also the Low Back Chapter.

Recent evidence: ESIs should not be recommended in the XX region, the FDA's Anesthetic and Analgesic Drug Products Advisory Committee concluded. Injecting a particulate steroid in the XX region, especially using the XX approach, increases the risk for sometimes serious and irreversible neurological adverse events, including stroke, paraplegia, spinal cord infarction, and even death. The FDA has never approved an injectable corticosteroid product administered via epidural injection, so this use, although common, is considered off-label. Injections into the XX region, as opposed to the lumbar area, are relatively risky due to the XX XXX space, and the risk for accidental injury in the XX system is greater in this location. (FDA, 2015) An AMA review suggested that ESIs are not recommended higher than the XX-XX level; no XX XX ESI should be undertaken at any segmental level without preprocedural review; and particulate steroids should not be used in therapeutic XX transforaminal injections. (Benzon, 2015) According to the American Academy of Neurology (AAN), ESIs do not improve function, lessen need for surgery, or provide long-term pain relief, and the routine use of ESIs is not recommended. They further said that there is in particular a paucity of evidence for the use of ESIs to treat XX XX pain. (AAN, 2015) In this comparative-effectiveness study, no significant differences were found between ESI and conservative treatments. (Cohen, 2014)

- 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.