C-IRO Inc.

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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 XX of the XX XX, initial encounter (XX.XXXA). XXXX.

Per a follow-up visit note dated XXXX got excellent relief with a XX epidural block at the XX-XX XX. However, at the time, XXXX felt that XXXX pain was returning, and XXXX needed ongoing nonsteroidal anti-inflammatory drug (NSAID) support, and muscle relaxant and XX XX therapy. XXXX was also treated for the sympathetic effects of XX, XX syndrome, and XX pain. XXXX had decreased range of motion of the XX. XXXX pain was escalating back to XX-XX/10 with shooting sensations into both the XX and the XX, which XXXX stated abated with the first previous injection over XX weeks prior. XXXX recommended and supported the second block.

An MRI of the XX spine dated XXXX revealed XX XX XX at multiple levels, most notably at XX-XX, XX-XX, and XX-XX. Straightening of the normal XX was noted. A XX Drug Screen dated XXXX was XX for XX.

The treatment to date included medications (XXXX), physical therapy, and XX epidural steroid injection at XX-XX and XX-XX on XXXX (more than XX% improvement in XX pain).

Per a utilization review determination letter dated XXXX, the request for a XX epidural steroid injection under fluoroscopy with intravenous sedation at XX-XX was denied by XXXX with the

following rationale: The history and documentation do not objectively support the request for a XX-XX XX epidural steroid injection under fluoroscopy with intravenous (IV) sedation. The Official Disability Guidelines (ODG) state that ESIs are 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. 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, nonsteroidal anti-inflammatory drugs [NSAIDs], and muscle relaxants}. (3) Injections should be performed using fluoroscopy (live X-ray) for guidance. (4) No more than XX nerve root levels should be injected using XX blocks. (5) No more than XX XX level should be injected at one session.(6) In the therapeutic phase, repeat blocks should only be offered if there is at least XX percent pain relief for six to eight weeks, with a general recommendation of no more than XX 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 XX-XX-XX injections in either the diagnostic or therapeutic phase. We recommend no more than XX ESI injections. (9) It is currently not recommended to perform epidural blocks on the same day of treatment as XX XX or XX XX blocks or XX blocks or XX XX 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. In this case, there is no evidence of XX XX or any apparent exceptions to the above ODG recommendation. There are no physical findings demonstrating XX XX at level XX-XX in the records. The medical necessity of this request has not clearly been demonstrated. A clarification/modification was not obtained. Thus, the request for a XX-XX XX epidural steroid injection under fluoroscopy with intravenous (IV) sedation is not medically necessary."

Per a utilization review determination letter dated XXXX, the prior denial was upheld. The decision was reviewed by XXXX. Rationale: "The request is for a XX-XX XX epidural steroid injection under fluoroscopy with IV (intravenous) sedation. In this case, a prior review of the request for XX-XX XX epidural steroid injection was denied with the reviewer stating that the history and documentation did not support the request. An appeal dated XXXX from the clinician states that the procedure is 'consistent with the ODG (Official Disability Guidelines) guideline, apparently the doctors unfamiliar with cervical epidural blockade under the sympathomimetic or sympathetic treatment on the ODG.' First, the guideline the clinician references does not exist in ODG. Second, the medical records provided by the clinician provide no objective findings of radiculopathy. ODG guidelines for cervical ESI's clearly states '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.' There has been no objective evidence of XX documented on examination. Therefore, the appeal of a XX-XX XX epidural steroid injection under fluoroscopy with IV sedation is not medically necessary and the original denial is upheld."

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

Two reviews determined that a repeat XX ESI was not consistent with ODG guidelines. Their analysis was correct in that they sought standard clinical information that would substantiate the ESI. However, the request is not for a XX ESI XX XX. The request for a repeat XX ESI. The XX ESI in XXXX produced XX% pain relief together with functional improvement and decreased pain medication usage. The duration of effect was not clearly stated in the record but probably exceeded XX-XX weeks, because a clinical note in XXXX, some XX months later reported a partial return in pain. So, the criteria for a repeat XX ESI have been met, based on the ODG. The use of anesthesia for the procedure is therefore also indicated. However. I note that there is no requisite documentation of XX XX or XX.

The discussion in the record of CRPS, and the effects of XX ESI on sympathetic function, or XX XX XX are irrelevant to the current question. Given the documentation available, the requested service(s) is considered 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

XX and XX XX (updated 7/6/2018)

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 XX pain in conjunction with active rehab efforts, but they are not recommended for XX XX or for nonspecific XX XX 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 XX blocks.

(5) No more than one XX 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 "XX-XX-XX" 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 XX blocks or XX XX blocks or XX blocks or XX XX 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 XX 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 XX (e.g., XX XX), 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 XX surgery.

In a previous Cochrane review, there was only one study that reported improvement in pain and function at XX weeks and at XX XX in individuals with XX XX XX pain. (Peloso-Cochrane, 2006) (Peloso, 2005) Other reviews have reported moderate short-term and long-term evidence of success in managing XX XX with XX ESIs. (Stav, 1993) (Castagnera, 1994) Some have also reported moderate evidence of management of XX XX XX pain using a XX approach. (Bush, 1996) (Cyteval, 2004) A previous retrospective review of XX XX ESIs found that approximately two-thirds of patients with symptomatic XX XX from XX XX 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 injection. (Beckman, 2006) (Ludwig, 2005) XX 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 XX symptoms with epidural or XX XX injections with XX, 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 XX XX and XX for chronic XX with XX

findings. (Peloso-Cochrane, 2006) The FDA has warned that injection of XX 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, XX XX XX, and even death. The FDA has never approved an injectable XX product administered via epidural injection, so this use, although common, is considered off-label. Injections into the XX region, as opposed to the XX area, are relatively risky due to the XX epidural 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 XX 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.