C-IRO Inc.
An Independent Review Organization
1108 Lavaca, Suite 110-485
Austin, TX 78701
Phone: (512) 772-4390
Fax: (512) 387-2647
Email: resolutions.manager@ciro-site.com

Description of the service or services in dispute:
Epidural steroid injection at the C5-C6 level

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)
The patient is a XX-year-old XXXX who was diagnosed with injury, unspecified (T14.90).

XXXX had a XXXX accident on XXXX and had experienced right-sided neck and upper back pain. The initial diagnosis was sprain of ligaments of the cervical spine.

On XXXX, XXXX was diagnosed with status-post anterior cervical fusion at C3-C4 level, status-post new work-related accident on XXXX. A nerve conduction study was performed on XXXX, which showed no frank evidence for radiculopathy. During physical examination, there was tenderness to palpation somewhat on the facets, but lesser than before. The pain was radiating to the interscapular area, subscapular area, right posterior shoulder and the right upper extremity in the C5 distribution. Spurling's test was slightly positive on that side.

Treatment to date consisted of medial branch blocks (MBB) at C4-C5 and C5-C6 levels on XXXX, medial branch block (MBB) on XXXX with 90% improvement for one day then slowly pain returned at baseline. On XXXX, bilateral C4-C5 and C5-C6 radiofrequency ablation (RFA) was performed. An initial improvement of about 70% was reported but then returned to only 50% relief, followed by persistent pain in the right subscapular area, right upper extremity at C5 distribution.

An MRI cervical spine dated XXXX showed interval anterior cervical discectomy and fusion (ACDF) with improvement in facet joint osteoarthritis at that level and worsened facet joint osteoarthritis on the right at C4-C5, which was severe and resulted in marrow edema on either side of the joint.

Per a utilization review dated XXXX by XXXX, MD (Orthopedic Surgery), the request for epidural steroid injection was not certified. It was determined that there was no EMG study reported and the neurological examination did not confirm an objective radiculopathy. The Spurling's test was equivocal.

The ODG (Official Disability Guidelines) did not support the use of a cervical epidural steroid injection as a medical necessity.

Per a letter dated XXXX, by XXXX, (Pain Management/Anesthesiology) the request for cervical epidural steroid injection was denied. The determination was made on the basis of the clinical report dated XXXX, which indicated the presence of clinical radiculopathy, but the radiculopathy was not confirmed by the electrodiagnostic testing. As per the available medical records the claimant underwent medial branch block radiofrequency ablation under fluoroscopic guidance on XXXX. The documentation did not substantiate the claimant was actively engaged in conservative therapy following the medial branch block. As per the report, the claimant had 70% improvement after the medial branch block. The severity of the claimant's complaint was not documented on visual analog scale (VAS). Moreover, an MRI demonstrated mild annular bulge and mild bilateral neural foraminal stenosis at the C5-C6 level. But there was no evidence of nerve root compression at that level. Therefore, the requested C5-C6 epidural steroid injection (ESI) was not medically necessary.

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

In the review by XXXX dated XXXX; the review correctly identified that the neurological examination failed to confirm an objective radiculopathy. Spurling's test was equivocal. No EMG report was available. A prior MRI confirmed the presence of a prior cervical fusion.

In the review dated by XXXX dated XXXX; the review again noted an equivocal Spurling's test. No EMG report was available. An objective finding that supported a clinical radiculopathy was lacking. The MRI noted that there was no evidence of nerve root compression at C56.

First and foremost, cervical ESI is not recommended given the serious risks of this procedure in the cervical region and the lack of quality evidence for sustained benefit. **Radiculopathy must be documented by physical examination and corroborated by imaging studies and/or electrodiagnostic testing**.

"ESIs should not be recommended in the cervical region, the FDA's Anesthetic and Analgesic Drug Products Advisory Committee concluded." Injecting a particulate steroid in the cervical region, especially using the transforaminal 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.

No exceptions to the guidelines were provided as per Appendix D.

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 um knowledgebase

☐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

Neck and Upper Back (Acute and Chronic) (updated 10/12/17)

Epidural steroid injection (ESI)

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. This treatment had been recommended as an option for treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy), with specific criteria for use below.

While not recommended, cervical 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) Radiculopathy 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) Cervical and lumbar 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 C6-7 level;

(ii) Cervical transforaminal 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 cervical nerve root pain using a transforaminal approach. (Bush, 1996) (Cyteval, 2004) A previous retrospective review of interlaminar cervical ESIs found that approximately two-thirds of patients with symptomatic cervical radiculopathy 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 cerebellar infarct and brainstem herniation as well as spinal cord infarction after cervical transforaminal injection. (Beckman, 2006) (Ludwig, 2005) Quadriparesis with a cervical ESI at C6-7 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 cervical 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 radicular lumbosacral 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 radicular cervical 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 spine 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 cervical region, the FDA's Anesthetic and Analgesic Drug Products Advisory Committee concluded. Injecting a particulate steroid in the cervical region, especially using the transforaminal 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 cervical region, as opposed to the lumbar area, are relatively risky due to the narrower epidural space, and the risk for accidental injury in the arterial system is greater in this location. (FDA, 2015) An AMA review suggested that ESIs are not recommended higher than the C6-7 level; no cervical interlaminar ESI should be undertaken at any segmental level without preprocedural review; and particulate steroids should not be used in therapeutic cervical 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 radicular cervical pain. (AAN, 2015) In this comparative-effectiveness study, no significant differences were found between ESI and conservative treatments. (Cohen, 2014)

Appendix D

Documenting Exceptions to the Guidelines

The purpose of this section is to outline a process so patients can receive appropriate medical treatment even if it is not covered in ODG. As explained on the Copyright Page:

"These publications are guidelines, not inflexible proscriptions, and they should not be used as sole evidence for an absolute standard of care. Guidelines can assist clinicians in making decisions for specific conditions and also help payors make reimbursement determinations, but they cannot take into account the uniqueness of each patient's clinical circumstances." http://www.odg-twc.com/preface.htm#COPYRIGHTPAGE

ODG outlines a system for ranking the medical evidence, using an alphanumeric rating system from 1a to 11c. It is explained in the Chapter Explanation of Medical Literature Ratings located here: http://www.odg-twc.com/odgtwc/ExplanationofMedicalLiteratureRatings.htm. The highest quality evidence would be a Systematic Review/Meta-Analysis or a Randomized Controlled Trial (RCT), that have been accepted for publication in a peer reviewed journal included in Medline® by the National Library of Medicine. Users can search for these studies online at www.nlm.nih.gov. When other medical treatment guidelines are based on the high quality evidence, they can also be good sources to summarize the evidence and make concrete recommendations, so these other treatment guidelines can be valuable as well. The Agency for Healthcare Research and Quality (AHRQ) in the United States maintains a searchable database of clinical practice guidelines that have met their criteria, at www.guideline.gov. This would be a recommended source of medical treatment guidelines for conditions that are not covered in ODG.

There will be situations where injured workers will need medical care outside of the guidelines. There are a variety of ways that this can be achieved, including understandings, both formal and informal, where an insurance carrier and a provider have agreed, as a result of proven outcomes and adherence to evidence-based treatment guidelines from that provider that the insurance carrier will defer to the provider's recommendations for a particular course of medical care. This document is meant to address situations where such agreements do not exist. The following topics are covered in detail below.

I. Instructions for Providers
   - A. Situations not addressed in the guidelines
     1. Conditions not commonly seen in workers compensation
     2. Documenting functional improvement & patient co-morbidities
     3. Examples not addressed in the guidelines
   - B. Treatments that are covered but not recommended
     1. Patient co-morbidities
     2. Documenting functional improvement
     3. Examples not recommended in the guidelines

II. Instructions for Carriers
   - A. Limitations of guidelines
   - B. Peer to peer discussions recommended

- ☐ 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)