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Description of the service or services in dispute:

Transforaminal epidural steroid injection under fluoroscopy with monitored anesthesia by CRNA

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 is a XX-year-old XX who was diagnosed with cervical disc disorder with radiculopathy and spinal stenosis. The patient was injured on XXXX. He XXXX and injured his neck and thoracolumbar junction. The medical history was significant for hypertension, headache and diabetes.

XXXX was evaluated by XXXX, ANP-BC on XXXX for pain in the left neck and upper extremities. The pain began after a single episode of XXXX in XXXX. The neck pain was located in the left upper posterior neck, left mid-posterior neck, left lower posterior neck and left suprascapular region. The pain was described as burning and constant. The pain was worsened by cervical extension, twisting and wearing a hard hat. The pain was made better by changing positions. Left upper extremity numbness was noted in the posterior shoulder, upper arm posteriorly (triceps), elbow anteriorly (antecubital), ulnar forearm, hand and ring/little fingers. The pain was present constantly and was varying in intensity. The symptoms were worse with sitting. He also reported a headache and dizziness with vertigo. Per the note, XXXX was unable to do maneuver treatment due to neck pain. The upper extremity symptoms had gradually worsened since the onset. The associated symptoms were numbness, sleep alteration, tingling in the upper extremities, weakness in the ipsilateral upper extremity and occipito-temporal headache. XX reported pain as 4-5/10 in severity. The examination revealed that the patient was moderately overweight and in mild distress. He ambulated without assistance or assistive device. The cervical spine examination showed maximum tenderness at the left lower cervical para-vertebrates. XX did need some assistance with activity of daily living and quality of life was impacted. Motor and sensory reflexes were intact, absent at left C5 and pain with left rotation. Electromyogram/nerve conduction studies showed mild acute left C5 root consistency with radiculitis. Review of an MRI of the cervical spine showed multilevel pathologies, either central, lateral recess or foraminal stenosis, likely to cause radicular pathology. The assessment included cervical facet arthropathy at C3-C4 and C4-C5 bilaterally, moderate neuroforaminal stenosis at C5-C6 bilaterally and mild neuroforaminal stenosis at C4-C5 and C3-C4 bilaterally, cervical disc disorder with radiculopathy at left C5 and spinal stenosis. Cervical selective

nerve block/transforaminal epidural steroid injection at left C5 and epidurogram interpretation or fluoroscopy were ordered.

Treatment to date: Diclofenac without any improvement, non-steroidal anti-inflammatory drugs; trial of Gabapentin with no relief; activity modifications with minimal relief; physical therapy which made the pain worse; cervical transforaminal steroid injection on XXXX with 80% improvement in the first month and 30% improvement by the second month; cervical facet intra-articular injection on XXXX, which helped for three days with return of pain. XX had negative steroid response with no relief of pain after the local anesthesia effects had dissipated.

Significant diagnostic findings: The XXXX cervical MRI noted C2-C3 mild right foraminal stenosis; C3-C4 disc bulge, mild-moderate central canal stenosis, marked left foraminal and mild-moderate right foraminal stenosis, moderate left facet arthropathy; C4-C5 mild central canal stenosis, moderate-marked left foraminal and moderate right foraminal stenosis, marked left facet arthropathy, mild right facet arthropathy; C5-6 disc bulge effacing ventral thecal sac, marked central canal stenosis, mild cord impingement, mod foraminal stenosis, mild left facet arthropathy; C6-C7 disc bulge flattening ventral thecal sac, slightly impingement cord, marked central anal stenosis, marked left foraminal and moderate right foraminal stenosis, market left sided arthropathy; C7-T1 moderate left foraminal stenosis, marked left facet arthropathy; benign chronic compression fracture of C5, C6, C7 vertebral bodies. Overread of MRI found C5, C6, C7 chronic compression deformity, no bone marrow edema, multilevel facet arthrosis and degenerative disc disease (DDD); C5-C6 moderate diffuse post spondylosis with bilateral uncovertebral spurring, spur/disc complex abutting the cervical cord without compression, mild bilateral facet degeneration, moderate bilateral osseous foraminal narrowing with mild central stenosis; C6-C7 moderate diffuse spondylosis with bilateral uncovertebral spurring, spur/disc complex abutting the cord without compression, mild bilateral facet degeneration, moderate bilateral osseous foraminal stenosis with mild central stenosis; mild bilateral uncovertebral spurring C7-T1, no focal protrusion, severe left facet degeneration with no central stenosis, severe left foraminal stenosis, mild extent on the right.

Per a utilization review determination by XXXX, DO dated XXXX, the initial request for transforaminal epidural steroid injection under fluoroscopy with anesthesia was denied. It was determined that the epidural steroid injection was not recommended based on recent evidence, given the serious risks of the procedure in the cervical region and lack of quality evidence for sustained benefit. The treatment had been recommended as an option for treatment of radicular pain.

Per a utilization review determination by XXXX, DO dated XXXX, the reconsideration request was denied. It was documented that the patient complained of radiating pain, which was rated as 4-5/10. The pain rating did not seem to be severe. Moreover, documentation substantiates EMG/NCV study demonstrated mild acute left C5 root consistent with radiculitis. However, the electrodiagnostic study report was not provided for review. The date of study was not specified, Furthermore, on recent examination the Spurling's test was negative. In addition to this, documentation did not substantiate the patient was provided with any form of active conservative therapy in order to resolve the underlying symptoms. The only approach seemed to be medication and one facet joint block. Documentation also substantiated depression noted on review of systems. This was likely contributing to the claimant's

complaints of pain. Therefore, the request for transforaminal ESI with fluoroscopy with monitored anesthesia by CRNA was not medically necessary or appropriate at this time.

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

This is a particularly complex case which revealed multilevel cervical disc disease with a clinical picture somewhat atypical for a classic radiculopathy. In the review by Dr. XXXX dated, XXXX, the reviewer cited the recent ODG guidelines regarding ESIs above C56. In the review by Dr. XXXX, dated XXXX, the reviewer was accurate in his analysis and review of the data. This provider therefore supports the prior adverse determinations for the following reasons:

- Clinical severity uncertain because there is a lack of objective pain quantification
- Pre-procedure conservative therapy ostensibly non-existent
- Spurling's test absent
- Prior facet injection and ESI in XXXX were not effective or documentation unclear
- Clinical status from XXXX – present unknown
- Recent EMG/NCV report not provided
- Therapeutic plan not stated
- Appendix D of ODG "Documenting Exceptions to the Guidelines" not applicable

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® 2018 - Official Disability Guidelines® (23rd annual edition) & ODG® Treatment in Workers' Comp (16th annual edition)
ODG Treatment Integrated Treatment/Disability Duration Guidelines
Neck and Upper Back (Acute and Chronic) (updated 10/12/17)
Epidural steroid injection (ESI)
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)

☐ 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)