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An Independent Review Organization
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Description of the service or services in dispute:

C3/C4 Cervical Epidural Steroid Injection

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

Board Certified Orthopedic Surgery

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 XXXX- who was diagnosed with cervical disc displacement of the mid-cervical region of the unspecified level and radiculopathy of the cervical region.

The patient was XXXX on XXXX, where XXXX was XXXX and XXX. XXXX was XXXX. The patient's head and torso were jerked forward and back in a whiplash mechanism. XXXX had a neck pain, rated at 7/10 intermittently, with numbness and tingling in the left hand. XXXX had a cervical epidural steroid injection on XXXX with 70% initial relief. Ibuprofen helped to relieve XXXX pain.

On XXX, the patient visited XXXX. The examination showed pain with percussion over L5 spinous process and bilateral paraspinal musculature tender to palpation. Left upper extremity dermatome sensation was decreased in C4 dermatome and diminished sensation in C5 dermatome. The cervical spine range of motion was grossly limited with pain. The flexion was 10 degrees, extension 15 degrees, bilateral rotation 10 degrees and bilateral lateral bending 10 degrees. There was pain with all ranges of motions. Cervical spine inspection showed C3-C4, C4-C5 and C5-C6 tender to palpation. There were palpable muscular spams noted. Cervical compression test was positive and Spurling's test was positive on the left side.

Treatment to date consisted of lumbar laminectomy on XXXX, right hip replacement in XXXX and left hip replacement in XXXX, cervical epidural steroid injection, medications and conservative therapy including physical and chiropractic therapy, massage therapy, intersegmental traction and activity modification.

An MRI of the cervical spine dated XXXX revealed cervical spinal canal from C2-C3 through C6-C7 showed moderate to severe canal narrowing due to combination of congenital spinal stenosis and degenerative changes. Spinal cord was impinged at C3-C4 and C5-C6 without cord edema. There was mild multilevel neural foraminal encroachment.
An EMG of the bilateral upper extremities dated XXXX showed findings consistent with mild acute bilateral C5 radiculopathies and median and ulnar neuropathies at the wrists.

Per a utilization review determination letter dated XXXX by XXXX, the request for cervical epidural steroid injection at C3-C4 level was denied. Rationale: "According to Official Disability Guidelines (ODG) regarding epidural steroid injections, the patient must have documented radiculopathy along with objective findings on examination and it must be corroborated by imaging studies. Furthermore, the patient must be unresponsive to conservative treatments. If the patient has had previous blocks, it should produce pain relief of at least 50-70% for at least six to eight weeks. Repeat injections should be based on continued objective documented pain relief, decreased need for pain medications, and functional response. Epidural steroid injections are not recommended higher than the C6-C7 level. In this case, the patient was diagnosed with herniated cervical disc (sizeable herniation at C3-C4 with cord contact) and cervical radiculopathy of the left C4. The request was for cervical epidural steroid injection at C3-C4. The patient had a prior epidural steroid injection and had 4 weeks of benefit and ODG requires 6-8 weeks of at least 50% benefit, which is not documented. Furthermore, epidural steroid injections are not recommended at levels higher than the C6-7 level and the request is for C3-C4. The request does not meet the guideline criteria and is therefore not medically necessary."

A letter dated XXX by XXXX, indicated that the reconsideration request for cervical epidural steroid injection at C3-C4 level was denied/non-certified. It was determined that that patient had underwent a previous epidural steroid injection at C6-C7 and had about 70% improvement in XXXX. Official Disability Guidelines (ODG) required six to eight weeks of at least 50% benefit, which was not documented. Also per the Official Disability Guidelines, epidural steroid injection were not recommended at levels higher than the C6-C7 level by ODG and the request was for C3-C4 level. As such, the request was not medically necessary and non-authorized.

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

Based on the clinical information provided, the request for cervical epidural steroid injection at C3-4 level is not recommended as medically necessary, and the prior denials are upheld. The Official Disability Guidelines note that cervical epidural steroid injections are 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. The Official Disability Guidelines specifically state that injections are not recommended above the C6-7 level. The submitted records fail to establish that the patient had adequate response to prior epidural steroid injection. Pre-injection pain level on XXXX was 3/10, and one month post-injection pain score on XXXX was 5/10.

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

Official Disability Guidelines Treatment Index, 22nd edition online, 2017-Neck and Upper Back Chapter 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.

See Autologous blood-derived products. See also the Low Back 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, 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)

☐ 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)