INDEPENDENT REVIEWERS OF TEXAS, INC.

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DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

epidural steroid injection of the XX XX XX-XX

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

MD, Board Certified Pain Medicine

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a XXXX whose date of injury is XXXX. The patient was XXXX. The patient sustained an injury to XXXX XX. Office visit note dated XXXX indicates that XX range of motion is XX XX, XX XX, XX XX XX XX and XX rotation XX degrees. Deep tendon reflexes are XX throughout. MRI of the XX spine dated XXXX revealed at XX-XX XX.XX mm XX XX XX XX causing XX mass effect and severe XX XX XX XX affecting XX nerve root. There is moderately severe XX XX XX. Letter dated XXXX indicates that since the date of injury the patient has been complaining of severe XX pain that XX to the XX arm, XX XX pain that radiates through the XX leg and XX XX pain with moderate XX. The patient reports XXXX pain is unrelieved with exercises, physical therapy, NSAIDs and muscle relaxants. Patient has been prescribed XXXX as well as XXXX. The patient was recommended for an epidural steroid injection at XX-XX and XX XX at XX-XX to reduce pain and

inflammation. Initial request for epidural steroid injection of the XX XX XX-XX was non-certified noting that per ODG XX and XX XX Chapter Epidural steroid injection, "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." In this case, there is no documentation of exceptional factors to support an epidural steroid injection outside of current evidence based guidelines that specifically indicate lack of support for this procedure. The denial was upheld on appeal noting that the patient's diagnosis does not support the need for an epidural steroid injection of the XX XX. Current evidence based practice does not recommend this treatment.

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 epidural steroid injection of the XX XX XX-XX is not recommended as medically necessary, and the previous denials are upheld. The Official Disability Guidelines note that XX epidural steroid injections 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. When treatment is outside the guidelines, exceptional factors should be noted. There are no exceptional factors of delayed recovery documented. There is no documentation of a XX or XX deficit in a XX or XX distribution. Therefore, medical necessity is not established in accordance with current evidence based guidelines.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

☐ **ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE**

☐ **AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES**

☐ **DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**

☐ **EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN**

☐ **INTERQUAL CRITERIA**

X MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

☐ **MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**

☐ **MILLIMAN CARE GUIDELINES**

X ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

☐ **PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**

☐ **TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & 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)**

Official Disability Guidelines Treatment Index, 23nd edition online, 2018-XX and XX XX Chapter updated 07/06/18

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 distribution 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 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% pain relief for XX to XX 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-of-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 blocks or XX XX 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 XX 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 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 infarct and XX herniation as well as XX XX infarction after XX XX injection. (Beckman, 2006) (Ludwig, 2005) Quadriparesis 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 selective root 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 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 XX XX 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 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 narrower 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)