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January 13, 2018

IRO CASE #: XXXX

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Transforaminal Lumbar Epidural Steroid Injection

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

Board Certified in Orthopedic Surgery for over 10 years

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 <u>each</u> of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:

Patient is a XXXX who has a history of low back/neck pain. XXXX is has myofascial pain syndrome, Postlaminectomy syndrome in the lumbar region, and lumbar radiculopathy. XXXX insurance company is denying XXXX coverage for a Transforaminal lumbar epidural steroid injection at right L3-L4 with fluoroscopy and intravenous sedation, as an outpatient procedure.

XXXX – CT Imaging Report- XXXX: Procedure: CT scan of the lumbar spine following myelography. Clinical History: Spinal stenosis, lumbar region; post-laminectomy syndrome, not elsewhere classified, low back pain with numbness and tingling in both lower extremities. Impression: 1) Mild findings of spondylosis at T12-L1, L1-L2, and L2-L3. These findings mildly narrow the central spinal canal at L2-L3. 2) Anterior bulging of the disc with anterior osteophyte formation at L3-L4. There is mild posterior bulging of the disc and there is asymmetrical broad based disc protrusion along the central and left posterolateral disc margin of moderate size. This produces a left anterior extradural defect on the thecal sac. It affects the origin of the left L4 root. Mild to moderate L3 foraminal stenosis is present on both sides with crowding of the exiting root sheath in the neural foramen on both sides. 3) Status post laminectomy, anterior fusion, and posterior fusion at L4 and L5. There is no significant acquired central spinal canal stenosis. The L4 foramen is slightly narrowed on both sides related to mild posterolateral

bony hypertrophy. 4) Mild degenerative joint disease involving the sacroiliac joint on both sides.

XXXX – Physician Notes- **XXXX**: HPI: XXXX states that the current episode of pain started **XXXX**. At this time the location of XXXX pain is primarily low back in the lumbar spine. The pt reports a VAS scoring today of 6. Pt is sleeping through the night. Pt is currently on additional medications which include anti-seizure med; Gabapentin, muscle relaxers; Soma 350 mg one tablet 3x daily; Ambien 12.5 mg once at bedtime; and Trazadone. XXXX comes in today as a referral from XXXX for eval and for consideration of treatment for low back pain and leg pain. The pt has a long history of problems with XXXX back dating back to a work injury, which occurred back in **XXXX**. XXXX had 3 surgeries for that and now has recurrent pain in the area above the previous surgery. XXXX saw XXXX and evaluated XXXX with a CT scan. XXXX found XXXX had narrowing at the L3-L4 level above the L4-S1 fusion from XXXX previous work-related injury. XXXX feels XXXX may need surgery at the L3-4 level, but would like for me to perform epidural steroid injections at L3 and L4 to see if we might give XXXX relief there. The pt is having severe pain in XXXX back and into XXXX legs with activities such as standing, walking, and bending. Assessment: 722.10 - M54.16 – Lumbar radiculopathy; 724.2 – M54.5 – Low back pain. Plan: I will schedule XXXX for a transforaminal lumbar epidural steroid injection bilateral L3, bilateral L4. This will be done with fluoroscopy and under IV sedation. The pt understands the plan, risks, benefits and gives consent.

XXXXX – Physician Notes- **XXXX**: **XXXX** is a XXXX. XXXX is here for a consult. XXXX presents with primary complaints of neck pain. The history is obtained from the pt. The history appears to be reliable. . XXXX was last seen on XXXX for eval of neck pain. XXXX describes XXXX pain today as burning, dull and tingling. The pt reports a VAS scoring today of 5. VAS scoring at last visit was 8. Verbal rating scale is reported as mild today. XXXX reports such that XXXX is now 50% better than before XXXX last visit. Pt is sleeping most of the night, waking 2-3 times during the night. Pt reports functional improvement in XXXX ADLs. Narcotic meds patient is taking include: Norco 10-325 1 tablet every 6 hours. Pt is currently on additional meds which include anti-seizure med – Neurontin 300mg tid, muscle relaxers – Soma 350mg one table 3x daily. Trazadone 150mg qhs, and Ambien 12.5mg qhs. . XXXX presents today for a f/u eval. XXXX suffers from chronic neck pain with radiation into the right arm secondary to cervical Postlaminectomy syndrome. XXXX has undergone previous cervical epidural injections without improvement and was previously implanted with a St. Jude spinal cord stimulator, which is turned off, as XXXX finds this treatment ineffective. This pain has remained stable and controlled with XXXX current meds. XXXX has tried and failed Cymbalta and Lyrica in the past. In XXXX I increased Neurontin from 300mg every 8 hrs to 60mg every 12 hrs, and XXXX denies any improvement with the increased dose. . XXXX also states the manufacturer of Soma changed with XXXX last refill at XXXX, and XXXX complains the new med makes XXXX feel drowsy and apathetic. XXXX would like to contact other pharmacies to determine which manufacturer is used regarding Soma, and if the older version is no longer available, XXXX would like to consider adjusting XXXX muscle relaxant. XXXX continues to maintain complete relief of the myofascial spasm near the right scapula and sharp, stabbing pain in the thoracic spine secondary to Airrosti. XXXX is ecstatic about the resolution of XXXX thoracic pain, as it was present for over XXXX and leading to much of XXXX discomfort. XXXX denies any new symptoms and requests refills on XXXX meds. Assessment: 722.83 – M96.1 – Postlaminectomy syndrome, lumbar region; 721.0 – M47.812 – Cervical spondylosis; 729.1 – M79.1 – Myofascial pain syndrome; V58.69 – Z79.891 – Patient visit for long term (current) drug use; other. Plan: I will obtain a random drug screen today per office protocol. Previous screens have been compliant. I reviewed XXXX meds. I will allow a one-month increase in Soma from 3 tablets a day to 4 tablets a day in order for XXXX to have enough meds while on vacation. Upon XXXX return, I will reduce the quantity and even consider exchanging the muscle relaxant should XXXX continue to experience side effects. XXXX will refill Norco today as prescribed. I will schedule a routine 3 month f/u appointment given the stability of XXXX pain.

XXXX – Physician Notes- **XXXX**: Pt is here for a consult and f/u visit. XXXX presents with primary complaints of neck pain. The history is obtained from the pt. The history appears to be reliable. XXXX was last seen XXXX for eval of neck pain. The pt reports a VAS scoring of 8 today. VAS scoring was 5 at last visit. XXXX reports worse than before XXXX last visit. Pt is sleeping most of the night, waking 2-3 times during the night. Pt reports functional improvement in ADLs. Narcotic meds pt is taking include: Norco 10-325 1 tablet every 6 hours. Pt is currently on additional meds which include antiseizure med – Neurontin 300mg qid, muscle relaxers – Soma 350mg one tablet 3x daily and Ambien 12.5mg qhs. . **XXXX** returns to clinic today for a f/u eval. XXXX states XXXX has had increase in pain over the last several months. XXXX pain is described as being constant and is rated an 8/10. XXXX describes it as having shooting, dull, burning and numbness sensation throughout XXXX spine. XXXX pain is alleviated with rest and lying down. It is aggravated with any type of activity, especially driving. XXXX is currently pending authorization from worker's comp. for lumbar surgery with XXXX. XXXX states XXXX current pain regimen is not helping to decrease the amount of pain XXXX is in and XXXX would like to discuss changes. Assessment: 722.10 – M54.16 – Lumbar radiculopathy; 729.1 – M79.1 – Myofascial pain syndrome. Plan: Based on the fact that XXXX pain is increased, **XXXX** will prescribe Fentanyl patch 12.5mcg q. 72 hrs and I will refill Norco 10/325 1 po q 6 hrs. . XXXX will f/u at next scheduled appointment that is set already.

XXXXX – Physician Notes- **XXXX**. **XXXX** is here for a consult. This visit is covered under worker's comp. Pt is here for a f/u visit. XXXX presents with primary complaint of low back pain. The history is obtained from the pt. The history appears to be reliable. Pt was last seen on XXXXfor eval of low back pain. XXXX describes XXXX pain today as burning, dull, sharp, and tingling. XXXX VAS score today is 8. Last visit VAS score was 6. Verbal rating scale is reported as severe today. XXXX reports worse than before XXXX last visit. Pt is sleeping most of the night, waking 2-3 times during the night. Pt reports functional improvement in ADLs. Narcotic meds pt is taking include Norco 10-325 1 tablet every 6 hrs and Duragesic 12mcg/hr Patch every 72 hrs. Pt is currently on additional meds which include anti-seizure med- Neurontin 300mg QID, muscle relaxers – Soma 350 mg one tablet 3x daily, Ambien 12.5mg qhs, and Trazadone 50mg once at bedtime. XXXX was injured at work leading to lumbar surgery. XXXX is fused from L4-S1 and states the most recent surgery was performed in XXXX. There is discussion about additional surgery to address the L3-4 level, which XXXX CT from XXXX demonstrates a disc protrusion at L3-4 with a left anterior extradural defect on the thecal sac with moderate left neuroforaminal stenosis and similar findings on the right. XXXXX requested a lumbar transforaminal epidural injection in April, but this was denied by worker's comp carrier given there was no mention of an updated CT scan or EMG report. XXXX last EMG report from 2013 demonstrated a bilateral S1 radiculopathy. . XXXX finds the burning foot pain to be most pronounced, but XXXX also complains of pain in XXXX back with radiation into XXXX anterior thighs with associated numbness and tingling. XXXX would like to move forward with the epidural injection, but understands an updated EMG study is required first. XXXX denies any new symptoms. Assessment: 724.2 – M54.5 – Low back pain; 722.83 – M96.1 – Postlaminectomy syndrome, lumbar region; 722.10 - M54.16 - Lumbar radiculopathy. Plan: I reviewed **XXXX** meds. Will not make any adjustments at this time. I will refer XXXX to XXXX previous neurologist for an updated EMG report to evaluate if there is an L3/L4 radiculopathy present. I will see XXXX back in 1 month to review results of EMG report.

XXXX – Physician Notes- XXXX: . XXXX is here for a consult. This visit is covered under worker's comp. Pt is here for a f/u visit. XXXX presents with primary complaint of low back pain. The history is obtained from the pt. The history appears to be reliable. Pt was last seen on XXXX for eval of low back pain. XXXX describes XXXX pain today as burning, dull, and tingling. XXXX VAS score today is 8. Last visit VAS score was 8. Verbal rating scale is reported as severe today. XXXX reports worse than before XXXX last visit. Pt is sleeping most of the night, waking 2-3 times during the night. Pt reports

functional improvement in ADLs. Narcotic meds pt is taking include Norco 10-325 1 tablet every 6 hrs and Duragesic 12mcg/hr Patch every 72 hrs. Pt is currently on additional meds which include antiseizure med-Neurontin 300mg QID, muscle relaxers – Soma 350 mg one tablet 3x daily, Ambien 12.5mg qhs, and Trazadone 50mg once at bedtime. XXXX was injured at work leading to lumbar surgery. XXXX is fused from L4-S1 and states the most recent surgery was performed in XXXX. There is discussion about additional surgery to address the L3-4 level, which XXXX CT from XXXX demonstrates a disc protrusion at L3-4 with a left anterior extradural defect on the thecal sac with moderate left neuroforaminal stenosis and similar findings on the right. XXXXX requested a lumbar transforaminal epidural injection in XXXX, but this was denied by worker's comp carrier given there was no mention of an updated CT scan or EMG report. XXXX last EMG report from XXXX demonstrated a bilateral S1 radiculopathy. However, XXXX brings in a letter from worker's comp dated **XXXX** stating an updated EMG was not required based on the pt's physical exam and CT myelogram. **XXXX** finds the burning foot pain to be most pronounced, but XXXX also complains of pain in XXXX back with radiation into XXXX anterior thighs with associated numbness and tingling. XXXX feels XXXX pain has worsened and would like our office to request an epidural injection in hopes of improving XXXX symptoms. Assessment: 722.10 – M54.16 – Lumbar radiculopathy; 729.1 – M79.1 – Myofascial pain syndrome. Plan: I will schedule **XXXX** for a lumbar transforaminal epidural injection to bilateral L3 and L4. I recommend XXXX schedule a f/u appointment with **XXXXX** should worker's comp deny the repeat request for an epidural injection in order to move forward with surgery.

XXXX – URA Determination- XXXX: XXXX, as the delegated agent for the insurer, has reviewed the prescribed plan of treatment. Treatment requested: Transforaminal lumbar epidural steroid injection at right L3-L4 with fluoroscopy and intravenous sedation, as outpatient. Determination: Recommend prospective request for 1 transforaminal lumbar epidural steroid injection at right L3-L4 with fluoroscopy and intravenous sedation, as outpatient between XXXX and XXXX be non-certified. Rationale/Clinical Summary: This case involves a now XXXX with a history of an occupational claim from **XXXXX**. The mechanism of injury was not detailed the documentation provided for review. The CT of the lumbar spine from **XXXXX** demonstrated mild findings of spondylosis at T12-L1, L1-L2, and L2-L3. These findings mildly narrow the central spinal canal at the L2-L3. There was anterior bulging of the disc with anterior osteophyte formation at the L3-L4. There was mild posterior bulging of the disc and there was asymmetrical broad-based disc protrusion along the central left posterior-lateral disc margin of moderate size. This produces a left anterior extradural defect on the thecal sac. It affects origin of the L4 nerve root. There was mild to moderate L3 foraminal stenosis present on both sides with crowding of the exiting root sheath the neural foramen on both sides. The patient was status post laminectomy, anterior fusion and posterior fusion at L4-L5. There was no significant acquired central spinal canal stenosis. The L4 foramen was slightly narrowed on both sides related to mild posterior lateral hypertrophy. There was mild degenerative joint disease involving the cingulate joint on both sides. The progress note from **XXXX** indicates the patient was seen for a follow-up visit. The patient complained of low back pain. The pain was described as burning, dull and tingling. The pain was an 8/10. The patient complained of back pain with radiation into the anterior thighs with associated numbness and tingling. The patient feels pain was worsened and XXXX would like to request an epidural steroid injection. On examination, there was diminished sensation to touch to the bilateral anterior thighs and medial and lateral aspects of the bilateral lower legs along L3-L4 and L5 nerve distributions. There was a positive straight leg raise on the right at 40% with pain in the right anterior thigh along the L3 dermatome. There was a positive straight leg raise on the left at 40% with left anterior thigh pain along the L3 distribution. The patient had 5-/5 hip flexion, knee flexion and extension as well as dorsiflexion and plantar flexion. The patient had 4+/5 hip flexion on the right. The **XXXX** notes that epidural steroid injections are recommended if there is evidence of radiculopathy that is corroborated by imaging findings. There needs to be evidence the patient has completed conservative treatment. Excessive sedation should be avoided. The use of sedation during epidural steroid injections

remains controversial and is indicated for anxiety. The documentation provided for review indicates the patient had a positive straight leg raise bilaterally in the L3 distribution. The patient had decreased strength on hip flexion bilaterally. The patient had diminished sensation in the L3, L4 and L5 nerve distributions. However, the documentation then failed to demonstrate the patient had significant anxiety to warrant the requested sedation. As such, the request for transforaminal lumbar epidural steroid injection at Right L3-L4 with fluoroscopy and intravenous sedation is not medically necessary.

XXXX - Physician Letter- XXXX: To whom it may concern: I recently received notification from XXXX that the request for the epidural injection was denied based on the failure to document the patient's anxiety. The patient does have anxiety and fear of needles, which would necessitate the need for sedation to perform an epidural injection. I feel the patient meets the requirements for injection therapy given XXXX documented radiculopathy as seen on a previous EMG report that correlates with XXXX CT myelogram. The patient's physical exam demonstrates radiculopathy to the L3 and L4 dermatomes based on motor weakness, sensory loss and positive straight leg raise. Given XXXX failure to improve with conservative measures, I feel XXXX meets all requirements for injection therapy to include sedation given XXXX documented anxiety. If I can be of further assistance, please feel free to reach me.

XXXXX – URA Re-Determination- XXXX: XXXX, as the delegated agent for the insurer, has reviewed the prescribed plan of treatment. Treatment requested: Transforaminal lumbar epidural steroid injection at right L3-L4 with fluoroscopy and intravenous sedation, as outpatient. This is a re-review of review 556803. Determination: Recommend prospective request for 1 reconsideration for transforaminal lumbar epidural steroid injection at right L3-L4 with fluoroscopy and intravenous sedation, as outpatient between XXXX and XXXX be non-certified. Rationale: The date of injury is XXXX. The patient complains of low back pain. There was no mechanism of injury in the current records. The patient underwent L4/L5 lumbar fusion. On lumbar CT/myelogram, there was no disc herniation, high-grade foraminal stenosis or nerve root compression. There was no compression of any neurological structure in support of the diagnosis of radiculopathy. The patient complained of low back pain radiating to the anterior thighs with numbness and tingling. There was decreased sensation in L3. L4 and L5 liberally. Straight leg raise test was positive on the right side and left side into the L3 distributions. Strength was slightly decreased bilaterally in several myotomes. The requesting doctor states there was electrodiagnostic testing, but there is no electro-diagnostic testing report. Requested were transforaminal lumbar epidural steroid injections at right L3 and L4. History is not typical for radicular pain. Physical examination presents diffuse loss of sensation spanning 6 different nerve roots. There was borderline loss of strength in multiple myotomes. Imaging disclosed no disc herniation, high-grade foraminal stenosis or nerve root compression. The diagnosis requires a dermatomal distribution of pain, numbness, and/or paresthesias in a dermatomal distribution. A root tension sign is usually positive. The diagnosis of herniated disc must be substantiated by an appropriate finding on an imaging study. The presence of findings on an imaging study in and of itself does not make the diagnosis of radiculopathy. There must also be clinical evidence as described above. The diagnosis of lumbar radiculopathy is unsupported. Epidural steroid injection is not recommended in the absence of radiculopathy. The available information does not support that the request is medically reasonable and necessary. The medical necessity of this request is not certified.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

The request for transforaminal lumbar epidural steroid injection (ESI) is denied.

This patient has pain in the lower back with radiation down XXXX anterior thighs. XXXX has undergone lumbar fusion at L4-5. The CT scan of the lumbar spine (XXXX) demonstrated a disc protrusion at L3-4 with an associated anterior osteophyte. XXXX last EMG (XXXX) demonstrated bilateral S1 radiculopathy. XXXX currently has decreased sensation in the L3, L4, and L5 dermatomes bilaterally. XXXX has weakness in hip flexion. The treating physician has recommended a right L3-4 ESI for this patient.

The Official Disability Guidelines (ODG) supports ESI in patients with lumbar radiculopathy due to a herniated nucleus pulposus. The imaging studies and/or electro-diagnostic testing should support the objective examination findings.

The lumbar CT scan confirms a central and left posterolateral L3-4 disc protrusion, but not a true herniated disc. There is bilateral mild-moderate L3 foraminal stenosis. There is no recent electro-diagnostic testing to support radiculopathy associated with significant nerve compression at the L3-4 level.

Based on the records reviewed, the proposed injection is not medically necessary. Therefore, the prior determination is upheld.

Per ODG:

Criteria for the use of Epidural steroid injections:

Note: The purpose of ESI is to reduce pain and inflammation, thereby facilitating progress in more active treatment programs, the reduction of medication use and the avoidance of surgery, but this treatment alone offers no significant long-term functional benefit.

- (1) Radiculopathy (due to herniated nucleus pulposus, but not spinal stenosis) must be documented. Objective findings on examination need to be present. Radiculopathy must be corroborated by imaging studies and/or electrodiagnostic testing.
- (2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs, muscle relaxants, and neuropathic drugs).
- (3) Injections should be performed using fluoroscopy (live x-ray) and injection of contrast for guidance.
- (4) *Diagnostic Phase:* At the time of initial use of an ESI (formally referred to as the "diagnostic phase" as initial injections indicate whether success will be obtained with this treatment intervention), a maximum of one to two injections should be performed. A repeat block is not recommended if there is inadequate response to the first block (< 30% is a standard placebo response). A second block is also not indicated if the first block is accurately placed unless: (a) there is a question of the pain generator; (b) there was possibility of inaccurate placement; or (c) there is evidence of multilevel pathology. In these cases, a different level or approach might be proposed. There should be an interval of at least one to two weeks between injections.
- (5) No more than two nerve root levels should be injected using transforaminal blocks.
- (6) No more than one interlaminar level should be injected at one session.
- (7) *Therapeutic phase:* If after the initial block/blocks are given (see "Diagnostic Phase" above) and found to produce pain relief of at least 50-70% pain relief for at least 6-8 weeks, additional blocks may be supported. This is generally referred to as the "therapeutic phase." Indications for repeat blocks include acute exacerbation of pain, or new onset of radicular symptoms. The general consensus recommendation is for no more than 4 blocks per region per year. (CMS, 2004) (Boswell, 2007)
- (8) Repeat injections should be based on continued objective documented pain relief, decreased need for pain medications, and functional response.
- (9) Current research does not support a routine use of a "series-of-three" injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections for the initial phase and rarely more than 2 for therapeutic treatment.

- (10) It is currently not recommended to perform epidural blocks on the same day of treatment as facet blocks or sacroiliac blocks or lumbar sympathetic blocks or trigger point injections as this may lead to improper diagnosis or unnecessary treatment.
- (11) Cervical and lumbar epidural steroid injection should not be performed on the same day. (Doing both injections on the same day could result in an excessive dose of steroids, which can be dangerous, and not worth the risk for a treatment that has no long-term benefit.)
- (12) Excessive sedation should be avoided.

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
MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
☐ MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
☐ MILLIMAN CARE GUIDELINES
ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
☐ PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
$\hfill \square$ 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)