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Notice of Independent Review Decision

April 13, 2014

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:**

Outpatient Bilateral L5 Transforaminal Lumbar Epidural Steroid Injection (ESI) with Wydase

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

An American Board Certified Anesthesiologist with over 37 years of experience

**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.

**INFORMATION PROVIDED TO THE IRO FOR REVIEW:**

**PATIENT CLINICAL HISTORY [SUMMARY]:**

The claimant is a male that was injured at work on xx/xx/xx when he slipped in some water on the floor and landed on his back. He has reported lower back pain ever since. The claimant has been on pain medication, had at least 7 ESI's, therapy, aqua therapy, chiropractic care, cuneal nerve blocks, used a bone stimulator, decompression, neuroplasty and a self home exercise program without dpermanent relief of pain.

11-18-03: Lumbosacral 5 Views interpreted. Impression: Minimal disc space narrowing L5-S1. Minimal anterolisthesis S1 relative to L5.

01-07-04: MRI of the Lumbar Spine interpreted. Impression: 1. At L5-S1, degenerative disc disease, grade I spondylolisthesis, small posterior central protrusion of the disc, associated with stenosis of the lateral recess, neural foramina, and relative spinal canal stenosis. 2. At L4-5, bulging disc with a suggestion of a tiny posterior central protrusion of the disc associated with bilateral lateral stenosis and borderline to minimal foraminal stenosis. 3. Scoliosis, degenerative disc disease, and minimal grade I spondylolisthesis at L5 on S1.

10-09-06: Office/Outpatient Visit Report. The claimant presented for a follow up visit from Bilateral S1 Transforaminal Neuroplasty with low back pain. He has a VAS score of 4 and has had about 50% pain relief from procedure. The claimant c/o pain primarily in the lumbar spine associated with stiffness that is present in the mornings and numbness in the posterior and lateral thigh bilaterally, posterior and lower leg bilaterally and to both feet plantar surface. Upon examination, the claimant is positive for chronic back pain and paresthesia (bilateral lower extremity). Assessment: Lumbar facet arthropathy L2-S1, Low back pain, Lumbar radiculopathy, Chronic adhesive arachnoiditis.

08-30-07: Procedure Note. The claimant is here for a bilateral L5 transforaminal epidural steroid injection, lumbar epidurogram and bilateral L5 transforaminal neuroplasty. Pre-op diagnosis: bilateral L5 lumbar radicular pain. Post-op diagnosis: same.

09-25-07: Log Note. The claimant called and states he is doing 75% better after last injection.

01-15-08: Office/Outpatient Visit Report. The claimant presents with VAS of 4 and is doing well with present medications of Lortab 10mg/500mg. Plan is to follow up in 6 months.

05-22-08: Office/Outpatient Visit Report. The claimant presents with a significant return of pain that radiates from lower back down to his legs with VAS of 6. Upon examination he is positive for back pain, limb pain (bilateral leg pain) and myalgias. Upon palpation, pain is elicited over the left and right lumbar paraspinal muscles. Deep tendon reflexes: 2/4 left and right patellar, 2/4 left and right Achilles. The claimant has positive bilateral Kemp and bilateral slump. Plan: Radicular syndrome of lower limbs and he would benefit from Bilateral L5 Transforaminal ESI with wydase and epidurogram.

06-02-08: Office/Outpatient Visit Report. The claimant presents for procedure: Bilateral L5 Transforaminal Epidural Steroid Injection, lumbar epidurogram and bilateral L5 Transforaminal Neuroplasty. Pre-op diagnosis: Bilateral L5 lumbar radicular pain. Post-op diagnosis: same.

07-31-08: Office/Outpatient Visit Report. The claimant presents with c/o chronic adhesive arachnoiditis. The pain is located in the lumbar spine and radiates to the lateral thighs bilaterally, lateral lower legs bilaterally and both feet dorsal

surface with associated radicular bilateral leg pain and numbness in the left lateral thigh and left lateral lower leg. Since last visit there has been consistent, sustained pain relief. Plan: Follow up in 3 months.

09-29-08: EMG and Nerve Conduction Study. Study was negative. Reevaluate in three to six months.

02-15-10: Office/Outpatient Visit Report. The claimant presents with VAS of 7 and is having pain in right lower back that travels down the back of his leg. Upon examination, the claimant has lower lumbar spine pain that radiates to the right buttock, right lateral thigh and right more than left posterior lower leg. Deep Tendon Reflexes: 2/4 left and right patellar, 2/4 left and right Achilles. He has positive right slump for back pain. Plan: Right L4 and right L5 transforaminal ESI with epidurogram.

02-25-10: Office/Outpatient Visit Report. The claimant presents for procedure: Right L4 transforaminal epidural steroid injection and lumbar epidurogram and right L5 transforaminal epidural steroid injection. Pre-op diagnosis: Right L4 and L5 lumbar radicular pain. Post-op diagnosis: same.

03-30-10: Office/Outpatient Visit Report. The claimant presents with VAS of 4 with 75% pain relief. Plan: Lumbar spondylarthritis and follow up in 3 months.

12-27-10: Office/Outpatient Visit Report. The claimant presents being able to complete ADL's without any assistance. Plan: Encouraged active lifestyle and follow up in 3 months.

02-15-11: Office/Outpatient Visit Report. The claimant presents with VAS of 8 and c/o pain in the lumbar region going down the side of his left leg that stops at the knee. Patient to be evaluated for lumbar spondylarthritis. Deep Tendon Reflexes: 2/4 bilateral patellar and 2/4 bilateral Achilles. Positive bilateral Kemp, positive left slump for back pain and radiculopathy, positive left straight leg raise for back pain and radiculopathy. Plan: New onset L3 radiculopathy, therefore, MRI recommended.

02-17-11: MRI LSpine with and without Contrast. Impression: 1. Postsurgical change related to posterior spinal fusion as above. 2. Suspected multilevel foraminal stenosis, sub optimally evaluated due to artifact. 3. Displacement of the nerve roots of the cauda equina along the periphery of the canal at the postsurgical levels. Findings may be indicative of arachnoiditis.

03-02-11: Office/Outpatient Visit Report. The claimant presents for procedure: Left L3 transforaminal ESI and lumbar epidurogram and level left L4 transforaminal ESI. Pre-op diagnosis: Left L3 and L4 lumbar radicular pain. Post-op diagnosis: same.

04-04-11: Office/Outpatient Visit Report. The claimant presents with VAS of 6 with pain medication and states received 90% relief from ESI. He states he still

has some axial back pain. Upon examination the claimant is positive for arthralgia, back pain and myalgias. Plan: Follow up in 3 months.

10-11-11: Office/Outpatient Visit Report. The claimant presents with VAS of 4 and states is able to complete ADL's without any assistance. Plan: Pain is well controlled with current regiment and he is on an exercise program. Follow up in 3 months.

04-16-12: Office/Outpatient Visit Report. The claimant presents with VAS of 6 with pain medication. He c/o pain in lower lumbar spine that radiates to the left buttock, left lateral thigh and left medial thigh. Conservative therapies include: narcotics with little relief. Deep Tendon Reflexes: 2/4 bilateral patellar, 2/4 bilateral Achilles. Positive left slump for back pain and radiculopathy and left straight leg raise. Plan: Will repeat the left L3 and L4 TF ESI with EPI.

04-26-12: Office/Outpatient Visit Report. The claimant presents here for procedure: Left L3 and L4 transforaminal ESI and lumbar epidurogram. Pre-op diagnosis: Left L3 and L4 lumbar radicular pain. Post-op diagnosis: same.

05-08-12: Office/Outpatient Visit Report. The claimant presents with VAS of 3 and states he is getting about 85% relief. He c/o bulging lumbar disc. However, has a significant reduction in pain.

08-09-12: Office/Outpatient Visit Report. The claimant presents with VAS of 3. No plan necessary, stable on current regimen.

11-29-12: Office/Outpatient Visit Report. The claimant presents with VAS of 8. Upon examination, positive for decreased force of urine stream and arthralgia, back pain and limb pain (bilateral leg pain). Stable on current regimen.

03-04-13: Office/Outpatient Visit Report. The claimant presents with VAS of 0 with pain medication. Continues to be stable on current regimen.

06-04-13: Office/Outpatient Visit Report. The claimant presents with VAS of 5 and states improved function. Upon examination, the claimant has primarily lower lumbar spine pain that radiates to the left buttock and lateral thigh with associated symptoms of stiffness, paravertebral muscle spasm and radicular left leg pain. No pain on palpation, FROM and unchanged deep tendon reflexes and maneuvers. Plan: Due to claimants c/o returning pain will proceed with a left L3 & L5 TF ESI with wydase.

06-12-13: Office/Outpatient Visit Report. The claimant is here for procedure: Left L3 and L4 transforaminal ESI, lumbar epidurogram and left L3 and L5 transforaminal neuroplasty. Pre-op diagnosis: Left L3 and L5 lumbar radicular pain. Post-op diagnosis: same.

06-21-13: Log Note. The claimant reports 90% pain relief post procedure.

09-23-13: Office/Outpatient Visit Report. The claimant presents with VAS of 8 with pain medication and overall improved function in ADL's and reduction in pain. He is stable on current regimen.

12-30-13: History and Physical Report. The claimant presents well with minor complaints and rates his pain level 6/10 at this time. The claimant c/o right low back pain radiating to right lateral thigh. Upon examination, present is arthritis, back, leg and neck pain with normal posture and gait.

02-12-14: History and Physical Report. The claimant presents with pain level of 7/10 on current medications (Hydrocodone-Acetaminophen 10mg/325mg). Upon examination, lumbar flexion is 45 degrees, slump test positive bilateral back pain and radiculopathy. Straight leg raising was negative for pain and radiculopathy, Normal sensation in the lower extremities and strength was normal. Plan: Bilateral LS TF ESI with Wydase.

02-18-14: URA. Rationale: It is the opinion of the reviewing physician that, "The claimant was injured on xx/xx/xx and on 06-04-13 one outpatient left L3 and L5 lumbar transforaminal Epidural Steroid Injection was approved. Last office visit on 02-12-13 noted patient presents with lumbar pain, located in the right low back. Pain radiates (ESI) with Wydase. As there is no indication of the result of the last ESI, there is not sufficient documentation or rationale for an outpatient bilateral L5 Trans-foraminal Lumbar Epidural Steroid Injection (ESI) with Wydase, thus the request is not approved.

03-14-14: URA. Rationale: It is the opinion of the reviewing physician that, "The records are incomplete, but there is mention of a bilateral L5 transforaminal epidural steroid injection with Wydase. History: This individual has notes dating back to 2003 regarding back pain. The date of injury is not specified. There have been several back surgeries, including an L4 through S1 fusion. The notes indicate that a radiofrequency ablation was performed on 02-12-14. Previously, trigger point injections have been performed, along with transforaminal epidural steroid injections, bilateral L5 with neuroplasty on 08-04-07. Epidural steroid injections were performed on 02-17-10. A note on 05-08-12 states that epidural steroid injections were helpful. On 06-04-13, L3, L5 epidural steroid injections on the left were approved. It is unclear whether that procedure was completed. There is persistent low back and right and left lateral thigh pain. An MRI on 02-17-11 was reported to show arachnoiditis. The requested procedure is not endorsed by ODG. Therefore, I recommend non-authorizing the requested procedure."

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

The adverse determination to deny the lumbosacral transforaminal epidural steroid injection is upheld for the following reasons. First, there has been little documentation of the beneficial effects of the recent LESI. The procedure was on June 12, 2013 and the report was 90% pain relief on June 21, 2013. This is

easily within the euphoria side effects of the injected steroid, rather than effects on the compensable injury itself. There is no documentation of effects 4 to 6 weeks post injection. To authorize subsequent injections, beneficial effects must be demonstrated at least six weeks post injection, which would be necessary to justify another epidural steroid injection through ODG criteria.

Secondly, the various reports are associated with degenerative disc and degenerative facet disease as well as multilevel foraminal stenosis. These do not meet the criteria through ODG to justify LESI, especially since there has not been long term beneficial effects reported.

The URA reports listed above are correct in stating the lack of sufficient documentation and multiple procedures without significant benefits all are reasons to deny subsequent LESI, and show that the requested procedure does not meet ODG criteria. Therefore, the request for the Outpatient Bilateral L5 Transforaminal Lumbar Epidural Steroid Injection (ESI) with Wydase is non-certified.

#### Per ODG:

Not recommended due to the lack of sufficient literature evidence (risk vs. benefit, conflicting literature). Also referred to as epidural neurolysis, epidural neuroplasty, or lysis of epidural adhesions, percutaneous adhesiolysis is a treatment for chronic back pain that involves disruption, reduction, and/or elimination of fibrous tissue from the epidural space. Lysis of adhesions is carried out by catheter manipulation and/or injection of saline (hypertonic saline may provide the best results). Epidural injection of local anesthetic and steroid is also performed. It has been suggested that the purpose of the intervention is to eliminate the effect of scar formation, allowing for direct application of drugs to the involved nerves and tissue, but the exact mechanism of success has not been determined. There is a large amount of variability in the technique used, and the technical ability of the physician appears to play a large role in the success of the procedure. In addition, research into the identification of the patient who is best served by this intervention remains largely uninvestigated. Adverse reactions include dural puncture, spinal cord compression, catheter shearing, infection, excessive spinal cord compression, hematoma, bleeding, and dural puncture. Duration of pain relief appears to range from 3-4 months. Given the limited evidence available for percutaneous epidural adhesiolysis it is recommended that this procedure be regarded as investigational at this time. ( ) ( ) ( ) ( [BlueShield](#) ) ( ) ( ) ( ) ( [Regence Group](#) ) ( ) ( ) ( ) This recent RCT found that after 3 months, the visual analog scale (VAS) score for back and leg pain was significantly reduced in the epidural neuroplasty group, compared to conservative treatment with physical therapy, and the VAS for back and leg pain as well as the Oswestry disability score were significantly reduced 12 months after the procedure in contrast to the group that received conservative treatment. ( )

#### **Adhesiolysis is Not Recommended by ODG.**

##### **Patient selection criteria for Adhesiolysis if provider & payor agree to perform anyway:**

- The 1-day protocol is preferred over the 3-day protocol.
- All treatment modalities have failed, including epidural steroid injections.
- The physician intends to conduct the adhesiolysis in order to administer drugs closer to a nerve.
- The physician documents strong suspicion of adhesions blocking access to the nerve.
- Adhesions blocking access to the nerve have been identified by Gallium MRI or Fluoroscopy during epidural steroid injections.

##### **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, reduction of medication use and avoiding 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 and muscle relaxants).
- (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. (↘) (↘)
- (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.)

**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**
- 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)**