

# Icon Medical Solutions, Inc.

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## Notice of Independent Review Decision

**DATE:** December 14, 2012

**IRO CASE #:**

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

Outpatient Bilateral Transforaminal L4-L5, L5-S1 Epidural Steroid Injection (ESI) and One (1) Post-Injection Session of Physical Therapy (PT) Consisting of One (1) Unit of Electrical Stimulation, Two (2) Units of Neuromuscular Re-Education and One (1) Unit of Manual Therapy

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

The reviewer is certified by the American Board of Anesthesiology with secondary practice in pain management with over 40 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:**

12/09/11: MRI of the Lumbar Spine with and without Contrast report interpreted by Dr. with Imaging Center

12/12/11: CT of the Thoracolumbar Spine without Contrast report interpreted by 07/27/12, 08/24/12, 09/21/12, 10/19/12: Progress Notes by MD with Solutions

09/07/12: CT of the Lumbar Spine without Contrast report interpreted by MD with Imaging Services

10/30/12: Preauthorization Request by for MD with Solutions

11/05/12: UR performed by MD

11/05/12: Request for Reconsideration by for MD

11/13/12: UR performed by MD

11/16/12: Progress Note by MD

## **PATIENT CLINICAL HISTORY [SUMMARY]:**

The claimant is a male who injured his low back while spreading sand at work on xx/xx/xx. He is status post multiple back surgeries including an iliotibial (IT) pump.

12/09/11: MRI of the Lumbar Spine with and without Contrast report interpreted by Dr. with Imaging Center. IMPRESSION: There is a tiny flow void seen within the posterior aspect of the canal from approximately T11 to L5, but the catheter is not well visualized. The catheter would be better visualized on radiographs and CT. The catheter within the paraspinous soft tissues is not visualized. There is multilevel degenerative disc disease with disc desiccation or loss of disc height. There is a Schmorl's node impression noted at the inferior aspect of L1 and L2. There is minimal 2-mm retrolisthesis L2 on L3. Multilevel foraminal stenosis, as described above.

12/12/11: CT of the Thoracolumbar Spine without Contrast report interpreted by. IMPRESSION: Free-floating catheter fragment within the thecal sac spanning T10-T11 to L5-S1. Intrathecal pain pump with catheter terminating at T10. Moderate thoracolumbar spondylosis, most severe in the lumbar spine with spinal canal stenosis at L3-L4. Interval development of bilateral diffuse patchy ground-glass opacities in the lungs with some tree-in-bud opacities in the bases in addition to multiple mediastinal lymph nodes. These findings are nonspecific and likely represent an infectious or inflammatory process. The differential diagnosis includes TB. Further evaluation with dedication CT chest is recommended. Unchanged 9 mm right lower lobe lung nodule. Sigmoid diverticulitis.

07/27/12: The claimant was evaluated by MD for pump refill and meds as well as back pain. It was noted that he had been having worsening numbness and tingling sensations in the lower extremities. He reached a high dose of Neurontin 3600 mg and also tried Lyrica with a maximum dose of 450 mg, which both failed to control his numbness and tingling sensations. On exam, the lumbosacral spine was tender along the midline in the upper and lower region. Lumbar paraspinals were tender in the upper and lower region. Sacroiliac joints were tender bilaterally. Faber's, Gaenslen's, and Yoeman's were positive bilaterally. Straight leg raise was positive bilaterally. Muscle strength testing was 4/5 in the lower extremities. Range of motion of the lower extremities was within normal limits. There was no clonus. Tinel's was negative at the fibular heads bilaterally. There was no muscle atrophy. Sensation was intact in the lower extremities. Heel-to-shin was intact bilaterally. TREATMENT: Continue Amitriptyline, Lortab, Ambien, Cymbalta, and Clonazepam. Decrease Neurontin. Start Valium. Uncontrolled neuropathic pain, he failed Lyrica and high doses of Neurontin. Patient was given kit samples for long-acting gabapentin Gralise. Patient had CT of the lumbar spine performed in December of 2011, which showed free-floating catheter fragment within the thecal sac spanning T10-T11 to L5-S1; moderate thoracolumbar spondylosis most severe in the lumbar spine with spinal canal stenosis at L3-L4. I like to consider repeating the CT lumbar spine or referring the

patient to neurosurgeon, Dr.. His pump was refilled with Fentanyl, clonidine, Baclofen, and bupivacaine.

08/24/12: The claimant was reevaluated by MD. He complained of moderate-severe levels of numbness and tingling sensations. He reported mild-moderate sharp shooting pain. He stated that his radiation to the lower extremities had been infrequent. He was able to engage himself in regular physical activities. He had been working in construction. Overall, he stated that his pain was adequately managed. Physical exam was unchanged from exam dated 07/27/12.

TREATMENT: Patient is referred to his primary care physician for blood workup to rule out metabolic causes of his neuropathy. We will continue with the Neurontin and Cymbalta. He has been off Lyrica. His pump was refilled.

09/07/12: CT of the Lumbar Spine without Contrast report interpreted by MD with Imaging Services. IMPRESSION: CT scan of lumbar spine without contrast enhancement with sagittal reconstruction shows multilevel lumbar spondylosis with disc space narrowing, bulging discs, osteophyte complex, hypertrophic facet arthropathy, and ligamentum flavum thickening. This results in multilevel spondylotic spinal canal stenosis as described above. It was noted in the findings "There of thecal sac catheter is in place the one extending superiorly and other one extending inferiorly."

09/21/12: The claimant was reevaluated by MD. His complaints remained unchanged from 08/24/12. His physical exam remained unchanged from 08/24/12. The treatment plan remained unchanged as well. His pump was refilled.

10/19/12: The claimant was evaluated by MD for low back pain and pump refill and meds. It was noted that he had been having increased low back pain, which was sharp and shooting with radiation into the lower extremities accompanied by numbness/tingling sensations, muscle spasms, and weakness. His pain was rated 8-9/10 with use of his oral medications and home-based PT. He had been having worsening sleep disturbance for the last three weeks due to increased pain by the end of the day. He had been inactive to avoid the worsening of his low back pain. He stated that his pain pump and oral medications relief had not been enough to make him more active. On examination, he had moderate-severe tenderness along the midline in the upper and lower regions of the lumbar spine. Lumbar paraspinals were tender in the upper and lower regions. The Sacroiliac joints were tender bilaterally. Fabers' Gaenslen's, and Yoeman's were positive bilaterally. Straight leg raise was positive bilaterally. He had 4/5 strength in the hip flexors bilaterally, 4/5 knee extensors bilaterally, 4/5 ankle dorsiflexors bilaterally, 4/5 ankle eversion bilaterally, 4/5 left extensor hallucis brevis, and 4/5 right extensor hallucis longus. Range of motion of the lower extremities was within normal limits bilaterally. There was no clonus. Tinel's of the peroneal nerve at the fibular head was negative bilaterally. There was no muscle atrophy present. Lower extremities were nontender bilaterally. McMurray's was negative bilaterally. Sensation to light touch was disturbed in an L4-S1 dermatome

fashion. Heel-shin was intact bilaterally. ASSESSMENTS: Thoracic or lumbosacral neuritis or radiculitis, unspecified. Lumbago. Intervertebral lumbar disc disorder with myelopathy, lumbar region. TREATMENT: Continue medications as prescribed; decrease Neurontin to 600 mg 2 capsules t.i.d. Start valium 5 mg p.r.n. Worsening lumbar radicular pain not responding to current therapy. His subjective and objective findings are supportive for an exacerbation of his radicular pain. I would like to recommend the BTF lumbar ESI to treat his inflammation over the nerve roots because his symptoms have worsened. This will be done under anesthesia with the guidance of fluoroscopy and it will be followed by one session of physical medicine post injection. PROCEDURES: The chart was reviewed. The pump was inspected WNL, and the patient was evaluated. No side effects reported. The pump was refilled 20 cc of Fentanyl, clonidine, Baclofen, and bupivacaine. PA increased to 250 mcg/10 min q. 8h.

11/05/12: UR performed by MD. DECISION: "Mr. injured his low back on xx/xx/xx. The claimant is a male who was injured spreading sand. He is status post multiple back surgeries including an iliotibial (IT) pump. On 10/19/12, Dr. noted that the patient complains of increased low back pain, shooting, with radiation to lower extremities accompanied by numbness/tingling, muscle spasms and weakness. He has been having worsening sleep disturbance for the last three weeks due to pain. He states the pain pump and oral meds have not been enough. On exam, there is lumbosacral spine tenderness along midline in upper and lower region. Lumbar paraspinals are tender. Sacroiliac joints are tender bilaterally. Faber's, Gaenslen's and Yoeman's are positive bilaterally. Straight leg raises (SLR) is positive bilaterally. Manual motor testing (MMT) is 4/5. Range of motion (ROM) and reflexes are within normal limits. Tinel's peroneal nerve at fibular head is negative. There is no tenderness to palpation in the lower extremities. Sensation is disturbed in an L4-S1 dermatomal fashion. Heel to shin is intact bilaterally. Lumbar MRI on 12/09/11 noted there is a tiny flow void seen within the posterior aspect of canal from approximately T11 to L5 but catheter is not well visualized. Catheter would be better visualized on radiographs and CT. Catheter within paraspinal soft tissues is not visualized. There is multilevel degenerative disc disease (DDD) with disk desiccation or loss of disk height. There is a Schmorl's node impression noted at the inferior aspect of L1 and L2. There is minimal 2 mm retrolisthesis of L2 on L3. Lumbar vertebral bodies otherwise demonstrate normal height, morphology, marrow signal, and alignment. No evidence of fracture and conus terminates at approximately L1. The request is for outpatient bilateral transforaminal L4-L5, L5-S1 epidural steroid injection and one (1) post-injection session of physical therapy consisting of one (1) unit of electrical stimulation, two (2) units of neuromuscular re-education and one (1) unit of manual therapy. As there are no positive imaging studies and/or electrodiagnostic testing indicating a radiculopathy, there is not sufficient documentation or rationale for outpatient bilateral transforaminal L4-L5, L5-S1 epidural steroid injection and one (1) post-injection session of physical therapy consisting of one (1) unit of electrical stimulation, two (2) units of neuromuscular re-education and one (1) unit of manual therapy, thus the request is not approved."

11/13/12: UR performed by MD. Decision: "There is insufficient documentation to assess this review. I have no idea how long this claimant has had an intrathecal pump, and no evidence that the current symptoms are not secondary to an intrathecal granuloma. Additional information must be provided, including evidence of a radiculopathy at the L4-L5 level to allow for an ESI as per the ODG. Physical therapy is also denied until an accurate diagnosis is established."

11/16/12: The claimant was reevaluated by MD. He rated his pain as 4-5/10 with the use of his oral medications and home-based PT. He reported significant improvement in his numbness and tingling sensation with combination of Neurontin and Cymbalta. His sleep pattern had improved as well as his activity level. He was tolerating his medications and denied any side effects. On examination, the lumbosacral spine scar was noted in the midline that was well healed and without any signs of inflammation or infection. He had moderate-severe tenderness along the midline in the upper and lower region. Lumbar paraspinals were tender in the upper and lower region. Sacroiliac joints were tender bilaterally. Faber's, Gaenslen's, and Yoeman's were positive bilaterally. Straight leg raise was positive bilaterally. Strength was 4/5 in the lower extremities. Lower extremity examination was unremarkable. Sensation to light touch was disturbed in an L4-S1 dermatome fashion. TREATMENT: Continue Amitriptyline, Lortab, Neurontin, Ambien, Cymbalta, and Clonazepam. Stop Valium. Start Klonopin. Patient to continue with home PT and exercise. His pump was refilled with Fentanyl, clonidine, Baclofen, and bupivacaine.

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

The previous adverse decisions are upheld. The chart has been reviewed, including the progress notes of MD and the various diagnostic procedures performed. Several conditions stand out, which appear to not have been fully addressed.

First, the claimant, on 12/12/2011, had a CT scan of the lumbosacral spine in which "ground glass opacities in the lungs with some tree-in-bud opacities in the bases in addition to multiple mediastinal lymph nodes. These findings are nonspecific and likely represent an infectious or inflammatory process. The differential diagnosis includes TB. Further evaluation with dedicated CT chest is recommended." In the presence of an infectious process, even localized but especially generalized in the lungs and potentially in the multiple mediastinal lymph nodes, steroid injections are contraindicated. There is no evidence in the chart presented that this finding has been fully evaluated. If it is an inflammatory process, would a steroid injection also be contraindicated? The answer would depend on the definitive diagnosis, which is not given. Thus, this is strong evidence for continuation of the adverse decision.

On the same CT, the description of "catheter fragment within the thecal sac spanning T10-T11 to L5-S1" is mentioned. There is no further delineation of that

statement. Thus, no diagnosis is made of the possible effects of the broken catheter on the adjacent nerve roots. The duration of time of this catheter, and whether it is a replacement for another (possibly the one which had the fragment?) is not stated. No precise history of efficacy of the catheter is given.

Lastly, the above independent utilization review specialists MD and MD, state that insufficient data is presented to define the existence of radiculopathy with no measured atrophy or EMG/NCV evidence. I concur with this assessment and, in addition, state that there is no definitive anatomic reason for the bilateral transforaminal L4-L5 and L5-S1 epidural steroid injections or for the post-procedure one session (1) of Physical Therapy consisting of one (1) unit of Electrical Stimulation, two (2) units of Neuromuscular Re-Education, and one (1) unit of Manual Therapy. In addition, on one of the physical examinations, Dr. states that “the lower extremity range of motion was within normal limits bilaterally” on October 19, 2012. Therefore, the request for Outpatient Bilateral Transforaminal L4-L5, L5-S1 Epidural Steroid Injection (ESI) and One (1) Post-Injection Session of Physical Therapy (PT) Consisting of One (1) Unit of Electrical Stimulation, Two (2) Units of Neuromuscular Re-Education and One (1) Unit of Manual Therapy is not medically necessary and is non-certified.

**ODG:**

<p>Epidural steroid injections (ESIs), therapeutic</p>	<p><b>Criteria for the use of Epidural steroid injections:</b>  <i>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.</i></p> <p>(1) Radiculopathy must be documented. Objective findings on examination need to be present. Radiculopathy must be corroborated by imaging studies and/or electrodiagnostic testing.</p> <p>(2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants).</p> <p>(3) Injections should be performed using fluoroscopy (live x-ray) and injection of contrast for guidance.</p> <p>(4) <i>Diagnostic Phase:</i> 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 (&lt; 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.</p> <p>(5) No more than two nerve root levels should be injected using transforaminal blocks.</p> <p>(6) No more than one interlaminar level should be injected at one session.</p> <p>(7) <i>Therapeutic phase:</i> 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. (<a href="#">CMS, 2004</a>) (<a href="#">Boswell, 2007</a>)</p> <p>(8) Repeat injections should be based on continued objective documented pain</p>
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	<p>relief, decreased need for pain medications, and functional response.</p> <p>(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.</p> <p>(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.</p> <p>(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.)</p>
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<p>Physical therapy (PT)</p>	<p><i>Post Epidural Steroid Injections:</i> ESIs are currently recommended as a possible option for short-term treatment of radicular pain (sciatica), defined as pain in dermatomal distribution with corroborative findings of radiculopathy. The general goal of physical therapy during the acute/subacute phase of injury is to decrease guarding, maintain motion, and decrease pain and inflammation. Progression of rehabilitation to a more advanced program of stabilization occurs in the maintenance phase once pain is controlled. There is little evidence-based research that addresses the use of physical therapy post ESIs, but it appears that most randomized controlled trials have utilized an ongoing, home directed program post injection. Based on current literature, the only need for further physical therapy treatment post ESI would be to emphasize the home exercise program, and this requirement would generally be included in the currently suggested maximum visits for the underlying condition, or at least not require more than 2 additional visits to reinforce the home exercise program. ESIs have been found to have limited effectiveness for treatment of chronic pain. The claimant should continue to follow a home exercise program post injection. (<a href="#">Luijsterburg, 2007</a>) (<a href="#">Luijsterburg2, 2007</a>) (<a href="#">Price, 2005</a>) (<a href="#">Vad, 2002</a>) (<a href="#">Smeal, 2004</a>)</p> <p><b>ODG Physical Therapy Guidelines –</b></p> <p>Allow for fading of treatment frequency (from up to 3 or more visits per week to 1 or less), plus active self-directed home PT. Also see other general guidelines that apply to all conditions under Physical Therapy in the <a href="#">ODG Preface</a>, including assessment after a "six-visit clinical trial".</p> <p><b>Lumbar sprains and strains (ICD9 847.2):</b> 10 visits over 8 weeks</p> <p><b>Sprains and strains of unspecified parts of back (ICD9 847):</b> 10 visits over 5 weeks</p> <p><b>Sprains and strains of sacroiliac region (ICD9 846):</b> Medical treatment: 10 visits over 8 weeks</p> <p><b>Lumbago; Backache, unspecified (ICD9 724.2; 724.5):</b> 9 visits over 8 weeks</p> <p><b>Intervertebral disc disorders without myelopathy (ICD9 722.1; 722.2; 722.5; 722.6; 722.8):</b> Medical treatment: 10 visits over 8 weeks Post-injection treatment: 1-2 visits over 1 week Post-surgical treatment (discectomy/laminectomy): 16 visits over 8 weeks Post-surgical treatment (arthroplasty): 26 visits over 16 weeks Post-surgical treatment (fusion, after graft maturity): 34 visits over 16 weeks</p> <p><b>Intervertebral disc disorder with myelopathy (ICD9 722.7)</b> Medical treatment: 10 visits over 8 weeks Post-surgical treatment: 48 visits over 18 weeks</p> <p><b>Spinal stenosis (ICD9 724.0):</b> 10 visits over 8 weeks</p>
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	<p>See 722.1 for post-surgical visits  <b>Sciatica; Thoracic/lumbosacral neuritis/radiculitis, unspecified</b> (ICD9 724.3; 724.4):  10-12 visits over 8 weeks  See 722.1 for post-surgical visits  <b>Fracture of vertebral column without spinal cord injury</b> (ICD9 805):  Medical treatment: 8 visits over 10 weeks  Post-surgical treatment: 34 visits over 16 weeks  <b>Fracture of vertebral column with spinal cord injury</b> (ICD9 806):  Medical treatment: 8 visits over 10 weeks  Post-surgical treatment: 48 visits over 18 weeks  <b>Work conditioning</b> (See also <a href="#">Procedure Summary</a> entry):  10 visits over 8 weeks</p>
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**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)**