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Notice of Independent Review Decision

DATE OF REVIEW: June 25, 2009

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Spinal Logic Bone Growth Stimulator

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

Fellow American Academy of Physical Medicine and Rehabilitation

REVIEW OUTCOME

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

X Upheld (Agree)

Medical documentation **does not support the medical necessity** of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Texas Department of Insurance:

- Utilization reviews (04/21/09, 05/08/09)
- Office visit (05/13/09)

- Office visits (10/04/04 – 03/14/08)
- Diagnostics (27/01/05 – 07/03/08)
- Surgery (05/16/06 – 05/07/07)

- Office visits (03/21/08 – 05/19/09)
- Surgery (11/18/08)

- Office visits (02/09/09 - 05/13/09)
- Utilization reviews (04/21/09, 05/08/09)
- Surgery (11/18/08 - 02/12/09)
- Diagnostics (07/03/08 - 02/02/09)

ODG has been utilized for the denials.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male who was sitting down on a chair and was leaning back, when the chair broke and he fell hitting the floor on xx/xx/xx.

1995 – 2003: No records are available.

2004 – 2005: From October through November 2004, the patient underwent physical therapy (PT).

In January 2005, magnetic resonance imaging (MRI) of the lumbar spine was obtained for pain in the lower back which revealed: (1) Transitional vertebral anatomy with a rudimentary disc between S1 and S2. (2) Prior anterior fusion at L4-L5 and L5-S1. Previous MRI from December 2003 as well as a previous computerized tomography (CT) myelogram had revealed interval decompression laminectomy at the L2-L3 level and prior lumbar fusion at L3-L4 and L4-L5.

2006: M.D., noted pain in the lower back coming from the sacroiliac (SI) joint and lumbosacral joint. The patient was utilizing Keppra and hydrocodone and had undergone radiofrequency in the past with a long-term pain relief. Examination revealed positive Patrick' Maneuver on the left aggravating the left SI joint, tenderness to palpation bilaterally over the SI joint, and tenderness bilaterally of the facet at L3-L4, L4-L5, and L5-S1. Dr. assessed lumbar laminectomy syndrome with history of a two-level fusion at L4-L5 and L5-S1 with continued low back pain, bilateral SI joint arthropathy, and lumbar facet arthropathy and spondylosis. He treated the patient with medications, bilateral SI joint injections, radiofrequency thermocoagulation rhizotomy of bilateral L5, S1, S2, S3 lateral branches and recommended a spinal cord stimulator (SCS) trial.

D.O., performed a required medical evaluation (RME) and noted over the last 11 years, the back pain had worsened and the patient had been started on pain management program. He had been provided 5% rating and later an additional rating was performed which placed him at a higher disability rating in the area of 15%. Dr. opined in terms of current medical status, the current medical treatment was appropriate and medically necessary and related to the original work injury; there were no underlying pre-existing injuries or conditions; and the additional treatment needed was an aggressive home exercise program (HEP), weaning the patient off the narcotics to non-narcotic anti-inflammatory such as Ultracet, and there was no need for any durable medical equipment (DME), injections, or diagnostic testing.

M.D., noted history was positive for a lumbar fusion at L5-S1 in 2002, hardware removal and laminectomy in 2004, epidural steroid injections (ESI) and right leg nerve ablation in 2005, and left leg nerve ablation in 2006. Dr. diagnosed postlaminectomy syndrome and lumbar herniated nucleus pulposus (HNP).

2007: On February 26, 2007, Dr. performed bilateral lumbar epidural percutaneous SCS trial which failed to respond. On May 7, 2007, he performed subcutaneous bilateral lumbar stimulator placement. However, it was removed the next day due to painful stimulation. From May thorough November, Dr.

treated the patient with medications including Lyrica, hydrocodone, Flexeril, Kadian, OxyContin and recommended an intrathecal pump trial.

Dr. treated the patient with medications including Lodine and Medrol Dosepak and trigger point injections (TPIs) in the lumbar paraspinal muscles with temporary relief.

2008: Post-myelogram computerized tomography (CT) of the lumbar spine revealed: (1) Moderately-severe central spinal stenosis at L2-L3 in part due to instability with partial obstruction to the caudad flow of contrast. (2) Solid-appearing anterior interbody fusion within L5 and S1 level and fusion across S1-S2 disc space. (3) Far lateral disc herniation towards the right at L3-L4, possibly encroaching upon the extra foraminal portion of the right laterally coursing L3 roots.

For frequent flare-ups of lower back pain, the patient was seen in the ER and was treated with IM injections and oral medications.

M.D., performed a peer review and opined the ergonomic chair was neither reasonable nor medically necessary and appropriate as there were no documentation of objective findings or on properly performed diagnostics.

Dr. continued to treat the patient with medications and bilateral L3 transforaminal ESI x 2 which got the patient 50% pain relief.

On November 18, 2008, M.D., performed laminectomy/foraminotomy at L2-L3, and L3-L4, posterolateral fusion at L2-L3 and L3-L4, and segmental instrumentation at L2-L4. Postoperatively, the patient developed fever. Bilateral upper extremity venous duplex ultrasound and chest x-rays were unremarkable.

2009: On January 7, 2009, Dr. noted new onset of left leg pain and back pain radiating into the left thigh. X-rays showed hardware in good position except left lateral L4 screw. Dr. suspected irritation of nerves or blood vessels from scar tissue or hardware. He prescribed Medrol Dosepak and recommended possible hardware removal.

CT of the lumbar spine revealed a broken pedicular screw in the right L5 pedicle, mild degenerative narrowing of the foramina due to hypertrophied facets related to fusion, heterotopic calcification along the extra osseous path of the left L4 screw, minimal degenerative narrowing of the L2 foramina due to facet arthropathy and similar changes producing moderate narrowing of the right L3 and mild to moderate narrowing of the left L3 foramina with degenerative changes of the SI joint, right greater than left.

On February 12, 2009, Dr. performed hardware removal. Postoperatively, the patient was seen in the ER for serous drainage from the surgical wound associated with fever and was treated with Augmentin. In March, x-rays showed postoperative findings. The patient was recommended PT and was advised to follow-up in three months.

In April, Dr. issued a letter of medical necessity for a bone growth stimulator (BGS) to increase the chance of healing and to reduce the need for further surgery.

On April 21, 2009, M.D., denied the request for BGS with the following rationale: *The claimant is reported to have a pseudoarthrosis however the x-rays from March 25, 2009, do not discuss this. The clinician's note from March 2009 did not discuss pseudoarthrosis but recommended a return visit in three months, June 2009. There is no evidence provided of pseudoarthrosis or other indication for BGS. The request is not certified.*

On April 28, 2009, Dr. in response to first denial, stated the patient had had a multilevel fusion and his surgery had a high incidence of fusion failure. Therefore, he prescribed a SpinaLogic BGS with a thirty-minute protocol to be used in adjunct with the surgery and to support compliance and to aid in solidifying the fusion.

On May 8, 2009, M.D., denied the appeal with the following rationale: *The request for SpinaLogic BGS is not recommended as medically necessary. The patient is reported to have undergone L2-L4 spinal fusion in November 2008. It is unclear why the patient did not receive a bone growth stimulator immediately after the surgery. It is now over six months from the date of surgery and there is no imaging studies submitted for review reporting evidence of failed fusion in the patient at this point. The clinical exams submitted for review reporting evidence the patient continues to have symptoms related to instability of the lumbar spine. Without clinical documentation of failed fusion, medical necessity for the request cannot be established at this time.*

On May 13, 2009, Dr. noted worsening back pain with left-sided numbness and weakness. He assessed status post fusion and healing intervals slower than expected and recommended an external stimulator.

On May 19, 2009, Dr. performed a peer review and opined the ergonomic chair was not validated to be reasonable and medically necessary or appropriate.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION. I HAVE REVIEWED THE RECORDS INCLUDING THE HISTORY, TREATMENT, THE DENIALS AND REBUTTALS AND TO DATE THERE ARE NO STUDIES TO SUPPORT THE CONCLUSION OF FAILED FUSION. WITHOUT OBJECTIVE EVIDENCE SEVEN MONTHS POST SURGERY A STIMULATOR IS NOT WARRANTED OR MEET ODG CRITERIA. ODG PRIMARILY ADDRESSES IMMEDIATE POST OP USE, BUT DOES STATE GRADE III SPONDYLOLISTHESIS AS ONE OF THE CRITERIA. AT THIS POINT THERE IS NO OBJECTIVE EVIDENCE BY DIAGNOSTIC TESTING TO SUPPORT THE NEED FOR BGS.

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

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES