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Notice of Independent Review Decision

DATE OF REVIEW: MARCH 16, 2011 **AMENDED MARCH 17, 2011**

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Insertion or Replacement of Spinal Neurostimulator Pulse Generator or Receiver,
Direct or Inductive Coupling

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

This physician is a Board Certified Neurosurgeon with 41 years of experience.

REVIEW OUTCOME

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

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

Provide a description of the review outcome that clearly states whether or not
medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

On August 10, 1993, the claimant underwent surgical intervention of the lumbar spine as performed by M.D. Procedures: 1. Left L4-5 laminectomy and nerve root decompression. 2. Left L5-S1 laminectomy and nerve root decompression.

On August 30, 1993, the claimant was re-evaluated by M.D. He no longer had radiating left hip pain or leg pain. He walks well and has good strength in the lower extremities.

On November 15, 1993, the claimant was re-evaluated by M.D. He has some aching in the low back and left hip but no radiating left leg pain. He has mild diminished flexibility of the low back.

On January 10, 1994, the claimant was re-evaluated by M.D. He has aching pain in the low back and occasional aching in the left hip and leg. He is significantly overweight.

On January 21, 1994, the claimant was re-evaluated by M.D. He does have a slight left antalgic gait. A lumbar myelogram was recommended.

On March 8, 1994, a lumbar myelogram was performed. Impression: 1. Small ventral defect of the thecal sac at L4-5. There is also incomplete filling of the L5 nerve root on the left. 2. Mild ventral indentation of the thecal sac centrally at L5-S1 level with no evidence of amputation of nerve root sleeves at this level as interpreted by, M.D.

On March 21, 1994, an MRI of the lumbar spine was performed. Impression: 1. Mild broad based bulging of disc material at L4-5 and L5-S1 level without significant impingement upon the nerve roots nor thecal sac identified, to suggest herniation. There is suggestion of prior laminectomy defect on the left. 2. Very slight prominence of disc material centrally at L3-4 of doubtful clinical significance and without definite evidence of herniation as interpreted by M.D.

On April 18, 1994, the claimant was re-evaluated by M.D. It would be helpful if he lost weight and get in better general physical condition. A lumbar regional Depo Medrol injection will be done.

On June 28, 1994, the claimant underwent surgical intervention of the lumbar spine as performed by M.D. Procedures: 1. Left L4-5 exploration and further opening of lateral recess and foraminotomy for nerve root decompression, recurrent, microscopic. 2. Left L5-S1 exploration with further laminectomy, lysis of adhesions, and further opening of lateral recess and foraminotomy for nerve root decompression, recurrent, microscopic. 3. L4-S1 bilateral transverse process and lateral facet fusion. 4. Left posteromedial iliac crest incision for donor graft.

On July 25, 1994, the claimant was re-evaluated by M.D. He no longer has hip or leg pain but does have postoperative low back pain.

On August 29, 1994, the claimant was re-evaluated by M.D. He has a little left leg pain. He is increasing his activities.

On October 10, 1994, x-rays of the lumbar spine were performed. Impression: Probably bilateral fusion masses from L4 through S1 as interpreted by M.D.

On November 21, 1994, the claimant was re-evaluated by M.D. He has no radiating hip or leg pain. Strength is good in the lower extremities. He also needs to lose weight.

On January 9, 1995, x-rays of the lumbar spine were performed. Impression: Evidence of prior fusion from L4 through S1 with no apparent interval change in the fusion grafts. Mild retrolisthesis of L3-4 is suggested on lateral view as interpreted by M.D.

On January 24, 1995, a lumbar myelogram was performed. Impression: Prior surgery from L4-S1. Lumbar myelogram otherwise shows no significant spinal canal narrowing or evidence for nerve root impingement or displacement as interpreted by M.D.

On June 8, 1995, the claimant was re-evaluated by M.D. He complains of aching pain in the low back across the hips and buttocks but no radiating leg pain. It would be helpful to start a re-conditioning program. He was assigned an 18% whole person impairment by Dr.. X-rays showed normal alignment of the spine with modest degenerative disc changes. No other abnormalities are noted.

On September 28, 1995, the claimant was re-evaluated by, M.D. His condition is basically stable. He walks with a slightly flexed posture at the low back and has some diminished mobility of the low back. He was unable to tolerate physical therapy.

On December 8, 1995, a CT/Myelogram of the lumbar spine was performed. Impression: Left L5 laminectomy and evidence of a posterior fusion. Mild lateral compromise of the subarachnoid space is observed at the L4-5 level as the result of some facet joint hypertrophy. Some mild bilateral facet joint hypertrophy is also observed as interpreted by M.D

On February 6, 1996, x-rays of the lumbar spine were performed. Impression: 1. Prior surgery at L4-S1 with posterolateral fusions. Moderate degenerative disc and facet changes are evidence. 2. No sublaxation or malalignment is observed as interpreted by M.D

On March 25, 1996, the claimant was re-evaluated by M.D. His symptoms have remained unchanged. He is disabled for any type of work.

On October 16, 1996, an MRI of the lumbar spine was performed. Impression: Previous fusions from L4-S1. Mild amount of enhancing scar tissue between the disk and thecal sac at L4-5 and L5-S1. No evidence of recurrent or residual focal disc herniation or spinal stenosis as interpreted by M.D.

On January 20, 1007, the claimant was re-evaluated by M.D. He is still overweight and deconditioned. He should enter a chronic pain program.

On July 29, 1997, a CT/Myelogram was performed. Impression: Dense bony fusions from L4-S1 without objective evidence of focal disc herniations or spinal stenosis as interpreted by M.D.

On October 29, 1997, the claimant was referred to M.D. He was referred for a spinal cord stimulator trial.

On March 2, 1998, the claimant was re-evaluated by M.D. He had excellent results from the temporary spinal cord stimulator. He is a good candidate for a permanent one.

On March 23, 1998, the claimant was referred to M.D. He concurred that a dorsal column stimulator is indicated for permanent use.

On May 5, 1998, the claimant underwent surgical intervention of the lumbar spine as performed by M.D. Procedures: 1. T10-T11 thoracic laminectomy. 2. Placement of Medtronic epidural spinal cord stimulator. 3. Right lateral abdominal incision for placement of battery generator.

On May 28, 1998, the claimant was re-evaluated by M.D. He has had excellent relief of his back and leg pain.

On January 28, 1999, the claimant was re-evaluated by M.D. He is doing very well with his spinal cord stimulator; he gets excellent relief of his back pain and bilateral leg pain. He appears to have lost some weight.

On January 3, 2000, the claimant was re-evaluated by M.D. He continues to do very well with the spinal cord stimulator. He only uses it while active. He is still losing some weight.

On January 15, 2001, the claimant was re-evaluated by M.D. His basic condition is the same. He uses his spinal cord stimulator intermittently for some aching pain in the low back and in the hips and legs.

On October 15, 2001, the claimant was re-evaluated by M.D. He returns early because he has had some pain in the left high paralumbar area. He feels his battery is not functioning properly.

On November 6, 2001, M.D. removed and replaced the Medtronic Irel spinal cord stimulator battery through right abdominal incision.

On November 26, 2001, the claimant was re-evaluated by M.D. He has had remarkable relief of his back and leg pain with a new battery.

On May 19, 2003, the claimant was re-evaluated by M.D. He uses his spinal cord stimulator 3 hours per day. He takes Ambien, Xanax and Talwin. He does a fair amount of walking, one to two miles per day. He is still out of shape and overweight.

On November 20, 2003, the claimant was re-evaluated by M.D. He now uses his stimulator 1 hour per day. He has no radicular leg pain.

On May 20, 2004, the claimant was re-evaluated by M.D. He is very stable. He only has to use the stimulator with activities. He walks well and has good strength in lower extremities.

On January 10, 2005, the claimant was re-evaluated by M.D. He still has some aching pain in the low back. He does quite a bit of walking. He has some diminished mobility of the low back. He is neurologically stable.

On January 5, 2006, the claimant was re-evaluated by M.D. He is still the same in regards to his spine. He still uses his spinal cord stimulator. He has had two myocardial infarctions in the 3 months since he has last seen him and coronary stents were placed.

On July 10, 2006, the claimant was re-evaluated by M.D. He still has some chronic aching in the low back and sometimes in the hips and legs but no worse.

On November 2, 2006, M.D. performed a peer review. He determined that the treatment is considered unreasonable, unnecessary and inappropriate.

On March 5, 2007, the claimant was re-evaluated by M.D. His spinal and neurological examinations are stable.

On September 6, 2007, the claimant was re-evaluated by M.D. He had colon surgery and has lost 50 pounds. He still has chronic back pain.

On March 6, 2008, the claimant was re-evaluated by M.D. He has no change in his complaints.

On March 16, 2009, the claimant was re-evaluated by M.D. He has an exhausted spinal cord stimulator battery that was replacement in 2001. A rechargeable battery was recommended.

On April 14, 2009 M.D. performed a right parathoracic paralumbar incision with exploration of spinal cord stimulator leads/extension lead connection with removal of previous extension lead and placement of a new extension lead. 2. Right lower quadrant incision with removal and replacement of Medtronic rechargeable generator battery with attachment of extension lead.

On November 5, 2009, the claimant was re-evaluated by M.D. He is very pleased with the rechargeable battery. He stays quite active.

On December 27, 2010, the claimant was re-evaluated by M.D. He is unable to charge his spinal cord stimulator battery because it is turned on end in the right flank. The battery needs to be changed and moved to the right posterior iliac area so that it will not shift.

On January 18, 2011, M.D., a neurosurgeon, performed a utilization review on the claimant. Rationale for Denial: The patient has not met with a representative regarding his battery. The spinal cord stimulator battery is unable to be charged because of positioning however the prior notes do not indicate that the battery positioning was the problem regarding charging. There is also no evidence of and spinal cord stimulator leads displacement which would require replacement leads. Therefore, it is not certified.

On February 8, 2011, M.D. a neurosurgeon performed a utilization review on the claimant Rational for Denial: The clinical documentation indicates that the patient has trouble recharging his battery however there is no documentation of any lead displacement which would require lead replacements at this time. Therefore, it is not certified.

PATIENT CLINICAL HISTORY:

On XX/XX/XX this XX year old male sustained an injury to the lumbar spine when he was twisting, lifting and carrying equipment.

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

The previous decisions are upheld. The records reveal that the claimant is having problems recharging the spinal cord stimulator battery. There is no medical evidence to support that the spinal cord stimulator leads have displaced, which would require replacement. Therefore, it is not certified. Please note the ODG was not utilized as it does not address this request.

Reference: *Joshua Rosenow, M.D. 1, Michael Stantom-Hicks, M.B.B.S. 1, Ali R. Rezai, M.D. 1, and Jamie M. Henderson, M.D.. Failure modes of spinal cord stimulation hardware. Journal of Neurosurgery September 2006, Volume 5, Number 3.3. Meyer SC, Swartz K., Johnson JP. Quadriparesis and spinal cord stimulation: case report. Spine (Phila Pa 1976). 2007 Sep 1;32(19): E565-8.*

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** *Joshua Rosenow, M.D. 1, Michael Stantom-Hicks, M.B.B.S. 1, Ali R. Rezai, M.D. 1, and Jamie M. Henderson, M.D.. Failure modes of spinal cord stimulation hardware. Journal of Neurosurgery September 2006, Volume 5, Number 3.3. Meyer SC, Swartz K., Johnson JP. Quadriparesis and spinal cord stimulation: case report. Spine (Phila Pa 1976). 2007 Sep 1;32(19): E565-8*