I-Decisions Inc.

An Independent Review Organization
71 Court Street
Belfast, ME 04915
Phone: (207) 338-1141
Fax: (866) 676-7547
Email: manager@i-decisions.com

NOTICE OF INDEPENDENT REVIEW DECISION

DATE OF REVIEW:
Jul/07/2009

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Spinal cord stimulator peripheral lead replacement

DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
M.D., Board Certified Orthopedic Surgeon

REVIEW OUTCOME:

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

[X] Upheld (Agree)

[ ] Overturned (Disagree)

[ ] Partially Overturned (Agree in part/Disagree in part)

INFORMATION PROVIDED TO THE IRO FOR REVIEW
ODG Guidelines and Treatment Guidelines
Office notes, Dr., 11/02/06, 11/30/06, 02/01/07, 05/24/07, 08/30/07, 01/15/08, 06/26/08, 08/07/08, 10/21/08, 01/21/09, 03/06/08
Addendum, 02/19/07
MRI cervical spine, 03/20/07
Procedure, Dr., 12/09/08
Office note, , NP, 12/16/08
Office notes, Dr., 02/20/09, 04/10/09, 05/08/09
Review, Dr., 04/02/09
MRI cervical spine, 04/03/09
CT cervical spine, 04/03/09
Adverse Determination Notice, 05/19/09
Request for reconsideration, 05/20/09
Adverse determination note, Dr., 05/28/09
Office note, , PA, 06/19/09
Patient History Form, 02/20/09
Official Disability Guideline for Lumbar SCS

PATIENT CLINICAL HISTORY SUMMARY

This xx year-old female claimant passed out at work on xx/xx/xx. When someone tried to pick her up, she was dropped hitting her head on the ground. In 2001 and 2005 the claimant underwent cervical surgeries, one of which included a C2-7 fusion. Her history was also significant for seizures, asthma, arthritis, hyperthyroidism, migraines and drug use. In 11/06 she was noted to have been clean for 20 months. Dr. saw the claimant on 11/02/06 for neck and right hip pain as well as increased depression. She was taking Belacet. Post laminectomy syndrome of the cervical region, headaches, seizures due to head contusion, depression from chronic pain, myofascial pain syndrome and right iliac crest graft site pain were diagnosed. The right anterior iliac crest graft site was injected on 11/30/06 with good relief. Dr. re-evaluated the claimant on 02/01/07 at which time she was taking Vicoprofen, Depakote, Seroquel and Ambien. The examination noted pain to palpation left cervical facet joints, myofascial tenderness of the left semispinals cervicis and left splenius cervicis, myofascial tenderness at supraspinatus (C4-6 and posterior deltoid C5,6). Left biceps and triceps strength were 3/5. She had myofascial tenderness of the shoulder area levator scapulae. Right biceps strength was 4/5 and right triceps strength 3/5. There was decreased cervical pinprick on the at right C6. Another right anterior iliac crest graft site injection was given.

A cervical MRI on 03/20/07 demonstrated mild posterior bulging of the disc at C2-3, postoperative changes from C3-6, disc desiccation at C6-7 with anterior degenerative spondylosis, circumferential posterior bulging of the disc which mildly narrowed the anterior aspect of the spinal canal and it slightly crowds the anterior spinal cord, but no substantial spinal cord compression was evident. The claimant continued treating for neck pain with medications through 08/07/08. She was not able to do the pain program due to childcare issues. She did not want to proceed with cervical fusion or injections.

On 10/21/08 a trial placement of a spinal cord stimulator was performed. At the 10/28/08 evaluation the claimant reported an initial 50 percent reduction of pain with the stimulator. She stated that during the trial had difficulty getting stimulation to complete neck area. She stated the stimulator was on the lower neck region and had significant stimulation in the upper extremities which was bothersome despite multiple attempts at reprogramming. She stated she had relief of neck with stimulation there. She had stimulation to the right arm which bothered her while trying to work. She was taking Soma, Levaquin, Opana ER, Effexor, Depakote and Seroquel. The leads were removed. On 12/09/08 she underwent placement of a peripheral nerve stimulator. At the 12/16/08 followup the claimant reported an initial 50 percent reduction of pain on the right side. She said she did not get stimulation on the left despite 2 reprogrammings. She had concerns about permanent placement that it will not work on the left side. She reported approximately 50-60 percent relief. On 01/21/09 the claimant was re-evaluated and was working full time. She reported a 60+ percent pain relief with peripheral nerve stimulation trial with the ability to tolerate work activity much better, slept better and used less pain medication and an improved quality of life during the trial. She stated she had better stimulator coverage on right than on left but overall was eager to proceed with implantation of device and leads.

Dr. saw the claimant on 02/20/09 noting neck pain and headaches despite traction, Opana ER, Soma, a transcutaneous electrical unit, therapy, trigger point injections and other treatments. Strength and sensation were normal. Post laminectomy syndrome of the cervical spine, degeneration of the cervical disc and chronic pain syndrome were diagnosed. A repeat cervical MRI and CT were recommended. A review by Dr. on 04/02/09 recommended further firm objective evidence prior to proceeding with permanent spinal cord placement. He also recommended a supervised detoxification program.

A cervical MRI and CT on 04/03/09 revealed an anterior cervical discectomy and fusion at C3-6 without complication and mild spondylosis above and below the fusion without abnormal

cord signal intensity. Dr. recommended a discogram to determine if C6-7 was the pain generator. This was denied twice. Dr. re-evaluated the claimant on 05/08/09 noting constant posterior neck pain without upper extremity pain. She had been missing work due to pain. The examination noted paraspinal and bilateral trapezius tenderness, pain with motion and normal upper extremity strength. A spinal cord simulator implantation was recommended, but denied on 2 reviews dated 05/19/09 and 05/28/09. This is currently under dispute.

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

I reviewed the determinations of Dr. dated 05/19/09 as well as that of Dr. 05/28/09 both of which do not feel a spinal cord stimulator with peripheral lead placement is indicated. Records reflect minimal relief of pain unilaterally. The patient has continued complaints of pain. There was insufficient relief from the spinal cord stimulator trial. The reviewer agrees with the prior reviewer's that the case does not meet guidelines for a spinal cord stimulator. The reviewer finds that medical necessity does not exist for Spinal cord stimulator peripheral lead replacement.

Official Disability Guidelines Treatment in Worker's Comp 2009 Updates, (i.e. Pain – Spinal Cord Stimulator and Psychological Screens)

– Pain Chapter - Indications for stimulator implantation

• Failed back syndrome (persistent pain in patients who have undergone at least one previous back operation and are not candidates for repeat surgery), when all of the following are present: (1) symptoms are primarily lower extremity radicular pain; there has been limited response to non-interventional care (e.g. neuroleptic agents, analgesics, injections, physical therapy, etc.); (2) psychological clearance indicates realistic expectations and clearance for the procedure; (3) there is no current evidence of substance abuse issues; (4) there are no contraindications to a trial; (5) Permanent placement requires evidence of 50% pain relief and medication reduction or functional improvement after temporary trial. Estimates are in the range of 40-60% success rate 5 years after surgery. Neurostimulation is generally considered to be ineffective in treating nociceptive pain. The procedure should be employed with more caution in the cervical region than in the thoracic or lumbar due to potential complications and limited literature evidence

• Complex Regional Pain Syndrome (CRPS)/Reflex sympathetic dystrophy (RSD), 70-90% success rate, at 14 to 41 months after surgery. (Note: This is a controversial diagnosis.

• Post amputation pain (phantom limb pain), 68% success rate (Deer, 2001)

• Post herpetic neuralgia, 90% success rate (Deer, 2001)

• Spinal cord injury dysesthesias (pain in lower extremities associated with spinal cord injury

• Pain associated with multiple sclerosis

• Peripheral vascular disease (insufficient blood flow to the lower extremity, causing pain and placing it at risk for amputation), 80% success at avoiding the need for amputation when the initial implant trial was successful. The data is also very strong for angina.

Psychological Evaluations - Recommended pre spinal cord stimulator (SCS) trial.

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

[ ] ACOEM-AMERICA 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

[X] MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

[ ] MERCY CENTER CONSENSUS CONFERENCE GUIDELINES

[ ] MILLIMAN CARE GUIDELINES

[X] 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)