

Becket Systems

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NOTICE OF INDEPENDENT REVIEW DECISION

DATE OF REVIEW:

Sep/26/2009

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Spinal Cord Stimulator Placement with Dual Octrodeleads @ T8

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:

Upheld (Agree)

Overturned (Disagree)

Partially Overturned (Agree in part/Disagree in part)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

ODG Guidelines and Treatment Guidelines

Denial Letters 07/29/09, 08/14/09

Office notes, Dr. 09/03/08, 10/31/08, 01/01/09, 02/02/09

Dr. 12/11/08, 02/19/09, 03/23/09, 04/21/09, 05/21/09, 07/07/09,

Psychological Assessment, 11/17/08

Placement trial 12/30/08

07/31/09, 08/04/09, 09/01/09

FNP 11/07/08, 12/02/08, 01/05/09

PATIENT CLINICAL HISTORY SUMMARY

The claimant is a female with a history of bilateral lower extremity reflex sympathetic dystrophy (RSD). She was treated with a sympathetic infusion. In October 2008, the claimant developed left leg symptoms whereas previously she had only right leg symptoms. There was allodynia and vasomotor changes in the right leg. On the left, there was allodynia to the mid shin that was non-dermatomal and the left foot was cooler than the right. A spinal cord stimulator was recommended. On 11/17/08 a Psychological Assessment found that she was a good candidate for medical techniques and on 12/30/08 she underwent placement of a trial spinal cord stimulator.

On 01/01/09, Dr. noted the claimant had fever and redness and as such removed the stimulator. The claimant reported she had 50 percent pain relief; she had increased function

and did housework and outdoor activities that she had not done in a long time; the claimant also noted she had cut down use of pain medication by 50 percent. The claimant continued to see Dr. for medications. The claimant had a second opinion from a doctor in 04/09 who agreed with the plan for a paddle stimulator through thoracic laminotomy. By 05/21/09, the SCS was still not approved. Her exam was "unchanged" and medications were continued. On 07/29/09, denied the spinal cords stimulator on peer review. The reviewer noted that the claimant had 50 percent relief with the trial but there was no documentation of increased function or decreased medication use and that an 8-day hospital stay was not appropriate.

On 08/04/09, the nurse practitioner noted the claimant was taking 10 Norco a day and that medications allowed her to stay functional. Mottling in both extremities persisted. An appeal for the spinal cord stimulator was denied. The claimant was seen on 09/01/09 for bilateral leg pain. Her treatment for the RSD had included therapy and behavioral therapy, a pain program and medications that made her functional although she desired to stop medications. The examination documented mottling and allodynia both lower extremities with numbness and tingling.

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

When one turns to the ODG guidelines, complex regional pain syndrome is indeed a well recognized indication for spinal cord stimulator placement. Apparently, previous sympathetic blockade was unsuccessful. Multiple medications have been unsuccessful. A psychologic screening was unremarkable. When one turns closely to the notes after the trial spinal cord stimulator, the treating physician clearly documented 50 percent relief of pain and also clearly documented an increased activity level around the home and outside of the home, as well as a 50 percent reduction in pain medication. The records do not contain any references to substance abuse issues. The records provided in this case satisfy the ODG guidelines for stimulator implantation. Excellent documentation has been provided of the response to the trial stimulator. The psychologic clearance was appropriately performed. Failure of very thorough conservative care was outlined. Complex regional pain syndrome is an accepted diagnosis for spinal cord stimulation as outlined in the ODG guidelines. The reviewer finds that medical necessity exists for Spinal Cord Stimulator Placement with Dual Octrodeleads @ T8.

Official Disability Guidelines 2009 Pain

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. (Flotte, 2004)

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

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)