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Notice of Independent Review Decision

DATE OF REVIEW: 12/03/08

IRO CASE #:

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

This case was reviewed by a Pain Management (Board Certified), Licensed in Texas and Board Certified. The reviewer has signed a certification statement stating that no known conflicts of interest exist between the reviewer and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent (URA), any of the treating doctors or other health care providers who provided care to the injured employee, or the URA or insurance carrier health care providers who reviewed the case for a decision regarding medical necessity before referral to the IRO. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Trial of spinal cord stimulator for chronic lumbar pain, as an outpatient

REVIEW OUTCOME

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

Overturned (Disagree)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- o Submitted medical records were reviewed in their entirety.
- o Treatment guidelines were provided to the IRO.
- o July 2, 2007 COPE Psychological Screening from Dr.
- o January 23, 2008 Follow-up report from Dr.
- o January 31, 2008 Procedure report - facet injections - from Dr.
- o February 14, 2008 Follow-up report from Dr.
- o March 3, 2008 Lumbar MRI as read by Dr.
- o March 7, 2008 Follow-up report from Dr.
- o April 9, 2008 Follow-up report from Dr.
- o June 25, 2008 Radiology report from Dr.
- o June 25, 2008 IME report from Dr.
- o June 25, 2008 Follow-up report from Dr.
- o July 15, 2008 Letter of Medical Necessity from Dr.
- o July 23, 2008 Radiology report from Dr.
- o July 23, 2008 Follow-up report from Dr.
- o August 21, 2008 Procedure Note - Hardware Injections - from Dr.
- o September 18, 2008 Follow-up report from Dr.
- o September 18, 2008 Pre-certification information sheets 3 pp.
- o September 24, 2008 Peer review for SCS trial non-certification from Dr.
- o September 25, 2008 Notice of denial of pre-authorization trial
- o October 16, 2008 Notice of denial for reconsideration for
- o November 19, 2008 Request for IRO

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records and prior reviews the patient is a xx-year-old employee who sustained an industrial injury to the low back on xx/xx/xx. The patient is followed with a diagnosis of post-op laminectomy and discectomy, post-op fusion of the lumbar spine at three levels, and degenerative disc disease of the lumbar spine. The patient is described as 5' 9" and 200 pounds.

The patient underwent spine surgery in 1999 which did not relieve his back pain. He was unable to work except for selling a few cars over the phone and he was considered for a revision surgery. A pre-surgical Psychological Screening was performed in July 2007. The patient was cleared for surgery with a good prognosis for pain reduction and functional improvement. The report indicated the patient has very broken English and did not understand some questions despite repeated rephrasing. On October 2, 2007 the patient underwent surgery of retroperitoneal spinal exposure of L4-5 and L5-S1 with immobilization of the aorta, inferior vena cava, iliac artery and vein, ureter and anterior lumbar interbody fusion with partial vertebrectomy, discectomy, and cage insertion. Three visits of work hardening were provided on March 3, 4, and 5 of 2008.

On reevaluation January 23, 2008 the patient reported continuing pain at the left lower lumbar region of one-week duration. He is scheduled for a facet injection on January 30, 2008. He is neurologically intact. After the injections we will get him enrolled in a chronic pain management program and see him back in 6-8 weeks at the tail end of the program.

On February 14, 2008 the patient reported 50% pain relief for two days with recently administered intra-articular facet injection L3 to S1. His pain has since returned to pre-injection intensity. He has full motor strength and sensation, symmetric reflexes and a negative straight leg raise. There is diffuse tenderness in the lumbar region and pain with flexion and extension.

Lumbar MRI of March 5, 2008 shows good interbody fusion which is stable. No significant compression of the exiting nerve roots or compression deformity of the lumbar vertebral bodies is visualized.

On March 7, 2008 the patient reported the 8-hour therapy sessions of the pain management program are too painful to complete. He also states he does not have the time for 8 hour sessions. The provider informed that it was imperative he complete the program. He complains of severe pain throughout the program and refuses to complete it at this point. Cross-reference with the IME report of July 25, 2008 indicates the patient participated in 3 visits of a Work Hardening Program on March 3, 4 and 5, 2008. An MRI is recommended.

At follow-up of April 9, 2008 the patient is noted to be enrolled in the chronic pain management program. Use of a spinal cord stimulator was discussed as his pain was not well localized. He has gone through numerous injections as well as a fusion at L5-S1. We would like him to complete the chronic pain management program and then we will reevaluate for a spinal cord stimulator.

When reevaluated on June 25, 2008 it was reported that the patient is currently being assessed psychologically in the chronic pain management program. He is somewhat better with this, but continues to have increasing symptoms from time to time. He has pain at the incision site and with flexion and extension. He is intact neurologically. Radiographs show well-placed pedicle screws, however the pedicle screw at L4 could be loose.

An Independent Medical Examination was performed on June 25, 2008. The patient is post-op surgery of October 2007. Due to his degenerative disc disease and surgical procedures he is anticipated to have ongoing, chronic complaints of back pain. There is no current indication for injections or surgery. He does not require DME or pain management or work hardening. He has already participated in aquatic therapy and work hardening for two weeks. At this time he should be transitioned to a home exercise program. He is using Celebrex. Absent gastrointestinal upset, he could be transitioned to over-the-counter anti-inflammatory medications. As he has a static state and is not showing a tremendous amount of improvement with Lyrica, it is recommended that Lyrica be weaned. ODG does not support continued, chronic long-term use of Zanaflex. Continued use of the short-acting opioid Lortab 10 should be considered in regards to guidelines. It is supported if he is showing decrease in pain and increase in function.

Per the IME, the patient has limited lumbar flexion and extension. He has full lower extremity motor strength and a normal sensory exam but he is unable to heel and toe walk or squat and rise due to low back pain. There is decreased sensation "on the L2" bilaterally. Straight leg raising is negative. He is not a surgical candidate at this time and does not need continued pain injections. Records review noted a consultation of April 2004 which reported the patient as status post lumbar laminectomy with motor deficit, history of arachnoiditis and a candidate for a dorsal column stimulator. A consultation of May 2004 noted that the patient is currently selling cars by phone and can continue to do so. It is noted that the medical records reviewed at IME are currently only up to March 5, 2008 at which time 3 visits of work hardening had been completed.

On July 15, 2008 continued use of TENS was requested as the trial of TENS showed decreased muscle spasms and 15% gain in range of motion.

On July 23, 2008 the patient reported continuing back pain with some numbness in his anterior thighs. He is tender along the incision sites. He has a normal neurologic examination. A hardware injection is planned to rule out hardware mediated pain. Radiographs were taken and show good fusion and positioning of the instrumentation although the pedicle screws at L4 could be loose.

Per the medical report of September 18, 2008 the patient is still having quite a bit of pain in his back that is radiating down to his leg. He underwent a hardware injection to rule out the possibility of hardware causing his pain. He did not have much in the way of relief with the injection and it is not necessary to remove his hardware. His back pain that radiates into his leg continues and a spinal cord stimulator is recommended for better pain control.

Request for trial of a spinal cord stimulator for chronic lumbar pain on an outpatient basis was not certified in review on September 24, 2008 with rationale that the patient was attending a pain management program and upon completion might not require a spinal cord stimulator. An attempt to discuss the case with the provider was attempted but not realized.

Request for reconsideration of trial of a spinal cord stimulator was not certified in review on October 16, 2008 with rationale that the injured worker has recently undergone an Interdisciplinary Chronic Pain Program, the COPE Program, and the provider has not addressed the results of this program in regards to providing additional intervention or procedures. "He did not indicate whether he had discussed with any provider from COPE as to whether this injured worker would benefit from a spinal cord stimulator as opposed to further follow-up with the COPE program."

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

The medical records indicate the provider is not able to localize the patient's continuing left lower back pain. Pedicle screw loosening was suspected but was ruled out with a hardware injection. Intra-articular facet injection provided relief for only several days which ruled out facet mediated pain. The patient was enrolled in a chronic pain management program (CPMP) but complained it was too painful and he did not have the time for daily 8-hour sessions.

The CPMP is not well reported. The report of January 23, 2008 indicates the CPMP was anticipated to be about 10 weeks in duration. On March 7, 2008 the patient states the 8-hour sessions are too painful and anyway he does not have the time. He is encouraged to continue participation in the CPMP. On April 9, 2008 the patient is reported to be still enrolled in the CPMP. On June 25, 2008 the patient states that "he is currently involved with a psychologist for a psychological exam as well as chronic pain management. He is somewhat better with this." The IME does discuss the CPMP although the Records Review notes the progress reports of the first 3 visits on March 3, 4, 5, 2008. The patient is recommended by the IME to continue self-management of his chronic pain condition. The pain is noted to be unable to heel and toe walk or squat and rise due low back pain, which indicates marked chronic pain.

In September the provider recommends a spinal cord stimulator to help control the back radiating into the patients' leg. The reviewer states the patient is "currently attending a pain management program." which is not likely. Unfortunately the provider did not return calls to discuss the case and present his rationale. The provider was also not available to present additional rationale and clarify the results of the CPMP during the reconsideration process.

Per ODG, there is some evidence supporting the use of Spinal Cord Stimulation (SCS) for Failed Back Surgery Syndrome (FBSS) and other selected chronic pain conditions. Further, the introduction of the percutaneous electrode implantation has enabled trial stimulation, which is now commonly recognized as an indispensable step in assessing whether the treatment is appropriate for individual patients. Fair evidence supports the use of spinal cord stimulation in failed back surgery syndrome, those with persistent radiculopathy after surgery, according to the recently released joint American College of Physicians/ American Pain Society guideline recommendations on surgery and interventional treatments. And finally, according to a quite recent study, at 24 months, the primary outcome was achieved by 37% randomized to SCS versus 2% to conventional medical management (CMM), and by 47% of patients who received SCS as final treatment versus 7% for CMM. Current guidelines support SCS as cost-effective in the long term.

The patient is status post two lumbar surgeries and can be considered to have FBSS. Injections and pain management have not resolved his persistent low back and left leg pain. He does not have frank radiculopathy but is unable to heel and toe walk or squat and rise due low back pain. The IME does not appear to have records more current than approximately 110 days prior to the examination of July 25, 2008 and the patient's participation in a pain management program is not mentioned. The IME Records Review notes "Work Hardening Program Progress Notes (total of 3 visits) dated March 3,4,5, 2008." The patient therefore initiated the CPMP on March 3, 2008. The CPMP was anticipated to last approximately 10 weeks. The patient has a poor command of the English language and so he may not have explained his participation in the CPMP to the IME. The medical report of April 9, 2008 indicates the patient is "currently enrolled in a CPMP." On June 25, 2008 the provider states the patient is involved with a psychologist and "chronic pain management." The patient appears to have participated in CPMP from March 3 through at least June 25, 2008.

The initial reviewer did not appear to have any objection to a trial of SCS other than further clarification of possible benefit from the pain management program. The second level reviewer also noted that the results of the COPE program were not clarified and, the provider "did not indicate whether he had discussed with any provider from COPE as to whether this injured worker would benefit from a spinal cord stimulator as opposed to further follow-up with the COPE program." The patient meets the basic guideline requirements for a trial of this device. It would not be fair to deny the patient a trial of this device solely on poor reporting in regards to the CPMP.

Therefore, my determination is to overturn the previous non-certification of trial of a spinal cord stimulator for chronic lumbar pain on an outpatient basis.

The IRO's decision is consistent with the following guidelines:

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

The Official Disability Guidelines - Low Back 11-17-2008:

Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated. See the Pain Chapter for Indications for stimulator implantation. There is some evidence supporting the use of Spinal Cord Stimulation (SCS) for Failed Back Surgery Syndrome (FBSS) and other selected chronic pain conditions. Spinal Cord Stimulation is a treatment that has been used for more than 30 years, but only in the past five years has it met with widespread acceptance and recognition by the medical community. In the first decade after its introduction, SCS was extensively practiced and applied to a wide spectrum of pain diagnoses, probably indiscriminately. The results at follow-up were poor and the method soon fell in disrepute. In the last decade there has been growing awareness that SCS is a reasonably effective therapy for many patients suffering from neuropathic pain for which there is no alternative therapy. There are several reasons for this development, the principal one being that the indications have been more clearly identified. The enhanced design of electrodes, leads, and receivers/stimulators has substantially decreased the incidence of re-operations for device failure. Further, the introduction of the percutaneous electrode implantation has enabled trial stimulation, which is now commonly recognized as an indispensable step in assessing whether the treatment is appropriate for individual patients. These implantable devices have a very high initial cost relative to conventional medical management (CMM); however, over the lifetime of the carefully selected patient, SCS may lead to cost-saving and more health gain relative to CMM for FBSS. See the Pain Chapter for complete list of references. Fair evidence supports the use of spinal cord stimulation in failed back surgery syndrome, those with persistent radiculopathy after surgery, according to the recently released joint American College of Physicians/ American Pain Society guideline recommendations on surgery and interventional treatments. (Chou, 2008) The National Institute for Health and Clinical Excellence (NICE) of the UK just completed their Final Appraisal Determination (FAD) of the medical evidence on spinal cord stimulation (SCS), concluding that SCS is recommended as a treatment option for adults with failed back surgery syndrome lasting at least 6 months despite appropriate

conventional medical management. (NICE, 2008)

Recent research: New 24-month data is available from a study randomizing 100 failed back surgery syndrome patients to receive spinal cord stimulation (SCS) plus conventional medical management (CMM) or CMM alone. At 24 months, the primary outcome was achieved by 37% randomized to SCS versus 2% to conventional medical management (CMM), and by 47% of patients who received SCS as final treatment versus 7% for CMM. All 100 patients in the study had undergone at least one previous anatomically successful spine surgery for a herniated disk but continued to experience moderate to severe pain in one or both legs, and to a lesser degree in the back, at least six months later. Conventional medical therapies included oral medications, nerve blocks, steroid injections, physical and psychological therapy and/or chiropractic care. (Kumar, 2008)