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Notice of Independent Review Decision

MEDICAL RECORD REVIEW:

DATE OF REVIEW: 05/05/2011

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) Doctor, 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

Outpatient permanent implantation of PNS stimulator as related to the cervical spine

REVIEW OUTCOME

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be: Overturn (Disagree)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records and prior reviews the patient is a female employee who sustained an injury to the neck and low back on when she fell about four feet from a ladder while doing her duties. She sustained a cerebral concussion, neck and low back pain. She is maintained on medications for chronic pain. Co-morbid conditions include recent cardiac issues including congestive heart failure and mitral valve insufficiency with prosthetic replacement surgery, history of migraine headaches, asthma, depression, chronic sinusitis, angina, COPD, GERD, Type 2 diabetes and tobacco abuse. Her history includes placement of a spinal stimulator in 2001 which was changed to a new one in 2006 and eventually removed in December 2009 because the skin had eroded through the generator site in her buttock region.

opinions were provided on April 19, 2007. The examiner noted that she has had a spinal cord stimulator (SCS) placed to address her neck and occipital neuralgia. The leads were revised about four months prior. She is using BuSpar, Norco, Ambien and Prozac. She notes her stimulator is not working well and she also has ongoing back pain that travels to the left leg. Imaging showed a right disc herniation at C4-5 and some narrowing of the C5-6 disc. She had mitral valve repair in August 2000 and congestive heart failure. She was on Coumadin at that time. She had left occipital nerve blocks and CESI in 2001 and 2002. In 2002 she was using a bilateral occipital nerve stimulator with good resolution of her headaches. Records from 2003 note she also has Major Depressive Disorder. Neck motion is limited and painful. Upper extremity circulation is intact. She has normal gait. A correct diagnosis would be neck and back strain plus occipital neuralgia secondary to chronic pain. She will need continued use of the SCS an ongoing treatment. She should see a doctor every 2-3 months. The SCS batteries will need to be revised about every

5 years. Her thoracic x-rays are unremarkable.

Psychiatric follow-up of February 9, 2009 indicate the patient has recurrent Major Depressive Disorder, chronic low back pain, neck pain, mitral valve regurgitation surgery (2000), fibromyalgia, IBS and a SCS in place. She will continue Cymbalta, Wellbutrin XL, Ambien and Flexeril.

The patient was seen for recurring headaches on April 16, 2009. She smokes an average of half a pack daily. She has a normal neurological exam. She has occipital neuralgia and brachial neuritis. She has a SCS and the leads may have migrated.

On October 6, 2009 the provider recommended her occipital nerve stimulator be reprogrammed. On November 5, 2009 she is doing better since the stimulator was reprogrammed. Her low back and left leg pain are flared up. She was provided a caudal ESI on November 23, 2009, which provided 60% improvement per report of December 21, 2009. It was noted on December 21, 2009 that her battery is exposed and must come out.

On December 31, 2009 procedures were undertaken for exposure of occipital nerve stimulation lead and removal of the battery and leads. She had a connection piece around the right scapula and a battery/lead in the right buttock. Chest films showed mild cardiomegaly status post midline sternotomy and prosthetic valve placement. On January 7, 2010 the wound site was healing well.

She developed itching with use of Keflex per report of January 11, 2010. This became worse and per report of January 18, 2010 had to go to the emergency department for steroids. Her wound is doing well at this time. When she is ready, the battery will be replaced.

Then patient was seen in the emergency department on February 25, 2010 for yellow/green drainage from her incision site. A stimulator was removed, but the wires remain. The neurosurgeon is reluctant to remove the wires without frank infection. Wound cultures were taken. Chest and lumbar x-rays were unremarkable. Antibiotics were provided. The patient was not admitted and was discharged with medication of Clindamycin for staph. On March 5, 2010 the patient underwent procedures for removal of her SCS leads. When seen on March 15, 2010 there was concern for purulent drainage and she was admitted for further evaluation.

The patient was admitted on March 15, 2010 for wound infection and fluid collection along the tract of the previous SCS. She underwent CT scan which showed hypodensity of the thyroid gland, cervical ultrasound which showed small non-specific presumably post-operative fluid collection near the incision site posteriorly at the C6-7 level, thoracic CT scan of which showed mild degenerative changes, and transesophageal echo which showed intact ring of her repaired mitral valve. Cultures were negative but she was recommended to continue IV antibiotics through the end of April.

On March 16, 2010 the consulting physician noted she did well with her first SCS from 2001 to 2006. In 2006 she had a broken lead and it had to be replaced. The new stimulator was placed in 2006 and remained in place until December 30, 2009 when it was removed because the skin had eroded through the generator area of her buttock region. The lead wires were left in place. She had an incision also in the scapular area that never really healed. She was visiting North Carolina and at that time she was seen

in an emergency room and given a course of antibiotics. She has had three rounds of antibiotics. Because of persistent drainage she went back to OR on March 5, 2010 and had the wires of her C-spine/T-spine area removed. She did well but then developed

increased purulence and drainage from her thoracic surgical site and she was admitted yesterday for further evaluation. She continues to smoke. Her blood and wound cultures are negative to date. Additional diagnostics and a course of IV antibiotic therapy were recommended.

Transthoracic echo was done on March 18, 2010. The physician determined that she needs an updated cardio catheterization due recent chest pains, but she is not symptomatic and it can be put off until she is free of infection. On March 23, 2010 some fluid

was aspirated from the posterior neck incision site. Chest films of March 26, 2010 showed mild left basilar atelectasis.

On April 12, 2010 the patient's work comp provider discontinued Bactrim, Cleocin, Kelflex and Norco. She was on Dilaudid in the hospital and this was the only thing that helped her headache. She has three more weeks of IV antibiotics remaining and her headaches are worse. Will restart Dilaudid for one month. Her wound is closed and healing nicely.

On April 29, 2010 the patient is using Ambien, Cymbalta, Dilaudid and Flexeril. Her primary concern is right lower extremity pain, although her headaches are again a problem. Lumbar MRI was recommended. She is scheduled for further cardiac evaluation. Lumbar MRI performed May 21, 2010 showed some impingement on the exiting left L5 nerve root at L4-5 in the left neural foramen due a left lateral focal small disc herniation and at L5-S1, mild impingement on the exiting right L5 nerve root in the right neural foramen due a right far lateral broad-based disc herniation or disc-osteophyte complex. There is no central stenosis at any level.

On May 27, 2010 the patient was provided in-office transforaminal lumbar epidural steroid injection at right L4-S1. On July 1, 2010 she reported her back and radiating pain were much better. Her headaches continue. Consideration was given for greater and lesser occipital nerve pulsed RFTC in-office instead of re-implanting her occipital nerve stimulator. On July 12, 2010 pulsed RFTC procedures were performed to lesion the greater and lesser occipital nerve.

On August 31, 2010 the patient complained of increased severe headache. She had done well with the last occipital RFTC and she would like a repeat procedure. Approval would be sought. In the meantime, she will use Norco. On September 30, 2010 repeat RFTC procedures were carried out. On November 4, 2010 she reported the sub-occipital pain had resolved on the right but continues slightly on the left. Her low back pain is also increased. Trigger point injections were provided for lumbar myofascial pain.

The patient was seen on November 4, 2010 for recurrent left occipital and left posterior neck pain. Trigger point injections were provided.

On February 10, 2011 her occipital pain is already returning. She is asking to have the occipital stimulator replaced. The plan is to re-implant bilateral large quadrodes with St. Jude rechargeable battery to the bilateral occipital nerves.

Request for outpatient permanent implantation of PNS stimulator as related to the cervical spine was considered in review on February 23, 2011 with recommendation for non-certification with rationale that PNS or sympathetic therapy is not recommended by ODG and there is no documentation of a PNS trial. The documents reviewed included a report dated 2/10/11 and a nurse case summary.

The patient was reevaluated on February 25, 2011. Occipital PNS denied because she has not had a trial. Her pain level is higher than prior. The effectiveness of Cymbalta, Norco and Flexeril is fair. She responded well to nerve lesioning for about two months, and then the pain returned. She is also using Ambien. She currently smokes an average of one pack daily. She had an occipital stimulator for years that worked as the best treatment for her. Unfortunately it had eroded through her skin at the battery site and had to be removed. It is absurd to deny placing the stimulator back in because she has not had a trial when she had the device implanted for years. Request for reconsideration outpatient permanent implantation of PNS stimulator as related to the cervical spine was considered in review on March 22, 2011 with recommendation for non-certification. Documents reviewed include a report dated 2/25/11 and a nurse summary. Per the reviewer, a permanent stimulator implant is requested for occipital nerve placement for sub-occipital pain from severe headaches. The patient has a previous spinal cord stimulator (SCS) that eroded through her skin at the battery site. She has a history of wound infection requiring IV antibiotics. This included infection of her leads. It appears the SCS was not working appropriately for several years. She has a history of migraine headaches, congestive heart failure, mitral valve insufficiency, depression and diabetes. In May she had a heart catheter that showed 85% blockage and an aneurysm. Her other arteries were blocked 50%. She has been on Coumadin in the past. A current list of meds taken from underlying medical disease is not given. She smokes one pack per day. She has not only cervical pain and headaches but also has low back and right leg pain. Rationale for denial notes, this is an end-stage procedure and there has been no attempt to rule out medication rebound headaches as the etiology of her symptoms. There has been no evidence of a complete medical evaluation by her PCP to rule out other medical causes of headaches. The provider does not include a complete medical history including medications. The records do not indicate that this treatment was successful. There has been no trial. There is no recent psychological evaluation. The denial is based on ODG.

The patient was most recently reevaluated on March 28, 2011. The stimulator re-implantation was denied a second time. The denial will be appealed. She would like the stimulator replaced and it makes no sense to do a trial again.

Request was made for an IRO.

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

ODG - SCS is recommended as a treatment option for adults with chronic neuropathic pain lasting at least 6 months despite appropriate conventional medical management, and who have had a successful trial of stimulation. Recommended conditions include failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS), post amputation pain (phantom limb pain), post herpetic neuralgia, spinal cord injury dysesthesias (pain in lower extremities associated with spinal cord injury) and pain associated with multiple sclerosis. ODG recommends psychological screening prior to all SCS implantations.

The patient previously had a peripheral stimulator in place which per medical records did offer pain relief with regard to her occipital headaches. The initial UR review erroneously described the PNS re-implantation request as sympathetic therapy and issued a denial without foundation. Given the patient's prior history of successful occipital stimulator use, another trial is not

medically necessary. Assuming that she is medically cleared with regard to her history of infection, it would be reasonable to re-implant the PNS device at this time.

Therefore, my recommendation is to disagree with the previous non-certification for outpatient permanent implantation of PNS stimulator as related to the cervical spine.

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 04-18-2011 Pain Chapter: Spinal Cord Stimulators:

Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated, for specific conditions indicated below, and following a successful temporary trial. Although there is limited evidence in favor of Spinal Cord Stimulators (SCS) for Failed Back Surgery Syndrome (FBSS) and Complex Regional Pain Syndrome (CRPS) Type I, more trials are needed to confirm whether SCS is an effective treatment for certain types of chronic pain.

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.

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 chronic neuropathic pain lasting at least 6 months despite appropriate conventional medical management, and who have had a successful trial of stimulation. Recommended conditions include failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS).

Only 25% of SCS patients in this study received psychological screening prior to the trial, whereas ODG recommends psychological screening prior to all SCS implantations. Because few patients in any group in this study achieved success at any follow-up, the authors suggested that no treatment has a substantial impact on average in this patient group.

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)

For average hospital LOS if criteria are met, see Hospital length of stay (LOS).