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An Independent Review Organization

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Notice of Independent Review Decision

Case Number:

Date of Notice: 01/21/2016

Review Outcome:

A description of the qualifications for each physician or other health care provider who reviewed the decision:

Orthopedic Surgery

Description of the service or services in dispute:

1 spinal cord stimulator medtronic battery restore and additional lead placement under epidurogram and fluorsocopy

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)

Patient Clinical History (Summary)

The patient is a male with a longstanding history of low back pain dating back to an on the job injury in XXXX. The patient's surgical history was noted to include microdisectomy in XXXX and lumbar fusion at L4-5 and L5-S1 in XXXX as well as permanent spinal cord stimulator placement in XXXX. The patient was also noted to undergo spinal stimulator replacement in XXXX. As of XX/XX/XXXX, the patient was noted to have been noticing sharp pains in the leg that was described as "bee stings" intermittently. On XX/XX/XX, the patient was being seen for re-evaluation and medication refills. At that time, the patient was noted to have complaints of low back pain that radiated to the left lower extremity. It was also noted at that time, the patient stated that he began to slowly worsen over the years. On physical examination, the patient was noted to be sitting uncomfortably; however, he did not have difficulty acquiring a full upright position when getting out of a chair. There is evidence of antalgic gait on the left. Straight leg raise was positive on the left at 75 degrees. Lower extremity strength was symmetrical and present in all lower extremity muscle groups. Sensory examination demonstrated decreased sensation to light touch in the L4-5 dermatomes. The most recent clinical note dated xxxxx indicated the patient was being seen for a 3 month followup. It was noted at that time, the patient had complaints of new pain in the right posterior vertebral angle. The patient denied any new injuries. It was also noted at that time, the patient's medications were not covering the pain very well. The patient had no urinary tract symptoms. It was indicated at that time that the patient had to take more of his prescribed Vicodin; approximately 6 per day, which brings the patient's pain down from a 9 to a 6. On physical examination, the patient had an antalgic gait on the left. Straight leg was positive on the left at 75 degrees. There was no tenderness over the right costovertebral angle to palpation and percussion. Lower extremity strength was symmetrical and present in all lower extremity muscle groups. Sensation remained decreased to light touch in the L4-5 distribution. It was noted at that time that patient was recommended to discuss this new pain with his primary care provider. A surgery slip dated xxxxxx indicated the patient was being recommended to undergo Medtronic restore battery replacement and placement of additional lead for left leg pain.

Analysis and Explanation of the Decision include Clinical Basis, Findings and Conclusions used to support the decision.

According to X, spinal cord stimulators should be reserved as a late resort for patients with chronic intractable pain when there is evidence of other treatment modalities (pharmacological, surgical, physical, or psychological therapies) having been tried and failed and there was documentation that the patient had received relief from temporary implanted electrode prior to permanent implantation. In regards to the request for replacement of the battery, the restore neurostimulator battery is capable of providing 9 years of operation, however, it is recommended that the battery be replaced between 8 and 8.5 years as the neurostimulator stops providing stimulation at the xxx year mark.

It remain unclear as to why the patient is being recommended for placement of an additional lead. The most recent clinical note dated XX/XX/XX indicated that the patient has new complaints of costovertebral angle pain which is an indication of a potential underlying renal problem. There was no clear evidence provided that the patient was having new complaints associated with the lumbar spine or documentation as to what level the requested additional lead placement was being recommended. Furthermore, there is also no documented evidence of the patient having failed all other treatments prior to the consideration of the placement of an additional spinal cord stimulator lead. It also remains unclear as to why the patient is being recommended for replacement of the spinal cord stimulators battery. Medtronic neurostimulator batteries last xxxx years and the documentation indicated that the patient had underwent spinal cord stimulator replacement in XXXX, meaning that the battery should have approximately 3 years left better replacement is required. In addition, there is no documentation that the spinal cord stimulators elective replacement indicator is displayed indicating the need for battery replacement.

Therefore, the request for 1 spinal cord stimulator Medtronic battery restore and additional lead placement under epidurogram and fluoroscopy is not medically necessary and thus the prior determination is upheld.

A description and the source of the screening criteria or other clinical basis used to make the decision:

- ACOEM-America College of Occupational and Environmental Medicine um
- knowledgebase AHCPH-Agency for Healthcare Research and Quality Guidelines
- DWC-Division of Workers Compensation Policies and
- Guidelines European Guidelines for Management of Chronic
- Low Back Pain Interqual Criteria
- Medical Judgment, Clinical Experience, and expertise in accordance with accepted medical
- standards Mercy Center Consensus Conference Guidelines
- Milliman Care Guidelines
- ODG-Official Disability Guidelines and Treatment
- Guidelines Pressley Reed, the Medical Disability Advisor
- Texas Guidelines for Chiropractic Quality Assurance and Practice
- Parameters Texas TACADA Guidelines
- TMF Screening Criteria Manual
- Peer Reviewed Nationally Accepted Medical Literature (Provide a description)

The Centers for Medicare and Medicaid Services. National Coverage Determination for Electrical Nerve Stimulators. Publication 100-3. Manual Section 160.7. Version 1.

Medtronic, (2014). Neurostimulation systems for pain. System Eligibility, Battery Longevity, & Specifications. Retrieved from http://manuals.medtronic.com/wcm/groups/mdtcom_sg/@emanuals/@era/@neuro/documents/documents/contrib_205867.p df

- Other evidence based, scientifically valid, outcome focused guidelines (Provide a description)