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Notice of Independent Review Decision

DATE OF REVIEW: 08/11/2008

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 Orthopaedic Surgery, 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

External bone growth stimulator

REVIEW OUTCOME

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

Overtuned (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 February 11, 2008 X-ray report from hospital
- o February 11, 2008 Operative Report, repair of C5-6 pseudoarthrosis, from Dr.
- o February 12, 2008 Prescription form for post-op DME of neck brace from (illegible)
- o March 20, 2008 Progress notes from RDP
- o April 18, 2008 Progress notes from RDP
- o May 13, 2008 Initial report from Dr.
- o May 30, 2008 Progress notes from Orthopedic Center
- o June 17, 2008 Non-certification of request for DME purchase external bone growth stimulator
- o June 27, 2008 Progress notes from Orthopedic Center, from RDP
- o July 8, 2008 Non-certification of appeal, DME purchase external bone growth stimulator
- o July 30, 2008 Request for IRO

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records and prior reviews available for my review, the patient is a xx year-old employee who sustained an industrial injury to the cervical spine with a date of injury xx/xx/xx. The medical records indicate the patient was shoved from behind by a student involved in an altercation on xx/xx/xx.

The patient was treated for cervical and right upper extremity pain and paresthesias. Her prior medical history is significant for diabetes and hypercholesteremia. The patient was provided a diagnosis of intervertebral cervical disc herniation, cervical radiculitis, cervical sprain/strain, right upper extremity paresthesias, cervicgia, right C6 nerve root compression, and resolved adhesive capsulitis of the right shoulder. On August 14, 2004 she underwent an anterior cervical discectomy and interbody fusion at C5-6 and C6-7. Cervical x-rays of January 15, 2008 demonstrated an obvious non-union and psuedoarthrosis of C5-6 which was confirmed via CT scan. On February 11, 2008 the patient underwent a repair of the C5-6 pseudoarthrosis with removal of

the old plate and screw and reapplication of the bone graft in place. Post-op radiographs on February 11, 2008 showed anterior plate with two screws in seen fused in the C5 and C6 and intervertebral bone graft appears in place and there is normal alignment.

On March 30, 2008 the patient was seen in follow-up by the surgeon. The patient is working. Restrictions were recommended. X-rays have shown the instrumentation and bone graft are in place. The provider requested a bone stimulator with rationale that the patient continued with a non-union.

On April 14, 2008 the patient reported she is doing better. There is restricted motion with flexion and extension. There is some spasm throughout the cervical region. Motor function is normal. X-rays today show good alignment of the plate and screws. It is early to determine the quality of the bone graft.

On May 13, 2008 the patient's provider provided a reevaluation. The patient denies any motor weakness, peripheral numbness or paresthesias. On examination, there is decreased range of motion with reproduction of trace pain over the bilateral trapezius and the bilateral paraspinal from C3-T1. There is trace tenderness to palpation over the bilateral trapezius. There is no tenderness to palpation over the bilateral paraspinal from C5-T1 or over the midline from C5-T1. Muscle strength is complete and does not elicit radicular pain. Spurling's test is negative. X-rays of May 13, 2008 show a well maintained fusion.

On follow-up with the surgeon on May 30, 2008 and June 27, 2008 a bone growth stimulator is requested as a must due to the [prior] pseudoarthrosis. On June 27 the surgeon states the patient continues with pain to the cervical spine. Fusion is not coming together yet.

Request for DME of an external bone growth stimulator was not certified in review on June 17, 2008 with rationale that the medical records failed to report the patient is a smoker and radiographs are reported to show the recent fusion consolidating slowly. Additionally, it was noted that the request should include a radiology report by an independent radiologist indicating the maturity of the bone graft.

Request for reconsideration of an external bone growth stimulator was not certified in review on July 8, 2008 with rationale that on April 18, 2008 the patient was reported to be doing better although there was also limitation of neck motion and muscle spasms. X-rays were reported to demonstrate a well-situated anterior plate and screws. It was too early to assess the quality of the one graft. It was noted that the provider authored a note on June 24, 2008 stating that the bone graft was consolidating very slowly and may require additional surgery. The reviewer noted that serial radiographs have not shown signs of breakdown or loss of hardware fixation. It was noted that reports of June 11, 2008 and June 24, 2008 [not available for review] 12 months (sic) post-op state the bone graft is consolidating very slowly. The medical records failed to document a CT scan or risk factors for non-union such as smoking.

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

The medical records document revision fusion to repair a pseudoarthrosis. The Official Disability Guidelines states that some limited evidence exists for improving the fusion rate of spinal fusion surgery in high risk cases (e.g., revision pseudoarthrosis, instability, smoker). There is no consistent medical evidence to support or refute use of these devices for improving patient outcomes; there may be a beneficial effect on fusion rates in patients at "high risk", but this has not been convincingly demonstrated. The patient meets the criteria for an external bone growth stimulator of a history of pseudoarthrosis and the surgeon is currently concerned with the progress of the consolidation and seeks to ensure that additional surgery will not be needed. Therefore, my determination is to disagree with the previous non-certification of the request for post-op DME of an external bone growth stimulator and certify the request for an external bone growth stimulator.

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 - Bone Growth Stimulator 7-7-08:

Under study. Some limited evidence exists for improving the fusion rate of spinal fusion surgery in high risk cases (e.g., revision pseudoarthrosis, instability, smoker). (Mooney, 1990) (Marks, 2000) (Akai, 2002) (Simmons, 2004) There is no consistent medical evidence to support or refute use of these devices for improving patient outcomes; there may be a beneficial effect on fusion rates in patients at "high risk", but this has not been convincingly demonstrated. (Resnick, 2005) Also see Fusion for limited number of indications for spinal fusion surgery. See Knee & Leg Chapter for more information on use of Bone-growth stimulators for long bone fractures, where they are recommended for certain conditions.