May 5, 2004

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TWCC Medical Dispute Resolution
MS-48
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MDR Tracking #: M2-04-1188-01
IRO #: 5251

___ has been certified by the Texas Department of Insurance as an Independent Review Organization. The Texas Worker's Compensation Commission has assigned this case to ___ for independent review in accordance with TWCC Rule 133.308 which allows for medical dispute resolution by an IRO.

___ has performed an independent review of the proposed care to determine if the adverse determination was appropriate. In performing this review, all relevant medical records and documentation utilized to make the adverse determination, along with any documentation and written information submitted, was reviewed.

The independent review was performed by a matched peer with the treating doctor. This case was reviewed by a licensed Medical Doctor board certified and specialized in Orthopedic Surgery. The reviewer is on the TWCC Approved Doctor List (ADL). The ___ health care professional has signed a certification statement stating that no known conflicts of interest exist between the reviewer and any of the treating doctors or providers or any of the doctors or providers who reviewed the case for a determination prior to the referral to ___ for independent review. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

CLINICAL HISTORY

The request submitted to Texas Pre-authorization regarding this review, is the desire to remove hardware, from a lumbar fusion placed at L5-S1 for a spondylilothesis, with manifestation of back pain, from an alleged work event, from a date of injury as reported to be ___. The patient apparently underwent evaluation and treatment, and after failed conservative care proceeded to spinal surgery, that consisted of an L5-S1 decompression and in-situ fusion, with pedicle screw fixation and posterior lateral bone grafting. A clinic note from January 6, 2004, from the treating physician, ___, reports that the patient had improvement of pre-surgical pain, but developed a right-sided "achy" pain, that "may be" hardware-based, experienced when he lays flat. The report revealed a normal examination. The medication was not helping. The patient was progressing well in therapy, prior to experiencing this pain. ___ opined that, "It may make sense to inspect his fusion, and remove the instrumentation", and then if need to repeat a posterior lateral fusion. ___ also discussed that the MMI was December 2003, and if he needed instrument removal, he would require an additional three months to recover from this.

The MRI from October 24, 2003 showed the hardware at L5-S1, no significant pathology above, other than some facet changes. The request was submitted for pre-authorization and was declined, on the basis that a telephone call between the reviewing physician and the attending physician, was that this patient was going to improve with his current complaints without surgery, and should continue conservative care, which was reported to have been agreed upon. This, however, was submitted for an appeal. The second reviewing physician, based on the initial review, did not over-rule those opinions, and the decision to deny surgery stood, in regards to the pre-authorization process. An appeal letter was submitted by the client himself, who reports, "The implants in my back are causing me discomfort. They are limiting my flexibility. The MRI said that it was healed. I strongly believe that if the metal was removed, that the pain would go away, and I would be able to be productive again. Also, if I wait any longer, my benefits will expire. I will not be able to afford the removal. I no longer wish to take medications, because of the pain the metal is causing, I am forced to. Thank you."

The patient was referred to ___, an Orthopaedic surgeon, to perform an RME on January 28, 2004. The PATIENT was given a 10% impairment, whole person, using the DRE model from The 4th Edition Guide to Evaluation of Permanent Impairment, and created the statutory date of MMI on December 28, 2003.

REQUESTED SERVICE

Removal of posterior segmental instrumentation with possible re-fusion is requested for this patient.

DECISION

The reviewer agrees with the prior adverse determination.

BASIS FOR THE DECISION

The rationale for this current review decision on review, of the two previous pre-authorization review, is that this patient is less than one year out from surgery. The recommendation on surgery is on speculation that it will help this patient's residual pain, and there is no real discussion of attempts to differentiate the pain generators to confirm the surgical indications. The initial request for surgery was declined on pre-authorization and was discussed between the reviewing physician and attending physician, according to the report. It is also reported that a mutual acceptance that the surgery may not be indicated at this time. There are no dynamic x-rays to show that the fusion site is stable, and that the transitional level above is stable. There is no information that the fusion has completely healed. The MRI may or may not be the best test for scrutiny, whereas a CT scan, etc., may be more efficacious. Differential injections oftentimes are employed to distinguish a pain generator, in regards to soft tissue around metal. If this procedure were to be carried out without additional scrutiny, the hardware was removed, and the fusion was not solid; this could start a cascade of additional surgeries to go back in and re-fuse, re-instrumentate, and take out the instrument again. It is appreciated that the patient's concern, regarding financial coverage for elective surgery, may be exhausted by a certain

deadline, but it is unclear that surgery should be based on "deadlines", in regards to third-party coverage. In discussing a surgery that may or may not have the desired benefits, could place the initial surgery at risk, if the arthrodesis has not matured, not to mention having to re-place hardware, and start the process all over. There is no real discussion on physical exam, where the point-tenderness is—whether it is directly over the hardware, or above, or to the side, or below.

Evidence-based medicine reports, in particular in reports of the Cochrane Collaberation, that back surgery for back pain does not carry an advantage over non-operative conservative care. If there is history of significant radiculopathy, and/ or instability, then decompression and fusion are reasonable procedures with demonstrable efficacy, in regards to natural history. The medical information leading up to this surgery was absent for review. There is only one or two clinic notes submitted for perusal, in addition to the third-party decisions, regarding pre-authorizations. All this being said, the FDA does approve of removal of hardware, if it becomes symptomatic, and if this gentleman is a thin individual, with prominent hardware, exquisitely tender, confirmed by differential injections, then at some point, removal would be appropriate. However, if removed before maturation of the fusion, it could place the fusion at risk. In being less than one year, it appears appropriate to leave the hardware in place at this time, to ensure maximum protection and stability, for this level that may still be immature in it's healing, for posterior stabilization, and treatment of this grade I/II spondylilothesis. It is unclear the situation, in regards to what the patient referred to, as his benefits will expire. Typically, in Texas, a back injury, or any other injury of this sort, that is deemed compensable, can have access to medical care for the duration. It is assumed that the benefits this patient is referring to, is a paid benefit, not a medical benefit, and it is assumed that if this case should continue to evolve to the point to where all parties, both provider and reviewing parties, are in agreement with the treatment options, that the further care would meet the coverage, as decided upon, at that projected time.

To recapitulate, this patient underwent a spinal fusion, a single-level, posterior only, for symptomatic spondylolithesis, with radiculopathy, in June 2003, for an injury that was reported in ___. It appears that the post-operative course has been satisfactory, but he continues to have low back pain that is recurred with exercise. It was opined that possibly removing the hardware would help; however, differential injections and further scrutiny has not confirmed. Being less than one year from surgery, removal of hardware may jeopardize the maturation of the fusion mass, and could allegedly set up a cascade of multiple spine surgeries, that one could speculate, that unfortunately occurs without intent. Without directing patient care, in a reviewing physician, it would seem appropriate to retain the hardware for the time being, while all efforts are made to condition and rehabilitate this patient, and when it becomes clear to all parties that the hardware is a source of problem, confirmed by objective testing, such as differential injections, computerized imaging with either x-ray or MRI, and/or dynamic views of flexion/ extension, and rotation, etc. It is unclear why this patient cannot return back to some limited capacity, in some form of job, with restrictions on his back, at eight months post-operatively.

___ has performed an independent review solely to determine the medical necessity of the health services that are the subject of the review. ___ has made no determinations regarding benefits available under the injured employee's policy.

As an officer of ___, I certify that there is no known conflict between the reviewer, ___ and/or any officer/employee of the IRO with any person or entity that is a party to the dispute.

___ is forwarding by mail and, in the case of time sensitive matters by facsimile, a copy of this finding to the treating doctor, payor and/or URA, patient and the TWCC.

Sincerely,

YOUR RIGHT TO REQUEST A HEARING

Either party to medical dispute may disagree with all or part of the decision and has a right to request a hearing.

If disputing a spinal surgery prospective decision, a request for a hearing must be in writing, and it must be received by the TWCC Chief Clerk of Proceedings within **10** (ten) calendar days of your receipt of this decision (28 Tex. Admin. Code 142.5(c)).

If disputing other prospective medical necessity (preauthorization) decisions, a request for a hearing must be in writing, and it must be received by the TWCC Chief Clerk of Proceedings within **20** (twenty) calendar days of your receipt of this decision (28 Tex. Admin. Code 142.5(c)).

This decision is deemed received by you 5 (five) days after it was mailed or the date of fax (28 Tex. Admin. Code 102.5(d)). A request for a hearing and a **copy of this decision** must be sent to:

Chief Clerk of Proceedings / Appeals Clerk
P.O. Box 17787
Austin, Texas 78744
Fax: 512-804-4011

The party appealing this decision shall deliver a copy of its written request for a hearing to other party involved in this dispute.

I hereby certify, in accordance with TWCC Rule 102.4 (h), that a copy of this Independent Review Organization decision was sent to the carrier, requestor, claimant (and/or the claimant's representative) and the TWCC via facsimile, U.S. Postal Service or both on this 5th day of May 2004.