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Notice of Independent Review Decision

MEDICAL RECORD REVIEW:

DATE OF REVIEW: 10/28/2010

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

1 Purchase of thoracolumbosacral orthosis (TLSO) between 09/08/2010 and 11/07/2010

REVIEW OUTCOME

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

Upheld (Agree)

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 01-17-05 7 medical reports from Dr. between 01-17-05 and 12-21-05
- o 03-22-06 6 medical reports and L-facet injection procedure from Dr. through 10-16-2006.
- o 01-15-07 8 reports between 10-15-07 and 08-28-07 from Dr..
- o 02-04-09 11 reports from Dr. through 12-09-2009
- o 03-12-09 Lumbar MRI read by Dr.
- o 04-22-09 SI joint injection procedure from Dr.
- o 02-20-10 3 reports from Dr. from 02-10-10 to 10-15-08
- o 03-01-10 Five reports from Dr. through August 6, 2010
- o 07-20-10 Reevaluation report from Dr.
- o 07-20-10 Lumbar MRI read by Dr.
- o 07-28-10 Lumbar CT scan read by Dr.
- o 08-06-10 Follow-up Medical Report from Dr.
- o 09-02-10 Op report from Dr. - lumbar surgery with fusion
- o 09-02-10 Follow-up Medical Report from Dr.
- o 09-08-10 Operative Notes from Dr. - lumbar fusion surgery
- o 09-08-10 Operative Notes from Dr. regarding lumbar fusion L4-5
- o 09-13-10 Initial denial letter and review
- o 09-17-10 Follow-up Medical Report from Dr.

- o 09-28-10 Appeal denial letter and review
- o 10-11-10 Request for IRO from the Claimant
- o 10-11-10 Confirmation of Receipt of Request for IRO from TDI
- o 10-12-10 Notice to P&S of Case Assignment from TDI

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records and prior reviews the patient is a male employee who sustained an industrial injury to the low back on xx/xx/xx. He is status post a two-staged lumbar surgery on September 2, 2010 and September 8, 2010 with procedures of hemilaminectomies L4-S1, fusion of L5-S1, cage placement L5-S1, posterior instrumentation L4-S1, posterolateral fusion L4-S1 and intrathecal Duramorph spinal followed one week later by extreme lateral lumbar interbody fusion L4-5, ORIF of L4-5 spondylolisthesis, intervertebral cage placement L4-5 and lateral plating L4-5.

Medical report of 2005 indicate the patient was being treated for an exacerbation of his chronic low back condition. He fell in January of 2005 and re-injured his back. He did exercises and epidural injections were considered.

In 2006 the patient was treated with conservative exercises, independent walking and facet injections on May 25, 2006.

During early 2007 SI joint injections were considered but not approved. In April 2007 the patient was provided a left lumbar trigger point injection. An SI joint injection was desired but not approved.

In February 2008 the patient's symptoms escalated when his medications were interrupted. He stretches and walks regularly and uses Soma and Lortab. In December 2008 he was given prescriptions for Darvocet, Soma, Ambien and tramadol. He had not been seen since May 2008 and had been managing with medications.

The patient was seen 12 times in 2009 in follow-up. The patient's symptoms increased. Updated lumbar MRI was recommended. An SI joint injection was provided. A surgery was denied in June 2009. A grade I spondylolisthesis was noted at L4-5. The patient underwent an IRO in September 2009 and a lumbar surgery was not supported as a psychological assessment was lacking. He was cleared psychologically and in December 2009 surgery was gain requested.

Lumbar MRI performed on March 12, 2009 was given impression: 1. L4-5: Disc bulge producing moderately severe bilateral foraminal stenosis with overlying left paracentral epidural mass. There may be some enhancement of this mass consistent with a component of epidural fibrosis. I don't identify a laminotomy site, however. 2. L5-S1: Shallow 4 mm paracentral disc protrusion to the left without neural displacement."

Left SI joint injection was provided on April 22, 2009.

Lumbar MRI performed on July 20, 2009 was given impression: L4-5: 9 mm central right paracentral disc protrusion impinging on the right L5 nerve root. This is seen in the setting of disc bulging and osteophytic ridging with moderately severe bilateral neural foraminal impingement. 2. L5-S1: Shallow 2-3 mm disc protrusion without neural displacement.

During early 2010 the patient had administrative difficulties realizing an IRO appeal. Finally in June 2010 surgery was approved in IRO appeal. In August 2010 he is again cleared for a surgery.

Reevaluation of July 20, 2010 notes authorization has finally been obtained for surgery with extreme lateral lumbar interbody fusion of L4-5 using bone graft cage and possible lateral plating as well as staged posterior lumbar decompression and fusion of L4-5 and L5-S1. An updated MRI was needed as well as a CT scan.

Lumbar CT scan performed July 28, 2010 was given impression: 1. Multilevel, multifactorial changes as described level by level above having its greatest effect in the neural foramen on the left L4-5 and L5-S1. Findings also note diffuse lumbar spondylosis and marked atheromatous changes in the abdominal aorta.

On August 6, 2010 the patient reports low back pain of 10/10. Motor and sensation deficits are noted in the left leg. He desires to proceed with left L4-5 XLIF with plate as well as posterior lumbar decompression and fusion. His labs are reviewed and he is cleared for a surgery.

Operative report dated September 2, 2010 describes surgical procedures of left L4-5 redo hemilaminectomy with re-exploration of nerve root, right L4-5 hemilaminectomy, redo left L5-S1 hemilaminectomy with re-exploration of nerve root, right L5-S1 hemilaminectomy, transforaminal lumbar interbody fusion of L5-S1, cage placement of L5-S1, segmental posterior instrumentation from L4-S1, posterolateral fusion L4-S1 and intrathecal Duramorph spinal.

On Sep 2, 2010 the provider noted the patient's fixation is not optimal as he has osteoporosis. A bone stimulator and TSLO are needed as soon as possible for optimal fusion. He will need a bone stimulator for optimum healing of a two-level fusion. He will also need a front wheel walker, a 3-in-1-commode and a cold therapy machine.

Operative report dated September 8, 2010 describes procedures of extreme lateral lumbar interbody fusion of L4-5, ORIF of the L4-5 spondylolisthesis, intervertebral cage placement of L4-5 and lateral plating of L4-5.

Request for 1 purchase of thoracolumbosacral orthosis (TLSO) between 09/08/2010 and 11/07/2010 was considered in review on September 13, 2010 with recommendation for non-certification. Per the reviewer, the patient had a work injury in xxxx and is

status post extreme lateral interbody fusion L4-5 with ORIF of the L4-5 spondylolisthesis on September 1, 2010; the DME was requested due to osteoporosis and sub-optimal fusion. However, there was no medical evaluation from the provider with subjective and objective findings post-operatively or a recent post-op assessment or a treatment plan that identifies the requested device. The frequency of use and duration were also not stated. Regarding request for a bone growth stimulator, there was no documentation of non-union of the lumbar spine fusion. Guidelines also do not support bracing since there are no evidence-based benefits of the use of braces in improving fusion rates. Additionally, the requested equipment was not accompanied by additional plans to treat the patient via conservative measures aimed at restoration of function. The clinical information obtained does not establish the medical necessity, clinical utility and anticipated potential benefits of this request.

The patient was reevaluated post-op on September 17, 2010. He was in a hospital gown and complaining of constant uncontrollable pain. He has been denied an orthopedic mattress. He appears to be very sleepy and groggy. The surgical wounds are clean and dry and the staples have been removed. Left straight leg raise is positive but he is neuromuscularly intact. He stands from a seated position with use of his walker in a very slow over-dramatic format. He ambulates in an extremely slow pattern with a shuffled gait never actually lifting his feet. X-rays show all the hardware and screws and cages to be in good location.

Request for reconsideration 1 purchase of thoracolumbosacral orthosis (TLSO) between 09/08/2010 and 11/07/2010 was considered in review on September 28, 2010 with recommendation for non-certification. Per the reviewer, ODG states there is no scientific information of the benefit of bracing for improving fusion rates or clinical outcomes following instrumented lumbar fusion for degenerative disease. The use of bracing antedates the use of spinal hardware. The (patient has) implanted hardware which would indicate the fusion was supported and stable, thus external lumbar bracing would be redundant.

Request was made for an IRO.

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

ODG: Back brace - following lumbar fusion surgery: Under study, but given the lack of evidence supporting the use of these devices, a standard brace would be preferred over a custom post-op brace, if any, depending on the experience and expertise of the treating physician...Mobilization after instrumented fusion is logically better for health of adjacent segments, and routine use of back braces is harmful to this principle. There may be special circumstances (multilevel cervical fusion, thoracolumbar unstable fusion, non-instrumented fusion, mid-lumbar fractures, etc.) in which some external immobilization might be desirable.

The patient has good internal fixation as x-rays show all the hardware and screws and cages to be in good location. An external brace was requested prior to completion of the surgical procedures. There is no documentation of poor fusion/healing. There are no radiographic reports documenting osteoporosis, tobacco abuse or diabetes in the xx-year-old male patient. The patient's height and weight are also not stated. Per guidelines, there may be special circumstances (multilevel cervical fusion, thoracolumbar unstable fusion, non-instrumented fusion, mid-lumbar fractures, etc.) in which some external immobilization might be desirable. However, the patient does not have any of these conditions and therefore, external bracing would not be supported.

Therefore, my recommendation is to agree with the previous non-certification of the request for 1 purchase of 1 thoracolumbosacral orthosis (TLSO) between 09/08/2010 and 11/07/2010.

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 10-07-2010 Lumbar Chapter: Back Brace, post-operative (fusion):

Under study, but given the lack of evidence supporting the use of these devices, a standard brace would be preferred over a custom post-op brace, if any, depending on the experience and expertise of the treating physician. There is conflicting evidence, so case by case recommendations are necessary (few studies though lack of harm and standard of care). There is no scientific information on the benefit of bracing for improving fusion rates or clinical outcomes following instrumented lumbar fusion for degenerative disease. Although there is a lack of data on outcomes, there may be a tradition in spine surgery of using a brace post-fusion, but this tradition may be based on logic that antedated internal fixation, which now makes the use of a brace questionable. For long bone fractures prolonged immobilization may result in debilitation and stiffness; if the same principles apply to uncomplicated spinal fusion with instrumentation, it may be that the immobilization is actually harmful. Mobilization after instrumented fusion is logically better for health of adjacent segments, and routine use of back braces is harmful to this principle. There may be special circumstances (multilevel cervical fusion, thoracolumbar unstable fusion, non-instrumented fusion, mid-lumbar fractures, etc.) in which some external immobilization might be desirable.