The DYLL REVIEW
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Notice of Independent Review Decision

DATE OF REVIEW: 12/02/2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

L3 sacrum anterior interbody fusion and L3 sacrum posterior fusion with hardware

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION

The physician performing this review is a Diplomate of the American Board of Neurological Surgery. She is also a Juris Doctor. This reviewer had a clinic practice treating non-operative and operative peripheral nerve, spinal and cranial disorders in adults from 1989 until 2003. She has authored several publications. She presently consults in healthcare fraud and reviewing cases for standard of care, etc. She is licensed to practice medicine and law in the State of Texas.

REVIEW OUTCOME

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)

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

No. The surgery was not medically necessary.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Records received: 17 page fax on 11/17/2010 Texas Department of Insurance IRO request, 4 Faxes on 11/17/2010, 138 page fax, 168 page fax, 126 pate fax, 223 page fax on; URA response to disputed services including administrative and medical records evaluations and imaging study reports from 7/11/07 through 9/10.

PATIENT CLINICAL HISTORY [SUMMARY]:

Patient, a man, was evaluated by Dr. on xx/xx/xx with a complaint of back pain. had been on xx/xx/xx. The patient had a prior low back injury on xx/xx which had improved but never fully resolved. TM noted "occasional pain down both legs." On exam TM had a negative straight leg raise ("SLR") and normal reflexes.

On 7/26/07 the patient underwent a lumbar MRI which showed canal stenosis and mild bilateral foraminal narrowing at L3-4, mild to moderate foraminal narrowing at L4-5, and a left paracentral disc herniation with moderate left foraminal narrowing at L5-S1.

Dr. saw the patient on 7/30/07 with complaints of back and left leg pain and right thigh numbness.

The patient underwent chiropractic treatment in 9/07. On 11/15/07, TM had an EMG and NCV which showed acute right L4-S1 radiculopathies and acute left L5 and S1 radiculopathies. The patient returned to the chiropractor on 12/11/07.

Dr. saw the patient on 12/14/07. TM complained of low back pain with bilateral leg pain and left leg weakness. On exam the patient had 0/5 strength in the left AT and EHL, 2/5 strength in the left gastrocnemius, 3+/5 strength in the right AT and EHL, and 4/5 strength in the right gastrocnemius. The patient had 2+ reflexes except for 1+ ankle jerk on the right and trace on the left. He had decreased sensation in the left L4-S1 distributions.

A myelogram and CT scan on 1/15/08 showed severe canal stenosis at L3-4 with clear foramen, mild canal stenosis with clear foramen at L4-5 and no significant lesion at L5-S1.

Dr. recommended lumbar surgery and on 7/21/08 chiropractor MA wrote a letter requesting that the proposed surgery be approved.

On 7/28/08 underwent a physical performance evaluation. He was noted to have 4/5 strength in his arms and proximal lower extremities and 3-3-/5 in his distal lower extremities.

Dr. saw the patient on 8/5/08 with complaints of back pain and leg pain. On 8/11/08 saw Dr. with leg pain and numbness. On exam TM had 1/5 of the right

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AT and gastrocnemius and trace function of the left ankle. The physician recommended an L3-4 decompression.

On 8/27/08 the patient underwent a bilateral decompression at L3-4. In follow-up with Dr. on 10/6/08, the patient's lower extremity strength had not improved. On 11/7/08 the patient was ambulatory with a cane and a left leg orthosis. Dr. noted on 12/23/08 that the patient still had profound weakness of his lower extremities.

The patient underwent an MRI on 2/23/09 which showed a large recurrent central disc herniation at L3-4 with severe central canal and bilateral lateral recess stenosis, mild canal and severe bilateral foraminal stenosis at L4-5 and a left L5-S1 disc protrusion causing moderate canal stenosis and severe left lateral recess stenosis.

On 3/10/09 saw Dr. with complaints of low back pain and bilateral "lower extremity radiculopathy, right worse than left." TM had 0/5 in the left EHL, 2/5 in the left AT, 4/5 in the left gastrocnemius, 4/5 in the right EHL, gastrocnemius and AT and 5/5 quads and hamstrings bilaterally. The patient's left knee and ankle jerks were absent as was his right ankle jerk. He had a 1+ right knee jerk.

A myelogram on 4/17/09 showed severe stenosis at L3-4 and anterior defects at L4-5 and L5-S1 with severe canal and lateral recess stenosis at L4-5.

Dr. saw on 5/18/09. TM complained of intermittent back and bilateral leg pain along the lateral aspects of both legs. On 7/2/09 and EMG was suggestive of bilateral S1 radiculopathies.

On 8/25/09 was seen by Dr.. complained of low back pain and bilateral plantar surface foot pain. TM ambulated with a cane and had 0/5 in both EHLs and ATs. He had 4/5 gastrocnemius strength bilaterally. Lumbar x-rays done on 9/9/09 showed multilevel spondylosis with normal alignment on flexion and extension.

Dr. saw the patient on 1/12/10 with complaints of "occasional pain in his low back." TM continued to have left leg weakness. On exam the patient had "mild weakness on the right side…."

The patient's MRI on 2/3/09 was unchanged from his prior lumbar MRI. saw Dr. on 2/9/10 with back pain, bilateral leg pain and bilateral foot drop. On 2/26/10 TM had complaints of intermittent back and proximal right leg pain. His main complaint was numbness and a feeling of "ants" crawling on his ankles and feet, right greater than left. The patient was unable to heel or toe walk, had a negative SLR bilaterally, and 1+ reflexes in his legs.

On 4/19/10 Dr. performed an L3-S1 decompression with bilateral medial facetectomies and foraminotomies.

In follow-up on 6/10/10 the patient had back pain but less left leg pain with continued numbness. On 6/30/10 noted residual leg numbness but "most of his leg pain has been handled well." There was no change in his weakness.

underwent an MRI on 8/5/10 which showed a disc protrusion at L3-4 with mild canal stenosis and significant lateral recess stenosis and mild to moderate bilateral foraminal narrowing, moderate canal and left foraminal stenosis at L4-5 with mild right foraminal stenosis, and canal and moderate bilateral foraminal stenosis at L5-S1.

In August 2010 the patient attended a work conditioning program. On 8/13/10 the patient had complaints of back pain with occasional right leg pain. The physician stated that unless TM developed more significant leg pain correlating with the L5-S1 disc herniation additional lumbar surgery should be avoided. On 9/7/10 the patient complained of significant back pain. Dr. recommended a 360 degree L3-S1 fusion.

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

The proposed lumbar fusion is not medically necessary and not indicated for this patient. Surgery is not generally accepted in this setting. This patient has low back pain; he does not have a documented radiculopathy by history or exam.

Based on the ODG, fusion is recommended as an option in patients with low back pain for more than 6 months if the patient has a spinal fracture, dislocation, spondylolisthesis, or frank neurogenic compromise. There is no documentation of these conditions in this patient. Although the patient had MRI evidence of lumbar canal stenosis and foraminal stenosis, he does not have a documented history consistent with frank neurogenic compromise. He has longstanding lower extremity weakness without documented progression. Therefore, he is not a surgical candidate.

When examination of the lumbar spine reveals only common degenerative changes, the relationship of these findings to a patient's back pain is unclear.[1] Disk degeneration, annular fissures, small protrusions, and facet arthritis are commonly found in individuals with little or no back pain.[2] Mechanical or chemical changes in degenerative intervertebral discs comprise a hypothesized cause of low back pain without sciatica or neurological deficits.[3] This is

[1] E Carragee, *Surgical Treatment of Lumbar Disc Disorders*, 296 JAMA 2485-87 (2006).
[2] *Id.*
[3] R Deyo et al., *A Prospective Cohort Study of Surgical Treatment for Back Pain with Degenerative Discs; Study Protocol,* BMC Musculoskelet Disord. 2005.

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commonly referred to as "discogenic" low back pain, and is distinct from a herniated disc causing sciatica.[4] The diagnosis of discogenic low back pain may lead to spinal fusion surgery and may partly explain the recent rapid increase in lumbar fusion operations in the United States.[5] Although the concept of a painful disc causing back pain has merit on theoretical grounds, mechanical and chemical changes develop in all vertebral discs with aging.[6] Clinical studies have not firmly established diagnostic criteria that distinguish patients with painful discs from others with normal aging.[7]

It is clear that surgery for back pain is not the cure-all that many patients believe it to be.[8] Many patients who seek surgery for chronic back pain have other health problems which are not taken into account. Researchers have performed snapshot evaluations of more than 3,400 patients before and after back surgery.[9] They presented their results at the annual meeting of the American Academy of Orthopaedic Surgeons in Washington, D.C.[10] James Slover, MD, and colleagues from Dartmouth Medical College found that factors such as a low education level, depression, smoking, frequent headaches, and a workers' compensation claim had a profound impact on patients' functional abilities.[11] These were far more powerful than the influences of medical illnesses such as heart disease or rheumatoid arthritis. Dr. William Abdu stated that patients and doctors should be aware that such common psychological and social factors play a "huge role" in how patients fare before and after back surgery. "Patients, doctors, and others who take care of patients need to understand that," stated Dr. Abdu, associate professor and director of the Spine Center at Dartmouth Medical College in Hanover, N.H. Patients are inappropriately undergoing spine surgery. *Although patients with no other health problems did better, back surgery failed to provide even those patients with complete relief of symptoms or normal function. Dr. Abdu stated that after back surgery, people don't return to normal and still have the psychological and social problems they had before back surgery.* "The tone of this study is quite clear," said Nortin M. Hadler, MD, professor of medicine at the University of North Carolina. *I'm not sure there is a surgical solution to back pain.* "Back pain is not a thing you can surgically cut out or pharmacologically kill.[12]

[4] *Id.*
[5] *Id.*
[6] *Id.*
[7] *Id.*
[8] *Surgery Often Won't Cure Back Pain* at http://www.webmd.com/back-pain/news/20050225/surgery-often-wont-cure-back-pain (Feb. 25, 2005).
[9] *Id.*
[10] *Id.*
[11] *Id.*
[12] *Id.*

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Studies have shown that lumbar fusion rates rose more rapidly during the 1980s than did other types of lumbar surgery.[13] Lumbar fusion rates rose even more rapidly in the 1990s than in the 1980s.[14] In 2001, over 122,000 lumbar fusions were performed nationwide for degenerative conditions.[15] This represented a 220% increase from 1990 in fusions per 100,000.[16] The increase accelerated after 1996, when fusion cages were approved.[17] From 1996 to 2001, the number of lumbar fusions increased 113%, compared with 13 to 15% for hip replacement and knee arthroplasty.[18] While the number of spinal fusions performed in the U.S. has increased exponentially over the past decade, the incidence of diseases for which spinal fusion is performed has not had a parallel increase.[19] These increases in fusion rates have not been associated with reports of clarified indications or improved efficacy.[20] There is a need for better data on the efficacy of various fusion techniques for various indications.[21]

In addition, on 8/13/10 the physician stated that unless TM developed more significant leg pain correlating with the L5-S1 disc herniation, additional lumbar surgery should be avoided. There is no documentation of the development of significant leg pain. Also, the literature supports the finding that with successive lumbar surgeries success rates decrease and complication rates increase. This patient has not responded to two prior surgeries.

In summary, the surgery is not medically necessary for this patient.

[13] R Deyo et al., *United States Trends in Lumbar Fusion Surgery for Degenerative Conditions*, Spine 30 1441-445 (2005).
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] *Id.*
[18] *Id.*
[19] A Goodman, *Too Many Spinal Fusions for Low Back Pain, More Research and Better Indications Needed [Special Report]*, Neurology Today 5 37-38 (2005).
[20] R Deyo et al., *United States Trends in Lumbar Fusion Surgery for Degenerative Conditions*, Spine 30 1441-445 (2005).
Id.
[21] *Id.*

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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 FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)

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REFERENCES:

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Surgery Often Won't Cure Back Pain at http://www.webmd.com/back-pain/news/20050225/surgery-often-wont-cure-back-pain (Feb. 25, 2005).