MATUTECH, INC.

PO Box 310069
New Braunfels, TX 78131
Phone: 800-929-9078
Fax: 800-570-9544

Notice of Independent Review Decision

DATE OF REVIEW: SEPTEMBER 4, 2007

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE
Total disc replacement surgery at L4-S1

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

REVIEW OUTCOME

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

X Upheld (Agree)

Medical documentation does not support the medical necessity of the total disc replacement surgery at L4-S1

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Texas Department of Insurance
- Office notes (02/22/05 - 06/19/07)
- Diagnostics (11/03/04 - 06/12/07)
- Procedure – lumbar ESIs (03/29/05)
- Utilization reviews (04/20/07 – 08/07/07)

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a female who injured her back, while pulling a heavy beverage cart while in flight.

In 2004, magnetic resonance imaging (MRI) of the lumbar spine was performed. It revealed postoperative changes of a left L4-L5 laminotomy with findings most suggestive of a focal recurrent left-sided herniated disc with some caudal extension into the left L5 lateral recess and L4-L5 degenerative disc disease (DDD).

In 2005, M.D., performed a lumbar epidural steroid injection (ESI) on three occasions. M.D., noted the patient was helped by physical therapy (PT). He reviewed x-rays, which revealed a transitional L5 segment and severe loss of disc height at L4-L5. However, there was no instability. Dr. assessed postlaminectomy syndrome and treated the patient with medications. A repeat MRI revealed slight retrolisthesis of L4 on L5, a left-sided laminectomy at L4-L5, 1-2 mm annular disc bulge with some granulation tissue within the anterior spinal canal and surrounding the left L5 nerve root within the lateral recess at L4-L5, and 1-2 mm broad-based disc protrusion at L5-S1. The patient complained of episodes of back pain about every week to two weeks that had been quite severe. Dr. felt that these symptoms were related to the original herniated disc problem. He refilled Norco, Flexeril, and Mobic.

M.D., noted that the patient had been treated with laminectomy and discectomy three years ago for a previous injury. He recommended computerized tomography (CT) discogram at L3-L4, L4-L5, and L5-S1.

In March 2007, a lumbar discogram demonstrated severe concordant pain at L5-S1 with a diffuse fissuring and severe disc narrowing and herniation. Post-discogram CT revealed contrast within the left side of the L4-L5 annulus, which could be related to some annular fissuring or an initial annular injection, 2-3 mm annular bulge suspected at L5-S1 with diffuse annular fissuring, and left-sided laminectomy identified along the inferior aspect of the disc space at L5-S1. After reviewing the discogram, Dr. assessed chronic low back pain secondary to discogenic syndrome at L5-S1 with previous laminectomy at L5-S1 on the left. (*Dr. noted the lumbar laminectomy was previously termed as L4-L5 on the lateral scout view and as this would appear to be the second from the bottom mobile disc). For consistency sake; however, Dr. stated that he would keep the same terminology as of the radiologist.* He recommended disc replacement at L5-S1.

The request for the disc replacement at L5-S1 was non-certified. Rationale: *There is no clear evidence that disc replacement results in pain relief that is superior to fusion. There is no study that has clearly demonstrated that normal segmental motion has been consistently restored. Comparative long-term data demonstrating a reduced incidence of adjacent segment disease compared to fusion are not yet available. Given the extremely low level of evidence available for artificial disc replacement or percutaneous endoscopic laser discectomy, it is recommended that these procedures be regarded as experimental at this time. Presently there are multiple contraindications to total disc replacement surgery in the spine including lumbar stenosis, facet arthrosis, herniated nucleus pulposus (HNP) with radiculopathy, postsurgical deficiency of the posterior elements, pseudoarthrosis, osteoporosis, scoliosis, spondylosis, and spondylolisthesis.*

A reconsideration appeal for surgery was denied. The physician advisor recommended further evaluation with flexion-extension views and a repeat lumbar MRI as the previous study was performed in September 2005. He opined that the disc replacement surgery was not recommended for either DDD or mechanical low back pain.

On June 17, 2007, MRI of the lumbar spine revealed a broad-based ventral defect at L4-L5 measuring 4-5 mm, most compatible with posterior osteophytes; slight retrolisthesis of L4/L5; enhancing granulation tissue surrounding the proximal aspect of the left L5 nerve root sleeve along the superior aspect of the L5; and small broad-based posterior disc protrusion at L5-S1 measuring 1-2 mm without definite compromise and the S1 nerve root sleeves. Dr. felt that there were no new changes on the MRI.

The reviewing physician denied the reconsideration/appeal for the surgery. The physician advisor upheld the adverse determination for the surgery on the basis that the total disc replacement was not recommended for either DDD or mechanical low back pain. Additional rationale: *The studies have failed to demonstrate a superiority of disc replacement over simple fusion for limited indications for surgical treatment of low back pain. Disc replacement is considered a controversial and unproven alternative to fusion surgery.*

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

THERE IS NO EVIDENCE THAT TOTAL DISC ARTHROPLASTY IS SUPERIOR TO SPINAL FUSION FOR THE SURGICAL TREATMENT OF DEGENERATIVE DISC DISEASE WITH MECHANICAL LOW BACK PAIN. THOUGH SOME EVIDENCE EXISTS THAT ADJACENT MOTION SEGMENTS MAY BE PRESERVED IN THE SHORT TERM, AND THAT PATIENTS OFTEN HAVE BETTER MOTION AT THE OPERATIVE LEVEL, PATIENT SATISFACTION AND PAIN RELIEF HAVE NOT BEEN SHOWN TO BE SUPERIOR. IN ADDITION, MANY PEER REVIEWED ARTICLES DO NOT INCLUDE PATIENTS WITH ANY DEGREE OF INSTABILITY, PARTICULARLY FOLLOWING PREVIOUS LAMINECTOMY, AS THEY INCREASE LOAD ON THE POSTERIOR JOINT STRUCTURES. MULTISEGMENTAL TDA HAS A SIGINIFICANTLY HIGHER COMPLICATION RATE AND INFERIOR RESULTS AS OPPOSED TO MONOSEGMENT TDA. FOR THESE REASONS, I FEEL THAT TDA IN THIS SETTING IS NOT PREFERRED OVER SPINAL FUSION.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

X MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

X ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

X PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)

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