

# MATUTECH, INC.

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

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**DATE OF REVIEW:** May 18, 2009

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE**

Hybrid artificial disc replacement at L4-L5 with 360-degree fusion at L5-S1 with 3 day LOS

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

Diplomate American Board of Orthopaedic Surgery  
Fellowship Trained in Spine Disorders and Foot and Ankle Disorders

**REVIEW OUTCOME**

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

Upheld (Agree)

Medical documentation **does not support** the medical necessity of the health care services in dispute.

**INFORMATION PROVIDED TO THE IRO FOR REVIEW**

**TDI**

- Utilization reviews (04/13/09 and 04/17/09)
- Office visits (10/08/08 – 03/20/09)
- Diagnostics (09/13/08)
- Procedure notes (10/20/08 – 12/16/08)
- Utilization reviews (04/13/09 and 04/17/09)

**ODG criteria have been utilized for the denials**

**PATIENT CLINICAL HISTORY [SUMMARY]:**

The patient is a male who developed some back pain on xx-xx-xx.

In September, 2008, magnetic resonance imaging (MRI) of the lumbar spine revealed posterior disc contour abnormalities and facet degenerative changes at L4-L5 and L5-S1.

M.D., a physiatrist, evaluated the patient for low back pain. The patient was utilizing Darvocet, Flexeril, and Naprosyn. He assessed L5-S1 radiculopathy and performed left S1 selective nerve root block. There was 60% improvement in the leg pain but only 5% improvement in the back pain. Dr. suspected a facet

component to his pain and recommended left L3-L5 medial branch block with Marcaine.

In December, Dr. performed left L3-L5 medial/lateral branch block. This did not really help as he continued to have significant back pain that limited him on a daily basis. The pain was more on sitting.

The patient was referred to M.D., an orthopedic surgeon, for mid back pain (7/10), low back pain (8/10), and leg pain (6/10). X-rays of the lumbar spine revealed decreased disc height at L4-L5 and more severe at L5-S1. Dr. ordered a discogram at L3-L4, L4-L5, and L5-S1 and discussed the option of artificial disc replacement. The lumbar discogram was denied.

In February 2009, M.S., performed a psychological evaluation. The patient scored 10 on Beck Depression Inventory II (BDI) indicating mild depression and 2 on the Beck Anxiety Inventory (BAI) indicating minimal anxiety. Ms. diagnosed pain disorder associated with general medical condition and psychological factors and cleared the patient for a discogram.

In March, Dr. noted the lumbar discogram was denied.

Per utilization review dated April 13, 2009, Dr. denied the request for hybrid artificial disc replacement at L4-L5 with 360-degree fusion at L5-S1 with following rationale: *“Hybrid artificial disc replacement, L4-L5, with 360 degree fusion of L5-S1 is not medically indicated and appropriate. Disc replacement has shown promising early results, but has not been bore out within the literature to have lasting results. Therefore, it cannot be considered standard of care and as such it would be considered experimental and investigational until further information can be provided. This procedure should be undertaken only in clinical trials.”*

On April 17, 2009, Dr. denied the appeal for hybrid artificial disc replacement at L4-L5 with a 360-degree fusion at L5-S1 with the following rationale: *“The claimant is noted to be approaching eight months post onset of back and leg pain that has been unresponsive to conservative treatment. The physician has recommended artificial disc replacement at the L4-L5 level and fusion at L5-S1. While this claimant may very well be a candidate for fusion surgery, the request for artificial disc replacement cannot be supported. Evidenced-based medicine ODG and ACOEM guidelines recommend that there is insufficient peer reviewed literature to prove that disc replacement is superior to standard treatment of fusion. While FDA has approved artificial disc replacement as a safe procedure, FDA only grants approval relative to safety and does not make recommendation relative to the efficacy of the devices. While some early work has been done with lumbar disc replacement surgery, it is clearly not even close to being a mainstream operative procedure. Currently, this is an experimental procedure only in a small number of sites across the United States without a good long-term track record. There are no clear, double-blinded studies that document good long-term results or efficacy. Long-term studies are needed to determine if there is lower incident of adjacent segment disease as well as the long-term effects of implant debris. Therefore, the proposed surgery cannot be recommended as medically necessary.”*

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

Patient a, had a work incident with low back pain on xx-xx-xx.

On 9/13/08, a lumbar MRI completed at was read to show a 3 mm L4-5 disc bulge and moderate facet degenerative change and a 5 mm L5-S1 posterior disc protrusion without canal or foraminal stenosis.

On 10/8/08, Dr. (M.D.) evaluated the patient noting the prior chiropractic care by Dr. Patient reported low back and left lower extremity pain with numbness and tingling. There was a reported decreased left ankle jerk and a positive left straight leg raise. Dr. proposed Darvocet, discontinuation of chiropractic and a selective nerve root block (SNRB) on the left. Physical therapy was proposed.

On 10/20/08, the left S1 (SNRB) was completed with reported 50 percent decrease of the leg symptoms but minimal low back relief.

On 11/28/08, Dr. reported that the therapy had not helped (no report of the type of therapy). He had noted facet tenderness. Facet medial branch blocks were proposed and completed on the left L3 to L5 levels on 12/16/08.

On 12/29/08, Dr. reported no benefit with the branch blocks.

On 1/6/09, Dr. (M.D.) evaluated the patient and proposed a discogram from L3-4 through L5-S1 with possible two level artificial disc replacement or a hybrid construct. No spine instability was noted on the flexion/extension spine films.

On 2/9/09, Counselor performed a psychological assessment on the patient noting no apparent psychological issues.

On 3/20/09, Dr. noted the discogram had been denied by the carrier.

On 4/13/09 and 4/17/09, the utilization reviews for the artificial disc replacement at L4-5 and the fusion at L5-S1 were completed with the request denied.

Patient's therapy program is not adequately discussed to validate that non-operative care has been adequately done. Moreover, the proposed procedure is not validated by the ODG. There was reported moderate facet changes at L4-5, on the lumbar MRI. The artificial disc does not address the facet issues. The choice of treatment levels was done independent of any provocative testing.

Thus, the request is not approved as a medical necessity.

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

**ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**