

MATUTECH, INC.

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DATE OF REVIEW: JUNE 7, 2007

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

L4-L5 and L5-S1 arthroplasty

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

The physician providing this review is an orthopedic surgeon. The reviewer is national board certified in orthopedic surgery. The reviewer is a member of the American Society for Surgery of the Hand, the American Academy of Orthopedic Surgeons and the Orthopedic Trauma Association. The reviewer has been in active practice for six years.

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:

Insurance Company:
Utilization reviews (03/29/07 & 04/18/07)

PATIENT CLINICAL HISTORY [SUMMARY]:

This is a patient who sustained a lifting injury to his lower back on xx/xx/xx.

Magnetic resonance imaging (MRI) showed a small herniation at L4-L5 with mild effacement of the thecal sac and some mild contact with the S1 nerve root. An electromyography (EMG) was normal. Discogram was positive at L4-S1. He had had chiropractic care which was not helpful. He continued to have significant back pain.

On March 29, 2007, a request for anterior disc replacement at L4-L5 and L5-S1 was denied stating that: *Studies have failed to demonstrate the superiority of disc replacement over simple fusion for the limited indications for surgical treatment of low back pain. Disc replacement is considered a controversial and unproven alternative to fusion surgery. No additional clinical information was*

provided to support this request.

On April 18, 2007, an appeal for the surgery was non-certified. The rationale provided was: *While ProDisc was recently approved as being safe by the FDA, the procedure lacks well-controlled peer reviewed literature that proves its effectiveness. FDA literature documents the fact that although some artificial discs are approved for use, further investigation regarding their long-term efficacy is needed. There is very little evidence on outcomes of patients after disc replacement surgery beyond two or three years. Therefore, the artificial disc ProDisc remains investigational at this time and cannot be recommended as being medically necessary for this patient.*

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

Although comprehensive clinical data is lacking, there is enough information provided in the patient clinical history to render a determination in this case. From a clinician's perspective, this issue of disk replacement should be decided based on what is best for the patient based on the information that can be gleaned from the literature at the time a decision must be made. Although long term studies are lacking in support of the use of disk replacement, in this reviewer's opinion there is enough good clinical data to support its use in well selected patients. The criterion required for disk replacement to be chosen is: 1. the absence of facet arthrosis. 2. The absence of radicular symptoms. 3. The absence of listhesis greater than 3mm. 4. Selection of the level to be replaced should be limited to L4/5 or L5/S1. 5. Pressure specific adjacent level discogram should be negative. 6. Disk replacement should be limited to a single level. 7. The patient should have failed at least 6 months of conservative treatment prior to disk replacement consideration. Because this patient had a two level positive discogram and the request is for two-level replacement, it should be rejected on clinical grounds. Therefore, it is this reviewer's opinion that the denial be upheld.

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

The guidelines utilized in arriving at recommendations for this case are based on well established standards recognized within the orthopedic community and supported by professional literature, training standards and experience. Additional referencing is taken from the National Guidelines Clearinghouse at www.guidelines.gov.