

MATUTECH, INC.

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DATE OF REVIEW: MAY 1, 2007

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Purchase of RS-LSO spinal orthosis with System LOC™ bracing.

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

The physician providing this review is a physician, doctor of medicine. The reviewer is national board certified in physical medicine and rehabilitation. The reviewer is a member of American Academy of Physical Medicine and Rehabilitation. The reviewer has been in active practice for twenty-three years.

REVIEW OUTCOME

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

X Upheld (Agree)

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.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

- Office notes (01/23/99 – 03/15/07)
- Therapy notes (09/03/98 – 02/25/99)
- Procedure notes (11/30/99, 04/19/02, & 10/08/02)
- Medical reviews (12/19/03, 01/28/04, & 04/12/06)
- Radiodiagnostic studies (05/01/03)
- Electrodiagnostic studies (07/16/02)

- Office notes (08/24/06 – 12/21/06)

PATIENT CLINICAL HISTORY [SUMMARY]:

This is a male who injured his back while lifting a nitrogen cylinder/container weighing 100-125 pounds.

The patient attended a total of 16 sessions of chiropractic therapy in 1998 and 1999. M.D., a physiatrist, assessed maximum medical improvement (MMI) as of January 15, 1999, and assigned 7% whole person impairment (WPI) rating. The

patient received a lumbar epidural steroid injection (ESI) and a prescription for Celebrex, Tylenol, Valium, Trileptal, and Ultram. Per physician note, a lumbar discogram had shown an evidence of degenerative herniation at L5-S1 along with transitional vertebrae as well as facet pain at that level. In 2000, M.D., prescribed a CyberTek back brace. In 2001, M.D., diagnosed severe lumbar strain and a herniated nucleus pulposus (HNP) at L5-S1. He prescribed Ultram, Skelaxin, Vioxx, Effexor, Elavil, and Talwin-NX. In a psychological evaluation, the patient was noted to have had two motor vehicle accidents (MVA). He had sustained an injury to his back in the second MVA. The patient was diagnosed with a pain disorder, major depressive disorder, and anxiety disorder, rule out Schizo-affective disorder. A chronic pain management program (CPMP) was recommended. In the second half of 2001, the patient attended several sessions of physical therapy (PT). M.D., noted that magnetic resonance imaging (MRI) of the lumbosacral spine had shown degenerative disc disease (DDD) at L5-S1 with narrowing of the disc space without herniation. Post-discogram MRI had also revealed advanced disc degeneration at L5-S1. Towards the end of 2001, the patient had several emergency room (ER) visits for pain where, analgesics and narcotic medications were prescribed.

In 2002, M.D., reviewed electromyography/nerve conduction velocity (EMG/NCV) studies that were indicative of a left L5 radiculopathy. He prescribed medications. M.D., diagnosed lumbar syndrome with lumbar discogenic pain and lumbar radicular syndrome; prescribed medications and an adjustable cane; and recommended a detoxification program. D.O., refilled and adjusted the dose of analgesics, muscle relaxants, and narcotics. M.D., diagnosed disc resorption syndrome at L5-S1 and recommended a surgical correction. M.D., administered an epidural block at L5-S1. Repeat EMG/NCV studies were significant for acute ongoing radicular changes in the L5 distribution on the left, chronic and mildly acute changes at the S1 level, and acute on chronic L5-S1 radicular changes on the right side. Dr. assessed L5 radiculopathy, cervical discogenic pain, rule out cervical radiculopathy, and probable carpal tunnel syndrome (CTS). MRI of the lumbar spine showed: (a) DDD with disc desiccation and diminished disc height at L5-S1 with a broad-based annular disc bulge and endplate spurring with bilateral foraminal stenosis; and (b) suggestion of an annular fissure or tear at L4-L5 on the left. On October 8, 2002, Dr. performed bilateral laminectomy, foraminotomies, and transverse process fusion at L5-S1, and pedicle fixation at L5-S1 on the right. The postoperative diagnoses were disc disruption syndrome with spinal stenosis at L5-S1 and radiculopathy. Postoperatively, medications were prescribed and exercises were initiated. A back brace was provided. A month later, M.D., noted aggravation of the back pain while the patient was exercising. X-rays showed the lumbar hardware to be in good position and no evidence of fusion. Dr. noted that narcotics had become fairly ineffective in providing relief. Valium was started. Neurontin and MS Contin was refilled.

In 2003, Dr. regularly refilled the prescriptions for MS Contin, Zanaflex, and Neurontin. D.C., prescribed a new back brace. A lumbar computerized tomography (CT)-myelogram reflected postoperative changes. Dr. assessed statutory MMI as of August 28, 2000, and assigned 22% whole person impairment (WPI) rating. M.D., assessed clinical MMI as of December 19, 2003, and assigned 22% WPI rating. In 2004, Dr. provided monthly refills of MS Contin, Zanaflex, and Neurontin. He also prescribed an RS-4i muscle stimulator.

The patient also received occasional chiropractic care. M.D., assessed statutory MMI as of August 17, 2000, and assigned 27% WPI rating. Dr. recommended PT and/or surgical treatment.

In 2005 and 2006, Dr. refilled the above medications on a monthly basis for his chronic intractable low back pain. In December 2006, Dr. prescribed an RS-lumbosacral orthosis (LSO) with system LOC bracing.

On January 2, 2007, the RS-LSO brace was denied stating that there was a lack of efficacy through clinical trials. On January 9, 2007, a reconsideration request was once again denied for the following reason: *Clinical literature does not provide any specific support for the use of lumbar bracing as a treatment option. In reviewing the accurate progress notes, there was no mention that the patient had used a brace and that it had been beneficial.* Dr. continued to treat the patient's chronic intractable back and leg pain with MS Contin, Neurontin, Zanaflex, Topamax, and Effexor XR.

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

The following is a direct quote from RS Medical website:

“The RS-LSO™ Spinal Orthosis is prescribed for non-surgical patients with low back pain. The orthosis decreases abdominal pressure and reduces load on the intervertebral discs. Light and sturdy, the RS-LSO is available in a variety of sizes to fit most body sizes and types”.

ODG reports: “There is strong and consistent evidence that lumbar supports were not effective in preventing neck and back pain. (Jellema-Cochrane, 2001) (van Poppel, 1997) (Linton, 2001) (Assendelft-Cochrane, 2004) (van Poppel, 2004) (Resnick, 2005)

Studies do not support the efficacy of pain prevention or benefit in this patient population.

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)