

Clear Resolutions Inc.

An Independent Review Organization
3616 Far West Blvd. Suite 337-117
Austin, TX 7831

DATE OF REVIEW:
APRIL 20, 2007

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE
Arthroplasty L4-5 and L5-S1

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

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.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Office note, Dr. 06/08/06, 06/22/06, 10/12/06, 11/02/06, 12/14/06 and 01/25/07
Lumbar spine MRI with and without contrast, 06/1/06
Office notes, Dr. 07/05/06, 07/12/06, 07/17/06, 07/20/06, 07/24/06, 08/02/06, 08/07/06, 08/14/06, 08/21/06, 08/30/06 and 09/25/06
Operative report, 10/25/06
Note, RN for Dr. 11/02/06
Lumbar discogram, 01/05/07
Post discogram CT, 01/05/07
Office note, Dr. 01/08/07

Surgery scheduling form, 01/25/07
Pre-authorization request for, date unknown
Office notes, Dr. 02/01/07, 02/08/07 and 03/01/07
Note from peer review, Dr. 03/01/07
I Medicine evaluation/pre-surgical screening, MA, PC and Dr. 03/06/07
peer review, Dr. 03/19/07
Note from Dr. 03/22/07
Request for IRO regarding arthroplasty, 03/30/07
Article "ProDisc, Retrospective Clinical study: 7-11 year follow-up" noted
Article "Minimally invasive total disc replacement: surgical technique and preliminary clinical results" Eur, Spine Journal, 2002
JBJS, Lumbar total disc replacement 7-11 year follow-up, 2005

PATIENT CLINICAL HISTORY [SUMMARY]:

The Patient is a who is status post lumbar discectomy, performed in 2003 with excellent results in relieving her left leg pain. She developed low back pain and left leg pain with weakness following an injury. Dr. evaluated the Patient on 06/08/06 noting 2 episodes of pain-related temporary incontinence which was not ongoing or severe at that time. She ambulated with a cane and was unable to work. She was leaning, had a severely antalgic gait, positive tension signs reproducing low back and left posterior thigh pain with crossover. There was left sided weakness of 3/5 in the anterior tibialis and 4/5 in the extensor hallucis longus. Tension signs were dramatically positive for back and posterior left leg pain as little as 15 degrees. X-rays that day showed no instability.

An MRI of the lumbar spine performed on 06/11/06 revealed a prior left laminectomy at L5-S1, mild annular disc bulging and spondylitic spurring accentuated in the right foramina with apparent mild contact with the exiting right nerve root and mild annular bulging and spondylitic spurring at L4-5. As of 06/22/06 the Patient was improving, but reported feeling like her perineal discomfort strength was normal bilaterally and there was some give-way weakness in the quadriceps which was aggravating her right low back pain. Continuation of medications and chiropractic care were recommended.

The Patient continued treating with transforaminal epidural steroid injections and lumbar facet injections without relief. A lumbar discogram of 01/05/07 demonstrated concordant pain at L4-5 and L5-S1. The post discogram CT showed mild partial posterior fissuring at L3-4; a posterocentral radial fissure extending into the superficial annular margin with diffuse moderate partial anterior circumferential fissuring and a morphologic disc protrusion at L4-5; and moderate disc narrowing with diffuse fissuring and mild facet arthropathy and tropism at L5-S1. Arthroplasty of L4-5 and L5-S1 was recommended. This was denied on Peer Review and is now under appeal.

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

The Patient has had persistent low back and left lower extremity complaints following an injury and was diagnosed with internal derangement of L4-5 and L5-S1. While her complaints, findings and failure to respond to treatment to date are understood, the Reviewer cannot recommend the arthroplasty of L4-5 and L5-S1 as being medically necessary. ProDisc was approved by the FDA on 08/14/06 as being safe. Results to date appear promising; however; there is a lack of well-controlled, quality peer reviewed literature which proves it is effective surgical treatment. Further long term studies are necessary to determine its effectiveness compared with other mainstream procedures. That being said, the ProDisc remains investigational at this time and cannot be recommended as medically necessary. The Reviewer therefore, agrees with the prior determinations.

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):

Tropiano P, Huang RC, Girardi FP, Cammisa FP, Marnay T: Lumbar Total Disc Replacement: Seven to Eleven Year Follow-Up. The Journal of Bone and Joint Surgery, Volume 87-A, Number 3, March 2005 (artificial disc)