

# MEDICAL REVIEW OF TEXAS

10817 W. Hwy. 71  
Phone: 512-288-3300

Austin, Texas 78735  
FAX: 512-288-3356

## Notice of Independent Review Decision

**DATE OF REVIEW:**           **MAY 7, 2007**

**IRO CASE #:**

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

Charite disc replacement at L4

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

MD, Board Certified in Neurologic Surgery  
Member of the American College of Surgeons

**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**

1. Texas Department of Insurance packet of information outlining the previous reviewer's opinion.
2. medical records dated through 3/27/07.
3. dated from 2003 through 3/7/07 for shoulder issues.
4. Conquer Pain Effectively, chronic pain management program from Institute regarding a Psychiatric screening performed 3/13/07.

5. Discogram performed in 2005 and 2007.
6. Office notes from Dr., Institute from 2005 through 2007.
7. Institute pain management from Dr. ranging from 2004 through 2007.
8. occupational and physical therapy notes.
9. Multiple required medical examinations performed by Dr., etc. These include impairment ratings as well.
10. FCE performed by Dr. on 2/5/06.
11. Multiple O.R. notes describing selective nerve root blocks, epidural steroid injections, as well as the surgical procedure to perform spinal arthroplasty on 7/8/05.
12. Two EMGs, both of which were to be found normal.
13. Physical therapy notes from Health South for treatment of cervical and lumbosacral strains.
14. Treatments with Dr. with Institute, presumably a pain management physician.
15. Various records regarding spinal stimulators and sequential stimulators.
16. Rehabilitation for work hardening as well as progress notes.
17. follow up office notes.
18. Pre-operative assessment from Internal Medicine dictated by Dr., as well as psychiatric evaluations by Dr..
19. MRI of the lumbar spine from 10/22/03 describing the loss of T2 disc signal at L5, not other annular bulging or disc herniation identified.
20. 5/25/04 Center with intra articular facet arthrograms and facet joint injections with cortical steroids performed by Dr..

**PATIENT CLINICAL HISTORY [SUMMARY]:**

This now woman was injured. At that time she was working for as a driver and apparently the seatback let go and she fell, striking a retaining wall, sustaining what is being described as a whiplash type injury to her neck and right shoulder as well as having low back pain. She had extensive treatment of her right shoulder but that falls out of the scope of this review. With regards to her low back, she has had extensive evaluations ranging from 2003 forward. She has had evaluations of her cervical spine in September which was found to be normal. She had MRI scans of her low back at that time and at L5 she is noted to have some disc bulging and what is being described as degenerative disc disease. This was felt by all involved to be unremarkable given the patient's age. She was given an initial impairment rating in November of 2003 with a 0% impairment. Dr., her Primary Care Physician felt that she had not reached MMI at that time and recommended that she have lumbar epidural steroid

injections. She continued to complain of both low back as well as right leg pain.

She was then referred to Institute where she began to have chiropractic management and then was moved on to pain management with Dr., also with Institute. Shortly after that, she had another IME performed by Dr.. Dr. found that the patient had several positive Waddell signs as well as subjective complaints of pain out of proportion to objective findings. At that point, she was again complaining of low back and radiating right leg pain. He strongly discouraged any further investigations as he found her clinical exam to be most consistent with the cervical and lumbar strain without any evidence of radiculopathy. To prove this point, an EMG was also reviewed and she was found to be within normal limits.

The patient, through Dr. ultimately had trigger point injections in her back as well as her right levator muscle group with no substantial improvement. Because of a lack of benefit, she ultimately was referred to for work hardening with no substantial improvement. She had Botox injections in both the paraspinus muscle groups.

She was getting psychiatric and psychological support and despite all of this, she ultimately came to an orthopedic surgeon at the Institute, Dr., who ordered a discogram indicating that she had an annular fissuring at L5 and concordant pain. At that point she underwent a lumbar disc replacement on 7/8/05 and not unexpectedly the patient did not improve. She continued to complain of the low back pain as well as the radiating right leg pain.

Of note, the disc replacement was done in the setting of what is felt to be a lumbar radiculopathy. She subsequently had more Independent Medical Examinations and MMIs and ultimately was concluded to be at 15% impairment rating. Currently she continues to complain of persistent neck as well as low back as well as right shoulder pain. Further, she is complaining of worsening right leg pain. This has prompted a CT myelogram which showed a small disc bulge at L4. This prompted another discogram which was performed on 2/12/07 which found her to have severe concordant right low back pain. Because of this, she has returned to Dr. who has recommended that she have a 2<sup>nd</sup> arthroplasty, now at L4 and this is the procedure in discussion.

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

This patient has received extensive conservative. Clearly, the disc replacement that she had in 2005 has not helped her. As one could expect, disc replacements are contraindicated in the setting of radicular pain and this is what Dr. as well as Dr. have diagnosed. To proceed now in a similar setting, with low back and radiating right leg pain, would be inappropriate. The has used lumbar radiculopathy as a contraindication for lumbar disc replacement. The makers of Charite disc also have discouraged its use in the setting of lumbar radiculopathy, not to mention the fact that this patient has been noted to have multiple Waddell signs, which are a strong indicator of a poor outcome. As well as a number of studies that show that arthroplasties are not superior to lumbar spine fusions and that the lumbar spine fusions themselves have generally poor outcomes. This situation is compounded by the fact that articles have found that total disc replacement should only be considered experimental procedures and only be performed under strict clinical trials under strict clinical criteria which this patient does not meet.

Finally, this patient has not had a comprehensive neurologic exam, of note, this includes the orthopedic spine surgeon who wants to put in a second artificial disc. This, of course, is another disqualifying feature. Sources of screening criteria include the FDA panel recommendations for artificial discs, recommendations for using Charite discs from Johnson & Johnson/Depew, the *Occupational Medicine Practice Guidelines*, and the *American Association of Neurologic Surgeons Guidelines* regarding back fusions.

## Medical Review of Texas

---

### 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**
  - \* *American Association of Neurologic Surgeons Guidelines*
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**