

MEDICAL REVIEW OF TEXAS

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Notice of Independent Review Decision

DATE OF REVIEW: NOVEMBER 21, 2007

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Artificial disc replacement at L5-S1.

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

MD, Board Certified in Orthopedic Surgery

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

- * MD medical notes [2/1/07-9/16/07]
- * TWCC – First report of injury
- * Radiographic studies – lumbar spine and right knee [8/21/07]
- * MRI of the left knee and lumbar spine [2/14/07, 2/13/07 respectively]
- * Operative reports regarding epidural steroid injections [4/24/07]
- * Operative report regarding discogram at the L3-4, L4-5 and L5-S1 levels [8/21/07]
- * position letter [11/8/07]
- * Diagnostics [9/5/07]
- * P-IRO Review [5/26/06]
- * Orthopaedic Knowledge Update – Spine

* Direct correspondence [9/14/07, 9/25/07]

PATIENT CLINICAL HISTORY [SUMMARY]:

This claimant is a xx-year-old female who was injured on xx/xx/xx. She was riding a bus and the bus was apparently struck by a train. She was attempting to get out of the bus when it was struck and she was thrown into the seat on the right side of the bus. She initially reported soreness all over, but had primarily low back and right knee pain.

Dr. saw her on 2/1/07 with complaints of low back pain and right knee pain. She was noted to be a smoker of ½ pack of cigarettes a day. Exam showed tenderness of the lumbar spine with decreased range of motion. Neurological exam was normal. The right knee was tender on the lateral aspect and showed normal stability. Dr. diagnosed a lumbar strain and right knee contusion and recommended physical therapy, medications, and an MRI. X-rays on that date interpreted by Dr. showed mild levoscoliosis and mild narrowing of the L5-S1 disc space with some anterior spur formation in the lumbar spine. Right knee x-ray showed mild degenerative changes medially.

On 2/1/07, the patient was also seen at Care Clinic by Dr.. He completed the TWCC-73 indicating the patient could work full duty with a diagnosis of lumbar strain and right knee contusion. He noted decreased lumbar range of motion and tenderness over the S1 joints with a normal neurological function.

On 2/14/07, MRI of the right knee, which may be a typographical error, indicated the claimant had chondromalacia of the patella and cystic structure around the posterior cruciate ligament. Lumbar spine MRI showed a 2 mm disc protrusion at L2-L3 and a 2.5 mm disc protrusion at L5-S1, which was indenting the left side of the thecal sac and the left S1 nerve root. There was also noted to be very significant foraminal stenosis with the left side being more narrow than the right.

On 3/15/07 Dr. saw the patient again indicating she could not work. She complained of continued low back pain. He noted the MRI showed an L5-S1 disc protrusion. He noted decreased range of motion and tenderness on the lumbar spine. The patient had a computerized muscle test and that also showed decreased lumbar range of motion. Dr. recommended epidural steroid injection, physical therapy, and medications.

On 4/24/07 claimant had a lumbar epidural steroid injection by Dr..

On 5/10/07, Dr. saw the patient and again completed the TWCC-73 indicating she could not work. Computerized muscle testing showed decreased lumbar range of motion. The claimant was complaining of low back pain and then noted minimal-to-no relief from the epidural steroid injection. Dr. noted she had a positive Kemp's sign. She was tender over the lower back and abnormal neurological function. He diagnosed a protruding L5-S1 disc with discogenic pain and the right knee contusion. He recommended medications, facet injections, and consideration possibly for surgery at some point. On 7/10/07, the

patient had another computerized muscle test showing decreased lumbar range of motion and TWCC-73 form completed by Dr. indicating she could not work and he noted she has been treated with physical therapy and epidural steroid injections and continued lower back pain, which is rated as 8/10. Her straight leg raising test caused back pain. She had decreased range of motion and normal neurological exam. He diagnosed discogenic pain and recommended discograms.

On 8/21/07, the patient had discograms noted L3-L4, L4-L5, and L5-S1. The L3-L4 and L4-L5 disc appeared to show relatively normal anatomy. The L5-S1 disc showed evidence of an annular tear and produced congruent pain, which was stated to be 7/10. Post discogram CT showed an L3-L4 disc protrusion with foraminal narrowing, and L4-L5 disc protrusion with facet joint degenerative changes and foraminal narrowing, and at L5-S1 there were some extravasation of the dye with a 2 mm disc protrusion, facet arthropathy, moderate spinal canal stenosis, and significant foraminal narrowing on the left side more so than the right.

On 9/5/07, Dr. saw the patient again and completed TWCC-73 indicating she could not work. He noted she was continuing to have back pain and right radicular pain. He noted on exam that she had lower back pain with straight leg raises and had a normal neurological examination. He reviewed the discograms and felt that the L5-S1 disc was the pain generator. He recommended fusion or arthroplasty and apparently the patient wished to proceed with arthroplasty.

On 9/14/07 there was a note regarding Dr. conversation with Dr.. On 9/16/07, Dr. wrote a note regarding his conference with Dr.. He stated Dr. had indicated that the disc replacement would not be a covered benefit as it was considered experimental.

On 9/14/07, an adverse determination was rendered for the artificial disc replacement. The Reviewer decided that the literature was unclear in general stage regarding controlled long-term studies on efficacy of artificial disc replacements and that long-term results were not available and per the ODG Guidelines treatment was experimental and not medically necessary.

On 9/25/07, there was an appeal of the adverse determination. The adverse determination was upheld stating that the discogram showed degenerative changes at L3-L4 and L4-L5 and thus the patient had multilevel involvement, which falls outside the FDA recommendations for disc arthroplasty.

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

THE DISC ARTHROPLASTY FOR THIS CLAIMANT DOES NOT MEET THE REQUIREMENTS OF HEALTH CARE REASONABLY REQUIRED. AS PER THE ODG GUIDELINES ON PATIENT ON PAGE 1006, DISC PROTHESIS IS NOT RECOMMENDED FOR EITHER DEGENERATIVE DISC DISEASE OR

MECHANICAL LOW BACK PAIN. FURTHER MORE, THE ODG STATES THAT RADICULOPATHY IS AN EXCLUSION CRITERIA FOR THE FDA STUDIES ON LUMBAR DISC REPLACEMENT. MULTIPLE STUDIES THAT INCLUDED THE OUTCOME IN THE PATIENT'S DISC DISEASES ARE SIMILAR TO SPINAL FUSION. FURTHERMORE, CMS HAS DETERMINED THAT LUMBAR ARTIFICIAL DISC REPLACEMENT IS NOT REASONABLE NECESSARY TREATMENT FOR MEDICARE PATIENTS. FURTHERMORE, AS NOTED BY THE PREVIOUS REVIEW, THIS CLAIMANT DOES DEMONSTRATE EVIDENCE OF MULTILEVEL DEGENERATIVE CHANGES AT ALL 3 LOWER DISC LEVELS. ADDITIONALLY, SHE HAS SIGNIFICANT EVIDENCE OF CANAL STENOSIS, FORAMINAL STENOSIS, AND FACET ARTHROPATHY AT L5-S1, WHICH WOULD NOT LIKELY BE CORRECTED BY AN ANTERIOR ARTIFICIAL DISC PROCEDURE. THEREFORE, BASED UPON THE AVAILABLE CLINICAL EVIDENCE AND THE ODG GUIDELINES, DISC ARTHROPLASTY IN THIS CLAIMANT IS NOT MEDICALLY REASONABLE OR NECESSARY FOR TREATMENT OF HER LOWER BACK PAIN.

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 – NOT SUPPLIED
- 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)**