



PROFESSIONAL ASSOCIATES

Notice of Independent Review Decision

DATE OF REVIEW: 06/20/07

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Pro-Disc at L5-S1 (22857, 0163T)

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

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

An MRI of the lumbar spine interpreted by M.D.
A lumbar discogram interpreted by M.D. dated 07/21/06
A CT scan interpreted by M.D. dated 07/21/06
An evaluation with P.A.-C. for M.D. dated 10/30/06

Evaluations with Dr. dated 12/06/06, 02/23/07, 03/28/07, and 04/23/07
Evaluations with D.O. dated 12/12/06, 01/12/07, 01/23/07, 02/21/07, 03/23/07,
04/20/07, and 05/18/07
A psychological evaluation with Ph.D. dated 12/13/06
An MRI of the lumbar spine interpreted by M.D. dated 03/22/07
Surgery scheduling checklist from Dr. dated 03/28/07
Undated preauthorization request forms from Dr.
A letter of non-certification from M.D. dated 04/13/07
A letter from M.D. dated 04/25/07
A letter of non-certification from M.D. dated 05/01/07
An undated Prodisc retrospective clinical study

PATIENT CLINICAL HISTORY [SUMMARY]:

An MRI of the lumbar spine interpreted by Dr. revealed a mild disc bulge at L4-L5 and old wedging deformities of T12 and L1. A lumbar discogram interpreted by Dr. on 07/21/06 revealed internal disc disruption with concordant pain at L4-L5. A CT scan interpreted by Dr. on 07/21/06 revealed a radial tear at the L4-L5 level and moderate spinal canal stenosis. Ms. recommended lumbar surgery and continued off work duty. On 12/12/06, Dr. took the patient off Hydrocodone and gave him Percocet and Zanaflex. On 12/13/06, Mr. cleared the patient psychologically for surgery. On 02/21/07, Dr. prescribed Kadian. An MRI of the lumbar spine interpreted by Dr. dated 03/22/07 revealed narrowing at L5-S1 with a broad-based ventral defect, a disc bulge at L3-L4, a broad-based ventral defect at L1-L2, and spondylolisthesis with a bulge at L2-L3. On 03/28/07, Dr. requested a disc replacement or an anterior/posterior fusion. On 04/13/07, Dr. wrote a letter of non-certification for disc replacement. On 05/01/07, Dr. also wrote a letter of non-certification for the surgery. On 05/18/07, Dr. prescribed Kadian, Ambien CR, and MiraLax.

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

Disc replacement and disc prosthesis at this point are considered experimental and I will quote the ODG Guidelines. "Disc prosthesis or disc replacement are not recommended at this time for either degenerative disc disease or mechanical low back pain. Studies have concluded that outcomes in patients with disc disease are similar to spinal fusion. A recent META analysis published prior to the release of Charite disc replacement prosthesis for the use in the United States even concluded that total disc replacement should be considered experimental procedures and should only be used in strict clinical trials. At the current time radiculopathy is an exclusion criteria for the F.D.A. studies on lumbar disc replacement." This explains very clearly that Pro Discs are still experimental at best and the long term results cannot be relied upon. For this reason, the majority of treatment guidelines including ACOEM and ODG advise

against the patient using such prosthesis for low back pain. Therefore, the Pro-Disc at L5-S1 (22857, 0163T) would not be reasonable or necessary.

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

- X ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE AND KNOWLEDGE BASE**
- 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**
- X 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)**