MAXIMUS Federal Services, Inc.
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Notice of Independent Review Decision

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Notice of Independent Medical Review Decision

Reviewer's Report

DATE OF REVIEW: August 8, 2011

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Three days inpatient length of stay (IP LOS) for artificial disc replacement at L4 within motion disc.

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

M.D., Board Certified in Orthopedic Surgery.

REVIEW OUTCOME

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

[X] Upheld	**(Agree)**
[ ] Overturned	(Disagree)
[ ] Partially Overturned	(Agree in part/Disagree in part)

The requested service, three days inpatient length of stay (IP LOS) for artificial disc replacement at L4 within motion disc, is experimental/investigational for treatment of the patient's medical condition.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient sustained a work-related injury to her low back on xx/xx/xx when she slipped and fell exiting the cabin of a truck. The patient reported a twisting type injury to her lumbar spine. The patient is status post right L5-S1 laminectomy and microdiscectomy on 7/23/10. An MRI of the lumbar spine performed on 11/16/10 showed L4-L5 internal desiccation, bulging and Luschka joint hypertrophy without significant canal stenosis; L5-S1 circumferential bulging; facet arthropathy with right lateral recesses neural foraminal stenosis and intervertebral osteochondrosis with bone marrow edema and plates of L5-S1 and edema of the right pedicle. An evaluation performed on 4/21/11 noted that the patient continued to have severe pain and discomfort in her back. Discogram showed non-concordant pain at L3 and concordant pain at L4; L5 was not evaluated. MRI revealed a normal disc at L3-L4. On 6/22/11, the patient was diagnosed with lumbar disc displacement and lumbalgia. Artificial disc replacement at L4 within motion disc has been recommended. Spinal fusion has also been suggested at L5-S1. The request for artificial disc replacement has been denied on the basis that the service is experimental/investigational.

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

A service is considered to be experimental/investigational if there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the service, but the service is not yet

broadly accepted as the prevailing standard of care. Artificial discs or disc prostheses are not suggested treatments in the Official Disability Guidelines. In some cases, the procedure has been utilized in conjunction with single, adjacent level spinal fusion and standalone single level pathology. However, the procedure is not broadly accepted as the prevailing standard of care in this clinical setting. To date, there is inadequate peer-reviewed evidence demonstrating that artificial disc replacement is a standard of care modality. Therefore, the requested procedure remains experimental/investigational at this time.

Based upon the information set forth above, I have determined the requested service, three days inpatient length of stay (IP LOS) for artificial disc replacement at L4 within motion disc, is experimental/investigational for treatment of the patient's medical condition.

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

[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)

[X] OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)

1. Heisel, C., et al. Short-Term in Vivo Wear of Cross-Linked Polyethylene *J Bone Joint Surg Am*, 2004;86:748-751.

2. Moumene, M., et al. Effect of artificial disc placement on facet loading: unconstrained vs. semi-constrained. Presented at the 4th Annual Meeting of the *Spine Arthroplasty Society*, May 5, 2004.

3. McAfee, P., et al. A Prospective, Randomized, Multicenter Food and Drug Administration Investigational Device Exemption Study of Lumbar Total Disc Replacement with the CHARITÉ™ ARTIFICIAL DISC versus Lumbar Fusion: Part II – Evaluation of Radiographic Outcomes and Correlation of Surgical Technique Accuracy with Clinical Outcomes. *Spine*, 2005;30(14).

4. O'Leary, P., et al. Response of CHARITÉ™ Total Disc Replacement under Physiologic Loads: Prosthesis Component Motion Patterns. *Spine Journal*, 2005;(5):590-599.