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Notice of Independent Review Decision

DATE OF REVIEW: 08/12/08

IRO CASE NO.:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Item in dispute: Arthroplasty L4-5, L5-S1 (63090, 63091, 22851, 22865, ONEIA Prosthetic Device)

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 determination should be:

Denial Upheld

Arthroplasty L4-L5, L5-S1 (63090, 63091, 22851, 22865 ONEIA Prosthetic Device) is not medically necessary.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

1. Medical records, D.C., 12/14/07 thru 04/02/08
2. MRI of the lumbar spine dated 04/11/08
3. Medical records Dr., 04/17/08 thru 06/26/08
4. Procedure reports right transforaminal epidural steroid injection, 05/06/08
5. Procedure report lumbar facet injections, 05/06/08
6. Report CT discography dated 06/23/08
7. Psychiatric evaluation dated 07/01/08
8. Utilization review determination dated 07/09/08
9. Utilization review determination dated 07/16/08
10. **Official Disability Guidelines**

PATIENT CLINICAL HISTORY (SUMMARY):

The employee is a xx year old male with a history of low back pain which radiates into the right lower extremity.

The employee was seen at the Back Institute on xx/xx/xx by, D.C. It was reported that the employee was involved in a motor vehicle accident on xx/xx/xx.

He was rear-ended and seen at the Medical Center, and then subsequently his care was transferred to Dr. at the Back Institute.

The employee was initially evaluated by Dr. and prescribed anti-inflammatories, muscle relaxants, and pain medications. He was subsequently referred for chiropractic treatment. The employee's initial diagnosis included lumbar sprain, differential with lumbosacral radiculitis, and sacroiliac ligament sprain. Records indicate that the employee underwent flexion/extension radiographs on 12/14/07. Lateral views were reported to show decreased disc space at the L5-S1 level. There was retrolisthesis of L4 upon L5 that did demonstrate 1 mm to possibly 2 mm of translation on extension.

The employee was seen by Dr. on 01/11/08. At that time, Dr. reported that he had previously performed an L5-S1 discectomy, and the employee did well after this. The claimant subsequently had a car accident on xx/xx/xx, and this exacerbated his symptoms.

Records indicate that the employee underwent a transforaminal epidural steroid injection on 03/21/08, and later underwent facet injections at L4-L5 and L5-S1 on 05/06/08.

The employee was referred for an MRI of the lumbar spine on 04/11/08. This study reported a 3 mm posterocentral disc protrusion with associated annular tear which enhanced post contrast. There was disc desiccation with facet arthropathy and tropism at L4-L5. At L5-S1, there were changes of a previous left laminectomy and discectomy. Post contrast there was some posterior annular enhancement greater on the left with some epidural fibrotic enhancement as well. There was a 2 mm posterior osteophyte with no residual or recurrent focal disc herniation evident. There was disc space narrowing and disc desiccation.

The employee was seen in follow up by Dr. on 05/16/08. The employee returned post facet injections and indicated he did not obtain any significant relief. The physical examination was unchanged. Strength was graded as 5/5 in the lower extremities. There was no hyperreflexia. Dr. opined that the employee had failed nonoperative treatment, and that he had more than six months of care including adjustments, therapy, oral medications, and spinal injections. Dr. opined that the employee was a candidate for surgery and recommended lumbar discography.

This study was performed on 06/23/08. The employee was reported to have severe concordant pain at L4-L5 and L5-S1 with posterior fissuring with extensive epidural contrast extravasation. This study reported abnormal disc morphology at all three levels tested.

The employee was referred for psychiatric evaluation on 07/01/08. The employee was reported to be cleared for surgery with a fair prognosis.

Dr. requested total disc arthroplasty at L4-L5 and L5-S1.

On 07/09/08, this case was reviewed by Dr.. Dr. opined that total disc arthroplasty was not supported by the **Official Disability Guidelines**, and as such was not recommended.

The case was subsequently appealed, and on 07/16/08, the case was reviewed by Dr.. Dr. noted that the **Official Disability Guidelines** do not recommend or support disc prosthesis nor does CMS recommend disc prosthesis at this time. Dr. reported that with the surgical procedure not being recommended, the requested two day inpatient stay was not considered medically necessary.

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

The request for total disc arthroplasty at L4-5 and L5-S1 is not considered medically necessary, and I would concur with the two previous reviewers. Current evidence-based guidelines do not support the performance of total disc arthroplasty and consider it investigational in that there is a clear lack of peer reviewed literature that establishes both the safety and efficacy of this device in a U.S. patient population. While it is noted that total disc arthroplasty has been utilized for many years in Europe, the FDA has required the manufacturers of these devices to perform both five and seven year post marketing approval studies. The data from these studies is currently not available, and therefore, the long term safety and efficacy of this device is not established in a U.S. patient population and would be considered investigational. It is additionally noted that current evidence-based guidelines from which the Texas Workers Compensation system follows does not support this device for those reasons. It is further noted that total disc arthroplasty has been approved for single level placement and that multilevel placement would be outside the FDA recommended guidelines. Currently there are numerous studies involving multilevel disc placement throughout the United States; however, the data from these studies has not been validated, and therefore, again use of this device would be considered investigational and a multilevel total disc arthroplasty would be outside the current FDA recommendations.

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

1. The **Official Disability Guidelines**, 11th edition, The Work Loss Data Institute.
2. United States Food and Drug Administration PRODISC®-L Total Disc Replacement. Approval Date: August 14, 2006. Found: <http://www.fda.gov/cdrh/pdf5/p050010a.pdf>.
3. FH, SL, Rd, et al. Neurological complications of lumbar artificial disc replacement and comparison of clinical results with those related to lumbar arthrodesis in the literature: Results of a multicenter, prospective, randomized investigational device

exemption study of Charite intervertebral disc. J Neurosurg (Spine 2). 2004; 1:143-154.

4. SH, DD, RD, SL. Artificial disc: Preliminary results of a prospective study in the United States. Eur Spine J. 2002; 11(Suppl 2):S106-S110.
5. Zigler J, Burd T, Vialle E, Sachs B, Rashbaum R, Ohnmeiss D; Lumbar Spine Arthroplasty: Early Results Using the ProDisc II: A Prospective Randomized Trial of Arthroplasty versus Fusion; Journal of Spinal Disorders and Techniques; Vol. 16, 4: 362-361.
6. Regan J; Clinical Results of Charite Total Disc; Replacement Journal of Spinal Disorders and Techniques.