



Medical Review Institute of America, Inc.
America's External Review Network

DATE OF REVIEW: July 11, 2007

IRO Case #:

Description of the services in dispute:

Items in Dispute for medical necessity: Lumbar Disc replacement, CPT #22857.

A description of the qualifications for each physician or other health care provider who reviewed the decision

The physician providing this review is board certified in Orthopaedic Surgery. The reviewer has held academic appointments as Assistant Instructor at a state university, Assistant Professor of Orthopaedics, Assistant Professor of Neurosurgery and Director of an orthopaedic hospital spine center. The reviewer has been extensively published and has given numerous presentations and organized seminars in his field of expertise. The reviewer has been in active private practice since 1983.

Review Outcome

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

Upheld

The available clinical evidence in the prevailing peer reviewed published medical literature is not adequate to conclude that the artificial disc is safe and effective for the long-term treatment of back pain. With this in mind disk arthroplasty is not medically appropriate for this patient at this time.

Information provided to the IRO for review

RECORDS FROM THE STATE:

Confirmation of receipt of request for review, 1 page

Company request for Independent review organization, 4 pages

Request for review by independent organization, 3 pages

5/16/2007 denial of request for authorization of the proposed treatment, 4 pages

6/19/2007 reconsideration of medical determination, 3 pages

RECORDS FROM CARRIER:

5/10/2007 fax cover sheet, 1 page

MRI scan of the lumbar spine report June/2003. Impression degenerative changes and 4/5, 2 pages
diskogram CT scan lumbar spine 12/11/2003. The impression is degenerative pattern of 4/5, 3 pages

12/11/2003 lumbar diskogram identifying showed severe concordant pain at L4/5, 1 page

4/19/2004 lumbar intradiskal electrotherapy pill 4/5, 1 page

3/14/2005 progress report, 2 pages

3/28/2005 progress report, 1 page

4/11/2005 electrodiagnostic study bilateral lower extremities indicates bilateral anterior tarsal tunnel syndrome, evidence of chronic fried L4/5 posterior ramus irritation no peripheral neuropathy noted, 3 pages

5/6/2005 progress report, 1 page

5/9/2005 progress report, 1 page

6/27/2005 progress report, 1 page

7/18/2005 progress report, 1 page

9/9/2005 report from insurance company state approval for disc replacement, 1 page

10/13/2006 progress report, 2 pages

12/4/2006 progress report, 1 page

1/3/2007 progress report, 1 page

2/14/2007 letter requesting disc replacement surgery, 2 pages

4/4/2007 progress report, 1 page

4/13/2007 MRI scan the lumbar spine report indicates L4/5 disc degenerative changes in central posterior disc extrusion inferior migration of the disc material with mild central canal stenosis, 2 pages

4/20/2007 progress report, 1 page

6/1/2007 progress report, 1 page

fax cover sheet, 1 page

US food and drug administration literature regarding ProDisc, 29 pages

MEDICAL RECORDS FROM PROVIDER:

1/29/2004 progress report, 3 pages

4/19/2004 progress report, 1 page

4/27/2004 progress report, 1 page

5/18/2004 progress report, 1 page

6/9/2004 progress report, 1 page

EMG study date not mentioned, 7 pages

Patient clinical history [summary]

This is a patient with date of injury. MRI scan of the lumbar spine showed degenerative changes L4/5. Diskogram was positive at L4/5 level only. On 4/19/2004 the patient had intradiskal electrotherapy procedure. His symptoms continued. September 2005 lumbar disc replacement L4/5 request was approved. Repeat MRI scan was performed and showed degenerative disc changes with extrusion of the disc at L4/5 posteriorly and centrally with inferior migration. The size of the extrusion decreases the canal diameter to 9 mm. There is 7 mm of inferior extrusion of the disc. The MRI scan is reported to show disk desiccation at L3/4 also.

Analysis and explanation of the decision include clinical basis, findings and conclusions used to support the decision.

Prodisc artificial disc replacement was approved by the FDA subject to a post approval study regarding long-term safety and effectiveness. The device has been shown to be only equivalent to circumferential fusion for the treatment of low back pain with degenerative disc disease at a single level. Prospective studies to investigate the long-term safety and effectiveness of the device have been required by the FDA. Long-term safety of this artificial disc has not been established in the literature.

This patient has chronic low back pain and initially was thought to have only L4/5 degenerative changes with disk herniation. The MRI scan is reported to show a two level problem at this time with disk desiccation changes at the L3/4 level also as well as L4/5 degenerative changes and disk herniation noted to have inferior migration 7 mm.

Flexion extension radiographs have been requested but have not been performed.

Anterior disc replacement at L4/5 has been requested but it is difficult to see how the inferiorly migrated disc herniation can be addressed from this approach without bone resection which in turn would militate against a successful disc replacement construction.

Artificial disc replacement has not been shown to have long-term safety. Long-term review is underway at this time as instructed by the FDA.

Prodisc artificial disc replacement has been approved for the treatment of back pain for a single level degenerative disc change from L3/S1 in patients who have failed six months of nonsurgical treatment.

Psychological evaluation has not been performed or supplied. In the presence of chronic pain discography may be unreliable and should be considered only after psychological evaluation and

clearance.

A description and the source of the screening criteria or other clinical basis used to make the decision:

The available clinical evidence in the prevailing peer reviewed published medical literature is not adequate to conclude that the artificial disc is safe and effective for the long-term treatment of back pain. With this in mind disk arthroplasty is not medically appropriate for this patient at this time.

The available published peer reviewed literature with randomized clinical trials shows only equivalence of the artificial disc placement to lumbar spinal fusion at one level. There are no long-term randomized clinical trials showing equivalence or superiority of the artificial disc replacement over the currently accepted standard of care which is a lumbar spinal fusion for the diagnosis provided.

There is little information on long-term results compared with the more commonly accepted fusion surgery in terms of pain, function, disability, flexibility, and complications. In view of the many complicating physical and psychosocial factors present in back pain syndromes to specific criteria for determining the ideal patients to benefit from this procedure remains to be identified according to Milliman Care Guidelines: Ambulatory Care.

Milliman care guidelines noted that though there was faster immediate improvement in pain and disability for the artificial disc group, equal improvement was found between the groups at six months postoperatively. [Delamarter RB, ProDisc artificial total lumbar disc replacement: introduction and early results from the United States clinical trial. Spine 2003; 28 [20]: S 167 -- 175].

There is little information on long-term 10 years or longer results compared with the more commonly accepted fusion surgery in terms of pain, function, disability, flexibility and complications. In view of the many complicating physical and psychosocial factors present in the discogenic back pain syndromes, specific criteria for determining the ideal patients to benefit from the procedure remain to be identified.

Artificial disc replacement surgery is 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 the Charite disc replacement prosthesis for use in the United States (on 6/2/2004 an FDA panel recommended approval of the Charite disc from Johnson & Johnson DePuy), even concluded, "Total disc replacements should be considered experimental procedures and should only be used in

strict clinical trials.” (deKleuver, 2003) At the current time radiculopathy is an exclusion criteria for the FDA studies on lumbar disc replacement. (McAfee–Spine, 2004) Even though medical device manufacturers expect this to be a very large market (Viscogliosi, 2005), the role of total disc replacement in the lumbar spine remains unclear and predictions that total disc replacement (TDR) will replace fusion are premature. One recent study indicates that only a small percentage (5%) of the patients currently indicated for lumbar surgery has no contraindications to TDR. (Huang–Spine, 2004) Furthermore, despite FDA approval, the disc prosthesis is not generally covered by non workers' comp health plans (BlueCross BlueShield, 2004), or by some workers' comp jurisdictions. (Wang, 2004) Because of significantly varying outcomes, indications for disc replacement need to be defined precisely. In this study better functional outcome was obtained in younger patients under 40 years of age and patients with degenerative disc disease in association with disc herniation. Multilevel disc replacement had significantly higher complication rate and inferior outcome. (Siepe, 2006) With an implementation date of October 1, 2006, the Centers for Medicare & Medicaid Services (CMS), upon completion of a national coverage analysis (NCA) for Lumbar Artificial Disc Replacement (LADR), determined that LADR with the Charite lumbar artificial disc is not reasonable and necessary for Medicare patients. (CMS–coverage, 2006) (CMS–review, 2006) While disc replacement as a strategy for treating degenerative disc disease has gained substantial attention, it is not currently possible to draw any conclusions concerning disc replacement's effect on improving patient outcomes. The studies quoted above have failed to demonstrate a superiority of disc replacement over simple fusion for the limited indications for surgical treatment of lower back pain. Thus disc replacement is considered a controversial and unproven alternative to fusion surgery. Note: On August 14, 2006, the FDA approved the ProDisc® Total Disc Replacement by Inc.

References:

1. The treatment of disabling single–level lumbar discogenic low back pain with total disc arthroplasty utilizing the Prodisc prosthesis: a prospective study with 2–year minimum follow–up. Spine. 2005 Oct 1;30(19): 2230–6. Bertagnoli R, et al
2. Lumbar spine arthroplasty: early results using the ProDisc II: a prospective randomized trial of arthroplasty versus fusion. J Spinal Disord Tech. 2003 Aug;16(4): 352–61. Zigler JE, et al
3. Lumbar total disc replacement using ProDisc II: a prospective study with a 2–year minimum follow–up. J Spinal Disord Tech. 2006 Aug;19(6): 411–5. Chung SS, et al
4. Clinical results of total lumbar disc replacement with ProDisc II: three–year results for different indications. Spine. 2006 Aug 1;31(17): 1923–32. Siepe CJ, et al
5. Lumbar spine arthroplasty using the ProDisc II. Spine J. 2004 Nov–Dec;4(6 Suppl): 260S–267S. Zigler JE.
6. Clinical results with ProDisc: European experience and U.S. investigation device exemption study. Zigler JE. Spine. 2003 Oct 15;28(20): S163–6
7. The indications for lumbar and cervical disc replacement. Spine J. 2004 Nov–Dec;4(6 Suppl):

177S–181S. McAfee PC.

8. J Neurosurg Spine. 2005 Jun;2(6): 662–9. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 6: magnetic resonance imaging and discography for patient selection for lumbar fusion. Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, Mummaneni P, Watters WC 3rd, Wang J, Walters BC,
9. Surgery for degenerative lumbar spondylosis Gibson JNA, Waddell G. The Cochrane Database of Systematic Reviews 2007 Issue 1
10. Official disability guidelines
11. FDA safety and effectiveness data Prodisc–L, August 2006

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