



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

DATE OF REVIEW: October 26, 2007

IRO Case #:

Description of the services in dispute:

Item(s) in dispute: Total Disk Arthroplasty L5-S1, Medical necessity.

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

The physician who provided this review is a fellow of the American Board of Orthopaedic Surgery. This reviewer is a fellow of the North American Spine Society and the American Academy of Orthopaedic Surgeons. This reviewer has been in active practice since 1990.

Review Outcome

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

Upheld

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.

Total disc arthroplasty is still considered investigational due to the lack of available long term studies regarding the safety and efficacy of this device in a U.S. population.

Information provided to the IRO for review

Records Received from the State:

Notice to MRIoA of Case Assignment from the Texas Department of Insurance-10/9/07-1 page
Confirmation of Receipt of Request for Review by an IRO-10/8/07-5 pages

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Request for Review by an IRO from, DO-10/5/07-3 pages
Denial Letter to DO-9/13/07-3 pages
Denial Letter to DO-9/28/07-3 pages

Records Received from Carrier:

Notice to Utilization Review Agent of IRO Assignment from the Texas Department of Insurance-
10/9/07-1 page
Fax Cover Sheet from DO Requesting Approval for Treatment-9/10/07-1 page
Patient History Form from Diagnostic -9/5/06-1 page
Lumbar Discogram Report from Center-3/9/07-2 pages
Operative Report from Hospital-7/27/07-2 pages
Follow-up Note from DO-8/9/07-1 page
Lumbar Spine MRI Report-9/5/07-2 pages
Follow-up Note from DO-9/6/07-2 pages
Insurance Verification/Pre-certification Form9/10/07-1 page
Appeal Request from, DO-9/20/07-1 page
Letter of Medical Necessity from, DO-9/21/07-1 page

Patient clinical history [summary]

The patient is a female who is reported to have sustained an injury to her low back. The available medical records do not indicate a mechanism of injury nor do they provide a detailed history of treatment. The first available record is a report of lumbar discography dated 09/05/06. This study reports disruption of all three discs with production of concordant pain components. The disruption and pain are greatest at L5-S1 but L3-4 and L4-5 produced pain. There is right L4-5 facet arthrosis and left L5-S1 facet arthrosis. The patient subsequently was referred for a second lumbar discogram on 03/09/07. This study reports negative discs at L1-2 and L2-3.

The patient was subsequently taken to surgery on 07/27/07. The patient is reported to have unresolved low back pain with lumbar radicular syndromes that are unresponsive to conservative measures of physical therapy and medication as well as injections over the last 2 years. At this time Dr. implanted percutaneous neurostimulator electrode arrays for trial of spinal cord stimulation. The patient was seen in follow up on 08/09/07 and at this time the patient reported some difficulty with the device initially. She states that the stimulator worked for several days; however, it did not relieve her pain to her satisfaction. The patient is reported to have 80% low back pain and 25% lower extremity pain with left being greater than right. The patient is recommended to undergo MRI of the lumbar spine. This study performed on 09/05/07 indicates a 2 mm broad based disc protrusion at

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L4-5, a 1-2 mm broad based posterior protrusion at L3-4, slight posterior spondylosis without superimposed protrusion at L5-S1, mild multiple level bilateral lumbar facet arthropathy, and mild lumbar levoscoliosis. The patient was seen in follow up on 09/06/07. On examination the patient is reported to have right sided dorsiflexor weakness and bilateral effective half life (EHL) weakness. Lower extremity sensation is grossly intact. Deep tendon reflexes are present and symmetrical. The patient has a negative Babinski and no ankle clonus. Dr. reports in an effort to avoid multiple level fusion or even a single level fusion it has been recommended that the patient undergo an L5-S1 total disc arthroplasty.

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

1. Is a total disc arthroplasty at L5-S1 medically necessary?

No. The available medical record indicates that the patient has multilevel degenerative disease as well as posterior element disease. It is further noted that the patient has a bilateral lower extremity leg pain. All 3 of these conditions would exclude the patient from total disc arthroplasty under the FDA post marketing approval guidelines. Total disc arthroplasty is still considered investigational due to the lack of available long term studies regarding the safety and efficacy of this device in a U.S. population. It would be further noted that the current standard of care would be lumbar fusion rather than total disc arthroplasty. The FDA has approved the Charite Artificial Disc for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at one level from L4-S1. The indications for the implantation of the Charite Artificial Disc define DDD as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. According to the FDA-approved labeling, these DDD patients should have no more than 3 mm of spondylolisthesis at the involved level. The FDA approved labeling states that patients receiving the Charite Artificial Disc should have failed at least six months of conservative treatment prior to implantation of the Charite Artificial Disc. According to the FDA-approved labeling, the Charite Artificial Disc should not be implanted in patients with the following conditions: osteoporosis; osteopenia; pars defect; bony lumbar stenosis; active systemic infection or infection localized to the site of implantation; allergy or sensitivity to implant materials; and isolated radicular compression syndromes, especially due to disc herniation. The FDA-approved labeling of the Charite Artificial Disc states that the safety and effectiveness of the device has not been established in patients with the following conditions: pregnancy; morbid obesity; two or more degenerative discs; spondylolisthesis greater than 3 mm; or two or more unstable segments.

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

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1. McAfee PC, Cunningham B, Holsapple G, et al. A prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: Part II: Evaluation of radiographic outcomes and correlation of surgical technique accuracy with clinical outcomes. *Spine*. 2005; 30(14): 1576–1583; discussion E388–390.
2. Letter from Donna–Bea Tillman, Ph.D., Director, Office of Device Evaluation, Center for Devices and Radiological Health, U.S. Food and Drug Administration, Rockville, MD, to William Christenson, Vice President, Clinical and Regulatory Affairs, DePuy Spine, Inc., Raynham, MA, regarding FDA approval of Charite Artificial Disc, P040006, October 26, 2004.
3. Lemaire JP. [SB Charite III intervertebral disc prosthesis: Biomechanical, clinical, and radiological correlations with a series of 100 cases over a follow–up of more than 10 years.] *Rachis [Fr]*. 2002; 14: 271–285, cited in DePuy Spine, Inc. Charité Artificial Disc. Technical Monograph. SA01–030–000. JC/AG. Raynham, MA: DePuy; November 2004.
4. Tropiano P, Huang RC, Girardi FP, et al. Lumbar total disc replacement. Seven to eleven–year follow–up. *Bone Joint Surg Am*. 2005; 87(3): 490–496.
5. Ohio Bureau of Workers' Compensation (BWC). Position paper on artificial lumbar disc. *Medical Position Papers*. Columbus, OH: Ohio BWC; February 2005.
6. Blumenthal S, McAfee PC, Guyer RD, et al. A prospective, randomized, multicenter Food and Drug Administration investigational device exemptions study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: Part I: Evaluation of clinical outcomes. *Spine*. 2005; 30(14): 1565–1575; discussion E387–391.
7. Huang RC, Sandhu HS. The current status of lumbar total disc replacement. *Orthop Clin North Am*. 2004; 35(1): 33–42.
8. Benini A. Indications for single–segment intervertebral prosthesis implantation. *Revista Di Neuroradiologia*. 1999; 12(Suppl): 171–173.
9. van Ooij A, Oner FC, Verbout AJ. Complications of artificial disc replacement: A report of 27 patients with the SB Charite disc. *J Spinal Disord Tech*. 2003; 16(4): 369–383.
10. Zeegers WS, Bohnen LM, Laaper M, et al. Artificial disc replacement with the modular type SB Charite III: 2–year results in 50 prospectively studied patients. *Eur Spine J*. 1999; 8(3): 210–217.
11. Diwan AD, Parvataneni HK, Khan SN, et al. Current concepts in intervertebral disc restoration. *Orthop Clin North Am*. 2000; 31(3): 453–464.
12. de Kleuver M, Oner FC, Jacobs WC. Total disc replacement for chronic low back pain: Background and a systematic review of the literature. *Eur Spine J*. 2003; 12(2): 108–116.
13. Zigler JE, Burd TA, Vialle EN, et al. Lumbar spine arthroplasty: Early results using the ProDisc II: A prospective randomized trial of arthroplasty versus fusion. *J Spinal Disord Tech*. 2003; 16(4): 352–361.
14. Guyer RD, Ohnmeiss DD. Intervertebral disc prostheses. *Spine*. 2003; 28(15 Suppl): S15–S23.