

November 8, 2006

TX DEPT OF INS DIV OF WC
AUSTIN, TX 78744-1609

CLAIMANT: ___

EMPLOYEE: ___

POLICY: M2-07-0031-01

CLIENT TRACKING NUMBER: M2-07-0031-01-5278

Medical Review Institute of America (MRIOA) has been certified by the Texas Department of Insurance as an Independent Review Organization (IRO). The Texas Department of Insurance Division of Workers Compensation has assigned the above-mentioned case to MRIOA for independent review in accordance with DWC Rule 133 which provides for medical dispute resolution by an IRO.

MRIOA has performed an independent review of the proposed care to determine if the adverse determination was appropriate. In performing this review all relevant medical records and documentation utilized to make the adverse determination, along with any documentation and written information submitted, was reviewed. Itemization of this information will follow.

The independent review was performed by a peer of the treating provider for this patient. The reviewer in this case is on the DWC approved doctor list (ADL). The reviewing provider has no known conflicts of interest existing between that provider and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent, or any of the treating doctors or insurance carrier health care providers who reviewed the case for decision before referral to the IRO.

Records Received:

Records from the State:

Notification of IRO assignment dated 9/29/06 – 2 pages

Medical Dispute Resolution Request/Response form dated 8/30/06 – 1 page

Table of Disputed Services – 1 page

Provider information page – 1 page

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Non authorization notice dated 7/18/06 – 2 pages
Non authorization after reconsideration notice dated 8/10/06 – 1 page

Records from Requestor:

Texas Back Institute Preauthorization Request Form undated – 1 page
Case management notes undated – 1 page
Patient contact form updated 4/19/06 – 1 page
Office records/questionnaire undated – 4 pages
MRI Lumbar Spine dated 11/13/03 – 2 pages
Lumbar Discography dated 11/10/04 – 4 pages
Medical records from Dr. Scott Blumenthal dated 4/26/06 – 1 page
Thank you note from Dr. Scott Blumenthal dated 4/26/06 – 1 page
DEXA Bone Density Scan report dated 04/29/06 – 1 page
Texas Back Institute Patient Profile dated 7/3/06 – 1 page
Surgery Scheduling Slip/Checklist dated 7/5/06 – 1 page
Follow up note dated 7/5/06 – 1 page
Letter from Dr. Scott Blumenthal to Darren Howland, DC dated 7/5/06 – 1 page
Non authorization notice dated 7/18/06 – 2 pages
Rebuttal dated 7/31/06 – 2 pages
Peer to Peer form dated 8/3/06 – 1 page
Non authorization after reconsideration notice dated 8/10/06 – 1 page

Records from Insurance Company:

Letter from Flahive, Ogden & Latson to Medical Review Institute of America, Inc. dated 10/6/06 – 2 pages
Letter from Flahive, Ogden & Latson to Medical Review Division, MS-48 TDI, Division of Workers' Compensation dated 9/19/06 – 2 pages

Summary of Treatment/Case History:

The patient is a 57-year-old female who is reported to have sustained an injury to her low back on _____. The available record indicates that the patient was referred for a MRI scan of the lumbar spine on 11/13/03. On this date, this study reports there is no evidence of herniated disc, spinal stenosis, or foraminal stenosis at L3-4. At L4-5 there is a broad based posterior disc bulge of the annulus fibrosis of approximately 3 mm, which contacts but does not impress or displace the thecal sac. The neural foramen are patent. At L5-S1 there is a central, short based disc protrusion of approximately 3 mm, which contacts the thecal sac but does not displace or impress this structure.

The neural foramina are patent, and the facet joints are unremarkable. The overall impression is moderate desiccation at L4-5, mild degenerative disc disease at L4-5 with moderate changes

surrounding the L4 disc space secondary to degenerative changes.

The patient was referred for lumbar discography on 11/10/04. This study reports non-concordant pain at L2-3 with a normal nucleus and no extravasation of contrast. The patient's pain pattern was reported to be non-concordant; however, she reported significant pain. At L4-5 the patient was reported to have concordant pain with radiation down the right leg. Disc morphology was noted to be monolobular with extravasation of water-soluble contrast bilaterally and posteriorly into the epidural space. At L5-S1 the patient was reported to have non-concordant pain more intense than her usual pain radiating to the left leg. She reported the pain to be 10/10. Disc morphology was noted to be a monolobular disc nucleus with extravasation of water-soluble contrast bilaterally and posteriorly into the epidural space. The patient was referred for a post procedure CT scan.

The patient was seen by Dr. Scott Blumenthal on 04/26/06. At this time, he reports that the patient has undergone fairly extensive nonsurgical treatment including therapy, chiropractic, medication, and injections. The patient has been previously worked up and been found to have markedly abnormal discs at L4-5 and L5-S1 with some abnormalities noted at L3-4 and a normal disc at L2-3. On physical examination the patient has pain with extremes of flexion and extension. She is neurologically intact. Sciatic tension is negative. Reflexes are reported to be 2+ and symmetric at the patella, 1+ and symmetric at the Achilles. The patient is diagnosed with discogenic disease of the lumbar spine and it was recommended that she undergo a DEXA scan. The patient is reported to have a normal bone mineral density on 04/29/06.

The patient was seen in follow up by Dr. Blumenthal on 07/05/06. At this time, he reports that the patient has single level disease at L4-5 only, and recommends that the patient undergo a single level disc replacement. This has been denied by two previous physician reviewers.

Questions for Review:

Preauthorization request: Lumbar Disc Arthroplasty @ L4-5 with 1 day of stay (#22899 and #22999).

Explanation of Findings:

1. Is the request for a lumbar disc arthroplasty at L4-5 with one-day stay medically necessary?
No. The patient clearly has multilevel degenerative disc disease at two levels. This would preclude the implantation of an artificial disc. The FDA has approved the Charite Artificial Disc for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at one level from L5-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

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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.

References Used in Support of Decision:

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.

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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.
15. Caspi I, Levinkopf M, Nerubay J. Results of lumbar disk prosthesis after a follow-up period of 48 months. *Isr Med Assoc J.* 2003; 5(1): 9–11.
16. Geisler FH, Blumenthal SL, Guyer 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.
17. Hochschuler SH, Ohnmeiss DD, Guyer RD, Blumenthal SL. Artificial disc: Preliminary results of a prospective study in the United States. *Eur Spine J.* 2002; 11(Suppl 2): S106–S110.
18. 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.
19. Regan J; Clinical Results of Charite Total Disc; Replacement *Journal of Spinal Disorders and Techniques.*

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.

Your Right To Appeal

If you are unhappy with all or part of this decision, you have the right to appeal the decision. The decision of the Independent Review Organization is binding during the appeal process.

If you are disputing the decision (other than a spinal surgery prospective decision), the appeal must be made directly to a district court in Travis County (see Texas Labor Code §413.031). An appeal to District Court must be filed not later than 30 days after the date on which the decision that is the subject of the appeal is final and appealable.

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If you are disputing a spinal surgery prospective decision, a request for a hearing must be in writing and it must be received by the Division of Workers' Compensation, Chief Clerk of Proceedings, within ten (10) days of your receipt of this decision.

Chief Clerk of Proceedings/Appeals Clerk
P. O. Box 17787
Austin, TX 78744

A copy of this decision should be attached to the request. The party appealing the decision shall deliver a copy of its written request for a hearing to all other parties involved in the dispute

In accordance with Division Rule 102.4(h), I hereby verify that a copy of this Independent Review Organization (IRO) Decision was sent to the carrier, the requestor and claimant via facsimile or U.S. Postal Service from the office of the IRO on this 8 day of Nov/2006.

Laura Daley

MRIOA is forwarding this decision by mail, and in the case of time sensitive matters by facsimile, a copy of this finding to the treating provider, payor and/or URA, and the DWC.

It is the policy of Medical Review Institute of America to keep the names of its reviewing physicians confidential. Accordingly, the identity of the reviewing physician will only be released as required by state or federal regulations. If release of the review to a third party, including an insured and/or provider, is necessary, all applicable state and federal regulations must be followed.

Medical Review Institute of America retains qualified independent physician reviewers and clinical advisors who perform peer case reviews as requested by MRIOA clients. These physician reviewers and clinical advisors are independent contractors who are credentialed in accordance with their particular specialties, the standards of the American Accreditation Health Care Commission (URAC), and/or other state and federal regulatory requirements.

The written opinions provided by MRIOA represent the opinions of the physician reviewers and clinical advisors who reviewed the case. These case review opinions are provided in good faith, based on the medical records and information submitted to MRIOA for review, the published scientific medical literature, and other relevant information such as that available through federal agencies, institutes and professional associations. Medical Review Institute of America assumes no

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liability for the opinions of its contracted physicians and/or clinician advisors. The health plan, organization or other party authorizing this case review agrees to hold MRloA harmless for any and all claims which may arise as a result of this case review. The health plan, organization or other third party requesting or authorizing this review is responsible for policy interpretation and for the final determination made regarding coverage and/or eligibility for this case.

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Case Analyst: Laura D ext 415

Cc: Requestor and Respondent