

July 18, 2005

TEXAS WORKERS COMP. COMISSION  
AUSTIN, TX 78744-1609

CLAIMANT: \_\_\_  
EMPLOYEE: \_\_\_  
POLICY: M2-05-2046-01  
CLIENT TRACKING NUMBER: M2-05-2046-01 /5278

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Medical Review Institute of America (MRIOA) has been certified by the Texas Department of Insurance as an Independent Review Organization (IRO). The Texas Workers Compensation Commission has assigned the above-mentioned case to MRIOA for independent review in accordance with TWCC 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 TWCC approved doctor list (ADL). The reviewer has signed a statement indicating they have no known conflicts of interest existing between themselves and the treating doctors/providers for the patient in question or any of the doctors/providers who reviewed the case prior to the referral to MRIOA for independent review.

**Records Received:**

FROM THE STATE:

Notification of IRO assignment dated 7/6/05 1 page  
Texas Workers Compensation Commission form dated 7/6/05 1 page  
Medical Dispute Resolution Request/Response form 2 pages  
Provider form 1 page  
Table of disputed services 1 page  
Provider contact information dated 6/30/05 1 page  
Letter from Liberty Mutual dated 4/14/05 2 pages  
Letter from Liberty Mutual dated 4/14/05 2 pages  
Letter from Liberty Mutual dated 6/1/05 2 pages  
(continued)

FROM THE PROVIDER/REQUESTOR:

Neurosurgery consultation notes dated 6/30/98 2 pages  
Neurosurgery consultation notes dated 8/7/98 1 page  
Neurosurgical followup report dated 9/18/98 1 page  
Neurosurgery followup report dated 11/3/98 1 page  
Prospective review letter dated 7/6/05 1 page  
Shannon Clinic chart notes dated 2/1/05 1 page  
Shannon Clinic chart notes dated 2/25/05 1 page  
Operative report dated 3/24/05 1 page  
Operative report dated 3/24/05 1 page  
Shannon Clinic chart notes dated 3/24/05 2 pages  
Radiology report dated 3/24/05 1 page  
Radiology report dated 3/24/05 1 page  
Radiology report dated 3/24/05 1 page  
Shannon Clinic chart notes dated 4/22/05 1 page  
Shannon Clinic chart notes dated 5/31/05 1 page

FROM THE RESPONDENT:

Texas Workers Compensation Commission form dated 6/28/05 1 page  
Neurosurgery procedure order and pre-certification form dated 3/29/05 1 page  
Letter from Utilization Management Liberty Mutual Group dated 6/30/05 1 page  
Letter from Utilization Management Liberty Mutual Group dated 6/30/05 1 page  
Letter from Utilization Management Liberty Mutual Group dated 7/7/05 1 page  
MRI lumbar spine report dated 12/9/04 1 page  
Shannon Clinic chart notes dated 2/1/05 1 page  
Shannon Clinic chart notes dated 2/25/05 1 page  
Shannon Clinic chart notes dated 3/24/05 1 page  
Operative report dated 3/24/05 1 page  
Operative report dated 3/24/05 1 page  
Operative report dated 3/24/05 1 page  
Radiology report dated 3/24/05 1 page  
Peer review analysis case report 4 pages  
Peer review analysis case report 4 pages  
Medical dispute resolution request/response form 1 page  
Provider form 1 page  
Table of disputed services 1 page  
Instructions on completing TWCC-60 form 1 page  
Letter from patient dated 6/22/05 2 pages  
Letter from Liberty Mutual dated 4/14/05 1 page  
Shannon Clinic chart notes dated 5/31/05 1 page  
(continued)

Letter from Liberty Mutual dated 6/1/05 1 page

Fax cover sheet from Dr. Luis Durarte, MD dated 7/12/05 1 page

Copy of check from Liberty Mutual dated 7/6/05 1 page

**Summary of Treatment/Case History:**

This 38 year old male was seen on 6/30/98 with a history of low back pain since a lifting injury on \_\_\_\_\_. There are no details of how the injury occurred. Based on his history, examination and review of a MRI on 6/22/98, he made a diagnosis of degenerative disc disease at L4-5 and L5-S1 with a central bulge. After physical therapy and work hardening, he was returned to work without restrictions on 11/3/98.

On 12/3/04 he had some type of injury to his low back; the details of which are not in the various records.

The next information is a report of a MRI Lumbar Spine on 12/10/04; there is "mild central disc bulges are detected at the L 4-5 and L5 -S1 levels. Both discs are desiccated. There has been no significant interval change when compared with the remote examination of 6/22/98."

On 1/1/05, he came under the care of Dr. Durarte again and continued under his care until 5/31/05 for low back pain. Dr. Durarte sent him for physical therapy and ESI. As there was no response to his complaints of LBP and inability to work, the patient underwent Lumbar Myelogram with CAT Scan following and Lumbar Discogram on 3/24/05. As near as various reports of the studies and office notes, the diagnosis seems to be diffuse disc bulging at L4-5 and L5-S1, internal fissuring at these levels, hypertrophic changes posteriorly at L4-5, disrupted disc at L4-5 and L5-S1 causing mechanical low back pain, due to degenerative lumbar disc disease at the two lower levels.

Repeated examinations state he has normal strength and reflexes in both lower extremities; paravertebral muscle spasm, pain with flexion and extension of his back, straight leg test is mildly positive. In short, his exam is non-specific. On 3/24/05, the patient underwent anterior interbody fusion at L5-S1, and total disc replacement with Charite at L4-5 was requested. This was denied on 4/14/05 because the FDA restricts use of Charite for individuals with only one lumbar level that needs repair. This individual has need of repair at two levels. Also, the criteria from reference 1 and 2 were not met. On 6/1/05, there was a second denial of requested surgery based on Charite disc replacement being a new procedure.

The final note of 5/31/05 by Dr. Durarte states: "Impression: mechanical low back pain secondary to disruption of L5-S1 disc. The patient will be scheduled for total disc replacement at L4-5 and fusion at L5-S1. I have counseled the patient to see if he can get a lawyer to help him. He needs to have disc replacement instead of a two-disc fusion." (This is confusing in that he does not seem to agree with the FDA approval of the Charite disc replacement for only individuals with one level of disease, or if he only wants to do this and this alone at L5-S1. If he wants to do this, then it would not be warranted, as there is disease at two levels. If he has changed his diagnosis to DJD at one level, L5-S1 and wants to fuse this with the Charite disc, he should clearly state this).

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**Questions for Review:**

1. Item/s in dispute: Preauthorization denied for total disc replacement (charite) at L4–L5 and a lumbar fusion at L5–S1; purchase of Iso brace.

**Explanation of Findings:**

The diagnosis seems to be diffuse disc bulging at L4–5 and L5–S1, internal fissuring at these levels, hypertrophic changes posteriorly at L4–5, disrupted disc at these levels causing mechanical back pain at these two lower levels.

Repeated examinations state he has normal strength and reflexes in lower extremities, paravertebral muscle spasm, pain with flexion and extension of his back, straight leg test is mildly positive. In short, his exam is non-specific.

On 3/24/05, anterior interbody fusion at L5–S1 total disc replacement with Charite at L4–5 was requested. This was denied on 4/14/05, as the FDA restricts Charite for individuals with only one lumbar level that need repair; this person needs two levels repaired. Also, criteria from Reference 1 and 2 were not met. On 6/1/05, there was a second denial based on Charite being a new procedure. The final note of 5/31/05 is confusing. The Impression: Mechanical low back pain secondary to disruption of L5–S1 disc. The patient will be scheduled for disc replacement at L4–5 and fusion at L5–S1. I have counseled the patient to see if he can get a lawyer to help him. He needs to have a two disc fusion.

**Conclusion/Decision to Not Certify:**

1. Item/s in dispute: Preauthorization denied for total disc replacement (charite) at L4–L5 and a lumbar fusion at L5–S1; purchase of Iso brace.

The diagnosis in this case is degenerative disc disease at L4–5 and L5–S1. The requested procedure has been refused two times and certain criteria not been met and references for this refusal have been given. This reviewer agrees with these, and the decision is to add a third refusal with references and criteria.

In Chapman's Orthopedics, which is generally accepted by most as an authoritative source, the criteria for operative approach to DJD is given for disease at one level. There are no indications for fusion at two levels. As this individual has disease at two levels, he does not meet the criteria. Dr. Durarte states that even if he fuses at the two lower levels, the patient may develop DJD at the spaces above. (Most of the movement in the lumbar spine takes place at the two lower levels, so when they are fused, movement is moved to the spaces above). The results from fusions at the lower levels does not give long term relief. DJD at numerous levels is an ongoing process related to use and movement of the spine. Surgery has not been proven of long-term benefit in disc disease at multiple levels, as this patient has. Dr. Durarte states even with fusion, it is doubtful that this person will return to work without many restrictions.

**References Used in Support of Decision:**

- 1) Journal of Neurosurgery–Spine Vol 1 (2): September 2004, (143–154).

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- 2) Journal of Spinal disorders and Techniques. Focus Issue: Disc Arthroplast. 16(4):369–383, August 2003.
- 3) McAfee, P.C. et al. Charite Disc Replacement– a radiographic outcome analysis of 276 consecutive patients. Journal of Bone & Joint Surgery– British Volume. 86–B Supplement IV:460,2004.
- 4) Chapman Orthopedics. Section VIII, The Spine, Chapter 145, Degenerative Disc Disease, Operative Treatment 3788–3797.
- 5) Johnson & Johnson DUPUY Spine who sell the Charite disc in the USA. The company states – this disc is for individuals who have DHJD at only one level. Web site: [www.depuyaccromed.com](http://www.depuyaccromed.com)
- 6) [www.syntheses-stratec.com](http://www.syntheses-stratec.com). this is reference to an article stating there are even better methods of disc replacement than Charite due to its poor results. See Lumbar total disc replacement for low back pain by John A. Pelosa, MD, Center for spine cre where the PRO disc II is used for DJD.

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The specialist providing this review is board certified in Neurosurgery. The reviewer has served as the chief Neurosurgeon at several VA Hospitals throughout the country. The reviewer is a member of the American Medical Association, the American College of Surgeons, the American Paraplegia Society, Congress of Neurological Surgeons and the American Association of Neurosurgeons. The Reviewer has served as an association professor, assistant professor and clinical instructor at the university level. The reviewer also has publishing, presentation and research experience within their specialty. The reviewer has been in active practice for over 20 years.

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, patient and the TWCC.

**YOUR RIGHT TO REQUEST A HEARING**

Either party to the medical dispute may disagree with all or part of this decision and has a right to request a hearing.

If disputing a spinal surgery prospective decision, a request for a hearing must be in writing and it must be receiving the TWCC chief Clerk of Proceedings within ten (10) days of your receipt of this decision as per 28 Texas Admin. Code 142.5.

If disputing other prospective medical necessity (preauthorization) decisions, a request for a hearing must be in writing and it must be received by the TWCC Chief Clerk of Proceedings within twenty (20) days of your receipt of this decision as per Texas Admin. Code 102.4 (h) or 102.5 (d). A request for hearing should be sent to:

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Chief Clerk of Proceedings  
Texas Workers' Compensation Commission  
POB 40669  
Austin, TX 78704-0012

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

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 MRloA 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 MRloA 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 MRloA 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 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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cb

cc Requestor:Luis Durarte  
Respondent: Liberty Mutual