

MEDR X

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Notice of Independent Review Decision

DATE OF REVIEW: 2/17/2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

The services under dispute include the medical necessity of the removal of cervical clamps with a one day LOS (22850).

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION

The reviewer is a Medical Doctor who is board certified in Orthopedic Surgery. This reviewer has been practicing for greater than 10 years.

REVIEW OUTCOME

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

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

The reviewer agrees with the previous adverse determination regarding the medical necessity of the removal of cervical clamps with a one day LOS (22850).

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Records were received and reviewed from the following parties: and MD.

These records consist of the following (duplicate records are only listed from one source): : preauth request 12/14/09, notes by, MD 7/2/04 to 12/1/09, cervical MRI 12/1/09, neurodiagnostic report 12/1/09 and 12/22/09 reconsideration request.

Dr.: patient medication list dated 2/9/10.

Records were received from Insurance after the reviewer had already made his decision on 2/15/10.

We did not receive the ODG Guidelines from Carrier/URA.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient was injured on xx/xx/xx. A prior cervical spine fusion had required revision with Halifax clamps. A "solid" interbody C5-6 fusion had been noted on an MRI in 2002, with laminectomies from C4-C6. In 11/09, the claimant was noted to have increased cervical pain with right arm radiation. Although motor and reflex exam had been unremarkable, sensation was diminished in the left C6-7 distribution. A mild chronic right C6 radiculopathy was noted in December 2009 electrodiagnostics. A 12/1/09 dated cervical MRI noted the solid prior fusion. The AP was noted to be concerned about the upper Halifax hook regarding spinal impingement. The diagnosis included brachial neuritis or radiculopathy. Reviewer Dr. felt that the hardware removal wasn't indicated as imaging studies had not been provided evidencing impingement.

The 12/30/09 dated reconsideration denial was based on rationale of the lack of clearly defined clinical and radiographic abnormalities related to the clamp device. Dr. notes from 12/09 document concerns regarding pain and hook impingement, with his indication for removal denoted. The cervical MRI was dated 12/1/09 and revealed the solid fusion at C5-6. The 12/1/09 dated electrodiagnostic findings were noted. On 11/9/09, the AP indicated that the right arm finding was new. On 7/2/04 it was noted the Halifax clamps were not unstable on flexion and extension cervical films.

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

The reviewer states that without any objection clinical findings on examination, and, without evident imaging (or other) studies delineating or supporting evidence of clamp-hook impingement, pain generation or instability, the proposed surgical intervention has not been reasonably documented to support the proposed removal and overnight stay post-removal, as per applicable guidelines; therefore, this treatment is not medically necessary.

References/Guidelines:

ODG GUIDELINES regarding SURGERY (in general); Recommended in some cases; see specific types of surgery. Available randomized trials are small and do not provide reliable evidence on the effects of surgery for cervical spondylotic radiculopathy or myelopathy. It is not clear whether short-term risks are offset by any long-term benefits. Generally, surgical intervention may be considered in severe cases when conservative treatment fails to resolve radicular symptoms.

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J Neurosurg. 1993 May;78(5):702-8.

Halifax interlaminar clamp for posterior cervical fusion: a long-term follow-up review.

Aldrich EF, Weber PB, Crow WN.

Division of Neurosurgery, University of Texas Medical Branch, Galveston.

Fifty consecutive patients requiring posterior cervical fusion for various pathologies were treated with Halifax interlaminar clamps for internal spinal fixation. Fusion involved the C1-2 level in 17 cases, the C1-3 level in one, and the lower cervical area (C2-7) in 32. No patient was lost to follow-up review, which varied from 6 to 40 months (average 21 months). Fusion failed in five patients, three at the C1-2 level, one at the C1-3 level, and one at the C2-3 level. Screw loosening was the cause of failure in four patients, and in one the arch of C-1 fractured. No other complications occurred. Because of the lack of complications, avoidance of the hazards of sublaminar instrumentation, and an excellent fusion rate, this technique is highly recommended for posterior cervical fusion in the lower cervical spine. Atlantoaxial arthrodesis was achieved in only 14 (82%) of 17 patients, however, which might be due to the higher mobility at this multiaxial level. Improved results in this region may be possible by using a new modified interlaminar clamp, by performing adequate bone fusions, and by postoperative external halo immobilization in high-risk patients.

Spine (Phila Pa 1976). 1998 Jan 15;23(2):181-6; discussion 186-7.

The significance of hardware failure in anterior cervical plate fixation. Patients with 2- to 7-year follow-up.

Lowery GL, McDonough RF.

Research Institute International, Gainesville, Florida, USA.

STUDY DESIGN: In this retrospective study, the incidence of anterior cervical hardware failure was reviewed in 109 patients with degenerative disorders treated by one surgeon.

OBJECTIVES: To evaluate the risk of injury caused by hardware failure in anterior cervical spine reconstruction. SUMMARY OF BACKGROUND DATA: Anterior plating is used for stabilization after cervical spine trauma and other conditions of instability. There has been a concern among surgeons about the risks involved when anterior cervical plating fails (fracturing or loosening of the construct).

METHODS: The series included placement of 70 non-constrained plates and 39 constrained plates. The average length of follow-up was 43 months. Hardware failure was defined as any broken or loosened screw or plate, regardless of clinical significance. RESULTS: There were 32 Orozco (Synthes, Inc., Paoli, PA) failures, 5 cervical spine locking plate failures, and 2 Orion (Sofamor Danek USA, Inc., Memphis, TN) failures. There were no injuries to tracheoesophageal or neurovascular structures as a result of hardware implantation or failure. CONCLUSIONS: The incidence of prominent hardware that endangers tracheoesophageal structures is minimal. In most cases, careful and long-term follow-up can ensure that failed hardware has not progressed and can confirm that late failure has not occurred. Hardware failure should increase the surgeon's suspicion of a nonunion, but immediate removal of the failed hardware is rarely necessary. If reoperation is necessary for nonunion repair, kyphosis correction, or other secondary procedures, the hardware can be removed at that time. Constrained systems (cervical spine locking plate, Orion) had significantly ($P = 7.65$, $P < 0.01$) fewer failures than the non-constrained Orozco system.

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

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN
- INTERQUAL CRITERIA
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- MILLIMAN CARE GUIDELINES
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- TEXAS TACADA GUIDELINES
- TMF SCREENING CRITERIA MANUAL
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)
PUBMED.COM J Neurosurg. 1993 May;78(5):702-8
Spine (Phila Pa 1976). 1998 Jan 15;23(2):181-6; discussion 186-7