



MedHealth Review, Inc.
661 E. Main Street
Suite 200-305
Midlothian, TX 76065
Ph 972-921-9094
Fax (972) 827-3707

Notice of Independent Review Decision

DATE NOTICE SENT TO ALL PARTIES: 1/31/14

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

The item in dispute is the prospective medical necessity of hardware removal at C4, C5, C6 and C3-C4 ACDF/AISF with a one day length of stay.

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. The 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 disagrees with the previous adverse determination regarding the prospective medical necessity of hardware removal at C4, C5, C6 and C3-C4 ACDF/AISF with a one day length of stay.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Records were received and reviewed from the following parties:

These records consist of the following (duplicate records are only listed from one source): Records reviewed: 1/24/13 denial letter, 1/7/14 denial letter, and 1/7/14 notification letter.

12/30/13 peer review report, 1/7/14 peer review report, 9/30/08 to 12/17/13 office notes, 12/11/13 office report, 12/11/13 discogram worksheet, 2/21/13 report,

11/14/12 cervical MRI report, 8/18/08 operative report, 7/10/13 office note, and undated preauth request.

appeal request for reconsideration form. All other records were duplicative of those listed above.

A copy of the ODG was not provided by the Carrier or URA for this review.

PATIENT CLINICAL HISTORY [SUMMARY]:

Records were reviewed, including most recently from 12-17-13. The injury mechanism was not evident. There is a history of chronic neck pain with a diagnosis of failed neck syndrome post prior cervical fusion C4-6 in 2008. The claimant has increasing neck pain with radiation into both upper extremities, along with paresthesias and weakness. Exam findings revealed tenderness and decreased range of motion of the cervical spine, along with decreased sensation in the C6-C7 distribution as noted on 12/11/13. Motor findings were noted to be intact on some visits and associated with weakness of shoulder abduction bilaterally on other visits. Multiple units of segmental collapse were noted at the region of the prior fusion, along with AP-reported adjacent segment disease on the MRI Scan review dated 1/23/13. The radiologist's report of the same MRI dated 11-14-12 revealed only "mild posterior bulging of the disc" at C3-C4. A discogram from 12-11-13 revealed concordant pain at C3-4, with a negative discogram at C6-7. Treatments have included pain management including with restricted activities and medications. Denial letters revealed the lack of recent comprehensive nonoperative treatment trials and failures, the lack of objective clinical findings corresponding to C3-4, the lack of reliability of discography and the lack of a psychosocial screen.

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

The claimant has had documented increasing neck pain with radiation into the upper extremities. The proximal (C3-4) level at which the claimant has positive concordant pain on discogram. This level of apparent pathology has been associated with abnormal objective findings. The nonoperative treatment has been documented to have gone on for an extensive period of time and has included restricted activities and numerous medications. The preceding has been quite adequately tried and failed. The voluminous records have never revealed any indication of abnormal psychological mileau in this patient. Adequate identification of the pain generator has occurred to the exclusion of other levels. Reasonable nonoperative treatment has been tried and failed. The hardware removal would not at all be considered routine and would be appropriate at the same operative setting. This is in order to allow for the current considered procedure at C3-4 and to decrease future potential retained and now superfluous hardware associated risks at the already fused levels. Overall intent of applicable clinical guidelines referenced below has now been met.

Reference: ODG Neck Chapter

Anterior Cervical Discectomy/Fusion-Recommended as an option in combination with anterior cervical discectomy for approved indications, although current evidence is conflicting about the benefit of fusion in general. (See Discectomy/laminectomy/laminoplasty.) Evidence is also conflicting as to whether autograft or allograft is preferable and/or what specific benefits are provided with fixation devices. Many patients have been found to have excellent outcomes while undergoing simple discectomy alone (for one- to two-level procedures), and have also been found to go on to develop spontaneous fusion after an anterior discectomy. Cervical fusion for degenerative disease resulting in axial neck pain and no radiculopathy remains controversial and conservative therapy remains the choice if there is no evidence of instability. Conservative anterior cervical fusion techniques appear to be equally effective compared to techniques using allografts, plates or cages. (Cervical fusion may demonstrate good results in appropriately chosen patients with cervical spondylosis and axial neck pain. This evidence was substantiated in a recent Cochrane review that stated that hard evidence for the need for a fusion procedure after discectomy was lacking, as outlined below:

(1) Anterior cervical discectomy compared to anterior cervical discectomy with interbody fusion with a bone graft or substitute: Three of the six randomized controlled studies discussed in the 2004 Cochrane review found no difference between the two techniques and/or that fusion was not necessary. The Cochrane review felt there was conflicting evidence of the relative effectiveness of either procedure. Overall it was noted that patients with discectomy only had shorter hospital stays, and shorter length of operation. There was moderate evidence that pain relief after five to six weeks was higher for the patients who had discectomy with fusion. Return to work was higher early on (five weeks) in the patients with discectomy with fusion, but there was no significant difference at ten weeks. One disadvantage of fusion appears to be abnormal kinematic strain on adjacent spinal levels. The advantage of fusion appears to be a decreased rate of kyphosis in the operated segments.

(2) Fusion with autograft versus allograft: The Cochrane review found limited evidence that the use of autograft provided better pain reduction than animal allograft. It also found that there was no difference between biocompatible osteoconductive polymer or autograft (limited evidence). A problem with autograft is morbidity as related to the donor site including infection, prolonged drainage, hematomas, persistent pain and sensory loss. (Autograft is thought to increase fusion rates with less graft collapse. See Decompression, myelopathy.

(3) Fusion with autograft with plate fixation versus allograft with plate fixation, Single level: A recent retrospective review of patients who received allograft with plate fixation versus autograft with plate fixation at a single level found fusion rates in 100% versus 90.3% respectively. This was not statistically significant. Satisfactory outcomes were noted in all non-union patients.

(4) Fusion with different types of autograft: The Cochrane review did not find evidence that a vertebral body graft was superior to an iliac crest graft.

(5) Fusion with autograft versus fusion with autograft and additional instrumentation:

Plate Fixation: In single-level surgery there is limited evidence that there is any difference between the use of plates and fusion with autograft in terms of union rates. For two-level surgery, there was moderate evidence that there was more improvement in arm pain for patients treated with a plate than for those without a plate. Fusion rate is improved with plating in multi-level surgery. See Plate fixation, cervical spine surgery.

Cage: Donor site pain may be decreased with the use of a cage rather than a plate, but donor site pain was not presented in a standardized manner. At two years pseudoarthrosis rate has been found to be lower in the fusion group (15%) versus the cage group (44%). A six-year follow-up of the same study group revealed no significant difference in outcome variables between the two treatment groups (both groups had pain relief). In the subgroup of patients with the cage who attained fusion, the overall outcome was better than with fusion alone. Patients treated with cage instrumentation have less segmental kyphosis and better-preserved disc height. This only appears to affect outcome in a positive way in cage patients that achieve fusion (versus cage patients with pseudoarthrosis). See also Adjacent segment disease/degeneration (fusion).

(6) Fusion with allograft alone versus with allograft and additional instrumentation:

Plate Fixation: Retrospective studies indicate high levels of pseudoarthrosis rates (as high as 20% for one-level and 50% for two-level procedures) using allograft alone. In a recent comparative retrospective study examining fusion rate with plating, successful fusion was achieved in 96% of single-level cases and 91% of two-level procedures. This could be compared to a previous retrospective study by the same authors of non-plated cases that achieved successful fusion in 90% of single-level procedures and 72% of two-level procedures. See Plate fixation, cervical spine surgery.

Discectomy/Laminectomy-ODG Indications for Surgery-- Discectomy/laminectomy (excluding fractures):

Washington State has published guidelines for cervical surgery for the entrapment of a single nerve root and/or multiple nerve roots. Their recommendations require the presence of all of the following criteria prior to surgery for each nerve root that has been planned for intervention (but ODG does not agree with the EMG requirement):

A. There must be evidence of radicular pain and sensory symptoms in a cervical distribution that correlate with the involved cervical level or presence of a positive Spurling test.

B. There should be evidence of motor deficit or reflex changes or positive EMG findings that correlate with the cervical level. Note: Despite what the Washington State guidelines say, ODG recommends that EMG is optional if there is other evidence of motor deficit or reflex changes. EMG is useful in cases where clinical findings are unclear; there is a discrepancy in imaging, or to identify other etiologies of symptoms such as metabolic (diabetes/thyroid) or peripheral pathology (such as carpal tunnel). For more information, see EMG.

C. An abnormal imaging (CT/myelogram and/or MRI) study must show positive findings that correlate with nerve root involvement that is found with the previous

objective physical and/or diagnostic findings. If there is no evidence of sensory, motor, reflex or EMG changes, confirmatory selective nerve root blocks may be substituted if these blocks correlate with the imaging study. The block should produce pain in the abnormal nerve root and provide at least 75% pain relief for the duration of the local anesthetic.

D. Etiologies of pain such as metabolic sources (diabetes/thyroid disease) non-structural radiculopathies (inflammatory, malignant or motor neuron disease), and/or peripheral sources (carpal tunnel syndrome) should be addressed prior to cervical surgical procedures.

E. There must be evidence that the patient has received and failed at least a 6-8 week trial of conservative care.

For hospital LOS after admission criteria are met, see Hospital length of stay (LOS).

Hardware Removal-Hardware implant removal (fracture fixation)

Not recommend the routine removal of hardware implanted for fracture fixation, except in the case of broken hardware or persistent pain, after ruling out other causes of pain such as infection and nonunion. Not recommended solely to protect against allergy, carcinogenesis, or metal detection. Although hardware removal is commonly done, it should not be considered a routine procedure.

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)