



Specialty Independent Review Organization

**DATE OF REVIEW:** 7/29/2011

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE**

The item in dispute is the prospective medical necessity of a cervical disc fusion with graft fixation (22554, 22585, 63075, & 63076).

**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 agrees with the previous adverse determination regarding the prospective medical necessity of a cervical disc fusion with graft fixation (22554, 22585, 63075, & 63076).

**INFORMATION PROVIDED TO THE IRO FOR REVIEW**

**PATIENT CLINICAL HISTORY [SUMMARY]:**

On xx/xx/xx, the claimant sustained neck pain in association with lifting and transferring a 30 lb. object. There has been ongoing neck pain with right upper extremity radiation into the hand and thumb, along with numbness and tingling of the right ulnar two digits. An MRI dated 8/3/10 revealed degenerative changes and stenosis at C4-5 especially, however, from C4-7 overall. A 5/28/10 dated electrical study revealed C5 radiculopathy. Treatments have included medications, injections and therapy. The Attending Physician's records from 6/14/11 and prior were reviewed. The recent exam findings document a positive Spurling's sign, and trace right-sided biceps reflex and decreased sensation in the C5 dermatome. Weakness in the right shoulder girdle musculature has been noted. The diagnosis included right "C5 radiculopathy". On 5/10/11, the Attending Physician discussed decompression and fusion from C4-7.

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

The claimant has clinical, imaging and electrical study evidence of C5 radiculopathy. Although the claimant has clinical symptoms and chronic MRI findings compatible with degenerative changes and radiculitis corresponding to other cervical spinal levels, objective clinical examination and electrical findings do not corroborate radiculopathy at those levels. Therefore, the proposed decompression and fusion at multiple cervical spine levels is not reasonable or necessary at this time, as per applicable clinical guidelines such as ODG.

**ODG/Cervical Spine - Fusion, anterior cervical:**

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.

*(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.

*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).

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

*Complications:*

*Collapse of the grafted bone and loss of cervical lordosis:* collapse of grafted bone has been found to be less likely in plated groups for patients with multiple-level fusion. Plating has been found to maintain cervical lordosis in both multi-level and one-level procedures. The significance on outcome of kyphosis or loss of cervical lordosis in terms of prediction of clinical outcome remains under investigation.

Fusion, posterior cervical

Under study. A posterior fusion and stabilization procedure is often used to treat cervical instability secondary to traumatic injury, rheumatoid arthritis, ankylosing spondylitis, neoplastic disease, infections, and previous laminectomy, and in cases where there has been insufficient anterior stabilization. Although the addition of instrumentation is thought to add to fusion rate in posterior procedures, a study using strict criteria (including abnormal motion between segments, hardware failure, and radiolucency around the screws) reported a 38% rate of non-union in patients who received laminectomy with fusion compared to a 0% rate in a group receiving laminoplasty. In a study based on 932,009 hospital discharges associated with cervical spine surgery for degenerative disease, complications and mortality were more common after posterior fusions or surgical procedures associated with a primary diagnosis of cervical spondylosis with myelopathy. The overall percent of cases with complications was 2.40% for anterior decompression, 3.44% for anterior fusion, and 10.49% for posterior fusion. Patients undergoing occipitocervical fusion or C1–2 (high cervical region) fusion is an absolute contraindication for returning to any type of activity with a risk of re-injury (such as contact sports), because the C-1 arch is relatively fragile and stability depends on the status of the periodontoid ligaments.)

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

**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)