

<b>Case Number:</b>	CM15-0144440		
<b>Date Assigned:</b>	08/05/2015	<b>Date of Injury:</b>	06/13/2012
<b>Decision Date:</b>	09/02/2015	<b>UR Denial Date:</b>	07/01/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/24/2015

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:  
 State(s) of Licensure: Illinois, California, Texas  
 Certification(s)/Specialty: Orthopedic Surgery

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This injured worker is a 48-year-old female who sustained an industrial injury on 6/13/12, relative to cumulative trauma while employed as an office administrator. She underwent C5/6 disc replacement and C6/7 anterior cervical discectomy and fusion on 2/17/14 with evidence of pseudoarthrosis at C6/7 on CT scan. A bone growth stimulator was authorized on 8/11/14. The 12/30/14 cervical spine CT scan conclusion documented previous anterior interbody fusion procedure at C6/7 with incomplete osseous fusion across the fusion site. She was status post anterior discectomy and artificial disc replacement at C5/6 with no evidence of hardware failure. The 4/11/15 electrodiagnostic conclusion documented mild focal median neuropathy at the right carpal tunnel. There was no evidence of cervical radiculopathy. The 6/11/15 treating physician report cited continued significant neck symptoms and some arm pain. Physical exam documented restricted cervical range of motion with pain on palpation. Upper extremity neurologic exam documented intact motor and sensory function. The diagnosis included C5/6 and C6/7 degenerative disc disease, and worsening right sided C7 radiculopathy. X-rays continued to reveal pseudoarthrosis at the C6/7 level. The injured worker had debilitating pain. Authorization was requested for removal of hardware at C6/7, osteotomy C6/7, partial corpectomies C6/7, possible disc replacement C6/7, possible instrumentation C6/7, and possible iliac crest bone graft, with inpatient stay and bone stimulator and fitting. The 7/1/15 utilization review modified the request for removal of hardware at C6/7, osteotomy C6/7, partial corpectomies C6/7, possible disc replacement C6/7, possible instrumentation C6/7, and possible iliac crest bone graft to allow removal of hardware at C6/7, osteotomy C6/7, partial corpectomies C6/7, possible instrumentation C6/7, and possible iliac crest bone graft.

The rationale for modification noted peer-to-peer discussion and agreement by the treating physician. The request for inpatient stay was modified to allow for a 3-day inpatient stay consistent with a revision procedure. The request for a bone stimulator and fitting was modified to allow for the continued use of the previously authorized bone stimulator.

### **IMR ISSUES, DECISIONS AND RATIONALES**

The Final Determination was based on decisions for the disputed items/services set forth below:

**Removal of hardware C6-7, osteotomy C6-7, partial corpectomies C6-7, possible disc replacement C6-7, possible instrumentation C6-7, possible iliac crest bone graft: Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints, Chapter 12 Low Back Complaints Page(s): 179, 306. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Neck & Upper Back Chapter (Online Version) Fusion, anterior cervical.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Neck and Upper Back: Disc prosthesis; Fusion, anterior cervical.

**Decision rationale:** The California MTUS are silent regarding artificial disc replacement and do not address revision cervical fusion surgery. The Official Disability Guidelines (ODG) state that pseudoarthrosis is recognized as an etiology of continued cervical pain and unsatisfactory outcome. Treatment options include a revision anterior approach vs. a posterior approach. Regardless of approach, there is a high rate of continued moderate to severe pain even after solid fusion is achieved. The ODG indicate that disc prostheses are under study. While comparative studies with anterior cervical fusion yield similar results, the expectation of a decrease in adjacent segment disease development in long-term studies remains in question. And there is an additional problem with the long-term implications of development of heterotopic ossification. Additional studies are required to allow for a "recommended" status. The general indications for currently approved cervical-ADR devices (based on protocols of randomized-controlled trials) are for patients with intractable symptomatic single-level cervical DDD who have failed at least six weeks of non-operative treatment and present with arm pain and functional/ neurological deficit. Suggested exclusions include evidence of facet arthritis, spinal instability or significant deformity. Guideline criteria have not been met for the cervical artificial disc replacement. This patient presents with two-level cervical degenerative disc disease, which fails to meet the criteria of single level disease. The use of an artificial disc in this revision surgery is not supported by guidelines. The 7/1/15 utilization review modified the request to allow removal of hardware at C6/7, osteotomy C6/7, partial corpectomies C6/7, possible instrumentation C6/7, and possible iliac crest bone graft noting discussion and agreement with the treating physician. There is no compelling rationale presented to support the medical necessity of additional certification at this time. Therefore, this request is not medically necessary.

**Associated surgical service: Inpatient stay: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Neck & Upper Back Chapter, Low Back Chapter, Hospital length of stay (LOS).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Neck and Upper Back: Hospital length of stay (LOS).

**Decision rationale:** The California MTUS does not provide hospital length of stay recommendations. The Official Disability Guidelines recommend the median length of stay (LOS) based on type of surgery, or best practice target LOS for cases with no complications. The recommended median length of stay for cervical laminectomy is 2 days. The recommended median and best practice target for anterior fusion is 1 day. The 7/1/15 utilization review modified this non-specific request to 3 days noting it was a revision procedure. There is no compelling rationale to support the medical necessity of additional certification at this time. Therefore, this request is not medically necessary.

**Associated surgical service: Bone stimulator and fitting:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Neck and Upper Back Chapter, Low Back, Lumbar and Thoracic Chapter (Online Version) Bone Growth Stimulators (BGS).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Neck and Upper Back: Bone-growth stimulators (BGS).

**Decision rationale:** The California MTUS guidelines are silent regarding bone growth stimulators. The Official Disability Guidelines indicate that the use of bone growth stimulation remains under study for the cervical spinal fusion. Bone growth stimulators may be considered medically necessary as an adjunct to lumbar fusion for patients with any of the following risk factors for failed fusion: one of more previous failed spinal fusion(s); grade III or worse spondylolisthesis; multilevel fusion; current smoking habit; diabetes, renal disease, or alcoholism; or significant osteoporosis. This injured worker has been diagnosed with pseudoarthrosis at the level of C6/7 and a revision surgery is planned. Prior use of a bone growth stimulator was documented with authorization of a bone growth stimulator. While the post-operative use of a bone growth stimulator would be consistent with guidelines, there is no compelling reason to support the purchase of an additional bone growth stimulator for this injured worker. Therefore, this request is not medically necessary.