

Case Number:	CM15-0074258		
Date Assigned:	04/24/2015	Date of Injury:	07/22/2014
Decision Date:	07/02/2015	UR Denial Date:	04/17/2015
Priority:	Standard	Application Received:	04/20/2015

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:

The injured worker is a 45 year old female who sustained an industrial injury on 7/22/14. Injury occurred while she was working as a certified nursing assistant and a patient fell on her. Past surgical history was positive for right shoulder biceps and rotator cuff surgery on 11/17/14, followed by post-operative physical therapy. The 10/9/14 electrodiagnostic study impression documented an abnormal right upper extremity study with C5 radiculopathy. The 11/5/14 cervical spine MRI impression documented disc herniation at C5/6 with more prominent left paracentral component which was impinging on the cord, without myelomalacia or ischemic changes. At C5/6, there was a broad-based central and left paracentral disc protrusion measuring 5 mm and deforming the left ventral surface of the cord with mild cord compression. There were no ischemic changes within the cord. At C6/7, there was a 3 mm broad-based disc osteophyte complex effacing the thecal sac without any cord compression. The 4/1/15 spine consult report cited worsening constant grade 8/10 neck pain and bilateral arm pain, numbness and weakness. She was unable to work due to neck and arm symptoms. Conservative treatment had included physical therapy and anti-inflammatory medication. Current medications included Norco, Motrin, Flexeril and Voltaren gel. Cervical spine exam documented positive Spurling's test, pain to palpation over C4/5, C5/6, and C6/7, and paraspinal muscle spasms. There was no muscle atrophy. Range of motion was decreased 20-50%. There was 4/5 muscle strength over the biceps, brachioradialis, and triceps bilaterally. Deep tendon reflexes and Hoffman's reflex were within normal limits. Sensation was slightly diminished over the C6 distribution. Imaging was reviewed with evidence of C4/5 disc bulge, C5/6 and C6/7 disc protrusions, and a large paracentral disc extrusion at C5/6, left worse than right. The EMG/nerve conduction study impression indicated C5 cervical radiculopathy, most likely from C4/5. The diagnosis included

C5/6 and C6/7 herniated nucleus pulposus causing stenosis and radicular symptoms, bilateral upper extremity radiculopathy/radiculitis, and C4/5 disc bulge. Authorization was requested for updated cervical imaging, x-rays, and cervical disc replacement C5/6 and C6/7 surgery. The spine surgeon opined that a 2-level disc replacement was indicated in this particular case given the adjacent sensitive disc pathology at C4/5, so it does not get stressed out and would be likely less symptomatic. Attached were the FDA pre-market approval indications for the Mobi-C cervical disc prosthesis. Authorization was requested for anterior cervical disc replacement at C5-C6 and C6-C7 with neuromonitoring, assistant surgeon, four days' inpatient stay, and pre-operative medical clearance. The 4/17/15 utilization review non-certified the anterior cervical disc replacement at C5/6 and C6/7 and associated surgical requests. The rationale was not provided.

IMR ISSUES, DECISIONS AND RATIONALES

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

Anterior cervical disc replacement at C5-C6 and C6-C7 with neuromonitoring: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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.

Decision rationale: The California MTUS are silent regarding artificial disc replacement. The Official Disability Guidelines, updated 6/25/15, state 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. The ODG guideline criteria have not been met. There is limited guideline (and/or long term, large volume literature) support for the use of cervical ADR with additional studies required to allow for a recommended status. This patient presents with multilevel cervical degenerative disc disease which fails to meet the ODG criteria of single level disease. The treating physician has provided FDA pre-market approval documents indicating that this device is indicated at two contiguous levels for intractable radiculopathy or myelopathy with herniated nucleus pulposus. However, he has documented the presence of adjacent segmental disease and guidelines state that the expected decrease in adjacent segment disease with artificial disc replacement remains in question. Additionally, detailed evidence of a recent, reasonable and/or comprehensive non-operative treatment protocol trial and failure has not been submitted. Therefore, this request is not medically necessary.

Related to surgery: assistant surgeon: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Centers for Medicare and Medicaid services, Physician Fee Schedule: Assistant Surgeons, <http://www.cms.gov/apps/physician-fee-schedule/overview.aspx>.

Decision rationale: As the surgical request is not supported, this request is not medically necessary.

Related to surgery: four days' inpatient stay: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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: As the surgical request is not supported, this request is not medically necessary.

Related to surgery: pre-operative medical clearance: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Institute for Clinical Systems Improvement (ICSI). Preoperative evaluation. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2010 Jun. 40 p.

Decision rationale: As the surgical request is not supported, this request is not medically necessary.