AccuReview

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Notice of Independent Review Decision

[Date notice sent to all parties]: February 8, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Exploration fusion at C5-C6, Removal of hardware at C5-C6, Anterior cervical discectomy and fusion at C5-C6 with plating and nerve monitoring with 1 day inpatient stay

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

This physician specializes in Orthopedic Surgery with over 49 years of experience.

REVIEW OUTCOME:

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

☒ Upheld (Agree)

INFORMATION PROVIDED TO THE IRO FOR REVIEW:
06-18-10: Cervical MRI w/3D Radiology Report
06-10-10: Brain MRI Radiology Report
06-30-10: Initial Evaluation
09-20-12: Cervical Myelogram
09-20-12: Post Myelogram CT Cervical Spine with Reconstruction including 3-D
11-09-12: Follow-up Visit
01-03-13: Request for Authorization of Spinal Surgery
01-08-13: UR performed
01-10-13: Request for Authorization of Spinal Surgery
01-06-13: UR performed

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a male with complaints of neck and left arm pain after an on the job injury on xx/xx/xx. The medical records do not denote mechanism of injury.

06-18-10: Cervical MRI w/3D Radiology Report. Impression: A broad-based, right lateral disc herniation at C5-C6 causes moderately severe compromise of the right lateral recess and right neural foramen.

06-30-10: Initial Evaluation. Claimant presented with complaints of neck pain, persistent back pain that worsens up to 8/10 in intensity with pain going into the intrascapular area. He denies weakness and tingling, but has some numbness in the left hand. He reported that Tramadol makes it better and driving makes it worse. Medications: Skelaxin, Advil. Physical Examination: Tenderness noted in the paraspinal cervical area. Impression: the claimant has never injury with left arm numbness. He has a herniated disc at C5-6 on the right side. The herniation appears to be the cause of his pain. However, he does not have right-sided findings. There is no role for surgical intervention in this case. This is a primarily a neck injury and requires conservative treatment for the local neck area. Claimant will start physical therapy soon. Claimant will be treated with anti-inflammatory medications. If he does not progress with therapy alone, ESI may be required. However, "there is no role for consideration of surgery down the line". Follow up as needed.

09-20-12: Cervical Myelogram. Impression: 1. C5-6 is status post ACDF with interbody graft. 2. The interbody graft, probably a bone plug, does not show solid bony healing. Instability is possible, to be correlated with flexion and extension radiographs. 3. The plate is slightly embedded at its lower margin, abutting a ridge at the lower anterior surface of C6.

09-20-12: Post Myelogram CT Cervical Spine with Reconstruction including 3-D. Impression: 1. Review of post myelogram CT study done 9/20/12 shows ACDF at C5-6 without solid interbody bony healing. 2. There is some question of bone growth within the spacer however this does not appear solid.

11-09-12: Follow-up Visit. The claimant underwent anterior cervical decompression and reconstruction by another spine surgeon and presented today with persistent pain in the neck region going into the left shoulder since. Recent imaging studies suggest possible failed fusion. Since surgery, the claimant has had chiropractic manipulations and therapy without relief. The pain goes down the left shoulder but does not shoot into the arm or hand since the operation. The symptoms are quite significant and impair his ability to engage in activities of daily living. Physical examination reveals tenderness to palpation of the cervical spine, decreased ROM in the neck. The claimant is suffering from failed fusion at C5-6 and has persistent neck pain radiating into the shoulder. He has failed maximum conservative care and requires exploration of the area with redo fusion. The claimant is a smoker and explained that this could be a major factor for why his fusion may have failed. Indicated to the claimant that it is critical that he quit smoking; and be smoke free six months postoperatively. We will pursue external bone growth stimulator; there is a high probability of achieving successful fusion via an anterior approach.

01-08-13: UR performed. Reason for denial: The previous CT myelogram stated nothing about a failed fusion at C5-6 and that if there were a failed fusion an evaluation of the CT myelogram by an independent radiologist would certainly be indicated. The request for the exploration and fusion at C5-C6 and removal of hardware at C5-C6 with anterior cervical discectomy and fusion at C5-C6 with plating and nerve monitoring with a one day inpatient stay is not certified. The Official Disability Guidelines would not support the exploration and fusion at C5-C6 and removal of hardware at C5-C6 with plating and nerve monitoring with one day inpatient stay as medically indicated. There is no documentation of any instability by the diagnostic imaging as required by the guidelines. This claimant has no objective evidence of radiculopathy of the physical examination. The official Disability Guidelines state all pain generators should be identified and treated. There is no documentation of lower levels of care of non steroidal anti inflammatories, muscle relaxers or epidural steroid injections status post the first surgery. The ODG does not support surgical fusion in smokers. The ODG would support a psychosocial screen with confounding issues addressed in a claimant who has already undergone a previous surgical fusion. There is no documentation of any psychosocial screening in the medical records. Based on the medical records available for review and this peer reviewed evidenced based guidelines, the request for exploration and fusion at C5-C6 and removal of hardware at C5-C6 with anterior cervical discectomy and fusion at C5-C6 with plating and nerve monitoring with a one day inpatient stay would not be supported as medically indicated. This request is not certified.

01-06-13: UR performed. Reason for denial: The reconsideration for request for exploration of fusion at C5-6, removal of hardware, ACDF C5-6 with plating and nerve monitoring and a one day inpatient stay cannot be recommended as medically necessary at this time. The extent of conservative treatment, status of smoking cessation, and current clinical status beyond November 2012 are not known and thus medical necessity for this procedure cannot be established. Recommend denial of pre-authorization.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:
After reviewing the medical records and documentation provided, the previous adverse decisions are upheld and agreed upon. There is no clear definition of mechanism of injury that the claimant said to have had on xx/xx/xx. It is also unclear is surgical procedure was done prior to or after said injury. Conservative care does not appear to be exhausted. There are no indications of instability on diagnostic imaging nor are there findings of radiculopathy on physical examine. Per ODG, if the claimant has no radiculopathy then conservative therapy remains the choice if there is no evidence of instability; furthermore there is no determining factor for medical necessity at this time. Request for Exploration fusion at C5-C6, Removal of hardware at C5-C6, Anterior cervical discectomy and fusion at C5-C6 with plating and nerve monitoring with 1 day inpatient stay is denied.

Per ODG:

Fusion, anterior	Recommended as an option in combination with anterior cervical discectomy for

cervical	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. (Bertalanffy, 1988) (Savolainen, 1998) (Donaldson, 2002) (Rosenorn, 1983) 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. (Bambakidis, 2005) Conservative anterior cervical fusion techniques appear to be equally effective compared to techniques using allografts, plates or cages. (Savolainen, 1998) (Dowd, 1999) (Colorado, 2001) (Fouyas-Cochrane, 2002) (Goffin, 2003) Cervical fusion may demonstrate good results in appropriately chosen patients with cervical spondylosis and axial neck pain. (Wieser, 2007) 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. (Jacobs-*Cochrane*, 2004) (Abd-Alrahman, 1999) (Dowd, 1999) (Martins, 1976) (van den Bent, 1996) (Savolainen, 1998) One disadvantage of fusion appears to be abnormal kinematic strain on adjacent spinal levels. (Ragab, 2006) (Eck, 2002) (Matsunaga, 1999) (Katsuura, 2001) The advantage of fusion appears to be a decreased rate of kyphosis in the operated segments. (Yamamoto, 1991) (Abd-Alrahman, 1999) *(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). (Jacobs-*Cochrane*, 2004) (McConnell, 2003) A problem with autograft is morbidity as related to the donor site including infection, prolonged drainage, hematomas, persistent pain and sensory loss. (Younger, 1989) (Sawin, 1998) (Sasso, 2005) Autograft is thought to increase fusion rates with less graft collapse. (Deutsch, 2007). 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. (Samartzis, 2005) *(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. (McGuire, 1994) *(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. (Wright, 2007) 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). (Poelsson, 2007) (Varuch, 2002) (Hacker 2000) 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. (Kaiser, 2002) (Martin, 1999) See Plate fixation, cervical spine surgery. *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. (Troyanovich, 2002) (Herrmann, 2004) (Katsuura, 1996) The significance on outcome of kyphosis or loss of cervical lordosis in terms of prediction of clinical outcome remains under investigation. (Peolsson, 2004) (Haden, 2005) (Poelsson, 2007) (Hwang, 2007) See also Laryngoscopy (screening for recurrent laryngeal nerve injury prior to revision ACDF). *Pseudoarthrosis:* This 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. (Kuhns, 2005) (Mummaneni, 2004) (Coric, 1997) *Anterior versus posterior fusion:* In a study based on 932,009 hospital discharges associated with cervical spine surgery, anterior fusions were shown to have a much lower rate of complications compared to posterior fusions, with the overall percent of cases with complications being 2.40% for anterior decompression, 3.44% for anterior fusion, and 10.49% for posterior fusion. (Wang, 2007) *Predictors of outcome of ACDF:* Predictors of good outcome include non-smoking, a pre-operative lower pain level, soft disc disease, disease in one level, greater segmental kyphosis pre-operatively, radicular pain without additional neck or lumbar pain, short duration of symptoms, younger age, no use of analgesics, gainful employment, higher preoperative NDI and normal ratings on biopsychosoical tests such as the Distress and Risk Assessment Method (DRAM). Predictors of poor outcomes include non-specific neck pain, psychological distress, psychosomatic problems and poor general health, litigation and workers' compensation. (Anderson, 2009) (Peolsson, 2006) (Peolsson, 2003) Patients who smoke have compromised fusion outcomes. (Peolsson, 2008) See Plate fixation, cervical spine surgery. See also Adjacent segment disease/degeneration (fusion) & Iliac crest donor-site pain treatment. *Use of Bone-morphogenetic protein (BMP):* FDA informed healthcare professionals of reports of life-threatening complications associated with recombinant human Bone Morphogenetic Protein (rhBMP) when used in the cervical spine for spinal fusion. The safety and effectiveness of rhBMP in the cervical spine have not been demonstrated, and these products are not approved for this use. These complications were associated with swelling of neck and throat tissue, which resulted in

	compression of the airway and/or neurological structures in the neck. (FDA MedWatch, 2008) Bone-morphogenetic protein was used in approximately 25% of all spinal fusions nationally in 2006, with use associated with more frequent complications for anterior cervical fusions. No differences were seen for lumbar, thoracic, or posterior cervical procedures, but the use of BMP in anterior cervical fusion procedures was associated with a higher rate of complication occurrence (7.09% with BMP vs 4.68% without BMP) with the primary increases seen in wound-related complications (1.22% with vs 0.65% without) and dysphagia or hoarseness (4.35% with vs 2.45% without). (Cahill-*JAMA*, 2009) For hospital LOS after admission criteria are met, see Hospital length of stay (LOS).

Hospital length of stay (LOS)	**ODG hospital length of stay (LOS) guidelines:** **Discectomy/ Corpectomy** (*icd 80.51 - Excision of intervertebral disc*) Actual data -- median 1 day; mean 2.1 days (± 0.0); discharges 109,057; charges (mean) $26,219 Best practice target (no complications) -- *1 day* **Cervical Fusion, Anterior** (*81.02 -- Other cervical fusion, anterior technique*) Actual data -- median 1 day; mean 2.2 days (±0.1); discharges 161,761; charges (mean) $50,653 Best practice target (no complications) -- *1 days*

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)