IMED, INC.
11625 Custer Road • Suite 110-343 • Frisco, Texas 75035 Office 972-381-9282
• Toll Free 1-877-333-7374 • Fax 972-250-4584 e-mail: imeddallas@msn.com

Notice of Independent Review Decision

[Date notice sent to all parties]:
06/26/2012

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
20931 femoral ring bone 22554 arthrodesis – ant interbod; cervical B 22585 anterior lumbar fusion add'l interspace 22845 anterior instrumentation 22851 application of prosthetic device 62272 spinal puncture, therapeutic; for drainage of C 62310 injection, W/WO contrast; diagnostic / therapeuti 63075 diskectomy ant w/ decomp; cervical s 63076 anterior cervical discectomy fusion add'l spa 69990 microsurgical tech; requiring use of operating microscope

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

Board Certified Orthopedic Surgeon

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

X Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for <u>each</u> of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

1. Clinical records D.C. 12/19/11-05/31/12
2. Functional capacity evaluation dated 12/12/11
3. EMG/NCV study dated 01/28/12
4. MRI lumbar spine dated 01/26/12
5. MRI cervical spine dated 02/13/12
6. Clinic note Dr. 04/03/12
7. Progress note Dr. dated 04/18/12
8. Utilization review determination dated 04/18/12
9. Utilization review determination dated 05/17/12, amended 06/06/12

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a female who is reported to have sustained work related injuries on xx/xx/xx. It is reported on the date of injury she was checking on food in cafeteria and when going back into her office she tripped with stool car losing her balance and falling down onto her left side twisting her left knee and left wrist which struck the stool car. The record includes functional capacity evaluation dated 12/12/11 which reported consistent effort. She is noted to be capable of light to medium capacity.

On 12/19/11 the claimant sought care from, D.C. At this time she reports she sustained injuries to her cervical spine, lumbar spine, left knee, and left wrist on 12/02/11. She is reported to have stepped on milk cart and subsequently fell. She has complaints of pain involving upper back, lumbar spine, and left shoulder. She reported pain radiating to left buttocks. She is pending MRI. On examination she is noted to have swelling, erythema, and tenderness to palpation over the anterior left wrist. Range of motion is reduced. She is reported to have tenderness in mid portion of lumbar spine with reduced range of motion. She is reported to have reduced strength in L3 nerve roots. Reflexes were reported to be 2/4 and symmetric. Sensory is reported to be intact and gait is normal. She was diagnosed with lumbar sprain, cervical sprain, knee sprain, and wrist sprain. She was recommended to participate in physical therapy. On 01/28/12 the claimant was referred for EMG/NCV studies. There is no identification of focal nerve entrapment in upper extremities. There was increased activity in left C5-6 distribution on EMG/NCV. The cervical paraspinal musculature was not tested. The evaluator suggests there is evidence of mild acute C6 radiculopathy on the right.

On 01/26/12 the claimant was referred for MRI of lumbar spine which showed no abnormalities at L1-2, L2-3, L3-4 and L5-S1. At L4-5 there is desiccated disc with diffuse disc bulge more prominent on right. The canal and bilateral foraminal stenosis right greater than left with degenerative changes of facets.

On 02/13/12 the claimant was referred for MRI of cervical spine. This study notes a loss of cervical lordosis with focal kyphosis from C4-6. At C3-4 there is bulging of disc with small central protrusion and no nerve root displacement, central or foraminal stenosis. At C4-5 there is a bulging disc, patent right foramen, left foraminal spur and protrusion with moderate stenosis. At C5-6 there is bulging of disc endplate spurs, moderate central stenosis, mild left foraminal stenosis, moderate right foraminal stenosis from spurring. At C6-7 there is a bulging disc, endplate spurs, moderate central stenosis with mild bilateral foraminal stenosis.

On 03/08/12 the claimant was seen in follow-up and noted to have continued cervical and lumbar pain. Current medications include Ibuprofen, Hydrocodone. There does not appear to be any substantive changes in physical examination. She is noted to be referred to neurosurgery.

On 04/03/12 the claimant was seen by Dr.. She presents with complaints of pain to her neck and lower back mostly concentrated in her neck. She is reported to have a history of a work place injury when she bumped into a cart with wheels and fell straight to the ground. The pain is reported to begin in her neck and goes down her spine but mostly remains in her shoulder blades, left arm, and travels down the forearm to the hand. She further reports

pain from her lower back down to her legs causing knee weakness. She has been treated by Dr. with physical therapy. She reports experiencing numbness and weakness in her upper and lower back. On physical examination she is 5'4" tall and weighs 185 pounds. She is noted to be a non-smoker. She is noted to have tenderness to palpation in the cervical spine and lower back with limited range of motion. She is reported to be able to heel toe walk with difficulties. Deep tendon reflexes are 2+ and symmetric. She has increased paravertebral muscle tone in the cervical area. She is reported to have giveaway weakness, weakness in the biceps bilaterally, questionable triceps, and opposition of the hand. Sensory is reported to be decreased in the thenar region bilaterally as well as some area of hyperesthesia. She subsequently is recommended to undergo ACDF with fusion.

On 04/18/12 the initial review was performed by an orthopedic surgeon. The request was for ACDF at C5-6 and C6-7. The reviewer non-certified the request as there is no evidence of cervical instability by flexion or extension x-rays. She has complaints of pain in the neck but deep tendon reflexes are 2+. She has give way weakness but no documented atrophy. There is some weakness in the biceps bilaterally and questionable triceps and opposition of the hand. EMG documented a mild acute C6 radiculopathy on the right which would correlate with the mild biceps weakness on the right. He notes that findings are not strong and are equivocal and epidural steroid injection should be performed as both diagnostic and therapeutic and subsequently non-certified the request. The records indicate that the claimant was seen in follow-up by Dr. on 04/19/12. She is noted to have diffuse complaints. There are no substantive changes documented in her physical examination. Sensory is reported to be intact. Reflexes are noted to be 2/4 and symmetrical. She was continued on conservative management. The appeal request was reviewed on 05/17/12. The reviewer reports that the claimant had a designated doctor evaluation for extent of injury which did not report any neurologic deficit and diagnosed the cervical spine with a myofascial pain syndrome. He notes that MRI showed moderate canal stenosis at C4-5, C5-6, and C6-7 and electrodiagnostic studies showed a right mild C6 nerve root radiculopathy. He opines that the fusion at C5-6 and C6-7 would not address the C4-5 level which is also with moderate stenosis.

The claimant was seen in follow-up by Dr. on 05/31/12. She has continued cervical and lumbar pain. There are no substantive changes documented in her physical examination.

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

The request for 20931 femoral ring bone 22554 arthrodesis – ant interbod; cervical B 22585 anterior lumbar fusion add'l interspace 22845 anterior instrumentation 22851 application of prosthetic device 62272 spinal puncture, therapeutic; for drainage of C 62310 injection, W/WO contrast; diagnostic / therapeuti 63075 diskectomy ant w/ decomp; cervical s 63076 anterior cervical discectomy fusion add'l spa 69990 microsurgical tech; requiring use of operating microscope is not supported as medically necessary. The submitted clinical records indicate that the claimant sustained a trip and fall on the date of injuries with initial reporting of injuries to the left knee and left wrist. Later the claimant had reported complaints involving the neck and low back. The submitted clinical records include serial records from Dr. which show no substantive changes in the claimant's

physical examination and no objective data on his reported examination which would establish the presence of a cervical radiculopathy. It is noted that the claimant underwent EMG/NCV study on 01/28/12 which was performed by a technician and subsequently later interpreted by Dr.. Of note, in review of this study there is some increased activity noted in the left C5-6 distribution. However, there is no evidence in this report that the cervical paraspinal musculature was tested. The increased insertional activity is noted in the left biceps in a C5-6 distribution. However, the report indicates right which was not consistent with the data. The claimant was subsequently referred for MRI of the lumbar spine which does not show significant pathology and evidence of degenerative changes at L4-5. The claimant underwent MRI of the cervical spine which showed evidence of moderate stenosis at C4-5, C5-6, and C6-7. There is evidence in the imaging of a loss of lordosis. The claimant was ultimately referred to Dr. who does not document any substantive findings in the cervical spine or substantive findings on physical examination. The claimant is noted to have giveaway weakness. There is reported to be a sensory deficit in the thenar region. There is not a significant amount of clinical data provided that correlates. The claimant's treatment to date has consisted of oral medications and physical therapy. There is no clear indication that all potential pain generators have been identified. The EMG/NCV study is invalid as it does not include any testing of the cervical paraspinous musculature and appears to have been performed by a technician and interpreted by a physician at a later date. Based upon the submitted clinical record there is potential pathology at C4-5, C5-6, and C6-7. However, the requested procedure would only address pathology at the C5-6 level. This would ultimately result in the claimant having to undergo a second surgery to address what would be rapidly developing adjacent segment disease at the C4-5 level. Therefore, based on the totality of the clinical information the prior utilization review determinations would be deemed not medically necessary.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

X MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

X ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

The 2012 Official Disability Guidelines, 17th edition, The Work Loss Data Institute. Online edition.

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. (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)

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).