Specialty Independent Review Organization

Notice of Independent Review Decision

Date notice sent to all parties: 6/4/2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
The item in dispute is the prospective medical necessity of C4, 5, 6, 7 – ACDF / AISF; inpatient stay x 1 day.

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.

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 C4, 5, 6, 7 – ACDF / AISF; inpatient stay x 1 day.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:
Records were received and reviewed from the following parties:

These records consist of the following (duplicate records are only listed from one source): Records reviewed:

Pre-authorization Request – undated
MRI Scan Review – 2/26/13
Office Visit Note – 3/12/13
Office Visit Surgical Consultation – 2/26/13
Prescription Script – 2/26/13
Pre-authorization Request Appeal - undated

Psychological Evaluation – 5/5/13

MRI Cervical Spine – 10/24/12

EMG/NCV Report – 2/13/13
Clinical Encounter Summaries – 1/23/13, 2/6/13
Action Sheet – 2/6/13

Physical Therapy Evaluation – 12/7/12
Daily Treatment Note – 12/10/12, 12/12/12, 12/18/12, 12/19/12
Neck Pain Disability Index Questionnaire – 12/19/12
Revised Oswestry Disability Index – 12/19/12

Denial Letters – 5/10/13, 5/17/13

Records reviewed
LHL009 – 5/20/13
Surgery Checklist & Expected Surgery Codes - undated

A copy of the ODG was not provided by the Carrier or URA for this review.

PATIENT CLINICAL HISTORY [SUMMARY]:
The claimant was noted to have been injured on xx/xx/xx in a motor vehicle accident while working as a xx, as noted in the 5/5/13 dated consultant's record. The xx has been noted to have an MRI scan that reveals (as per the provider's record of 2/26/13) evidence of multilevel cervical disc herniations with spinal stenosis. On 3/12/13, the provider indicated an assessment of "traumatic internal disc disruption syndrome with discogenic pain and clinical instability of cervical spine…with primarily right upper extremity radiculopathy with failure of conservative treatment greater than six months, surgical intervention pending." The 2/26/13 dated report discussed neck and arm pain with numbness and tingling. Examination findings included a positive compression test with paravertebral muscle spasm and trigger points, hypoactive reflexes of the right upper extremity (including biceps and triceps), along with motor weakness. (wrist extension and elbow flexion-extension.) Paresthesias were noted in the distribution of C6 and C7 on the right. A psychological evaluation-screen was dated 5/5/13 and was noted to reflect significant adverse issues. Within the report it was noted that "he has had chiropractic care and physical therapy, with little to no relief to his cervical spine. He had one epidural steroid injection to his cervical spine, which severely aggravated his condition." The 10/24/12 dated cervical spine MRI revealed a disc herniation at C4-5 with stenosis along with stenosis from C3-4 through C5-6. At C6-7 the radiologist noted "subtle disc bulge measuring 2 mm is noted without stenosis." Electrodiagnostic records from 2/13/13 were reviewed and were noted to be unremarkable for any evidence of radiculopathy or otherwise. Clinical notes dated 2/6/13 discussed treatment with medications. Therapy records as of 12/7/12 were reviewed. Denial letters

discussed a lack of "segmental instability" along with normal electrodiagnostic studies and a non-corroborated C6-7 level of radiculopathy.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:
Despite the most recent clinical findings including at C6-7; the completely normal electrodiagnostic study and the MRI (at C6-7) revealing only a "subtle disc bulge measuring 2 mm … without stenosis" do not therefore support the overall aggregate procedures as being medically necessary at this time. This is based on the overall documentation of the injury mechanism, subjective and objective findings and lack of meeting the applicable clinical guidelines records below.

ODG Cervical Spine Chapter:
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.

ODG hospital length of stay (LOS) guidelines: Cervical Fusion, Anterior (*81.02 -- Other cervical fusion, anterior technique*) Actual data -- median 1 day; mean 2.2 days (±0.1); Best practice target (no complications) -- *1 days*
Plate fixation, cervical spine surgery: Under study in single-level and multi-level procedures, with most studies (although generally non-randomized) encouraging use in the latter. *Indications:* There is no consensus as to when plates should be used for anterior cervical fusion in spite of widespread use. Common use is found in the treatment of degenerative disc disease, tumors, trauma and deformity. (Rhee, 2005) It remains unclear as to whether anterior plating provides benefit for many common spondylotic conditions of the cervical spine. In single-level surgery there has been a failure to demonstrate an improvement in fusion rates with plating. (Wang, 1999) (Samartzis, 2004) (Grob 2001) (Connolly, 1996). Plating does appear to improve fusion rates in multilevel procedures. (Wang 2000) (Wang 2001) *Potential benefits* as an adjunct to anterior cervical discectomy and fusion include that the plate may: (1) provide rigid fixation; (2) resist graft setting with less development of kyphosis; (3) provide higher fusion rates; (4) allow for less cumbersome instrumentation; (5) reduce the rate of graft extrusion; & (6) reduce the need for prolonged external immobilization of the neck. *Potential downsides:* (1) increased surgical time and cost; (2) increased potential of morbidity and mortality during revision as the plate must be removed; & (3) numerous implant related complications including esophageal erosion, injury to adjacent structures due to hardware, and adjacent level ossification. (Rao, 2006) *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)

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)**