AccuReview

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Notice of Independent Review Decision

[Date notice sent to all parties]: June 30, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

RC110 Inpatient Non-Surgical Room, 22856 TOT Disc Arthrp Art Disc Ant Appro, 95941 IONM Remote/Nearby/>1 Patient in OR (C5/6 Arthroplasty with 1 day Length of Stay)

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

This physician is a board certified Orthopaedic Surgeon with over 13 years of experience.

REVIEW OUTCOME:

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

☒ Upheld (Agree)

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

INFORMATION PROVIDED TO THE IRO FOR REVIEW:
04-04-11: New Work-comp Patient Consult
04-18-11: Work-comp Follow-up Office Visit
05-09-11: Work-comp Follow-up Office Visit
05-31-11: Work-comp Follow-up Office Visit
06-15-11: Work-comp Follow-up Office Visit
06-28-11: Work-comp Follow-up Office Visit
07-21-11: Work-comp Follow-up Office Visit
07-22-11: MRI Cervical Spine W/O Contrast
07-26-11: Follow-up Office Visit
08-23-11: Work-comp Follow-up Office Visit
09-22-11: Follow-up Office Visit
10-20-11: Work-comp Follow-up Office Visit

11-21-11: Work-comp Follow-up Office Visit
12-07-11: Consultation
12-07-11: Radiology Report
01-04-12: Operative Report
01-04-12: Radiography Note
01-09-12: Behavioral Medicine Evaluation
01-13-12: Consultation
02-22-12: Follow-up
03-22-12: Follow-up
04-30-12: Functional Capacity Evaluation
07-03-12: Case Management Conference
08-01-12: Follow-up
08-08-12: Office Visit
10-12-12: Office Visit
10-26-12: NCS
11-07-12: Office Visit
02-27-13: Discogram Report
02-27-13: Imaging Report
03-04-13: Office Visit
03-15-13: UR performed
05-15-13: UR performed

PATIENT CLINICAL HISTORY [SUMMARY]:
The claimant is a female who was injured on xx/xx/xx, when was dragged by a vehicle and fell onto the street. She sustained injured to her left upper and lower extremities and resulted in a sprained left index finger.

04-04-11: New Work-comp Patient Consult. Claimant is two weeks post injury and still has quite symptomatic left index finger injury. Clinical Evaluation shows bruising to left thigh, left hand bruising over the dorsum of the hand including the left index finger. Impression: Contusion of left thigh and ligamentous injury of left finger index. Plan: Buddy tape fingers, no work until further notice, follow up in two weeks.

04-18-11: Work-comp Follow-up Office Visit. Claimant presented with problems with her left shoulder secondary to the injury. Imaging studies are negative. Clinical Evaluation: There is still imitation of flexion at DIP and PIP joints. There is some tenderness on the region, especially rhomboid where she has trigger pointing. She has some limitation in range of motion of the shoulder due to trigger point in the area with neurovascular exam intact. Plan: Continue buddy taping it and allow her to take it off for range motion. Recommend stretching and icing. We have given her some Voltaren cream. Other treatment options are physical therapy and TENS unit will be offered if symptoms do not improve.

05-09-11: Work-comp Follow-up Office Visit. Claimant stated she is slowly getting better and has been working on range of motion at home. Clinical Evaluation: The claimant still has tightness and inability to abduct past 90 degrees and limitation in internal and external rotation with neurovascular exam of

the upper extremity good and bilaterally equal. Left index finger lacks the last 20 degrees of flexion at the DIP and PIP joint. There is some swelling. Plan: Continue rehab program at home and start formal physical therapy and occupational therapy for her hand. Follow up in three weeks.

06-15-11: Work-comp Follow-up Office Visit. Claimant presented with spasm, pain and tenderness in her thoracic area extending to her scapula. Clinical Evaluation: Noted spasming of the rhomboid and latissimus dorsi. Plan: Started her on Flexeril 5mg PO BID, Voltaren cream, icing, and stretching.

07-21-11: Work-comp Follow-up Office Visit. Claimant is having more spasm, pain and tenderness now in the cervical spine with trigger pointing in the rhomboid and trapezial groups. Clinical Evaluation: Examination again shows trigger pointing mostly on the left side with ROM improving. Plan: Recommend continue PT and work stimulation. Left upper extremity and cervical spine with new spasm, pain and tenderness in the neck which is not responding to treatment and with flare-up, recommend MRI to delineate the pathology. Follow up in one month.

07-22-11: MRI Cervical Spine W/O Contrast. Impression: Straightening of normal cervical lordosis, C5-6 degenerative disc disease, posterior disc osteophyte complex, apophyseal joint arthrosis, mild central canal stenosis. C6-7 disc desiccation, small non-compressive central posterior disc herniation of the protrusion type, apophyseal joint arthrosis, mild central canal stenosis.

07-26-11: Follow-up Office Visit. MRI showed some evidence of disc dissection at C6-C7 with protrusion, which may be responsible for symptoms. Plan: Recommend to continue therapy and referral to pain management for consideration of epidural steroid injection.

10-20-11: Work-comp Follow-up Office Visit. The claimant is scheduled for second ESI of cervical spine tomorrow. The first ESI seemed to help. The claimant continues to do HEP. Plan: Follow up in one month.

11-21-11: Work-comp Follow-up Office Visit. Claimant continues to have cervical problems, left quad and left hand pain. The two ESIs have not helped much. Plan: Referred to spine surgeon to get a surgical option.

12-07-11: Consultation. Chief Complaint: neck pain and left scapular pain. Claimant stated she has no numbness; however, when she uses the arm bike which has been given for her physical therapy, her left 4 fingers go numb not her thumb, but her 4 fingers go numb when she is on the arm bike. PE: Musculoskeletal: Claimant is able to extend her cervical spine and jaw 34 degrees above the horizontal line and able to flex chin 2 fingerbreadths from chest. She rotates to the right approximately 85 degrees and rotates to the left approximately 70 degrees. Sidebending is about 30 degrees bilaterally. She is slightly limited with her finger flexion of her index and ring finger of the left hand, pinky particularly due to her injuries from the fall, notes improvement. Assessment: 1. Neck pain with inspirational left scapular pain without signs of

radiculopathy following on-the-job injury on xx/xx/xx, superimposed on mild cervical spondylosis, C5-6 with bilateral facet joint arthropathy without signs of myelopathy or radiculopathy. 2. Left thigh and left hand injury, again secondary to on-the-job injury. Plan: Claimant is a candidate for cervical facet injections. Injections ordered.

12-07-11: Radiology Report. AP and lateral as well as flexion/extension x-rays revealed spondylosis. There is joint space loss at C5-6 and maybe very mildly at C4-5. On flexion/extension, there is no significant noted instability noted in a neutral position. The claimant has lost a little bit of her lordosis at the C4-5 and 5-6, but it does correct on the extension films.

01-04-12: Operative Report. Preoperative Diagnosis: 1. Neck pain, 2. Cervical facet syndrome. Postoperative Diagnosis: 1. Neck pain, 2. Cervical facet syndrome. Procedure: 1. Bilateral C5-6 facet joint injection, 2. Fluoroscopic guidance for needle placement.
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01-09-12: Behavioral Medicine Evaluation. The claimant presented with major complaints of pain in the neck and left arm. General Conclusions: Major Psychological Symptoms: very mild adjustment issues. Psychological Assets: Take no pain medication, positive coping, and strong support system. Psychological Liabilities: May have pacing problems upon return to work. Medical Treatment Recommendations and Client Management Suggestions: Based on this presurgical psychological screening she is clear for the discogram, without any concern that psychological issues will impact the results. Should she become a candidate for cervical spine surgery, based on this presurgical psychological screening she is clear for the surgery, with a good prognosis for pain reduction and functional improvement. The client needs to be aware that maximal surgical recovery will result from active participation in post-surgical rehabilitation and pain management activities. The patient needs a great deal of information and structure in order to achieve maximal gains from the surgery. The patient should be referred back for further psychological evaluation if pain does not remit or if progress is slower than expected.

01-13-12: Consultation. Chief complaint: neck pain. Assessment: 1. Neck pain with some radiating left scapular pain without radiculopathy at C5-6 and C6-7 and degenerative bulging and some facet changes. 2. Left thigh and left hand injury. Plan: 1. She is having persistent symptoms. She has not responded to the facet block, epidural steroid injections, oral medications, and physical therapy at this time has not considered an operative candidate. 2. Recommend consideration for a trial of some chiropractic care. We will continue the Neurontin. 3. Refer.

04-30-12: Functional Capacity Evaluation. According to the Physical Demand Characteristics of work (PDC) per the employer, the claimant must function at a light-medium physical demand level to perform this job. She is currently functioning at a light-medium physical demand level. This level is adequate for the job requirements. Deficits: decreased lifting ability, decreased positional tolerance, body mechanics, decreased cardiovascular endurance job demands,

overall conditioning, posture, decreased range of motion, tenderness: upper traps, levator scapula, decreased strength: left upper extremities. Recommendations: 1. Follow up for the review of functional status. 2. May benefit from left quad/thigh medical assessment: although left lower extremity was not a compensable injury it limited claimant with material handling and non-material handling activities involving the lower extremities. 3. Attend a work conditioning program for 2-3 weeks to address the listed deficits.

10-12-12: Office Visit. Claimant presented with neck pain. PE: Reflexes of the upper extremities are symmetric spurling maneuver is negative. Motor testing reveals no weakness. Assessment: Chronic neck pain with left scapular pain following on the job injury xx/xx/xx were left in discogenic syndrome C5-6 and possibly C4-5 facet of extensive conservative treatment, with multiple other injuries following the on-the-job injury. Plan: Proceed with EMG nerve conduction left upper extremity. The claimant was not approved for discography. She should not be able to work and neither is she at maximal medical recovery. Problems added to visit: Cervical Radiculopathy Syndrome 723.4.

10-26-12: NCS. Impression: 1. There is no electrodiagnostic evidence of an active left cervical radiculopathy. 2. Mild, asymptomatic left median neuropathy at the wrist. 3. Possible rotator cuff syndrome. Plan: Consider left shoulder work-up (MRI) is not previously done to rule out RC lesion from injury. Follow up.

02-27-13: Discogram Report. Impression: The C4-5 disc was normal and painless. On retest I over pressurized and saw a small leak, but this was technical, and in my opinion this is otherwise a normal disc. The C5-6 disc was degenerative and leaky. Resistance was reduced. Pressurization produced severe concordant pain, which the patient rated 9/10 VAS.

02-27-13: Imaging Report. Procedure: CT C-spine Post Disco. Impression: Spondylosis as described, most sever at C5-C6 with some extension of contrast material into the anterior epidural space.

03-04-13: Office Visit. Claimant continues to have neck pain and arm pain. Assessment: Chronic neck pain with left scapular pain following on the job injury xx/xx/xx. Secondary to cervical spondylosis with probable foraminal stenosis C5-6 with a positive discogram at the C5/6 level; with multiple other injuries following on-the-job injury. Plan: The claimant would be an excellent candidate for a one level artificial disc replacement at the C5/6 level. Once this is approved by workman's compensation we will see the claimant back for pre-operative consultation. Problems added in today's visit: Cervical Radiculopathy Syndrome 723.4.

03-15-13: UR performed. Reason for denial: Guidelines do not support disc prosthesis as it is currently under study for the cervical spine. Rationale or indications for use suggesting that mobility at the degenerative joint is the source of pain. There is no true documentation of instability or motion at the specific level noted support the need for a fusion or disc prosthesis at this time. The claimant

has no documentation of radiculopathy. Electrodiagnostic studies were negative and documentation of muscular weakness, muscular atrophy, and assessment was performed in January of 2012. Guidelines would not support surgery when there may be underlying psychiatric pathology or for those who have multi-level degenerative changes or facet pathology. The claimant has had multi-level degenerative disc changes at C5-C7 with prior documentation of facet symptoms and prior facet injections performed. The request for C5-C6 arthroplasty with one day length of stay is non-authorized.

05-15-13: UR performed. Reason for denial: The request for C5-C6 arthroplasty of the cervical spine with one day hospital stay is not certified. Based on treatment guidelines disc prosthesis or disc replacement surgery is considered to be under study and not supported for the cervical spine. It is also noted although the claimant has complaints of neck pain and left arm radicular symptoms, electrodiagnostic studies and physical examination findings do not support any evidence of a clinical radiculopathy. There is no significant loss of strength or loss of sensation in a specific dermatomal pattern. There is no documentation of any changes in reflexes or significant physical examination findings to support the medical necessity of surgical intervention at this time consisting of a disc replacement surgery or even a discectomy type procedure. The previous non-certification was reviewed, and based on the fact there were no clinical documentation of any radiculopathy. There was no documentation of any instability of the cervical spine on X-ray studies; therefore, the request was not certified. The treating provider has not provided any additional information that would result in an overturn of the previous determination. The request is non-authorized.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:
Previous adverse decision is upheld and agreed upon. The requested service of C5-6 arthroplasty is not an appropriate surgical option for this claimant. It is noted that the claimant has multiple levels of degenerative disease in her cervical spine. She has disc degeneration and facet disease at C5-6 and C6-7 identified on MRI. She also has facet disease at C4-5. All of these levels need to be addressed at the time of surgery. Isolated surgery at C5-6 will lead to further degeneration of the adjacent levels. The Official Disability Guidelines (ODG) specifically indicates that facet arthritis is an exclusionary criteria for disc replacement. The claimant has facet disease at C5-6, which may limit the amount of motion expected with a disc replacement. The ODG does not support disc replacement in patients with isolated axial neck pain without evidence of radiculopathy. Ms. has no arm symptoms or neurological findings. The nerve conduction study of October 26, 2012 identified no evidence of radiculopathy. Furthermore, the source of the left scapular pain is unclear at the present time. This pain may be referred from the spine or the shoulder. The pain generator for this region must be fully identified prior to moving forward with surgery on the cervical spine. Therefore, after review of the medical records and documentation provided, the request for RC110 Inpatient Non-Surgical Room, 22856 TOT Disc Arthrp Art Disc Ant Appro, 95941

IONM Remote/Nearby/>1 Patient in OR (C5/6 Arthroplasty with 1 day Length of Stay) is not medically necessary and denied.

Per ODG:

Disc prosthesis	Under study, with recent promising results in the cervical spine, but not recommended in the lumbar spine. 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. These should include an evaluation of the subset of patient who will most benefit from this procedure as well as study of advantages/disadvantages of disc design and surgical procedure in terms of outcomes (particularly for development of heterotopic ossification and adjacent segment disease). This recommendation is based on balancing what we know so far about the benefits and the risks for the patient. Adjacent segment disease seems to be a natural aging process, and ADR has not proven any benefit in altering that progression. The risks of heterotopic calcification associated with ADR may make it a sure way to end up with a solid fusion, and major risks also include potential revisions and technical learning curve issues with widespread use. ***Overall Comparison to Fusion:*** Overall studies have demonstrated statistically significant non-inferiority of ADR vs. fusion with superior trending on many outcomes but limited evidence of statistical superiority. This has persisted for longer-term follow-up (three to five years). Long-term studies have shown that necessity of adjacent-level surgery is similar in both the fusion and ADR groups along with similar rates of development of adjacent-segment disease. Complication rates are similar. Study quality is often severely limited with high dropout rates and there is no comparison to a non-surgical treatment. Neither treatment has been found to produce complete disappearance of symptoms. Return to work appears earlier in the ADR group but overall employment rate is not different at 2 years (including for a workers' compensation cohort) and 5 years. (Zechmeister, 2011) (Steinmetz, 2008) (Jawahar, 2010) (Kim, 2009) (Garrido, 2010) (Fekete, 2010) (Dettori, 2008) (Pointillart, 2001) (Cinotti, 1996) (Klara, 2002) (Zeegers, 1999) (Sekhon, 2003) (Sekhon, 2004) (Porchet, 2004) (Pimenta, 2004) (Sasso, 2007) (Heller, 2009) (Mummaneni, 2007) (Murrey, 2009) (Burkus, 2010) (ECRIb, 2009) (Tumialán, 2010) (Delamarter, 2010) (Kelly, 2011) See also the complete list, discussion, and rating of other Disc prosthesis references in the Fusion References Chapter. *Recommended Indications:* 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. At least one of the following conditions should be confirmed by imaging (CT, MRI, X-ray): (1) herniated nucleus pulposus; (2) spondylosis (defined by the presence of osteophytes); & (3) loss of disc height. (Dettori, 2008) At the current time radiculopathy is an exclusion criteria for the FDA studies on lumbar disc replacement, whereas cervical radiculopathy is an inclusion criteria for the FDA investigations of cervical arthroplasties. (McAfee, 2004) Decompression of nerve roots and/or the spinal canal is often the primary intervention that necessitates disc replacement with a goal of restoration of intervertebral disc and foraminal height to prevent recurrence of nerve root compression. Implant of a total disc requires intact

	ligaments, integrity of the facet joints, vertebral bodies with intact endplates and good bone quality. (Fekete, 2010) (Cepoiu-Martin, 2011) *Myelopathy:* ADR is also recommended for myelopathy. The findings from two cohorts at two years postoperatively suggest that arthroplasty is equivalent to arthrodesis for the treatment of cervical myelopathy for a single-level abnormality localized to the disc space, but the study did not evaluate the treatment of retrovertebral compression as occurs in association with ossification of the posterior longitudinal ligament. (Riew, 2008) *Recommended exclusions:* Suggested exclusions include evidence of facet arthritis, spinal instability or significant deformity. While patients with myelopathy are suggested as candidates this is precluded if there is evidence of multilevel pathology or significant degeneration. Other suggested exclusions include the following: (1) axial neck pain as the solitary presenting symptom; (2) osteoporosis/ osteopenia; (3) spinal stenosis by hypertrophic spondyloarthrosis; (4) severe spondylosis (defined as bridging osteophytes, a loss of disc height greater than 50%, or absence of motion at less than 2%); (5) active infection; (6) material allergies; (7) presence of underlying comorbid disease such as HIV, hepatitis B or C, insulin-dependent diabetes, and/or autoimmune spondyloarthropathies such as rheumatoid arthritis; & (8) morbid obesity (BMI > 40). As of yet there are no recommendations for precautions in terms of underlying psychiatric pathology, smoking history, current drug use history, workers' compensation status, or litigation status. (Auerbach, 2008) (Zechmeister, 2011) (Sasso, 2007) *Rationale for development of this treatment:* It is generally suggested that mobility in a degenerate joint is the cause of pain. In the spine a problem arises as the mechanism of pain is incompletely understood. Proponents of artificial disc replacement point out that while there is evidence of a high success rate for anterior cervical discectomy and fusion (ACDF) for treatment of radiculopathy and myelopathy, the procedure is thought to increase biomechanical stresses at adjacent segments that may hasten degeneration. This concept is controversial as there is debate over whether this is a stand-alone phenomenon accompanying fusion or a part of natural history of degeneration. By maintaining adjacent level kinematics the rate of adjacent level degeneration is thought to lessen, although there is limited evidence to support this. Other proposed benefits include quicker return to normal employment and lifestyle and elimination of risks and morbidity with bone graft procurement. Pseudoarthrosis is also not a problem with disc replacement. (Phillips, 2005) (Auerbach, 2008) (Cepoiu-Martin, 2011) (Zechmeister, 2011) ***Concerns with use:*** There is an increasing interest in spinal arthroplasty as an alternative to fusion in conjunction with cervical discectomy, but at this time there are no comparative studies of ADR with other treatment modalities besides fusion. Longevity of this new procedure is unknown, which is important based on the targeted age of most patients who fit the current criteria for treatment (with a relatively young average age in workers' compensation patients). There is limited data in terms of mechanical failure and aseptic loosening. There is also limited evidence as to the long-term effect on index-level facet arthrosis and/or adjacent level degeneration/disease. It has been noted that the theoretical position that symptomatic adjacent segment disease leads to more surgery after fusion compared to less aggressive treatment is poorly founded, plus theses devices appear at best to yield results equal to or only incrementally better than fusion for the same indications. (Resnick, 2007) Finally, the consequences of failure of an implant in close proximity to the spinal cord, the esophagus, and the trachea are of concern. Current literature suggests that an analysis of these types of questions will take from five to ten years. *Complications:* Implant malposition, loosening, subsidence, implant migration, fractures and infection have all been reported and may necessitate retrieval and proceeding with an interbody fusion. Other reported complications include delayed fusion around the prosthesis, asymmetric endplate preparation resulting in postoperative kyphosis, and reduction in vertebral body height. The most common complications of both ADR and fusion are wound infections, dysphagia/dysphonia

	and allergic reactions. (Zechmeister, 2011) (Anderson, 2008) (Yi, 2010) *Adjacent segment degeneration and disease:* Early studies of the Bryan disc vs. ACDF patients found non-significant difference in adjacent level surgery. The incidence of new symptomatic adjacent-disc disease in the TDR group was 1.3% vs. 13.9% in the ACDF group. A conclusion was that moderate or severe kyphosis was probably a contraindication for TDR as it produced significant decrease in subsequent motion and kyphosis might persist. (Robertson, 2005) While a 4-year study showed a 5% reoperation rate for adjacent level disease in the ADR group vs. 12% for the fusion group (not statistically significant) an 8-year follow-up found development in 19% of the ADR patients (four of 21). This appeared to be pre-existing. Spontaneous fusion occurred in 22% of cases (six patients) in the 8-year study. These authors suggested that their results were equivocal in supporting the theory that ADR reduced adjacent segment disease. (Garrido, 2010) (Quan, 2011) A recent comparison study found there was no significant difference between development of adjacent segment degeneration between ADR and fusion at a median follow-up of 37 months. The development is significantly higher in patients with concurrent DDD in the spine. Presence of osteopenia increases the risk. The authors also found that patients with concurrent lumbar spine degenerative disease also had a higher risk. (Jawahar, 2010) (Nunley, 2011) The current predicted rate of development of adjacent segment disease after ACDF is 13.6% at five years and 25.6% at 10 years of follow-up. See also Adjacent segment disease/degeneration (fusion). *Heterotopic ossification (HO): (Defined as undesirable bone formation outside the skeleton after ADR that precludes the motion preservation for which the artificial discs were designed).* An additional problem that has been published in the literature is development of heterotopic ossification. There appears to be a positive relationship between occurrence of HO and loss of movement of the cervical artificial disc, speculated to be due to bridging osteophyte formation. The effect of this on adjacent segment degeneration has yet to be determined but it is speculated that when this occurs at the intervertebral space it limits function of the disc and can possibly cause compression of the neural tissue. HO appears to increase with time, especially in bilevel procedures. One group of authors has gone so far as to indicate that HO is an inevitable postoperative complication. (Yi, 2010) A genetic predisposition has been suggested, and disc design appears to have an effect. Other contributing factors proposed include tissue trauma during surgery, surgical technique (including removal of bone dust), design allowing soft tissue or bony ingrowth to the disc space, osteolysis related to wear debris of metal on polyethylene component (in discs with this design), and use of nonsteroidal anti-inflammatories (for prophylaxis). (Yi, 2010) (Quan, 2011) Literature available is generally based on small subsets of IDE study patients, limiting power of the study and generalized interpretation. The incidence of HO after cervical TDR in the literature gives an upper range of as high as 76% for two-level procedures and 66% for single-level. A recent 8-year follow-up of the Bryan disc showed development in 48% of 27 operated segments with restricted range of motion in nine cases. Development was more likely in two-level procedures. In earlier studies HO was low-grade (less than grade 3), with the supposition that this is less likely to interfere with motion. Longer-terms studies have found development of HO at higher grades. Early studies found development to have little effect on outcome, with an explanation being that even in the worst case the functional result is similar to that of an interbody graft in an ACDF. In the 8-year study of the Bryan disc patients who developed HO findings showed a trend for slightly higher neck and arm pain analog scores (not statistically significant). (Quan, 2011) (Leung, 2005) (Heidecke, 2008) (Lee, 2010) (Tu, 2011) (Mehren, 2006) ***Types of ADR devices:*** Cervical discs all share important characteristics including restoration of intervertebral disc height, allowing motion and decompression, with removal of disc material. Devices differ in terms of articulating surfaces (metal-on-metal or metal-on-plastic), and biomechanical properties (constrained, semi-constrained, or non-constrained).

	Prestige Disc: On July 16, 2007 the FDA approved the Prestige® Cervical Disc System from Medtronic Sofamor Danek. (FDA, 2007) This is a two-piece prosthesis constructed of stainless steel, employing ball-in-groove articulation. In 2007 results were published of 541 patients with single-level disease enrolled in 32 sites comparing ADR replacement with the Prestige ST disc (276 patient) with ACDF (265 patients). Neurological success rate was significantly higher in the arthroplasty group at 24 months (92.8% vs. 84.3%, respectively) with similar success rates on other outcome measures. At the 24-month follow-up all joints in the treated group were mobile. Another comparison study at two years found no significant difference in clinical outcomes between ADR and fusion treated patients (AAOS, VAS, NDI, JOA, SF-36 and satisfactions scores). (Peng, 2011) *Bryan Disc:* A single piece metal-on-polymer prosthesis (a later version of the Prestige disc). On 5/12/09, the FDA approved the Bryan Cervical Disc (Medtronic; Memphis, Tennessee) in patients who have failed at least 6 weeks of conservative therapy for intractable radiculopathy and/or myelopathy secondary to disc degeneration or herniation. In 2007 results were published comparing this disc to ACDF, the latter being considered "gold standard." This was an FDA IDE trial. The results were limited to three sites (115 patients). At 24 months statistically significant improvement was found in the Neck Disability Index (NDI), the Neck Pain Score, and SF-36 Physical component scores. Arm pain relief was similar. The conclusion was that the prosthesis compared favorably. Two patients in both groups required ACDF for adjacent level disease. (Sasso, 2007) Later documentation, again reporting a 24-month follow-up, indicates this study was actually performed in 30 sites. Participants were now reported as 242 patients receiving the disc and 221 receiving an ACDF in this noninferiority trial. There was a 20% loss of patients following randomization (37 from the TDR group and 80 from ACDF). In addition, unblinding occurred as well as treatment crossover. Results showed a statistically significant decrease in both groups for NDI, with the ADR group showing a significantly improved score at 24 months (16.2 for disc and 19.2 for ACDF). Both of these scores fall into a moderate disability range. Neck pain score was significantly improved in the ADR group over ACDF scores (23 vs. 30.3, respectively). Arm pain was similar. Similar results were noted for SF-36, neurological success and return to work at 24 months. The ADR group returned to work earlier (41 day vs. 61 days). For the ADR group overall success rate was 80.4% vs. 71.8% for the ACDF group. (FDA, 2009) (Heller, 2009) *ProDisc-C:* Constructed of two chromium-cobalt endplates with sagittal fins for fixation into the adjacent vertebral body and a fixed polyethylene core. In 2007 a limited study group (25 patients with cervical disc herniation) received either an ADR or ACDF. Segmental motion decreased in both groups, but was significantly higher in the ACDF group. This study was only extended to six months. (Nabhan, 2007) In 2009 results were published in a 2-year follow-up of an IDE trial comparing the ProDisc-C (106) to ACDF in patients (103) from one of 13 investigational sites. There was no demographic measured for ongoing litigation or workers' compensation involvement, although pre-operatively 84.9% of the ACDF group and 82.5% of the TDR group were employed and at 24 months the numbers were 80% and 82.8%, respectively. In terms of medications approximately 48% of both groups were using schedule 2 and 3 drugs pre-operatively and this decreased to 13% in the fusion group and 11.2% of the TDR group. Results were similar in terms of VAS neck and arm pain and neurological success. Second surgeries were required by 8.5% fusion patients compared to 1.8% of TDR patients (p=0.033). Results show that at 24 months postoperatively, 84.4% of ProDisc-C patients achieved a more than or equal to 4 degrees of motion or maintained motion relative to preoperative baseline at the operated level. (Murrey, 2009) *Mobi-C:* A prospective study of 76 patients with two-year follow-up has been published on this cervical disc. Of note, 85.5% of segments were mobile at 2 years. HO was stated as responsible for the fusion of 6/76 levels, but the presence of HO did not alter clinical outcome. Adjacent segment degeneration was found in 9.1% of patients. (Beaurain, 2009)

	Study Designs: The general design the randomized controlled studies discussed is a non-inferiority design, one that is generally employed when a margin of inferiority for a new technology is accepted because it is offset by advantages (i.e. the new technology is less invasive or has lower cost). This is not the case for ADR. There are also problems with unblinding, high dropout rates, exclusion of patients after randomization and unclear or no intention-to-treat analysis. Non-validated instruments have been utilized for outcomes. *ADR in a workers' comp population:* A subgroup analysis of workers' compensation patients in the IDE trials of the Prestige and Bryan cervical arthroplasties has been published. The study population included 93 patients out of 1,004 total (9.2%). Preoperatively, 36.2% of arthroplasty patients and 32.6% of fusion patients were working. The total number of study-group patients that were working preoperatively was not given. At 24 months, 63% of the arthroplasty patients and 53% of the ACDF patients had returned to work (non-significant intergroup difference). Again, the percentage of total study-group patients that returned to work was not given. Return to work was earlier for TDR patients (median of 101 days as compared to 222 days). This was not statistically significant when controlled for sex, study, and work status. As noted above in a Bryan disc study (the only comparison data available), the TDR total-study group returned to work at 41 days vs. 61 days for the arthroplasty group. (Heller, 2009) Pre-operative work status was a significant factor for patients eventually working after surgery. While the arthroplasty group returned to work earlier as compared to the fusion group this was only significant for 3 months. It was noted that the increase in return to work in the TDR group could have been secondary to less disability in these patients. Details about work were not given (including full vs. limited duty). (Steinmetz, 2008) *Recent additional research:* A recent technology assessment by the California Technology Assessment Forum (CTAF) recommended that cervical disc replacement does not meet CTAF criteria for improvement in health outcomes. A particular concern was that long-term outcomes were not available, particularly in terms of benefit in prevention of development of adjacent segment disease. (Walsh, 2010) In a review performed by Washington State Health Technology Clinical Committee published in 2009 findings showed that there were no statistical differences in pain relief or functional improvement between cervical ADR and fusion as measured at one to two years. Neurological success (defined to include maintenance and improvement in neurological function) was 78% for ADR and 67% for fusion (statistically significant). They noted that no cost studies have been performed. There was insufficient evidence to draw conclusions regarding safety and efficacy in populations outside those studied by the FDA. There was no mention of HO or adjacent segment disease. The cervical disc was approved when used for FDA indications at a single level and with no contraindications. (Dettori, 2008), The North American Spine Society evidence-based clinical guideline for treatment of cervical radiculopathy due to degenerative disorders suggested fusion and ADR were comparable treatments in the short-term for single level disease. They also noted that anterior cervical decompression was comparable to anterior fusion, producing similar clinical outcomes in the treatment of single-level cervical radiculopathy from degenerative disorders (grade of recommendation: B for both comparisons). (Bono, 2011) See the Low Back Chapter for information on use in the lumbar region. 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* **Laminectomy** (*icd 03.09 - Laminectomy/laminotomy for decompression of spinal nerve root*)

	Actual data -- median 2 days; mean 3.5 days (±0.1); discharges 100,600; charges (mean) $34,978 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* **Cervical Fusion, Posterior** (*81.03 -- Other cervical fusion, posterior technique*) Actual data -- median 4 days; mean 5.7 days (±0.2); discharges 16,852; charges (mean) $97,781 Best practice target (no complications) -- *4 days* **Craniocervical Atlas-Axis Fusion** (*81.01 -- Atlas-axis spinal fusion*) Actual data -- median 5 days; mean 7.8 days (±0.3); discharges 2,966; charges (mean) $117,838 Best practice target (no complications) -- *5 days* **Artificial Disc** (*84.62 -- Insertion of total spinal disc prosthesis, cervical*) Actual data -- median 1 days; mean 1.4 days (±0.1); discharges 2,146; charges (mean) $40,203 Best practice target (no complications) – *1 day* **Artificial Disc revision** (*84.66 -- Replacement of artificial spinal disc prosthesis, cervical*) Actual data -- median 2 days; mean 2.1 days (±0.3); discharges 148; charges (mean) $45,761 Best practice target (no complications) – *2 days* **Fracture of vertebral column** (*03.53 - Repair of vertebral fracture*) Actual data -- median 9 days; mean 13.4 days (±0.6); discharges 3,458; charges (mean) $156,940 Best practice target (no complications) -- *9 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)**