

Health Decisions, Inc.
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Notice of Independent Review Decision

February 17, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Total Disk Replacement C5-C6 with 23 hour Observation

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

American Board Certified Orthopedic 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.

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a female that was injured in an xxxxx at work on xx/xx/xx, injuring her neck and back. She has had PT, NSAIDS, chiropractic, heat, massage, TENS, Facet injections Medial branch block and cervical ESI with no relief.

12-20-12 thru 02-27-13: Physical Therapy Notes. 12-20-12: Patient Problems: Neck pain, LE weakness, paresthesia's, limited motion in the spine. Upon inspection, cervical PROM: Rotation: Bilaterally 70 degrees, flexion and extension WNL, SB 35 degrees bilaterally. 01-02-13: Reported decreased neck pain post PT. 01-08-13: Improved cervical mobility. 02-15-13: Reports has had chiropractic care in the past and is still having improved cervical mobility. 02-25-13: Objective findings: Improved endurance, LE ROM and strength. Decreased pain and muscle tension and gentle cervical traction. 02-26-13: Improved cervical motion and posture but continued pain. 02-27-13: Pt has made excellent progress demonstrating mild limitations in strength and function. Decrease pt PT and increase pt self care.

01-15-13: EMG/NCV of the Upper Extremities. Impression: There is electrophysiological evidence of 1. Left cervical radiculopathy (C5, C6). 2. Bilateral median nerve entrapment at the level of the wrist (bilateral mild carpal tunnel syndrome). 3. Bilateral ulnar sensory neuropathy in the region of the wrists.

06-21-13: Office Visit Report. The claimant c/o pain in the cervical region. She reports pain 10/10. The cervical ESI on 05-29-13 gave her 5 days of relief and she still has numbness to both upper extremities. Medications: Lyrica, amitriptyline, Norco. ROS: Musculoskeletal: Hx of joint pain, muscular weakness, stiffness and muscular pain. Upon exam, palpation exhibited tenderness in pericervical area, mild spasms. Muscle Testing: Deltoid: Bilateral 5/5, wrist extensors R 5/5, L 4/5, abductor digiti bilateral 5/5, triceps reflex bilateral 2/4; brachioradialis reflex bilateral 2/4. Extremity sensation: C6 left is decreased. Special testing: Spurling's test R cervical pain, L positive. Impression: Cervical disc displacement. Plan: Repeat ESI and hold PT.

08-08-13: Office Visit Report. The claimant c/o cervical pain. She reports pain 10/10 with numbness and tingling radiating down her upper extremities predominantly on left. Medications: Flexeril, temazepam, Mobic, Norco. Plan: Up to date MRI.

09-27-13: Office Visit Report. The claimant reports cervical pain 7/10. She c/o pain when looking over her left shoulder. She gets bilateral hand numbness, even when her arms are at her side. Digits 3-5 on both hands go numb. Muscle Testing: Wrist extensors – bilateral break away. Impression: Cervical radiculopathy, neuritis NOS. Plan: This pt had stocking glove anesthesia because she has involvement of the L C6 nerve root and the bilateral medial and ulnar nerves at the wrist.

10-03-13: MRI Cervical Spine without and with Contrast. Impression: 1. There is straightening of the usual cervical lordosis. 2. Multilevel spondylosis. 3. C5-6 shows a broad-based posterior disc protrusion with annular fissure. 4. C6-7 shows a central protrusion.

11-04-13: Office Visit Report. The claimant c/o neck pain 10/10 with numbness and tingling radiating bilaterally down her upper extremities but predominately on her left side. Impression: Sprain of neck.

01-29-14: Orthopedic Report. The claimant c/o cervical pain 8/10 with numbness and tingling into BUE but more so on left. Upon exam, spasms in the cervical neck with decreased ROM. Spurling's sign was positive on left forearm but reproduced pain on right. She has decreased sensation around the medial and ulnar distributions of both hands. Plan: Cervical facet injections.

05-15-14: Office Visit Report. The claimant c/o axial and radicular neck pain. Neck exam: Inspection/palpation: Spinal tenderness, facet joint tenderness,

decreased ROM. Cervical spine ROM: flexion – severe decrease, extension – severe decrease, right/left side band – severe decrease, right/left rotation – severe decrease. Impression: Cervicalgia, cervical spondylosis w/o myopathy, cervical radiculopathy. Plan: Continue meds, cervical facet left injections, continue regular exercise.

07-11-14: Operative Report. Preop Dx: 1. Cervical spondylosis. 2. Cervical degenerative disease. 3. Cervical pain or Cervicalgia. Postop Dx: Same. Operation: Right C5-C6 and C6-C7 facet block.

09-04-14: Office Visit Report. The claimant states pain relief of 80% after injection. She rates pain 5-6/10 with meds. Impression: Cervicalgia, cervical spondylosis w/o myelopathy, cervical radiculopathy. Plan: Increase trazadone to 100mg.

10-29-14: Orthopedic Report. The claimant c/o scapular pain and has occasional numbness and tingling in her left forearm and thumb area. Upon exam, decreased cervical ROM, positive Spurling's sign on left, diminished sensation along the left C6 distribution and brachioradialis was slightly diminished on the left. Plan: Cervical total disk replacement at C5-C6.

11-11-14: URA. Rationale: The request for C5-6 total disc replacement with a 23 hour observation is not medically necessary. The guidelines state that general indications were currently approved cervical ADR devices are for patients with intractable symptomatic single level cervical degenerative disc disease who have failed at least 6 weeks of non-operative treatment and present with arm pain and functional/neurological deficits. The patient has had 2 years of symptoms; she has an EMG/NCV study done in 2013 which documented a left cervical radiculopathy at C5-6. And she has had physical therapy and epidural steroid injections, non-steroidal anti-inflammatory drugs as well. Her MRI does show that she does have a 1mm concentric posterior central bulge at C4-5 and at C6-7 she has moderate narrowing 2-3mm concentric posterior annular bulge lateralized to the left combined with unciniate arthropathy producing moderate foraminal encroachment. So she does have some wear and tear above and below to proposed surgical level. And as such, she has more than 1 level of involvement. As such, criteria has not met, medical necessity has not been established. Peer to peer was unsuccessful.

12-16-14: Office Visit Report. The claimant c/o axial neck pain 6/10 and feels her medication regimen provides good analgesic relief. ROS: C/o frequent headaches.

01-15-15: Office Visit Report. The claimant would benefit from injections for the radicular pain. She c/o paresthesia's. Upon exam, tenderness in the facets with palpation. Cervical ROM with moderate decrease. Plan: SCS implant, continue meds, regular exercise and weight loss.

01-23-15: URA. Rationale: The patient is a female who sustained an injury on xx/xx/xx when she was involved with a motor vehicle accident. The patient developed complaints of neck pain radiating to the left upper extremity with associated sensory loss. The patient had been recommended for a C5-6 total disc replacement with 23 hours observation. This is an appeal of a prior denial in which the reviewer noted multilevel pathology above and below C5-6 which would rule out the use of a total disc arthroplasty system. The patient's prior conservative treatment did include physical therapy as well as use of anti-inflammatories. The patient had no long term relief with epidural steroid injections. Electrodiagnostic studies from 01-15-13 did note evidence of a left C6 cervical radiculopathy. The 10-29-14 physical exam noted positive Spurling's sign to the left with diminished sensation in the left C6 distribution. There was slight diminished brachioradialis reflex to the left as compared to the right. MRI studies were completed on 10-3-13 which noted a disc bulge at C4-5 and 2-3mm disc bulging at C5-6 and C6-7. There was mild left foraminal encroachment at C5-6 due to uncinate hypertrophy as well as disc bulging. At C6-7 there was moderate foraminal encroachment primarily to the left due to lateralization of the disc bulge with associated uncinate hypertrophy. report on 12-11-14 noted that the C5-6 level was the symptomatic level. In review of the clinical documentation submitted, the prior reviewer's concerns regarding 2 level pathology are pertinent. Imaging does show more substantial pathology at C6-7 than at C5-6 with uncinate hypertrophy and moderate lateral foraminal encroachment present. Given the 2 level pathology, the patient's actual pain generator is unclear. Furthermore, the imaging studies available for review are now well over 1 year old and updated imaging studies have not been provided for review to help delineate a pain generator. Given the patient's outdated imaging and 2 level pathology primarily at C5-6 and C6-7 this reviewer would not recommend certification for the proposed C5-6 total disc replacement at this point in time. As the surgical request for this patient is not indicated, the requested 23 hour observation stay would not be medically necessary at this time. Peer to peer discussion was not achieved despite calls to office.

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

The previous decisions are upheld. The patient is not indicated for a C5-6 disc replacement based on the records reviewed. The patient currently has neck pain with radiation into the left arm. She has completed an EMG/NC study in 2013, which pointed towards cervical radiculopathy at C5-6. A 2013 MRI demonstrated mild foraminal stenosis at C5-6 and moderate foraminal stenosis at C6-7. She responded well to facet blocks at C5-6 and C6-7. It is unclear from the records reviewed whether C5-6 is the only source of pain for this patient. All pain generators should be identified before considering surgical intervention. An up-to-date MRI of the cervical spine is required. A repeat EMG/NC may be necessary as well. The C6-7 level may need to be addressed as well at the time of surgery, based on these studies. Disc replacement at C5-6 is not appropriate for this patient at the present time. Therefore, the request for Total Disk Replacement C5-C6 with 23 hour Observation in non-certified.

Per ODG:

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 these 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](#)) Device-related complications may occur in a delayed fashion with cervical arthroplasty (CA), and similar numbers of patients in the fusion and CA study groups present with symptoms attributed to adjacent segment disease. ([Hacker, 2013](#))

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. ([Beurain, 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](#)) Artificial disc acceptance has been poor. According to the latest AHRQ data, the volume of cervical disc prosthesis procedures (ICD 84.62) declined by over 20% in the latest year, to 1,871 in 2011 from 2,347 in 2010 (the procedure peaked in 2009 at 2,491), while average costs increased, from \$44,020 to \$62,249. ([HCUP, 2014](#)) It is difficult to assess the future potential of anterior cervical disc arthroplasty as an alternative to anterior cervical discectomy and fusion. Future studies are still needed to properly assess the continued use of artificial cervical disc arthroplasty and to determine the relative cost effectiveness compared with anterior cervical discectomy and fusion. ([Bakar, 2014](#)) There was an initial surge in the adoption of cervical disc

arthroplasty (CDA) in the early years of utilization (2005–2008), but this technology reached a plateau in the 3 years since its 2007 FDA approval (2008–2010). Studies have yet to demonstrate that CDA consistently and significantly reduces adjacent segment disease, and this was an important rationale behind CDA. Furthermore, contraindications of CDA, such as spondylotic changes, resulted in exclusion of many patients. Declining CDA growth rates may be due to a more cautious and stringent approach in the selection of CDA over traditional ACDF. ([Lu, 2014](#)) 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).

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)