



Medical Review Institute of America, Inc.
America's External Review Network

DATE OF REVIEW: March 27, 2008

IRO Case #:

Description of the services in dispute:

Items in dispute: anterior cervical disc arthroplasty at C5-6

A description of the qualifications for each physician or other health care provider who reviewed the decision

The physician who provided this review is board certified by the American Board of Orthopaedic Surgery. This reviewer is a member of the American Academy of Orthopaedic Surgeons, the Arthroscopy Association of North America, the American Orthopaedic Society for Sports Medicine and the American College of Physician Executives. This reviewer has been in active practice since 1985.

Review Outcome

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

Upheld

The request for anterior cervical disc arthroplasty at C5-6 is not medically necessary.

Information provided to the IRO for review

1. Utilization review correspondence
2. Utilization review determination dated 01/23/08
3. Utilization review determination dated 01/31/08
4. Treatment records, D.C.
5. MRI of the cervical spine dated 07/01/06
6. MRI of the cervical spine dated 03/01/07
7. Medical records Dr.
8. Procedure report dated 09/07/07
9. Medical records Dr.
10. Procedure report dated 12/21/07
11. EMG/NCV study dated 01/24/08
12. Medical records Dr.

13. Radiographic report bilateral shoulders dated 09/25/06
14. MRI of the right shoulder dated 10/17/06
15. Radiographic report cervical spine dated 02/27/07
16. Designated doctor evaluation dated 06/06/07
17. Procedure report dated 07/27/07
18. Procedure report dated 09/07/07
19. Procedure report dated 12/21/07
20. Designated doctor evaluation dated 03/14/08

Patient clinical history [summary]

The patient is a xx year old male who is employed as a xxxx who is reported to have sustained an injury to his neck on xx/xx/xx. On this date the patient was attempting to apprehend a suspect when his head was struck by a car door. He sustained significant pain as a result of this. He was able to complete his task and subsequently sought care from, D.C. The patient was treated conservatively with chiropractic manipulation and achieved relief. Six months later on 06/15/05 he developed recurrent neck pain with no precipitating event and subsequently received additional chiropractic treatments.

On 06/24/05 the patient had to wrestle an assailant and in the process struck his head on a parked car causing immediate return of cervical pain and stiffness. The patient again received conservative treatment. He was later referred for MRI of the cervical spine on 07/01/05. This study reports 2–3 mm left lateral disc protrusions at C5–6 and C6–7. There appear to be mild bony hypertrophic changes at 3 levels. The spinal canal remains in excess of 1 cm centrally at both levels; however, there is moderate left sided neural foraminal encroachment which could result in a left C6 or C7 radiculopathy. The right neural foramina are only mildly encroached at 3 levels. There is disc desiccation and minimal bony hypertrophic changes in the remaining cervical segments.

On 09/22/06 the patient was evaluated by Dr.. At this time the patient reports having right shoulder pain for the last 3 months. He has previously seen another physician and had a cortisone injection which gave him some relief and he has tried Naprosyn. He reports having intermittent left neck and shoulder pain for the past several years. He has seen a chiropractor which does give him relief. He reports that his right shoulder bothers him a lot at night and with overhead activity. On examination he has full range of motion of the right shoulder but a positive impingement sign and some mild weakness. He has full range of motion of the left shoulder. The patient is diagnosed with impingement syndrome and he was provided an injection of corticosteroids.

Radiographs of the shoulder were performed on 09/25/06. These studies are reported to be negative. An MRI of the right shoulder was performed on 10/17/06 and this was reported to be unremarkable. The patient was seen in follow up by Dr. on 11/22/06. The patient continues to have right shoulder discomfort. He reports that the previous shot made him better for about a month and a half and his pain subsequently recurred. He received a second corticosteroid injection in September which did not help. He had an MRI scan which was entirely normal. He continues to

have pain in the anterior aspect of the right shoulder in the region of the bicipital groove. The patient's physical examination reports a mildly positive impingement sign and he has excellent strength. He has full range of motion. Motor and sensory are intact. The patient is diagnosed with biceps tendonitis. He received a corticosteroid injection of the bicipital groove.

The patient was seen in follow up on 02/27/07. He is reported to have developed neck and shoulder pain the previous week. On examination the patient is in moderate distress. He ambulates slowly. He has a few degrees of flexion of his neck and lateral motions but no extension. His reflexes are 2+ in the bilateral biceps, 0 in the left triceps and 2+ in the right triceps. The patient was placed on a prednisone taper. Radiographs performed on 02/27/07 indicate minimal anterior vertebral body osteophytes and minimal calcification anterior margin of disc spaces at multiple levels without significant loss of disc space height likely related to minimal degenerative disc disease.

The patient had continued reports of cervical pain and was referred for a second MRI on 03/01/07. This study reports a moderate left paracentral bulging of the C5-6 disc impinging upon the left anterior thecal sac and cord and leading to moderate left lateral central spinal stenosis. There is impingement upon the left C6 nerve root. There is other minimal disc disease and mild to moderate bilateral neural foraminal stenosis at C3-4, C5-6 and C6-7. There is a minimal posterior central disc bulge of the C4-5 disc.

The patient was subsequently referred to Dr. on 03/07/07. At this time the patient presents with a history of chronic axial neck pain and left upper extremity radiculopathy. He complains of pain between his shoulder blades and pain radiating down his neck to his shoulder to his fingers with tingling and numbness. He reports that the current symptoms have been going on for the past 4 weeks but he does not recall any trauma. He has previously received chiropractic treatment. He has been started on a Medrol DosePak by Dr. with some relief. On physical examination he is well developed and well nourished. He is 5'8" and weighs 197 pounds. Examination of the cervical spine notes he is nontender to palpation to his posterior cervical spine. He is able to flex his chin to his chest, hyperextend his cervical spine to about 4 fingerbreadths of his dorsal spine. He has 70 degrees of lateral rotation to the left and to the right. Strength in the upper extremities is rated as 5/5. Sensation is intact to light touch. He has a negative Hoffman's sign and negative Spurling's test. Examination of the lumbar spine reveals point tenderness to palpation in the lumbosacral region. His strength is rated as 5/5 in his lower extremities. His deep tendon reflexes are 2+ and symmetric bilaterally. Dr. recommends that based on the MRI studies that the patient has a lateral disc herniation at C5-6 level with impingement of the exiting C6 nerve root. He recommends that the patient undergo a trial of cervical epidural steroid injections.

The patient was referred to Dr. on 04/10/07. Dr. notes that the patient has complaints of left sided cervical axial neck pain, left shoulder pain and suprascapular pain that occasionally does radiate and shoot down his left upper extremity down to the fingers. On physical examination he is well developed. He is normocephalic and atraumatic. The neck is reported to be supple. There is

decreased range of motion of the cervical spine, a positive Spurling's sign to the left and positive left paracervical tenderness. The strength is rated 5/5. There is a decreased left brachioradialis reflex. Sensation is intact to pinprick. Dr. recommends cervical epidural steroid injections.

The patient was evaluated by Dr. on 06/06/07. The patient was seen for designated doctor evaluation. Dr. notes the history above. On examination the patient is well developed and in no obvious discomfort. He has normal ambulation across the floor without evidence of pain behavior. He is able to get on and off the examination table without difficulty. There is no obvious guarding of the left arm. There is obvious paraspinal tenderness to palpation across the left facet column between C4 and C7. There is positive triggering, limited cervical flexion with intact cervical extension and positive Spurling's sign towards the left. There is no pain across the shoulder at the subacromial space with negative impingement sign and full range of motion. There is no upper extremity atrophy. There are subjective reports of decreased sensation involving C6. Reflexes were slightly decreased in the biceps at 1+. Dr. finds the patient not to be at maximum medical improvement and recommends cervical epidural steroid injections or cervical nerve block and possibly an EMG.

The patient was seen in follow-up by Dr. and underwent cervical epidural steroid injections on 09/07/07. He is reported to have received 80-90% improvement. It is recommended that he continue a home exercise program and follow up on an as needed basis and further injections would be performed as needed. The patient was seen in follow up on 11/15/07. He had recurrent cervical pain which radiated to the suboccipital region. On this date the patient underwent trigger point injections. Additional records indicate that the patient underwent a second cervical epidural steroid injection on 12/21/07.

The patient was seen in follow up by Dr. on 01/16/08. It is reported that the first two epidural steroid injections provided him 100% relief. A later cervical epidural steroid injection only provided 20% relief. He continues to report having pain and weakness radiating down his left upper extremity. On physical examination his left upper extremity motor strength is rated as 4+/5 in the deltoid and biceps. His wrist and triceps remain 5/5. The wrist extensors are 4+/5. Hoffman's sign is negative and sensation to light touch is grossly intact. Dr. opines that the patient would be a candidate for cervical disc arthroplasty at the C5-6 level to relieve his axial neck and left arm pain. A request was submitted and not recommended on utilization review. A recommendation was made for the patient to be referred for electrodiagnostic studies. On 01/24/08 the patient underwent EMG/NCV of the upper extremities which was reported as normal.

On 01/23/08 Dr. reviewed the case. It was his opinion that the patient required electrodiagnostic studies prior to consideration of surgery. These studies were performed and Dr. resubmitted a request. On 01/31/08 the case was again reviewed by Dr.. Dr. noncertifies the request and reports that Official Disability Guidelines do not recommend arthroplasty of the cervical disc noting that there is an extremely low level of evidence available for artificial disc replacement and it is recommended that this procedure is regarded as experimental.

The patient was evaluated by Dr. on 03/14/08. Dr. functioning as a designated doctor finds that the patient is not at maximum medical improvement. He notes that the patient's symptoms correlate with his imaging study and that the patient is refractory to conservative care. He recommends a cervical disc arthroplasty to help relieve the patient's radiculopathy. The patient is reported to be agreeable to this type surgery. It is noted that the patient had a normal EMG of his arms on 01/28/08. The patient was referred back to Dr. for definitive treatment.

Analysis and explanation of the decision include clinical basis, findings and conclusions used to support the decision.

There is agreement with Dr. initial determinations that the request for anterior cervical disc arthroplasty at C5-6 is not medically necessary due to the investigational nature of the procedure. While it is noted that this procedure has been performed in Europe for many years, this device has only recently been approved in the United States. There is limited clinical data to establish the long term safety and efficacy of this device. The PMA for this device requires that the producer conduct 10 year post implantation follow up studies to establish the long term safety and efficacy of this device in a U.S. population. Given the lack of peer reviewed literature which establishes the safety and efficacy of this device, the request for total disc arthroplasty is not considered medically necessary. It is further noted that the current standard of care for the patient's condition is considered to be anterior cervical discectomy with fusion.

A description and the source of the screening criteria or other clinical basis used to make the decision:

1. The Official Disability Guidelines, 11th edition, The Work Loss Data Institute.
2. Acosta FL Jr, Ames CP. Cervical disc arthroplasty: General introduction. Neurosurg Clin N Am. 2005; 16(4): 603-607, vi.
3. Pracyk JB, Traynelis VC. Treatment of the painful motion segment: Cervical arthroplasty. Spine. 2005; 30(16 Suppl): S23-S32.
4. Phillips FM, Garfin SR. Cervical disc replacement. Spine. 2005; 30(17 Suppl): S27-S33.
5. PMA Prestige Cervical Disc System dated 07/16/2007

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