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**DATE OF REVIEW:** 03.26.2008

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:**

Cervical Pro-Disc prosthesis C5-6

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

This case was reviewed by a Texas licensed MD, specializing in Neurological Surgery, Orthopedic Surgery. The physician advisor has the following additional qualifications, if applicable:

ABMS Orthopaedic Surgery  
 TX DWC ADL

**REVIEW OUTCOME:**

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

Upheld

Health Care Service(s) in Dispute	CPT Codes	Date of Service(s)	Outcome of Independent Review
Cervical Pro-Disc prosthesis C5-6		-	Upheld

**INFORMATION PROVIDED TO THE IRO FOR REVIEW:**

No	Document Type	Provider or Sender	Page Count	Service Start Date	Service End Date
1	Diagnostic Testing		4	02.26.08	02.26.08
2	Pre-surgical screening		4	02.21.08	02.21.08
3	Office Visits		6	11.27.07	01.22.08
4	Diagnostic Testing		2	07.11.07	07.11.07
5	Premarket Approval Application		40	12.17.07	12.17.07

**PATIENT CLINICAL HISTORY [SUMMARY]:**

1. Notice of assignment of independent review organization
2. Preauthorization report notification dated 02/28/08
3. Preauthorization report notification dated 03/06/08

4. EMG/NCV report dated 02/26/08
5. Behavioral medicine evaluation/pre-surgical screening (phone interview) dated 02/21/08
6. New patient office visit and radiology reports dated 11/27/07
7. Follow up office note dated 01/22/08
8. MRI of the cervical spine dated 07/11/07
9. Notice to utilization review agent of assignment of independent review organization dated 03/17/07
10. Confirmation of receipt of request for review by an independent review organization
11. FDA premarket approval application letter dated 12/17/07
12. Journal articles concerning cervical disc arthroplasty

Summary: The patient is a male whose date of injury is listed as xx/xxxx. On that date the patient was involved in a motor vehicle accident during the course of work. The records indicate that the patient was taken to the emergency room after the accident with complaints of neck pain, and x-rays were taken. Symptoms gradually became worse. The patient is noted to continue working full time. The patient reports that over the last year he began to have some tingling of the thumb, and in the last 6 months has noticed tingling into the arm and progressive pain in the left trapezii. The patient reports he does a lot of typing at work and this aggravates his symptoms. New patient visit report dated 11/27/07 by Dr. indicates that the patient has had no conservative treatment thus far but has had x-rays, MRI scans and myelogram. Physical examination reported the patient to be 5'9" and approximately 210 pounds. Spurling maneuver causes some symptoms in the superomedial angle of the trapezii. The patient has full range of motion of the shoulders. Sensation to light touch is within normal limits. Deep tendon reflexes noted both biceps to be slightly diminished, although not asymmetry. Manual motor testing of the deltoids and intrinsics was 5/5. Hoffman's sign was negative. There was no clonus. Reflexes at the lower extremities were symmetric. MRI of the cervical spine dated 07/11/07 revealed multilevel spondylosis with reduction in lordosis that may be due to muscle spasm or patient positioning. The central canal is somewhat narrowed at C5-6 and appears adequate elsewhere. No abnormal cord signal was noted at any level. At C5-6 there were circumferential endplate osteophytes and broad based disc bulge present accentuated on the left. There was contact with the left ventral margin of the cord. In addition uncinat joint changes are present bilaterally left greater than right. Electrodiagnostic testing done 02/26/08 reported normal nerve conduction studies of the left upper extremity, with electrodiagnostic evidence suggestive of mild old/chronic left C6 radiculopathy with no evidence of ongoing denervation. There was no evidence of left carpal or cubital tunnel syndrome and no left neurogenic thoracic outlet syndrome. The doctor performing the EMG/NCV agreed with a trial of cervical epidural steroid injections for diagnostic therapeutic purposes but notes that the patient has decided not to do injections at this time. Dr. reviewed cervical spine films on 11/27/07 and noted slight narrowing at the C5-6 level with very mild curvature convex to the right on AP view. Flexion/extension views showed no signs of instability. Dr. saw the patient in follow up on 01/22/08 and noted tenderness at the base of the cervical spine on the left and left Spurling maneuver does cause pain at that area. Reflexes revealed left biceps to be absent to trace, right is 2+. The patient has positive Tinel's sign bilaterally. Dr. recommended artificial disc replacement at C5-6. This request was denied on 02/28/08 by Dr. based his determination that the proposed procedure was investigational. Dr. also noted that the patient may benefit from a trial of cervical epidural steroid injection. An appeal request was denied on 03/06/08 by Dr. based on essentially the same rationale as that of Dr.. The request is determination of cervical ProDisc prosthesis C5-6.

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

: I concur with the two previous reviewers that cervical ProDisc prosthesis at C5-6 is not indicated as medically necessary. The patient is noted to have sustained an injury in xx/xx secondary to a motor vehicle accident. There is no indication that the patient has undergone conservative treatment including epidural steroid injections. The patient has continued to work full time full duty since the date of injury. The FDA has approved the ProDisc C for use in skeletally mature patients for reconstruction of disc from C3-C7 following single level discectomy for intractable symptomatic cervical disc disease. The approval letter indicates that patients receiving ProDisc C total disc replacement should have failed at least 6 weeks of nonoperative treatment, and there is no documentation that the patient has failed such conservative care. Per Dr. note dated 11/27/07 the patient has had no conservative treatment thus far. Moreover, there is no scientific literature to support the long term safety and efficacy of the proposed device. The FDA PMA letter requires a post-approval study to evaluate the long-term safety and effectiveness of the ProDisc C total disc replacement. Per the Official Disability Guidelines, disc prosthesis is regarded as experimental at this time given the extremely low level of evidence available for artificial disc replacement, and is not recommended as medically necessary.

ODG

FDA Premarket Approval letter dated 12/17/07

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

ODG:

