

Case Number:	CM14-0052298		
Date Assigned:	07/07/2014	Date of Injury:	08/10/2004
Decision Date:	09/22/2014	UR Denial Date:	04/17/2014
Priority:	Standard	Application Received:	04/21/2014

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in neurology, has a subspecialty in Pain Medicine and is licensed to practice in Florida. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

3/24/14 note indicates chronic pain since 2004 in the neck. EMG studies were reported to be "positive" with MRI showing disc protrusions at C4-5 and C5-6. There is radiating pain in the right arm with numbness of the hand. Neck pain is aggravated by activity. Examination noted sensory loss in C6 distribution and weakness of the biceps. There is absent biceps reflex. 4/9/12 MRI reports significant disc bulges with spinal cord compression at C4-5 and C5-6. 12/30/11 EMG reported as right cervical radiculopathy at C6-7. The assessment was that the insured had failed conservative treatment and was recommended for a two level prosthetic disc C4-6 or a two level fusion.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

cerv artific deskectomy: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://apgi.acoem.org/Browser/Section.aspx?cid=1&sid=732>.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) neck, 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.

Decision rationale: The medical records provided for review indicate chronic pain since 2004 but does not delineate the specific therapies previously tried and failed. The medical records indicate diagnostic studies which are old in comparison to present condition - MRI from 2012 and EMG study from 2011. The medical records do not demonstrate and support the use of cervical prosthetic disc at two levels as superior to other accepted surgical therapies for the spine congruent with ODG guidelines. Overall studies have demonstrated statistically significant non-inferiority of ADR vs. fusion with superior trending on many outcomes but limited evidence of statistical superiority. 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. Therefore, this request is not medically necessary.