

Oregon
Workers' Compensation Division
Medical Advisory Committee Recommendation
Regarding Cervical Artificial Disc Replacement (ADR)
November 14, 2008

Summary:

The Medical Advisory Committee of the Workers' Compensation Division researched and analyzed whether cervical artificial disc replacement should be a compensable medical service.

After conducting a thorough literature review and determining the most persuasive studies, the committee concluded that, based on the determination that it is "unproven" *, cervical artificial disc replacement is **not a compensable** medical service when using the following devices:

- ***Metal on polymer – unconstrained or fully constrained***
- ***Metal on metal - unconstrained or fully constrained.***

Additionally, the Committee concluded that cervical artificial disc replacement is a **compensable** medical service, under strict inclusion criteria, when **using the following devices:**

- ***Metal on polymer - semi-constrained;***
- ***Metal on metal - semi-constrained.***

The Committee delineated specific exclusion criteria when determining if a compensable cervical artificial disc replacement procedure is appropriate for an individual patient.

Findings:

- Cervical artificial disc replacement using 1) *an unconstrained or a fully constrained metal on polymer device, or 2) an unconstrained or a fully constrained metal on metal device*, is **not compensable** because the procedures using these devices are:
 - Unproven - the evidence does not demonstrate efficacy**
- Cervical artificial disc replacement using *a semi-constrained metal on polymer or semi-constrained metal on metal* device is **compensable, under certain criteria**, because the procedures using these devices are:
 - Scientific* - scientific method has been applied
 - Not outmoded* - is within the current standard of care
 - Proven* - the evidence demonstrates efficacy in short-term studies (two-years); **is not proven** in long-term studies
 - Not experimental* - there is sufficient evidence to reasonably assess in short-term studies (two years); is **experimental** in long-term studies.

* See December 7, 2001, Medical Advisory Committee Policy Memorandum for definitions

** For purposes of the Committee's analysis, efficacy is defined as evidence showing preservation of motion and protecting adjacent levels

Recommendations:

- 1) Cervical artificial disc replacement is **not a compensable** medical service **unless** the following criteria are met:

The procedure is a single level cervical artificial disc replacement with

- A semi-constrained metal on polymer or
 - A semi-constrained metal on metal device; and all of the following:
 - The patient is between 16 and 60 years old;
 - It is a single level artificial disc replacement between C3 and C7;
 - The patient underwent unsuccessful conservative treatment; and
 - There is intraoperative visualization of the surgical implant level.
- 2) Certain conditions **ALWAYS** make the cervical ADR **inappropriate** (**absolute contraindications**) for patients being considered for cervical ADR. Other conditions (depending on several factors including severity, location, etc) **MAY** affect whether cervical ADR is appropriate based on physician's judgment (**relative contraindications**):

A) Conditions that ALWAYS make cervical ADR inappropriate (absolute contraindications):

- Instability in the cervical spine which is greater than 3.5 mm of anterior motion or greater than 20 degrees of angulation
- Significantly abnormal facets
- Osteoporosis defined as a T-score of negative (-)2.5 or more negative (e.g. -2.7)
- Allergy to metal implant
- Bone disorders (any disease that affects the density of the bone)
- Uncontrolled diabetes mellitus
- Active infection, local or systemic
- Active malignancy, primary or metastatic
- Bridging osteophytes (severe degenerative disease)
- A loss of disc height greater than 75% relative to the normal disc above
- Chronic indefinite Corticosteroid use
- Prior cervical fusions at two or more levels
- ADR at the level of a pseudo-arthritis

B) Conditions (depending on severity, location, etc) that MAY, based on the physician's judgment, make cervical ADR inappropriate (relative contraindications):

- A comorbid medical condition compromising general health, e.g., hepatitis, poorly controlled diabetes, cardiovascular disease, renal disease, autoimmune disorders, AIDS, Lupus, etc.
- Multilevel Degenerative Disc Disease – cervical - moderate to severe, as shown radiographically.
- Osteopenia - based on bone density test with a T-score range of negative (-)1.5 to negative (-)2.5.
- Prior cervical fusion at one level.
- A loss of disc height of 50% to 75% relative to the normal disc above.
- Psychosocial disorders - Diagnosed as significant to severe.

3) The Workers' Compensation Division should:

- Develop a registry documenting all surgeries involving cervical artificial disc replacement;
- Work with the Information Management Division (IMD) to develop or review future prospective outcome studies regarding cervical artificial disc replacement;
- In three years, with IMD, prepare a report regarding the outcome studies and present it to the Medical Advisory Committee.