

Oregon
Workers' Compensation Division
Medical Advisory Committee Recommendation
Regarding Lumbar Artificial Disc Replacement
January 18, 2008

Summary:

The Medical Advisory Committee of the Workers' Compensation Division researched and analyzed whether lumbar 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 lumbar artificial disc replacement is a **compensable** medical service, under strict inclusion criteria, when **using the following devices:**

- ***Metal on polymer unconstrained or semi-constrained.***

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

Additionally, based on the determination that they are "unproven" **, the Committee determined that lumbar artificial disc replacement is a **non-compensable** medical service when using the following devices:

- ***Metal on polymer - fully constrained***
- ***Metal on metal - unconstrained, semi-constrained, or fully constrained.***

Findings:

Lumbar artificial disc replacement using an unconstrained or semi-constrained metal on polymer 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.

Lumbar artificial disc replacement using 1) a fully constrained metal on polymer device, or 2) an unconstrained, semi-constrained, or fully constrained metal on metal device, is **not compensable** because the procedures using these devices are:

- Unproven - the evidence does not demonstrate efficacy*

Recommendations:

- 1) Lumbar artificial disc replacement is a **compensable** medical service **when** the following criteria are met:

The procedure is a single level lumbar artificial disc replacement with an unconstrained or semi-constrained metal on polymer device, with the following:

- Age 16-60 years
- Single level artificial disc replacement between L3 and S1
- Minimum of 6 months unsuccessful exercise based rehabilitation

2) The committee considered whether certain conditions would **ALWAYS** make the lumbar ADR **inappropriate (absolute contraindications)** for patients being considered for lumbar ADR, or whether certain conditions (depending on several factors including severity, location, etc) **MAY** affect whether lumbar ADR is appropriate based on physician's judgment (**relative contraindications**).

The committee recommends the following:

A) Conditions that would ALWAYS make lumbar ADR inappropriate (absolute contraindications)

- Metabolic bone disease- for example, osteoporosis.
- Known spondyloarthropathy (seropositive and seronegative)
- Posttraumatic vertebral body deformity at the level of the proposed surgery.
- Malignancy of the spine
- Implant allergy - to the materials involved in the ADR device
- Pregnancy - currently
- Active infection, local or systemic
- Lumbar Spondylolisthesis or Lumbar Spondylolysis
- Prior fusion, laminectomy or facetectomy- Lumbar - at same level as proposed surgery
- Spinal stenosis – lumbar- moderate to severe lateral recess and central stenosis

B) Conditions (depending on severity, location, etc) that MAY, based on the physician's judgment, make lumbar 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.
- Arachnoiditis
- Corticosteroid use¹ (chronic ongoing treatment with adrenal immunosuppression.)
- Facet arthropathy - lumbar - moderate to severe, as shown radiographically
- Morbid Obesity - BMI > 40
- Multilevel Degenerative Disc Disease – Lumbar- moderate to severe, as shown radiographically.
- Osteopenia - based on bone density test
- Prior lumbar fusion at a different level than the proposed ADR
- Psychosocial disorders - Diagnosed as significant to severe.

3) The Workers' Compensation Division may:

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

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

****See Attachment E for definitions**

¹ One medical provider felt this was an absolute contraindication rather than a relative contraindication.