

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-03 Medicare National Coverage Determinations</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 60</b>	<b>Date: JUNE 23,2006</b>
	<b>Change Request 5057</b>

**Subject: Lumbar Artificial Disc Replacement (LADR)**

**I. SUMMARY OF CHANGES:** Upon completion of a national coverage analysis (NCA) for LADR, the decision was made that LADR with the Charite™ lumbar artificial disc is non-covered for Medicare beneficiaries over 60 years of age.

The addition of section 150.10, of Pub.100-03, is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, health care prepayment plans, the Medicare Appeals Council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4), effective May 1, 2005). An NCD is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

**NEW / REVISED MATERIAL**

**EFFECTIVE DATE: May 16, 2006**

**IMPLEMENTATION DATE: Carriers – July 17, 2006; FIs – October 1, 2006**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS:**

**R=REVISED, N=NEW, D=DELETED**

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
<b>R</b>	1/Table of Contents
<b>N</b>	1/150.10/Lumbar Artificial Disc Replacement (LADR) (Effective May 16, 2006)

**III. FUNDING:**

**No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.**

**IV. ATTACHMENTS:**

**Manual Instruction**

*\*Unless otherwise specified, the effective date is the date of service.*

# Medicare National Coverage Determinations Manual

## Chapter 1, Part 2 (Sections 90 – 160.25)

### Coverage Determinations

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*(Rev. 60, 06-23-06)*

*150.10 – Lumbar Artificial Disc Replacement (LADR) (Effective May 16, 2006)*

**150.10 – Lumbar Artificial Disc Replacement (LADR) (Effective May 16, 2006)**

**(Rev.60, Issued: 06-23-06, Effective: 05-16-06, Implementation: Carriers 07-17-06/FIs 10-01-06)**

**A. General**

*The LADR is a surgical procedure on the lumbar spine that involves complete removal of the damaged or diseased lumbar intervertebral disc and implantation of an artificial disc. The procedure may be done as an alternative to lumbar spinal fusion and is intended to reduce pain, increase movement at the site of surgery and restore intervertebral disc height. This national coverage determination focuses on LADR with the Charite™ lumbar artificial disc because it is the only Food and Drug Administration (FDA) approved lumbar artificial disc at this time. The FDA has approved the use of the Charite™ artificial disc for spine arthroplasty in skeletally mature patients with degenerative or discogenic disc disease at one level for L4 to S1.*

**B. Nationally Covered Indications**

*N/A*

**C. Nationally Non-Covered Indications**

*Effective for services performed on or after May 16, 2006, the Centers for Medicare and Medicaid Services has found that LADR with the Charite™ lumbar artificial disc is not reasonable and necessary for the Medicare population over 60 years of age; therefore, **LADR with the Charite™ lumbar artificial disc is non-covered for Medicare beneficiaries over 60 years of age.***

**D. Other**

*For Medicare beneficiaries 60 years of age and younger, there is no national coverage determination, leaving such determinations to continue to be made by the local contractors.*

*Since this NCD focuses on LADR with the Charite™ lumbar artificial disc, Medicare coverage under the investigational device exemption (IDE) for other lumbar artificial discs in eligible clinical trials is not impacted.*

*(This NCD last reviewed May 2006.)*