CMS Guidance Document	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Executive Guidance Number 0052	**Date: September 5, 2007**
Planned Web Site Address http://www.cms.hhs.gov/manuals/	**Release planned: September 19, 2007**

PROGRAM AREA: National coverage determination for LADR

SUBJECT: Lumbar Artificial Disc Replacement (LADR)

APPLIES TO: Hospital and Physicians

I. SUMMARY OF DOCUMENT: Upon completion of a national coverage analysis for the reconsideration of the national coverage determination for LADR, the decision was made that LADR is non-covered for Medicare beneficiaries over 60 years of age. This reconsideration decision reflects the change from non-coverage for a specific LADR implant (the CharitеTM) to non-coverage for the LADR procedure for the Medicare population over 60 years of age.

II. CHANGES IN POLICY INSTRUCTIONS: (If not applicable, indicate N/A)
STATUS: R=REVISED, N=NEW, D=DELETED.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	32/Table of Contents
R	32/170.1/General
R	32/170.2/Carrier Billing Requirements
R	32/170.3/Fiscal Intermediary (FI) Billing Requirements
R	32/170.4/Reasons for Denial and Medicare Summary Notice (MSN), Claim Adjustment Reason Code Messages, and Remittance Advice Remark Code
R	32/170.5/Advanced Beneficiary Notice (ABN) and Hospital Issued Notice of Noncoverage (HINN) Information

III. CLEARANCES:

Clearance & Point of Contact (POC)	Name/Telephone/Component
Senior Official Clearance	Barry Straube, M.D. (410) 786-6841/Office of Clinical Standards & Quality
Agency POC	Deirdre O'Connor (410) 786-3263/OCSQ

IV. TYPE (Check appropriate boxes for type of guidance)

	Audit Guide
X	**Change Request**
	HPMS
	Joint Signature Memorandum/Technical Director Letter
	Manual Transmittal/Non-Change Request
	State Medicaid Director Letters
	Other

V. STATUTORY OR REGULATORY AUTHORITY: N/A

Attachment - Business Requirements

Pub. 100-04	Transmittal:	Date:	Change Request: 5727

SUBJECT: Lumbar Artificial Disc Replacement (LADR)

EFFECTIVE DATE: AUGUST 14, 2007
IMPLEMENTATION DATE: OCTOBER 1, 2007

I. GENERAL INFORMATION

A. Background: This is a reconsideration of the national coverage determination (NCD) on LADR (section 150.10 of the NCD Manual).

On November 28, 2006, the Centers for Medicare and Medicaid Services (CMS) initiated a national coverage analysis for the reconsideration of the NCD on LADR. The original NCD for LADR was focused on a specific lumbar artificial disc implant (Charite™) because it was the only one with FDA approval at that time. In the original decision memorandum for LADR CMS stated that when another lumbar artificial disc received FDA approval we would reconsider our policy. Subsequently, another lumbar artificial disc, ProDisc®-L, received FDA approval which initiated the reconsideration of our NCD on LADR. After reviewing the evidence, CMS was convinced that indications for the procedure of LADR exclude the over age 60 population; therefore, the revised NCD addresses the procedure of LADR rather than LADR with a specific manufacture's implant.

This CR includes requirements for physicians and hospitals to provide appropriate liability notices to beneficiaries assuming the providers bill separately. Any provider who performs another part of the service described in this instruction that is expected to be non-covered on the basis of this coverage decision should also provide the beneficiary with appropriate liability notice in advance of the procedure consistent with chapter 30, Pub 100-04, the Medicare Claims Processing Manual.

B. Policy: Effective for services performed on or after August 14, 2007, the CMS has found that LADR is not reasonable and necessary for the Medicare population over 60 years of age. Therefore, LADR is non-covered for Medicare beneficiaries over 60 years of age as identified is section 150.10, of Pub.100-03, the NCD Manual.

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

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5727.1	Contractors shall consider LADR a non-covered service for Medicare beneficiaries over 60 years of age as indicated in Pub.100-03, the Medicare NCD	X		X	X							

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	Manual, section 150.10**.** **NOTE:** For Medicare beneficiaries 60 years of age and younger, there is no national coverage determination, leaving such determinations to continue to be made by local contractors.											
5727.1.1	Contractors shall deny claims submitted with Category III Codes 22857 and 0163T for Medicare beneficiaries over 60 years of age, (i.e. on or after a beneficiary's 61st birthday).	X			X							
5727.1.2	Contractors shall deny claims submitted with ICD-9-CM procedure code 84.65 for Medicare beneficiaries over 60 years of age.	X		X								
5727.1.3	Contractors need not search their files to recoup payment for claims already paid. However, contractors shall adjust claims brought to their attention.	X		X	X							
5727.1.4	Contractors shall use Medicare Summary Notice (MSN) 21.24 "This service is not covered for patients over age 60." Spanish translation: "Este servicio no está cubierto en pacientes mayores de 60 años."	X		X	X							
5727.1.5	Contractors shall use Claim Adjustment Reason Code 96 "Non-covered charge(s)."	X		X	X							
5727.1.6	Contractors shall use Remittance Advice Remark Code N386 "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD."	X		X	X							
5727.2	Contractors shall be aware that providers shall issue the appropriate liability notice to a beneficiary over 60 years of age for a LADR procedure.	X		X	X							
5727.2.1	Contractors shall be aware that providers shall issue an Advanced Beneficiary Notice (ABN) to beneficiaries over 60 years of age who choose to have this procedure. The ABN shall indicate that after a national coverage analysis, Medicare issued a national coverage determination (NCD) (section 150.10 of the Medicare NCD Manual) that states that	X			X							

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A / B MAC	DME MAC	FI	CARRIER	DME RC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	LADR is not reasonable and necessary for Medicare beneficiaries over 60 years of age. Therefore Medicare never pays for this service for this Medicare population.											
5727.2.2	Contractors shall advise hospitals that a hospital issued notice of noncoverage (HINN) must be signed by a beneficiary over 60 years of age who chooses to have LADR.	X		X								

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A / B MAC	DME MAC	FI	CARRIER	DME RC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5727.3	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X	X							

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
	N/A

B. For all other recommendations and supporting information, use this space:

V. CONTACTS

Pre-Implementation Contact(s):
Deirdre O'Connor, (410) 786-3263
Deirdre.oconnor@cms.hhs.gov (Coverage);
April Billingsley (410) 786-0140
April.billingsley@cms.hhs.gov (Carrier Claims);
Melissa Dehn (410) 786-5721
Melissa.Dehn@cms.hhs.gov (Institutional claims)

Post-Implementation Contact(s):
Appropriate RO

VI. FUNDING

A. *For Fiscal Intermediaries, Carriers, and the Durable Medical Equipment Regional Carrier (DMERC),*:

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

B. *For Medicare Administrative Contractors (MAC)*, use the following statement:

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare Claims Processing Manual
Chapter 32 – Billing Requirements for Special Services

Table of Contents
(Rev.)

170.1 - General
(Rev.)

Effective for services performed *from* May 16, 2006 *through August 13, 2007*, the Centers for Medicare & Medicaid Services (CMS) made the decision that lumbar artificial disc replacement (LADR) with the Charite™ lumbar artificial disc is non-covered for Medicare beneficiaries over 60 years of age. See Pub. 100-03, Medicare National Coverage Determinations Manual, section 150.10, for more information about the non-covered determination.

Effective for services performed on or after August 14, 2007, CMS made the decision that LADR with any lumbar artificial disc is non-covered for Medicare beneficiaries over 60 years of age, (i.e. on or after a beneficiary's 61st birthday).

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

170.2 - Carrier Billing Requirements
(Rev.)

Effective for services performed on or after May 16, 2006 through December 31, 2006, carriers shall deny claims, for Medicare beneficiaries over 60 years of age, submitted with the following Category III Codes:

- 0091T Single interspace, lumbar; and

- 0092T Each additional interspace (List separately in addition to code for primary procedure.)

Effective for services performed on or after January 1, 2007 *through August 13, 2007, for Medicare beneficiaries over 60 years of age, LADR with the Charite™ lumbar artificial disc,* carriers shall deny claims submitted with the following codes:

- 22857 Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), lumbar, single interspace; and

- 0163T Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), lumbar, each additional interspace.

Carriers shall continue to follow their normal claims processing criteria for IDEs for LADR performed with an implant eligible under the IDE criteria.

For dates of service May 16, 2006 through August 13, 2007, Medicare coverage under the investigational device exemption (IDE) for LADR with a disc other than the Charite™ lumbar disc in eligible clinical trials is not impacted.

Effective for services performed on or after August 14, 2007, carriers shall deny claims for LADR surgery, for Medicare beneficiaries over 60 years of age, (i.e. on or after a beneficiary's 61st birthday) submitted with the following codes:

- *22857 Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), lumbar, single interspace; and*

- *0163T Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), lumbar, each additional interspace.*

170.3 - Fiscal Intermediary (FI) Billing Requirements

(Rev.)

The FI*/A/B MAC* will pay for LADR when approved under the IDE/clinical trial criteria only when submitted with ICD-9-CM procedure code 84.65 with condition code 30 and diagnosis code V70.7 when submitted on type of bill (TOB) 11X *from May 16, 2006 through August 13, 2007.*

Special Billing instructions:

For services performed on TOB 11X in critical access hospitals (CAH), the payment will be 101% of reasonable cost.

For services performed on TOB 11X Indian Health Services (IHS) inpatient hospitals will pay under the inpatient prospective payment system (IPPS) based on the DRG.

For services performed on TOB 11X, IHS CAHs will pay under 101% facility specific per diem rate.

NOTE: ICD-9-CM procedure code 84.65 is never payable for beneficiaries over 60 years of age, with the Charite™ lumbar artificial disc, which is the only one that is FDA approved for any diagnosis. If a different manufacture's disc is used in one of the approved clinical trials or is an approved IDE, then condition code 30 and diagnosis code V70.7 must be on the claim for it to be payable.

Effective for discharges on or after August 14, 2007, CMS has found that LADR is not reasonable and necessary for the Medicare population over 60 years of age. Therefore, LADR is non-covered for Medicare beneficiaries over 60 years of age as identified is section 150.10, of Pub.100-03, the NCD Manual. FIs/A/B MACS shall deny claims with ICD-9-CM procedure code 84.65 for Medicare beneficiaries over 60 years of age.

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

170.4 – Reasons for Denial and Medicare Summary Notice (MSN), Claim Adjustment Reason Code Messages, *and Remittance Advice Remark Code*

(Rev.)

Contractors shall use the following messages when denying claims for Medicare beneficiaries over 60 years of age (i.e. on or after a beneficiary's 61st birthday).

21.24 "This service is not covered for patients over age 60."

"Este servicio no está cubierto en pacientes mayores de 60 años."

Use an appropriate Claim Adjustment Reason Code:

96 "Non-covered charge(s)."

Use an appropriate Remittance Advice Remark Code:

N386 "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD."

170.5 - Advance Beneficiary Notice (ABN) and Hospital Issued Notice of Noncoverage (HINN) Information

(Rev.)

Providers must be advised that the provider is liable for charges if the lumbar artificial disc *replacement* is used in the surgery, unless the beneficiary was informed that he/she would be financially responsible prior to performance of the procedure. To avoid this liability the provider should have the beneficiary sign an ABN.

The HINN model language should be adapted to this situation in the sections addressing description of the care at issue if the surgery is performed on an inpatient basis. Unless the beneficiary was informed prior to the admission that he/ she would be financially liable for the admission, the provider is liable. To avoid this liability the provider must issue a HINN. Other content requirements of a HINN still apply. Use the HINN letter most appropriate to the overall situation.