
CMS Manual System

Pub. 100-04 Medicare Claims Processing

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 992

Date: JUNE 23, 2006

CHANGE REQUEST 5057

SUBJECT: Lumbar Artificial Disc Replacement (LADR)

I. SUMMARY OF CHANGES: Upon completion of a national coverage analysis 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. This instruction includes the billing requirement for LADR.

NEW/REVISED MATERIAL –

EFFECTIVE DATE*: May 16, 2006

IMPLEMENTATION DATE: Carriers- July17, 2006, FI's – October 1, 2006

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. 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)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	32/Table of Contents
N	32/170/Billing Requirements for Lumbar Artificial Disc Replacement
N	32/170.1/General
N	32/170.2/Carrier Billing Requirements
N	32/170.3/Fiscal Intermediary (FI) Billing Requirements
N	32/170.4/Reasons for Denial and Medicare Summary Notice (MSN) and Claim Adjustment Reason Code Messages
N	32/170.5/Advance Beneficiary Notice (ABN) and Hospital Issued Notice of Noncoverage (HINN) Information

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:

X	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 992	Date: June 23, 2006	Change Request 5057
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SUBJECT: Lumbar Artificial Disc Replacement (LADR)

I. GENERAL INFORMATION

A. Background: This is a new national coverage determination (NCD). There is no existing NCD on LADR.

On August 16, 2005, a request for non-coverage for the Charite™ LADR initiated a national coverage analysis on LADR. The focus of the national coverage analysis for LADR was on the Charite™ lumbar artificial disc because this was the only lumbar artificial disc with Food and Drug Administration (FDA) approval at the time of the analysis. This change request communicates the findings and NCD resulting from that analysis.

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, of Pub 100-04, the Medicare Claims Processing Manual.

B. Policy: Effective for services performed on or after May 16, 2006, the Centers for Medicare & 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 as identified in section 150.10, of Pub.100-03, the NCD Manual.

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.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement

"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		F	R	C	D	Shared System Maintainers				Other
		I	H	a	M	F	M	V	C	
			H	r	E	I	C	M	W	
			I	r	R	S	S	S	F	
				e	C					
				r						

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
5057.1	Contractors shall consider LADR with a Charite™ lumbar artificial disc a non-covered service for Medicare beneficiaries over 60 years of age as indicated in Pub. 100-03, the Medicare NCD 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 the local contractors.	X		X		X				
5057.1.1	Contractors shall deny claims submitted with Category III Codes 0091T and 0092T for Medicare beneficiaries over 60 years of age, (i.e. on or after a beneficiary’s 61 st birthday). NOTE: The Charite™ lumbar artificial disc is the only artificial disc approved by the FDA at this time, therefore the procedure (0091T or 0092T) would be using the Charite™.			X						
5057.1.2	Contractors shall deny claims when submitted with ICD-9 CM procedure code 84.65 for Medicare beneficiaries over 60 years of age. NOTE: The Charite™ lumbar artificial disc is the only artificial disc approved by the FDA at this time, therefore the procedure (84.65) would be using the Charite™.	X				X				MCE
5057.1.3	Contractors shall use new 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				
5057.1.4	Contractors shall use Claim Adjustment Reason Code 96 "Non-covered charge(s)."	X		X		X				

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
5057.1.5	Contractors need not search their files to either retract payment for claims already paid or to retroactively pay claims. However, contractors shall adjust claims brought to their attention.	X		X						
5057.2	Contractors shall continue to process claims for LADR with an implant other than a Charite™ for Medicare beneficiaries over 60 years of age when performed under an investigational device exemption (IDE) and approved by the contractor.	X		X						
5057.2.1	Contractors shall allow claims under an approved IDE when submitted with 0091T or 0092T with the modifier QA.			X						
5057.2.2	Contractors shall allow claims under an approved IDE/Clinical trial when submitted with ICD-9 CM procedure code 84.65 with the condition code 30 and diagnosis code V70.7 when submitted on type of bill (TOB) 11X.	X				X				
5057.2.2.1	Contractors shall pay inpatient hospitals, including IHS TOB 11X under the inpatient prospective payment system (IPPS) based on the DRG.	X				X				
5057.2.2.2	Contractors shall pay IHS critical access hospitals, TOB 11X under 101 percent facility specific per diem rate.	X				X				
5057.2.2.3	Contractors shall pay critical access hospitals (CAHs), TOB 11X under the inpatient prospective payment system (IPPS) based on 101 percent of reasonable cost.	X				X				
5057.3	Contractors shall be aware that providers shall issue the appropriate liability notice to a beneficiary over 60 years of age when a Charite™ lumbar artificial disc is to be used in the procedure.	X		X						

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)							
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers			
F I S S	M C S					V M S	C W F		
5057.4	A provider education article related to this instruction will be available at 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 and incorporated into any educational events on this topic. 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					

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

<p>Effective Date*: May 16, 2006 Implementation Date: July 17, 2006 for Carriers; October 1, 2006 for FI's.</p> <p>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); Taneka Rivera (410) 786-9502 Taneka.Rivera@cms.hhs.gov (Institutional Claims)</p> <p>Post-Implementation Contact(s): Appropriate RO</p>	<p>No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.</p>
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Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

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

170 - Billing Requirements for Lumbar Artificial Disc Replacement

(Rev.992, Issued: 06-23-06, Effective: 05-16-06, Implementation: Carriers 07-17-06/FIs 10-01-06)

170.1 - General

(Rev.992, Issued: 06-23-06, Effective: 05-16-06, Implementation: Carriers 07-17-06/FIs 10-01-06)

Effective for services performed on or after May 16, 2006, 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.

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.

170.2 - Carrier Billing Requirements

(Rev.992, Issued: 06-23-06, Effective: 05-16-06, Implementation: Carriers 07-17-06/FIs 10-01-06)

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

- 0091T Single interspace, lumbar*
- 0092T Each additional interspace (List separately in addition to code for primary procedure)*

NOTE: *The Charite™ lumbar artificial disc is the only artificial disc approved by the Food and Drug Administration, therefore the procedure (0091T or 0092T) would be using the Charite™ unless those procedures are utilizing another artificial disc performed under an Investigational Device Exemption (IDE) or clinical trial.*

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

Carriers shall allow claims submitted for approved IDEs/clinical trials submitted with 0091T or 0092T with the modifier QA.

170.3 - Fiscal Intermediary (FI) Billing Requirements

(Rev.992, Issued: 06-23-06, Effective: 05-16-06, Implementation: Carriers 07-17-06/FIs 10-01-06)

The FI 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.

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.*

170.4 – Reasons for Denial and Medicare Summary Notice (MSN) and Claim Adjustment Reason Code Messages

(Rev.992, Issued: 06-23-06, Effective: 05-16-06, Implementation: Carriers 07-17-06/FIs 10-01-06)

When denying claims submitted with CPT codes 0091T and 0092T or ICD-9-CM code 84.65, for Medicare beneficiaries over 60 years of age, use the following new MSN:

- 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)."*

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

(Rev.992, Issued: 06-23-06, Effective: 05-16-06, Implementation: Carriers 07-17-06/FIs 10-01-06)

Providers must be advised that the provider is liable for charges if the Charite™ lumbar artificial disc 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.