

CMS Manual System

Pub 100-08 Medicare Program Integrity

Transmittal 147

Department of Health &
Human Services (DHHS)

Centers for Medicare &
Medicaid Services (CMS)

Date: MAY 19, 2006

Change Request 4233

SUBJECT: Evaluation of LCD Topics for NCD Consideration

I. SUMMARY OF CHANGES: Pursuant to Section 731 of the Medicare Modernization Act, CMS has developed a plan to evaluate new (LCDs) to decide which local decisions should be adopted nationally.

NEW/REVISED MATERIAL

EFFECTIVE DATE: June 19, 2006

IMPLEMENTATION DATE: June 19, 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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N	13/13.14/Evaluation of Local Coverage Determination (LCD) Topics for National Coverage Determination (NCD) Consideration

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:

Business Requirements

Manual Instruction

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

Attachment - Business Requirements

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SUBJECT: Evaluation of Local Coverage Determination (LCD) Topics for National Coverage Determination (NCD) Consideration

I. GENERAL INFORMATION

A. Background: The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), section 731, requires the Centers for Medicare & Medicaid Services (CMS) to develop a plan to evaluate new (LCDs) to decide which local decisions should be adopted nationally.

B. Policy: Pursuant to section 731 of the MMA, CMS developed a process where “new” LCDs developed after June 19, 2006, may be evaluated to determine whether they should be adopted nationally.

II. BUSINESS REQUIREMENTS

“Shall” denotes a mandatory requirement

“Should” denotes an optional requirement

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 / D M E P S C	Shared System Maintainers				Other
F I S S	M C S					V M S	C W F			
4233.1	When a Medicare contractor begins developing a new LCD and believes the topic may be appropriate as an NCD, the contractor medical director (CMD) should use the LCD evaluation criteria below to make a determination as to whether the topic is appropriate to send to the 731 Advisory Group for NCD consideration.	X	X	X	X					
4233.2	If a Medicare contractor, after reviewing the LCD evaluation criteria, determines that an LCD topic is appropriate for NCD consideration, the contractor shall submit the LCD topic, a formal evaluation (using the	X	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 / D M E P S C	Shared System Maintainers			
F I S S	M C S					V M S	C W F		
	format provided by the 731 Advisory Group), and appropriate supporting documentation, (as determined by the 731 Advisory Group), to the 731 Advisory Group.								
4233.3	Contractors have the discretion to continue development of the LCD throughout this process, regardless of the decisions made by the 731 Advisory Group and CAG.	X	X	X	X				

III. PROVIDER EDUCATION

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		
	None.								

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*: June 19, 2006</p> <p>Implementation Date: June 19, 2006</p> <p>Pre-Implementation Contact(s): Misty Whitaker mwhitaker@cms.hhs.gov, 410-786-3087</p> <p>Post-Implementation Contact(s): Misty Whitaker mwhitaker@cms.hhs.gov, 410-786-3087</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 Program Integrity Manual

Chapter 13 – Local Coverage Determinations

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13.14 – Evaluation of Local Coverage Determination (LCD) Topics for National Coverage Determination (NCD) Consideration

13.14 – Evaluation of Local Coverage Determination (LCD) Topics for National Coverage Determination (NCD) Consideration

(Rev.147, Issued: 05-19-06, Effective: 06-19-06, Implementation: 06-19-06)

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), section 731, requires the Centers for Medicare & Medicaid Services (CMS) to develop a plan to evaluate new LCDs to decide which local decisions should be adopted nationally. CMS currently has policies in place that address the MMA requirements to promote greater consistency among LCDs, require Medicare contractors within an area to consult on new local coverage policies, and to disseminate information on LCDs among Medicare contractors. These existing policies (see section 7 of this chapter) require Medicare contractors to:

- Consult with other contractors prior to developing a new policy;*
- Adopt/ adapt an existing LCD, if possible; and*
- Disseminate draft/final LCDs in the national CMS Medicare Coverage Database (www.cms.hhs.gov/mcd).*

Pursuant to section 731 of the MMA, CMS developed a process where “new” LCDs developed after [insert implementation date] may be evaluated to determine whether they should be adopted nationally. “New” LCDs, for purposes of this process, are initial evaluations of technologies and services and do not include existing LCDs developed prior to June 19, 2006, LCD reconsiderations based on new information, or reevaluation of previously available information. The term “Contractor,” for purposes of this process, includes but is not limited to fiscal intermediaries, durable medical equipment regional contractors, durable medical equipment program safeguard contractors, carriers, regional home health intermediaries and Medicare administrative contractors.

This process is distinct from, and should not be confused with, the current national coverage determination (NCD) request process described in the September 26, 2003, “Federal Register” (FR) Notice (68 FR 55634), “Revised Process for Making Medicare National Coverage Determinations,” and/or any current or future guidance documents that provide NCD guidelines. The NCD process outlined in the FR notice allows any interested party to request an NCD under specific sections of the Social Security Act and the Benefits Improvement and Protection Act of 2000.

Under this process, a 731 Advisory Group has been established to review LCD topic submissions and determine which LCD topics to forward to the CMS Coverage and Analysis Group (CAG). The 731 Advisory Group will establish standard operating procedures for the contractors to follow regarding how to refer an LCD topic within the following framework:

- 1. When a Medicare contractor begins developing a new LCD and believes the topic may be more appropriate to review as an NCD, the contractor medical director (CMD) should use the LCD evaluation criteria below to make a determination as to whether the topic is appropriate to submit to the 731 Advisory Group for NCD consideration. This*

evaluation will ideally be initiated early in the LCD development process before the contactor invests time into developing the policy. In addition to the CMD developing the policy, any other Medicare CMD or CMD Workgroup may utilize this process for any new LCD.

2. If a Medicare contractor, after reviewing the LCD evaluation criteria, determines that an LCD topic is appropriate for NCD consideration, the contractor shall submit the LCD topic, a formal evaluation (using the format provided by the 731 Advisory Group), and appropriate supporting documentation, (as determined by the 731 Advisory Group), to the 731 Advisory Group.

3. The 731 Advisory Group will review the LCD topic, evaluation, and supporting documentation to determine whether to refer the LCD topic to CAG for NCD consideration. The 731 Advisory Group will notify the requesting contractor of its decision. If the 731 Advisory Group determines that the LCD topic is appropriate for NCD consideration, it will refer the LCD topic to CAG.

4. The CAG will review each coverage topic referral and provide feedback to the 731 Advisory Group within 30 working days from the date that a request is deemed complete by CAG. (CAG will alert the 731 Advisory Group within 10 working days if it determines that the referral is incomplete, along with what is required for a complete referral). Final CAG feedback shall include both the decision to accept (or reject) the LCD topic for a formal NCD review, and the rationale for that decision.

5. If CAG accepts an LCD topic for NCD reconsideration, the ensuing process, time lines, etc., will follow those outlined in the September 26, 2003, FR notice for internally generated NCD requests and relevant coverage guidance documents. This process includes posting the proposed NCD topics on the CMS Web site.

6. The LCD topics submitted through this process will be tracked through a free-standing database by the 731 Advisory Group. The database will include, at a minimum, the following information: the date the topic is submitted to the 731 Advisory Group; the date the topic is accepted by the 731 Advisory Group as complete; the date of the 731 Advisory Group decision; the date the topic is referred to CAG; the date the referral is accepted by CAG as complete; and the date the CAG decision is provided to the 731 Advisory Group.

7. The CMS Program Integrity Group, in collaboration with CAG, CMDs, and Medicare contractors, will be responsible for assessing the new process and its impact on the volume of additional NCDs it might generate, as well as the characteristics of LCD topics forwarded for NCD consideration.

8. Contractors have the discretion to continue development of the LCD throughout this process, regardless of the decisions made by the 731 Advisory Group and CAG.

LCD Topic Evaluation Criteria for NCD Consideration

When assessing whether an LCD topic should be referred to the 731 Advisory Group for NCD consideration, contractors should consider the following criteria:

- Net impact on clinical health outcomes;*
- Current and projected local utilization patterns outside of perceived reasonable and necessary boundaries;*
 - Current and projected national utilization patterns outside of perceived reasonable and necessary boundaries;*
- Unit cost;*
- Collateral costs;*
- Associated quality and access to care issues including capacity of health system to use technology safely; and*
- Medicare payment error rate impact.*