CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-08 Medicare Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 473	**Date: June 21, 2013**
	Change Request 7829

Transmittal 443, dated December 14, 2012, is being rescinded and replaced by 473, dated June 21, 2013 to add a bullet to section 13.5.1 that was inadvertently omitted. All other information remains the same.

SUBJECT: Update to Pub. 100-08, Program Integrity Manual, Chapter 13

I. SUMMARY OF CHANGES: The purpose of this CR is to provide the manual revisions to describe the requirements Medicare MACs must follow, in that LCA provisions can no longer be used when developing LCDs and Articles. The manual revisions also have minimal wording changes.

EFFECTIVE DATE: January 15, 2013
IMPLEMENTATION DATE: January 15, 2013

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: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row*.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	Table of Contents
R	13/13.1.1/National Coverage Determinations (NCDs)
R	13/13.1.2/ Coverage Provisions in Interpretive Manuals
R	13/13.1.3/ Local Coverage Determinations (LCDs)
R	13/13.1.4/ Durable Medical Equipment Medicare Administrative Contractors (DME MACs) Adoption or Rejection of LCDs Recommended by Durable Medical Equipment Program Safeguard Contractors (DME PSCs)
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R	13/13.12/ Retired LCDs and The LCD Record
R	13/13.13/ Challenge of an LCD
R	13/13.1/ The Challenge
R	13/13.5/ Subpoenas
R	13/13.7/ Dismissals for Cause
R	13/13.11/ Effectuating the Decision
R	13/13.14/ Evaluation of Local Coverage Determination (LCD) Topics for National Coverage Determination (NCD) Consideration

III. FUNDING:

For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:

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

For Medicare Administrative Contractors (MACs):

The Medicare Administrative contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged 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.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

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

Attachment - Business Requirements

Pub. 100-08	Transmittal: 473	Date: June 21, 2013	Change Request: 7829

Transmittal 443, dated December 14, 2012, is being rescinded and replaced by 473, dated June 21, 2013 to add a bullet to section 13.5.1 that was inadvertently omitted. All other information remains the same.

SUBJECT: Update to Pub. 100-08, Program Integrity Manual, Chapter 13

Effective Date: **January 15, 2013**

Implementation Date: January 15, 2013

I. GENERAL INFORMATION

A. Background: To be consistent with Hays v. Sebelius, 589 F.3d 1279 (D.C. Cir. 2009), the Centers for Medicare & Medicaid Services (CMS) is updating the Program Integrity Manual, Chapter 13, Publication 100-08, to state that Medicare Administrative Contractors (MACs) shall no longer use Least Costly Alternative (LCA) provisions within their Local Coverage Determinations (LCDs).

B. Policy: The manual revisions describe the requirements Medicare MACs must follow, in that LCA provisions can no longer be used when developing LCDs and Articles. The manual revisions also have minimal wording changes along with information regarding one additional type of evidence that can be used by Medicare MACs to support the development of an LCD.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7829.1	Contractors shall ensure that LCDs and Articles do not contain Least Costly Alternative (LCA) provisions.	x	x	x	x	x					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	None										

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s): Karen Reinhardt, 410-786-1089, karen.reinhardt@cms.hhs.gov, Lori Ashby, 410-786-6322, lori.ashby@cms.hhs.gov.

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs),* and/or *Carriers*: No additional funding will be provided by CMS; contractor's activities are to be carried out within their operating budgets.

Section B: *For Medicare Administrative Contractors (MACs)*: The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. 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 Program Integrity Manual

Chapter 13 – Local Coverage Determinations

Table of Contents
(Rev.473, Issued: 06-21-13)

13.1.1 - National Coverage Determinations (NCDs)

(Rev.473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

The NCDs are developed by CMS to describe the circumstances for Medicare coverage nationwide for *an item or service*. NCDs generally outline the conditions for which *an item or* service is considered to be covered (or not covered) under §1862(a) (1) of the Act or other applicable provisions of the Act. NCDs are usually issued as a program instruction. Once published in a CMS program instruction, an NCD is binding on all Medicare carriers/DMERCS, FIs, Quality Improvement Organizations (QIOs, formerly known as Peer Review Organizations or PROs), Program Safeguard Contractors (PSCs) and beginning 10/1/01 are binding for Medicare+Choice organizations. NCDs made under §1862(a)(1) of the Act are binding on Administrative Law Judges (ALJ) during the claim appeal process. (See 42 CFR 405.732 and 42 CFR 405.860).

When a new NCD is published, the contractor shall notify the provider community as soon as possible of the change and corresponding effective date. This is a Provider Communications (PCOM) activity. Within 30 calendar days after an NCD is issued by CMS, contractors shall either publish the NCD on the contractor Web site or link to the MCD from the contractor Web site. The contractor shall not solicit comments on national coverage *determinations*. Contractors shall amend affected LCDs in accordance with §13.4C of this chapter. Since ALJs are bound by NCDs but not LCDs, simply repeating an NCD as an LCD will cause confusion as to the standing of the policy. If a contractor is clarifying a national "reasonable and necessary" policy, the contractor shall reference that national policy in the "CMS National Coverage Policy" section of the LCD.

The contractor shall apply NCDs when reviewing claims for *items or* services addressed by NCDs. When making individual claim determinations, contractors have no authority to deviate from NCD if absolute words such as "never" or "only if" are used in the policy.

National Coverage Determinations should not be confused with "National Coverage Requests" or "Coverage Decision Memoranda".

- National Coverage Request -- A national coverage request is a request from any party, including contractors and CMS staff, for CMS to consider an issue for a national coverage decision. The information CMS requires prior to accepting a national coverage request is described in the "Federal Register" (FR) Notice entitled "Revised Process for Making Medicare National Coverage Determinations" and is located *http://www.cms.gov/DeterminationProcess/01_overview.asp#reg*. If CMS decides to accept the request, information is posted on the coverage Web site at http://cms.hhs.gov/coverage. National Coverage Requests may contain Technology Assessments. Contractors should submit national coverage requests to Coverage and Analysis Group, Office of Clinical Standards and Quality, S3-02-01, 7500 Security Boulevard, Baltimore, Maryland 21244 and provide a copy to MROperations@cms.hhs.gov and the appropriate RO. State "National Coverage Request" in the subject line.

- Coverage Decision Memorandum - CMS prepares a decision memorandum before preparing the national coverage decision. The decision memorandum is posted on the CMS Web site, that tells interested parties that CMS has concluded its analysis, describes the clinical position, which CMS intends to implement, and provides background on how CMS reached that stance. Coverage Decision Memos are not binding on contractors or ALJs. However, in order to expend MR funds wisely, contractors should consider Coverage Decision Memo posted on the CMS Web site. The decision outlined in the Coverage Decision Memo will be implemented in a CMS-issued program instruction within 180 days of the end of the calendar quarter in which the memo was posted on the Web site.

National coverage determinations should not be confused with coverage provisions in interpretive manuals.

13.1.2 - Coverage Provisions in Interpretive Manuals

(Rev.473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

Coverage provisions in interpretive manuals are instructions that are used to further define when and under what circumstances *items or* services may be covered (or not covered). The contractor shall not solicit comments on coverage provisions in interpretive manuals. Contractors shall amend affected LCDs in accordance with this chapter.

The contractor shall apply coverage provisions in interpretive manuals to claims that are selected for review. When making claim determinations, contractors shall not deviate from these coverage provisions if absolute words such as "never" or "only if" are used. Requirements for prerequisite therapies listed in coverage provisions in interpretive manuals (e.g., "conservative treatment has been tried, but failed") shall be followed when deciding whether to cover *an item or* service.

13.1.3 - Local Coverage Determinations (LCDs)

(Rev.473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

Section 522 of the Benefits Improvement and Protection Act (BIPA) created the term “local coverage determination” (LCD). An LCD is a decision by a Medicare administrative contractor (MAC), fiscal intermediary or carrier whether to cover a particular *item or* service on a MAC-wide, intermediary wide or carrier-wide basis in accordance with Section 1862(a)(1)(A) of the Social Security Act (i.e., a determination as to whether the *item or* service is reasonable and necessary). The difference between LMRPs and LCDs is that LCDs consist of only “reasonable and necessary” information, while LMRPs may also contain benefit category and statutory exclusion provisions.

The final rule establishing LCDs was published November 11, 2003. Beginning December 7, 2003, local policies will be referred to as LCDs with the understanding of the relative standing of both LCDs and LMRPs. Effective December 7, 2003, contractors will issue LCDs instead of LMRPs. Additionally, over a 2 year period, contractors converted all existing LMRPs into LCDs. **Until that conversion was complete, the term LCD, for the purpose of section 522** challenges, will refer to both:

1) Reasonable and necessary provisions of an LMRP and,
2) An LCD that contains only reasonable and necessary language.

The CMS has developed an application within the Medicare coverage database back-end that will facilitate this conversion. This application was made available to contractors on or about December 3, 2003. The contractor converted the pertinent LMRP information into an LCD and *placed* the remaining information (benefit category, statutory exclusion, and coding provisions) in an article or delete it. Statutory exclusion and benefit category provisions in LMRPs existing before December 7, 2003, remained in effect until that policy is converted into an LCD.

Effective December 7, 2003, contractors directed to no longer create new LMRPs and shall instead create LCDs. All LMRP were converted to LCDs no later than December 2005. Any non-reasonable and necessary language a contractor wishes to communicate to providers were published through an article. Any draft LMRPS that are in the notice period before December 7, 2003, were entered into the MCD as a draft LCD. The draft LCD will then be released as a final LCD on the scheduled effective date. Additionally, when making the conversion from LMRP to LCD, contractors shall also research and revise their manual references in order to ensure their accuracy. Until all CMS manuals are revised, LMRPs will have the same effect as LCDs.

Codes describing what is covered and what is not covered can be part of the LCD. This includes, for example, lists of HCPCs codes that spell out which *items or* services the LCD applies to, lists of ICD-9-CM codes for which the *item or* service is covered, lists of ICD-9 codes for which the *item or* service is not considered reasonable and necessary, etc. These coding descriptions should only be included if they are integral to the discussion of medical necessity.

Coding guidelines are not elements of LCDs and should be published in articles or deleted. Inclusion in LCDs may mislead the public that they can be challenged under the 522 provision. The following are examples of coding guidelines:

> A provision stating that a 4-inch thick mattress should be billed using code XXYYZ.
>
> A statement that in order to be correctly coded a level X visit shall include complex medical decision making and a review of systems.

The LCDs specify under what clinical circumstances *an item or* service is considered to be reasonable and necessary. They are administrative and educational tools to assist providers in submitting correct claims for payment. Contractors publish LCDs to provide guidance to the public and medical community within their jurisdictions. Contractors develop LCDs by considering medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community.

The contractor should adopt LCDs that have been developed individually or collaboratively with other contractors. The contractor shall ensure that all LCDs are consistent with all statutes, rulings, regulations, and national coverage, payment, and coding policies.

Any policy developed between February 1, 2001 and December 7, 2003, that has not been converted to an LCD shall be in the format described in PIM Exhibit 6. Additional information on the LCD format is available on the Fu & Associates Web page.

Contractors shall ensure that LCDs present an objective and positive statement and do not malign any segment of the medical community. LCDs do not address fraud and contractors should not use terms such as "fraud" and "fraudulent" in their LCDs. For example, the following sentence would be inappropriate in an LCD. "If, on postpay review this carrier finds that XYZ procedure was billed to Medicare after the effective date of this LCD, it will consider that billing fraudulent." This sentence would be more accurate and less inflammatory if the word "fraudulent" were replaced with the phrase "not reasonable and necessary".

13.1.4 - Durable Medical Equipment Medicare Administrative Contractors (DME MACs) Adoption or Rejection of LCDs Recommended by Durable Medical Equipment Program Safeguard Contractors (DME PSCs)

(Rev.473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

The DME PSCs shall ensure that the LCDs they recommend to the DME MACs are developed and revised in accordance with this chapter. This section applies to the:

- DME PSCs that develop new policies and revise existing policies.
- DME MACs.
- DMERCs that have not yet transitioned to the DME MACs.

All references made to DME MACs in this section apply to DMERCs. The DME PSCs shall have on-going communication with the DME MACs as a new policy is being developed or when an existing adopted policy is being revised. CMS requires that the recommended LCDs developed by the DME PSCs be identical for each region to ensure uniformity for DMEPOS suppliers that operate nationally.

The DME PSCs shall maintain an LCD record as a new policy is being developed or when an existing adopted policy is being revised. The DME PSCs shall submit the LCD record, which includes a copy of the final draft of the recommended LCD, to the DME MACs, prior to adoption of the recommended LCD. The DME MACs shall ensure that the LCD record is received prior to adoption of the recommended LCD.

The LCD record shall consist of any document or material that the DME PSCs considered during the development of the new or revised LCD, including, but not limited to, the following:

1. The LCD

2. Any medical evidence considered on or before the date the LCD was recommended to the DME MACs for adoption, including, but not limited to, the following:

- Scientific articles
- Technology assessments
- Clinical guidelines
- Documentation from the FDA regarding safety and efficacy of a drug or device with the exception of proprietary data and privileged information
- Statements from clinical experts, medical textbooks, claims data, or other indication of medical standard of practice

3. Comment and Response Documents (a summary of all comments received by the DME PSCs concerning the recommended LCD). This applies only to new LCDs or revised LCDs that were sent for comment.

The DME MACs shall have someone available with a clinical background to review the recommended LCD by the DME PSCs and determine if the recommended LCD shall be adopted or rejected. The DME MACs shall have on-going communication and shall coordinate with the other DME MACs to ensure that a uniform decision is made to adopt or reject a recommended LCD across all DME MAC jurisdictions. The DME MACs shall notify the DME PSCs of their decision to adopt or reject the recommended LCD. The DME MACs shall ensure that the adopted LCDs are identical among the DME MACs.

If the DME MACs reject the recommended LCD by the DME PSCs, they shall explain in writing to the DME PSCs why the LCD was rejected. If the DME PSCs decide to modify the rejected LCD based on comments received from the DME MACs, the DME PSCs shall make the appropriate modifications and shall submit a final copy of the recommended LCD to the DME MACs.

In addition, the DME PSCs shall publish the adopted LCD via the Medicare Coverage Database (MCD). The DME MACs shall provide an Internet link on their contractor Web site to the MCD to provide access to the adopted LCD.

If an aggrieved party challenges an adopted LCD, the DME PSCs shall support the DME MACs in their efforts to defend the adopted LCD during the appeal. For example, if the DME MACs need the DME PSCs to provide oral testimony during an appeal, the DME PSCs shall provide such testimony. Questions concerning the extent of the DME PSCs' support to the DME MACs during the appeals process shall be directed to the appropriate Primary and/or Associate GTL(s).

The active LCD record shall be maintained by the DME PSCs until the LCD is retired. When an LCD is retired, the DME PSCs shall submit the retired LCD record to the DME MACs. The DME MACs shall retain the retired LCD record for 6 years and 3 months. The DME MACs shall have a mechanism for archiving retired LCDs. This mechanism shall allow the DME MACs to respond to requests and retrieve the LCD record. The DME MACs shall post on their Web site information regarding how to obtain retired LCDs. The DME MACs shall provide an

Internet link on their contractor Web site to the MCD to provide access to the retired LCD. The LCD record shall be destroyed 6 years and 3 months from the date the LCD is retired. However, the DME MACs shall not destroy the retired LCD record if it relates to a current investigation or litigation/negotiation; ongoing Workers' Compensation set aside arrangements; or documents which prompt suspicions of fraud and abuse of improper over-utilization of *items or* services. This will satisfy evidentiary needs and discovery obligations critical to the agency's litigation interests.

As referenced in Pub. 100-08, chapter 4, section 4.28, the joint operating agreement developed by the DME PSCs and the DME MACs shall be modified to address the major roles and responsibilities DME PSCs and DME MACs will delineate in order for the DME MACs to adopt or reject LCDs recommended by the DME PSCs.

Effective March 1, 2008, DME PSCs will no longer develop, revise or recommend LCDs to the DME MACs. In accordance to this chapter, the DME MACs will have full responsibility for developing and revising LCDs, maintaining the LCD record, and responsibility for LCD challenges. CMS requires that LCDs developed and revised by the DME MACs be identical for each jurisdiction to ensure uniformity for DMEPOS suppliers that operate nationally.

13.3 - Individual Claim Determinations
(Rev.473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

Contractors may review claims on either a prepayment or postpayment basis regardless of whether a NCD, coverage provision in an interpretive manual, or LCD exists for that *item or* service. However, automated denials can be made only when clear policy or certain other conditions (see chapter 3, §3.5.1) exist. When making individual claim determinations, the contractor shall determine whether the *item or* service in question is covered based on an LCD or the clinical judgment of the medical reviewer. *An item or* service may be covered by a contractor if it meets all of the conditions listed in §13.5.1, Reasonable and Necessary Provisions in LCDs below.

13.4 - When To Develop New/Revised LCDs
(Rev.473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

The use of a LCD helps avoid situations in which claims are paid or denied without a provider having a full understanding of the basis for payment and denial.

A. Contractors Shall Develop New/Revised LCDs

Contractors shall develop LCDs when they have identified *an item or* service that is never covered under certain circumstances and wish to establish automated review in the absence of an NCD or coverage provision in an interpretive manual that supports automated review.

B. Contractors May Develop New/Revised LCD

Contractors have the option to develop LCDs when any of the following occur:

A validated widespread problem demonstrates a significant risk to the Medicare trust funds (identified or potentially high dollar and/or high volume *items or* services. Multi-state contractors may develop uniform LCDs across all its jurisdictions even if data analysis indicates that the problem exists only in one state.

- A LCD is needed to assure beneficiary access to care.

- A contractor has assumed the LCD development workload of another contractor and is undertaking an initiative to create uniform LCDs across its multiple jurisdictions; or is a multi-state contractor undertaking an initiative to create uniform LCDs across its jurisdiction; or

- Frequent denials are issued (following routine or complex review) or frequent denials are anticipated.

C. Contractors Shall Review LCD

Contractors shall ensure that the LCDs appearing on the contractor's LCD Web site and the LCDs appearing in the Medicare Coverage Database are identical. Contractors are encouraged to make use of the Medicare Coverage Database "Save as HTML" feature to assist in keeping the LCDs on their contractor Web sites current.

Within 90 Days

Contractors shall review and appropriately revise affected LCD within 90 days of the publication of program instruction (e.g., Program Memorandum, manual change) containing:

- A new or revised NCD;
- A new or revised coverage provision in an interpretive manual; or
- A change to national payment

policy. Within 120 Days

The Medicare Coverage Database will notify contractors of each LCD that is affected by an update to a HCPCS code or ICD-9-CM code.

The database automatically incorporates code deletions into revised LCDs (and LMRPs and articles) that are placed in "to be reviewed" status. In all cases (code deletions, code insertions, and code description changes) a new version of the LCD (and LMRP and article) is automatically made to incorporate the change, and the new version is placed in the "to be reviewed" status.

Contractors shall review and approve and/or appropriately revise affected LCD within 120 days of the date of this notification. Contractors shall revise the effective date, revision number, and the revision history on all revisions due to major HCPCS and ICD-9-CM changes.

Contractors need not revise the effective date, revision number and revision history on revisions due to minor HCPCS changes. Contractors shall ensure that corresponding changes are made to the LCD appearing on the contractor's LCD Web sites.

NOTE: The Medicare Coverage Database will only alert contractors to the existence of new codes if the new code falls within a code range listed in the LCD.

Annually

To ensure that all LCDs remain accurate and up-to-date at all times, at least annually, contractors shall review and appropriately revise LCDs based upon CMS NCD, coverage provisions in interpretive manuals, national payment policies and national coding policies. If an LCD has been rendered useless by a new/revised national policy, the LCD shall be retired. This process shall include a review of the LCDs in the Medicare Coverage Database and on the contractor's Web site.

Contractors should consider retiring LCDs that are no longer being used for prepay review, post pay review or educational purposes. For example, contractors should consider retiring LCDs for outdated technology with no claims volume.

13.5 - Content of an LCD

(Rev.473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

Contractors shall ensure that LCDs are developed for *items or* services only within their jurisdiction. The LCD shall be clear, concise, properly formatted and not restrict or conflict with NCDs or coverage provisions in interpretive manuals. If an NCD or coverage provision in an interpretive manual states that a given item is "covered for diagnoses/conditions A, B and C," contractors should not use that as a basis to develop LCD to cover only "diagnoses/conditions A, B and C." When an NCD or coverage provision in an interpretive manual does not exclude coverage for other diagnoses/conditions, contractors shall allow for individual consideration unless the LCD supports automatic denial for some or all of those other diagnoses/conditions.

13.5.1 - Reasonable and Necessary Provisions in LCDs

(Rev.473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

A*n item or* service may be covered by a contractor *LCD* if:

- It is reasonable and necessary under 1862(a)(1)(A) of The Act.

Only reasonable and necessary provisions are considered part of the

LCD.

Reasonable and Necessary

Contractors shall describe *in the draft LCD* the circumstances under which *the item or service is reasonable and necessary under 1862(a)(1)(A)*. Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- *Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and*
- Appropriate, including the duration and frequency that is considered appropriate for the *item or* service, in terms of whether it is:
    - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
    - Furnished in a setting appropriate to the patient's medical needs and condition;
    - Ordered and furnished by qualified personnel;
    - One that meets, but does not exceed, the patient's medical need; and
    - At least as beneficial as an existing and available medically appropriate alternative.

There are several exceptions to the requirement that *an item or* service be reasonable and necessary for diagnosis or treatment of illness or injury. The exceptions appear in the full text of §1862(a)(1) and include but are not limited to:

- Pneumococcal, influenza and hepatitis B vaccines are covered if they are reasonable and necessary for the prevention of illness;
- Hospice care is covered if it is reasonable and necessary for the palliation or management of terminal illness;
- Screening mammography is covered if it is within frequency limits and meets quality standards;
- Screening pap smears and screening pelvic exam are covered if they are within frequency limits;

- Prostate cancer screening tests are covered if within frequency limits;
- Colorectal cancer screening tests are covered if within frequency limits; and
- One pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an interlobular lens;

13.5.2 - Coding Provisions in LCDs

(Rev.473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

Only codes describing what is covered and what is not covered can be part of the LCD. This includes, for example, lists of HCPCs codes that spell out which *items or* services the LCD applies to, lists of ICD-9 codes for which the *item or* service is covered, lists of ICD-9 codes for which the *item or* service is not considered reasonable and necessary, etc.

13.5.3 - Use of Absolute Words in LCDs

(Rev.473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

Contractors should use phrases such as "rarely medically necessary" or "not usually medically necessary" in proposed LCDs to describe situations where *an item or* service is considered to be, in almost all instances, not reasonable and necessary. In order to limit unsolicited documentation, clearly state what specific clinical situation would have to exist to be considered reasonable and necessary. If a contractor chooses to apply these kinds of policy provisions (whether in NCD *or other* national coverage provisions in interpretive manuals, or LCDs) during prepay review, they should not do so via automated review if documentation is to be submitted with the claim for manual review of such claims.

When strong clinical justification exists, contractors may also develop LCDs that contain absolute words such as "is never covered" or "is only covered for". When phrases with absolute words are clearly stated in LCDs, contractors are not required to make any exceptions or give individual consideration based on evidence. Contractors should create edits/parameters that are as specific and narrow as possible to separate cases that can be automatically denied from those requiring individual review.

13.5.4 - LCD Requirements That Alternative *Item or* Service Be Tried First

(Rev.473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

Contractors should incorporate into LCDs the concept that use of an alternative item or service precedes the use of another item *or* service. This approach is termed a "prerequisite." Contractors shall base any requirement on evidence that a particular alternative is safe, as effective, or appropriate for a given condition without exceeding the patients' medical needs. Prerequisites shall be based on medical appropriateness, not on cost effectiveness. Non-covered items (e.g., pillows to elevate feet) may be listed. Any prerequisite for drug therapy shall be consistent with the national coverage decision for labeled uses. Whenever national policy bases coverage on an assessment of need by the beneficiary's provider, prerequisites

should not be included in LCDs. As an alternative, contractors may use phrases in proposed LCDs like "the provider should consider..."

13.7 - LCD Development Process

(Rev.473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

When a new or revised LCD is needed, contractors do the following:

- Contact the CMD facilitation contractor, other contractors, the local carrier or intermediary, the DMERC (if applicable), the Medicare Coverage Database or QIOs (formerly PROs) to inquire if a policy which addresses the issue in question already exists;

- Adopt or adapt an existing LCD, if possible; or

- Develop a policy if no policy exists or an existing policy cannot be adapted to the specific situation.

The process for developing the LCD includes developing a draft LCD based on review of medical literature and the *Contractor's* understanding of local practice.

A. Multi-State Contractors

A contractor with LCD jurisdiction for two or more States is strongly encouraged to develop uniform LCDs across all its jurisdictions. However, carriers shall continue to maintain and utilize CACs in accordance with *this chapter*.

13.7.1 - Evidence Supporting LCDs

(Rev.473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

Contractor LCDs shall be based on the strongest evidence available. The extent and quality of supporting evidence is key to defending challenges to LCDs. The initial action in gathering evidence to support LCDs shall always be a search of published scientific literature for any available evidence pertaining to the item *or* service in question. In order of preference, LCDs should be based on:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and

- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:

    - Scientific data or research studies published in peer-reviewed medical journals;

    - Consensus of expert medical opinion (i.e., recognized authorities in the field); or

    - Medical opinion derived from consultations with medical associations or other health care experts.

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

LCDs which challenge the standard of practice in a community and specify that an item *or service* is never reasonable and necessary shall be based on sufficient evidence to convincingly refute evidence presented in support of coverage.

Less stringent evidence is needed when allowing for individual consideration.

13.7.4.1 - The Comment Period
(Rev.473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

A. When the Comment Period Begins

For LCDs that affect *items or* services submitted to carriers, the comment period begins at the time the policy is distributed to the CAC either at the regularly scheduled meeting or in writing to all members of the CAC. Contractors shall distribute these draft LCDs to the CAC members via hardcopy or via email.

For LCDs that affect *items or* services submitted to intermediaries, the comment period begins when the policy is distributed to medical providers or organizations. Contractors may distribute these draft LCDs to medical providers and organizations via:

Hardcopy mailing of the entire draft LCD,

- Hardcopy mailing of the title and Web address of the draft LCD, or
- E-mail containing the title and Web address of the draft LCD.

B. When the Comment Period Ends

Contractors shall provide a minimum comment period of 45 calendar days. Contractors have the discretion but are not required to accept comments submitted after the end of the comment period.

C. Draft LCD Distribution

When a new or revised LCD requires comment and notice(*outlined in this chapter),* all contractors shall solicit comments and recommendations on the draft LCD and get input from, at least:

- Groups of health professionals and provider organizations that may be affected by the LCD;

- Representatives of relevant specialty societies;

- Other intermediaries/carriers;

- Quality Improvement Organizations (formerly known as PROs) within the region;

- Other CMDs within the region;

- General public *(as outlined in this chapter)*;

- The regional office, associate regional administrator, for distribution to the appropriate regional staff (e.g., coverage experts, reimbursement experts). The RO (for PSCs, the GTL, Co-GTL, and SME) staff will review the LCDs for any operational concerns; and

- The appropriate Advisory process:

    - The CAC, for carriers (See §13.8.1)

    - The DAP, for DMERCs (See §13.8.2)

Contractors shall indicate in each distribution the date the comment period ends.

D. Draft LCD Open Meetings

Contractors shall provide open meetings for the purpose of discussing draft LCDs. Carriers shall hold these open meetings prior to presenting the policy to the CAC. To accommodate those who cannot be physically present at the meetings, contractors shall provide other means for attendance (e.g., telephone conference) and accept written or e-mail comments. Written and e-mail comments shall be given full and equal consideration as if presented in the meeting. Members of the CAC may also attend these open meetings.

Interested parties (generally those that would be affected by the LCD, including providers, physicians, vendors, manufacturers, beneficiaries, and caregivers) can make presentations of information related to draft policies. Contractors shall remain sensitive to organizations or groups which may have an interest in an issue (e.g., laboratories, providers who provide services in nursing facilities, home care, or hospice and the associations which represent the facilities/agencies) and invite them to participate in meetings at which a related LCD is to be specifically discussed.

13.8.1.4 - CAC Structure and Process
(Rev.473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

A. Number of Representatives

Each specialty shall have only one member and a designated alternate with approval of committee co-chairs. Additional members may attend when policies that require their expertise are under discussion. Carriers maintain a current local directory of CAC members that is available to CO, RO (for PSCs, the GTL, Co-GTL, and SME), or the provider community on request.

B. Tenure

Carriers have discretion to establish the duration of membership on the committee. The term should balance the duration of time needed to learn about the process to enhance the level of participation and functioning with the desire to allow a variety of physicians to participate. Consider a 2-3 year term.

C. Co-Chairs

The CAC shall be co-chaired by the contractor medical director and one physician selected by the committee. The co-chairs:

- Run the meetings and determine the agendas;
- Provide the full agenda and background material to each committee member at least 14 days in advance; and
- Encourage committee members to discuss the material and disseminate it to interested colleagues within their specialty and to clinic or hospital colleagues for whom the item may be pertinent. The members may bring comments back to the meeting or request that their colleagues send written comments to the CMD separately.

Attendance at the meeting is at the discretion of the committee members. If the item is of importance to their specialty, encourage members to attend or send an alternate. This is the primary forum for discussion of proposed LCDs developed by the CMD. The 45-calendar-day comment process required for all LCDs starts when the *draft* LCD is distributed to the committee members. (See PIM Chapter 13 §13.7.4.1).

Co-chairs present all proposed LCDs to the CAC for discussion. If the need arises to develop and implement LCDs before the next scheduled meeting, they solicit comments from committee members by mail or e-mail.

D. Staff Participation

The Director of Medicare Operations shall assure that appropriate contractor staff attends to address administrative issues on the agenda. Other staff may also be required to attend include:

- Professional relations representative;
- MR manager and
- MFIS/PSC Network.

E. Location

Carriers work with the State medical society and committee members to select a meeting location that will optimize participation of physician committee members.

F. Frequency of Meetings

Hold a minimum of 3 meetings a year, with no more than 4 months between meetings. In the circumstance where a contractor is switching from 4 CAC meetings per year to 3 meetings, it is acceptable to have more than 4 months between the meetings. However, the contractor shall notify the RO (for PSCs, the GTL, Co-GTL, and SME) that this one time occurrence is taking place.

G. Data

Each meeting should include a discussion and presentation of comparative utilization data that has undergone preliminary analysis by the carrier and relates to discussion of proposed LCD. Carriers solicit input from CAC members to help explain or interpret the data and give advice on how overutilization should be addressed. The use of data to illustrate the extent of problem billing (e.g., average number of *items or* services per 100 patients) might help justify the need for a particular policy. The comparative data should be presented using graphs, charts, and other visual methods of presenting data. Carriers may present egregious individual provider's data as long as the provider's identification is not disclosed or cannot be deduced.

H. Payment for Participation

Participation in the CAC is considered a service to physician colleagues. Carriers do not provide an honorarium or other forms of compensation to members. Expenses are the responsibility of the individuals or the associations they represent.

I. Recordkeeping

Carriers keep minutes of the meeting and distribute them to members. Carriers submit the following items from CAC meetings to the RO MR staff (for PSCs, the GTL, Co-GTL, and SME) within 10 days following the meetings:

- A copy of the meeting agenda (include the date of the meeting);
- A prompt copy of meeting minutes (not approved);
- A copy of the approved minutes from the prior meeting, including a summary of this discussion and the number of attendees, broken down into committee members, alternates or observers and RO staff (for PSCs, the GTL, Co-GTL, and SME); and
- Tentative date of the next meeting.

Contractors should (but are not required to) prepare a version of the CAC minutes to be placed on their Web site. This version could differ from a more detailed internal version. Contractors shall assure that the Web site version of the minutes does not include any information that would be protected by FOIA's exemption (b)(6) -- information that would be an invasion of personal privacy (such as a CAC member's home phone number) or any other kind of sensitive information. When contractors receive a request for a hard copy of CAC minutes, the request should go to the contractor's FOIA coordinator for processing through the freedom of information request process.

J. Communicating With CO on National Issues

While the CMD should encourage CAC members to work through their respective organizations and Practicing Physicians Advisory Council (PPAC) to effect national policy, the CAC is not precluded from commenting on these issues. When appropriate, the CMD may choose to forward a formal letter to CMS CO from the CAC. Send these letters through the RO, where they will be answered or forwarded to the appropriate component in CO for response.

K. Support for Beneficiary Member

Provide individual support to the beneficiary representative in understanding the CAC role and process. This includes assisting the beneficiary representative in understanding the LCDs so they are better able to determine the effect of the policy on the beneficiary community. Carriers are encouraged to find ways to involve the beneficiary community in efforts to stem abuse through LCD development.

13.11 - LCD Reconsideration Process

(Rev.473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

Contractors who have the task of developing LCDs shall have an LCD Reconsideration Process in accordance with the following instructions.

A. Purpose

The LCD Reconsideration Process is a mechanism by which interested parties can request a revision to an LCD.

B. Scope

The LCD Reconsideration Process is available only for final LCDs. The whole LCD or any provision of the LCD may be reconsidered.

C. General

Contractors shall respond timely to requests for LCD reconsideration. In addition, contractors have the discretion to revise or retire their LCDs at any time on their own initiatives.

D. Web site Requirements for the LCD Reconsideration Process

Contractors shall add to their current Web sites information on the LCD Reconsideration Process. This information should be on the home page or linked to another location. It shall be labeled "LCD Reconsideration Process" and shall include:

- A description of the LCD Reconsideration Process; and
- Instructions for submitting LCD reconsideration requests, including postal, e-mail, and fax addresses where requests may be submitted.

E. Valid LCD Reconsideration Request Requirements

1. Contractors:

SHALL consider all LCD reconsideration requests from:

- Beneficiaries residing or receiving care in a contractor's jurisdiction; and
- Providers doing business in a contractor's jurisdiction.
- Any interested party doing business in a contractor's jurisdiction.

2. Contractors should only accept reconsideration requests for LCDs published in final form.

Requests shall not be accepted for other documents including:

- National Coverage De*terminations* (NCD);
- Coverage provisions in interpretive manuals;

- Draft LCDs;
- Template LCDs, unless or until they are adopted by the contractor;
- Retired LCDs;
- Individual claim determinations;
- Bulletins, articles, training materials; and
- Any instance in which no LCD exists, i.e., requests for development of an LCD.

If modification of the LCD would conflict with an NCD, the request would not be valid. The contractor should refer the requestor to the NCD reconsideration process. Requestors can be referred to *http://www.cms.gov/DeterminationProcess/01_overview.asp#regs.*

3. Requests shall be submitted in writing, and shall identify the language that the requestor wants added to or deleted from an LCD. Requests shall include a justification supported by new evidence, which may materially affect the LCD's content or basis. Copies of published evidence shall be included.

The level of evidence required for LCD reconsideration is the same as that required for new/revised LCD development. (PIM Chapter 13, Section 13.7.1)

4. Any request for LCD reconsideration that, in the judgment of the contractor, does not meet these criteria is invalid.

5. Contractors have the discretion to consolidate valid requests if similar requests are

received.

F. Process

1. The requestor should submit a valid LCD reconsideration request to the appropriate contractor, following instructions on the contractor's Web site.

2. Within 30 days of the day the request is received, the contractor shall determine whether the request is valid or invalid. If the request is invalid, the contractor shall respond, in writing, to the requestor explaining why the request was invalid. If the request is valid, the contractor should follow the requirements below.

3. Within 90 days of the day the request was received, the contractor shall make a final LCD reconsideration decision on the valid request and notify the requestor of the decision with its rationale. Decision options include retiring the policy, no revision, revision to a more restrictive policy, or revision to a less restrictive policy.

4. If the decision is either to retire the LCD or to make no revision to the LCD, then within 90 days of the day the request was received, the contractor shall inform the requestor of that decision with its rationale.

5. If the decision is to revise the LCD, follow the normal process for LCD development.

6. Contractors shall keep an internal list of the LCD Reconsideration Requests received and the dates, subject, and disposition of each one.

13.12 - Retired LCDs and The LCD Record

(Rev.473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

Contractors shall list the retired date on all retired LCDs. The active LCD record shall be maintained by contractors until the LCD is retired. Contractors shall retain the retired LCD record for 6 years and 3 months. Contractors shall have a mechanism for archiving retired LCDs. This mechanism shall also allow the contractor to respond to requests and retrieve the LCD record. Contractors shall post on their Web site information regarding how to obtain retired LCD. The LCD record shall be destroyed 6 years and 3 months from the date the LCD is retired.

However, contractors shall not destroy the LCD record if it relates to a current investigation or litigation/negotiation; ongoing Workers' Compensation set aside arrangements; or documents which prompt suspicions of fraud and abuse of improper over-utilization of items or services. This will satisfy evidentiary needs and discovery obligations critical to the agency's litigation interests.

13.13 – Challenge of an LCD

(Rev.473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

In addition to creating the term "Local Coverage Determination" (LCD), BIPA 522 creates an appeals process for an "aggrieved party" to challenge LCDs/LCD provisions that are in effect at the time of the challenge. "Aggrieved party" is defined as a Medicare beneficiary, or the estate of a Medicare beneficiary, who is entitled to benefits under Part A, enrolled under Part B, or both (including an individual enrolled in fee-for-service Medicare, in a Medicare+Choice plan (MAC), or in another Medicare managed care plan), and is in need of coverage for *an item or* service that would be denied by an LCD, as documented by the beneficiary's treating physician, regardless of whether the service has been received.

The term LCD refers to both 1) A reasonable and necessary provision of an LMRP and 2) A separate, stand-alone LCD that contains only reasonable and necessary language.

If appropriate, CMS may choose to participate as a party in the process. (See §426.415 of the regulation).

13.13.1 - The Challenge

(Rev.473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

An aggrieved party who chooses to file an LCD challenge before receiving the *item or* service shall file a complaint within 6 months of the issuance of a written statement from his or her treating practitioner. An aggrieved party who chooses to file an LCD challenge after receiving the *item or* service shall file the complaint within 120 days of the initial denial notice.

The aggrieved party bears the burden of proof and burden of persuasion (which will be judged by a preponderance of the evidence) in an LCD challenge. In other words, the aggrieved party shall come forward with evidence to support his/her claim and prove that it is more likely than not that the provision(s) in question should be found invalid. (See section 426.30 of the regulation).

Upon acceptance of a complaint from an aggrieved party, the Administrative Law Judge (ALJ) will forward a copy of the complaint to the contractor. The contractor will then be required to send a copy of the LCD record to the ALJ and all other parties involved in the LCD review (i.e., the aggrieved party/parties) within 30 days (subject to extension for good cause shown). Addresses of these parties will be provided in the letter from the ALJ. The contractor shall also send a copy of the LCD record and a copy of all materials sent by the ALJ to CMS at 7500 Security Blvd, Baltimore, MD *21224*, Mail Stop S3-02-01, Attn: LCD Challenge Staff.

Within 10 days of receiving a valid challenge from the ALJ, the contractor shall initiate a reconsideration of the challenged policy. In instances where the contractor feels the policy is reasonable despite the new evidence presented, the contractor shall simply continue with the review process in order to defend the policy. In cases where the contractor feels that the policy is unreasonable in light of the new evidence, the contractor shall revise the policy through the reconsideration process and notify the ALJ within 48 hours of issuing a revised policy. The contractor shall then forward a copy of the revised LCD to the ALJ. If the provision in question is not entirely removed, the review will continue on the revised LCD. (See §426.420 of the regulation.)

13.13.5 - Subpoenas

(Rev.473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

A subpoena requires the attendance of an individual at a hearing and may also require a party to produce evidence at or before the hearing. A party seeking a subpoena shall file a written motion with the ALJ not less than 30 days before the date fixed for the hearing. The motion shall designate the witnesses, specify any evidence to be produced, describe the address and location with sufficient particularity to permit the witnesses to be found, and state the pertinent facts that the party expects to establish by the witnesses or documents and whether the facts could be established by other evidence without the use of a subpoena. (See § 426.435 of the regulation)

Within 15 days after the written motion requesting issuance of a subpoena is served on all parties, any party may file an opposition to the motion or other response.

If the ALJ grants a motion requesting issuance of a subpoena, the subpoena shall do the following:

(1) Be issued in the name of the ALJ.

(2) Include the docket number and title of the LCD under review.

(3) Provide notice that the subpoena is issued according to sections 1872 and 205(d) and (e) of the Act.

(4) Specify the time and place at which the witness is to appear and any evidence the witness is to produce.

The party seeking the subpoena will serve it by personal delivery to the individual named, or by certified mail return receipt requested, addressed to the individual at his or her last dwelling place or principal place of business. The individual to whom the subpoena is directed may file motion to quash the subpoena with the ALJ within 10 days after service.

The exclusive remedy for or refusal to obey a subpoena duly served upon any person is specified in section 205(e) of the Act (42 U.S.C. 405(e)). That section provides the appropriate district court of the United States, upon application of the Commissioner of the Social Security Administration/Secretary of the Department of Health and Human *Services*, can issue an order and charge a person who doesn't comply with that order with contempt of court.

13.13.7 - Dismissals for Cause

(Rev.473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

The ALJ may, at the request of any party, or on his or her own motion, dismiss a complaint if the aggrieved party fails to attend or participate in a prehearing conference or hearing without good cause shown or comply with a lawful order of the ALJ without good cause shown.

The ALJ shall dismiss any complaint concerning LCD provision(s) if the following conditions exist:

(1) The ALJ does not have the authority to rule on that provision

(2) The complaint is not timely.

(3) The complaint is not filed by an aggrieved party.

(4) The complaint is filed by an individual who fails to provide an adequate statement of need for the *item or* service from the treating practitioner.

(5) The complaint challenges a provision or provisions of an NCD

(6) The contractor notifies the ALJ that the LCD provision(s) is (are) no longer in

effect.

(7) The aggrieved party withdraws the complaint

13.13.11 - Effectuating the Decision
(Rev.473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

If the ALJ finds that the provision or provisions of the LCD named in the complaint is (are) invalid under the reasonableness standard, and no appeal is filed by the contractor, the contractor will provide the following according to §426.460(b) of the final regulation:

(1) **Individual claims:** If the contractor does not appeal the ALJ decision and if an aggrieved party's claim/appeal(s) had previously been denied, the contractor shall reopen the aggrieved party's claim and adjudicate the claim without using the provision(s) of the LCD that the ALJ found invalid. If a revised LCD is issued, the contractor will use the revised LCD in reviewing claim/appeal submissions or request for *items or* services delivered or services performed on or after the effective date of the revised LCD. If an aggrieved party has not yet submitted a claim, the contractor will adjudicate the claim without using the provision(s) of the LCD that the ALJ found invalid. In either case, the claim will be adjudicated without using the LCD provision(s) found invalid.

(2) **Coverage determination relief.** If the contractor does not appeal the ALJ decision, the contractor will implement the ALJ decision within 30 days by doing one of the following:

(i) Revise the LCD to remove the provision(s) of the LCD that the ALJ decision stated was/were not valid under the reasonableness standard. The revised LCD is effective for dates of service on or after the 30th day following the ALJ's decision.

(ii) Retire the LCD in its entirety and not use the LCD in adjudicating claims with dates of service on or after the 30th day following the ALJ decision. (See §426.460 of the final regulation.

The Board shall issue a written decision to all parties to the review of the ALJ decision. The decision shall include the following:

- The Board's Findings (i.e., A statement upholding the part(s) of the ALJ decision named in the appeal, a statement reversing the part(s) of the ALJ decision named in the appeal, a statement modifying the part(s) of the ALJ decision named in the appeal, or a statement dismissing the appeal of an ALJ decision and a rationale for the dismissal);
- The date of issuance;
- The docket number of the review of the ALJ decision;
- A summary of the ALJ's decision; and
- A rationale for the basis of the Board's decision.

The Board **may not** do the following**:**

- Order CMS or its contractors to add any language to a provision or provisions of an LCD;
- Order CMS or its contractors to pay a specific claim;
- Order CMS or its contractors to pay a specific claim;
- Set a time limit to establish a new or revised LCD;
- Review or evaluate an LCD other than the LCD named in the ALJ's decision;
- Include a requirement for CMS or its contractors that specifies payment, coding, or system changes for an LCD or deadlines for implementing these changes; or
- Order CMS or its contractors to implement an LCD in a particular manner.

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

(Rev.473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

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 may be evaluated to determine whether they should be adopted nationally. "New" LCDs, for purposes of this process, are initial evaluations of *items* 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.