Visited 08/05/2015

Medicare Program Integrity Manual

Chapter 13 – Local Coverage Determinations

Table of Contents
(Rev. 510, 04-11-14)

Transmittals for Chapter 13

13.1 - Medicare Policy

13.1.1 - National Coverage Determinations (NCDs)

13.1.2 - Coverage Provisions in Interpretive Manuals

13.1.3 - Local Coverage Determinations (LCDs)

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)

13.3 - Individual Claim Determinations

13.4 - When to Develop New/Revised LCDs

13.5 - Content of an LCD

13.5.1 – Reasonable and Necessary Provisions in LCDs

13.5.2 - Coding Provisions in LCDs

13.5.3 - Use of Absolute Words in LCDs

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

13.6 - LCD Format

13.6.1 - AMA Current Procedural Terminology (CPT) Copyright Agreement

13.7 - LCD Development Process

13.7.1 - Evidence Supporting LCDs

13.7.2 - LCDs That Require A Comment and Notice Period

13.7.3 - LCDs That Do Not Require A Comment and Notice Period

13.7.4 - LCD Comment and Notice Process

13.7.4.1 - The Comment Period

13.7.4.2 - Draft LCD Web Site Requirements

13.7.4.3 - The Notice Period

13.7.4.4 - Final LCD Web Site Requirements

13.8 - The LCD Advisory Process

13.8.1 - The Carrier Advisory Committee

13.8.1.1 - Purpose of the CAC

13.8.1.2 - Membership on the CAC

13.8.1.3 - Role of CAC Members

13.8.1.4 - CAC Structure and Process

13.8.2 - Durable Medical Equipment Regional Carrier (DMERC) Advisory Process (DAP)

Visited 08/05/2015

13.9 - Provider Education Regarding LCDs
13.10 - Application of LCD
13.11 - LCD Reconsideration Process
13.12 - Retired LCDs and The LCD Record
13.13 - Challenge of an LCD
    13.13.1 - The Challenge
    13.13.2 - The LCD Record
    13.13.3 - Ex Parte Contacts
    13.13.4 - Discovery
    13.13.5 - Subpoenas
    13.13.6 - Evidence
    13.13.7 - Dismissals for Cause
    13.13.8 - New Evidence
    13.13.9 - Contractor Options
    13.13.10 - The ALJ Decision
    13.13.11 - Effectuating the Decision
    13.13.12 - Appeals
    13.13.13 - Board Review of an ALJ Decision
    13.13.14 - Effect of a Board Decision
    13.13.15 - Future New or Revised LCDs

13.1 - Medicare Policies
(Rev. 71, 04-09-04)

The primary authority for all coverage provisions and subsequent policies is the Social Security Act (the Act). Contractors use Medicare policies in the form of regulations, NCDs, coverage provisions in interpretive manuals, and LCDs to apply the provisions of the Act.

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,

Visited 08/05/2015

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

Visited 08/05/2015

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.

Visited 08/05/2015

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:

Visited 08/05/2015

- 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 <u>§13.5.1, Reasonable and Necessary Provisions in LCDs</u> 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 <u>shall</u> 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.

Visited 08/05/2015

- 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)

An 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..."

13.6 - LCD Format
(Rev. 71, 04-09-04)

All contractor LCDs shall be listed in the Medicare Coverage Database.

All LCDs shall be posted on the contractor’s Web site in HyperText Markup Language (HTML). The Medicare Coverage Database has a feature that will allow a contractor to “save as HTML” a file of a recently entered LCD. Contractors should alter the appearance of the HTML file to meet their own Web site needs, e.g., change the background color.

13.6.1 - AMA Current Procedural Terminology (CPT) Copyright Agreement
(Rev. 71, 04-09-04)

Any time a CPT code is used in publications on the contractor Web site or in other electronic media such as tapes, disks or CD-ROM, contractors shall display the AMA copyright notice in the body of each LCD. Contractors shall use a point and click license on a computer screen or Web page any time CPT codes are used on the Internet.

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:

Visited 08/05/2015

- 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.

Visited 08/05/2015

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.

13.7.2 – LCDs That Require A Comment and Notice Period
(Rev. 71, 04-09-04)

Contractors shall provide for both a comment period and a notice period in the following situations:

- All New LCDs
- Revised LCDs that Restrict Existing LCDs - Examples: adding non-covered indications to an existing LCD; deleting previously covered ICD-9 codes.
- Revised LCDs that make a Substantive Correction - If the contractor identifies an error published in an LCD that substantively changes the reasonable and necessary intent of the LCD, then the contractor shall extend the comment and/or notice period by an additional 45 calendar days.

13.7.3 - LCDs That Do Not Require a Comment and Notice Period
(Rev. 71, 04-09-04)

When a comment and notice period is unnecessary, contractors may immediately publish a revised LCD electronically (e.g., Medicare coverage database, contractor Web site, email). In the following situations, the comment and notice processes are unnecessary:

- Revised LCD that Liberalizes an Existing LCD - For example, a revised LCD expands the list of covered indications/diagnoses. The revision effective date may be retroactive.
- Revised LCD Being Issued for Compelling Reasons - SHALL OBTAIN RO (for PSCs, the GTL, Co-GTL, and SME) APPROVAL - For example, a highly unsafe procedure/device.
- Revised LCD that Makes a Non-Substantive Correction - For example, typographical or grammatical errors that do not substantially change the LCD. The revision effective date may be retroactive.
- Revised LCD that makes a Clarification - For example, adding information that clarifies the LCD but does not restrict the LCD. The revision effective date may be retroactive.
- Revised LCD that Makes a Non-discretionary Coverage/Payment/Coding Updates - Contractors shall update LCDs to reflect changes in NCDs, coverage provisions in interpretive manuals, payment systems, HCPCS, ICD-9 or other standard coding systems within the timeframes listed in §13.4C. The revision effective date may be retroactive depending on the effective date of the NCD, etc.

Visited 08/05/2015

- Revised LCD to Make Discretionary Coding Updates That Do Not Restrict -adding revisions that explain a coding issue so long as the revision does not restrict the LCD. The revision effective date may be retroactive.

- **Revised LCD to Effectuate an Administrative Law Judge's Decision on a BIPA 522 challenge.**

13.7.4 - LCD Comment and Notice Process
(Rev. 71, 04-09-04)

When a new or revised LCD requires comment and notice (See §13.7.2) contractors shall provide a minimum comment period of 45 calendar days on the draft LCD. After the contractor considers all comments and revises the LCD as needed, the contractor shall provide a minimum notice period of 45 calendar days on the final LCD.

Contractors shall solicit comments from the medical community. Carriers solicit comments from the Carrier Advisory Committee (CAC.) DMERCs solicit comments through the DMERC Advisory Process (DAP.) Contractors respond to comments either individually or via a comment/response document (see §13.7.4.2). Where appropriate, the contractor shall incorporate the comments into the final LCD. Contractors notify providers of the LCD effective date. New LCDs may not be implemented retroactively.

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.

13.7.4.2 - Draft LCD Web site Requirements
(Rev. 71, 04-09-04)

Draft LCD on the Contractor Web site

Contractors shall post draft LCDs on their Web sites. The Web site shall clearly indicate the start and stop date of the comment period and list an e-mail and postal address to which comments can be submitted.

LCD Status Page

Contractors shall post to their Web sites an LCD status page that includes the draft LCD title, date of release of draft LCD for comment, e-mail and postal address for comments to be sent, end date for comment period, current status (see the following status indicators), Date of Release for Notice, and Web site link to the active LCD (i.e., the notice period is complete and the policy is in effect.)

LCD Status Indicators
D = draft under development; not yet released for comments C = draft LCD released for comment E = formal comment period has ended; comments now being considered F = final new/revised LCD has been issued for notice. A= active policy; notice period complete and the policy is in effect

Comment/Response Document

Contractors shall post to their Web sites a summary of comments received concerning the draft LMRP/LCD with the contractor's response. This comment/response document shall be posted prior to or on the start date of the notice period. The comment/response document shall be posted (remain visible) on the Web for at least a 6 month period.

The MCD allows users to attach comment/response documents to their draft document which will be visible when the LCD is reviewed.

13.7.4.3 - The Notice Period
(Rev. 71, 04-09-04)

When a new or revised LCD is issued following a comment period (see §13.7.2), contractors shall ensure that the effective date follows a minimum notice period of 45 calendar days.

A. When The Notice Period Begins

Contractors shall make final LCDs public via publication on their Web site. A summary of the LCD shall be published in a news bulletin.

B. When The Notice Period Ends

Visited 08/05/2015

The notice period ends 45 calendar days after the notice period begins unless extended by the contractor. If the notice period is not extended by the contractor, the effective date of the LCD is the 46th calendar date after the notice period began.

13.7.4.4 - Final LCD Web Site Requirements
(Rev. 71, 04-09-04)

A. Final LCD on the Contractor Web Site

Contractors shall post all final LCDs on their Web Site. Every contractor Web site shall contain all final LCDs for that contractor. The number of active LCDs in the Medicare Coverage Database should equal the number of final LCDs on the contractor Web Site.

Contractors who are an intermediary and a carrier within the same corporation shall have separate Web pages for their LCDs. Contractors shall notify all providers of the contractor LCD Web address. If a contractor becomes aware of a provider without web access, the contractor shall advise providers that they may request hard copy LCDs.

B. Final LCD in the Medicare Coverage Database (MCD)

The public can access the MCD at www.cms.hhs.gov/**mcd.**

Contractors shall update the MCD when they issue a new or revised LCD or retire an existing LCD.

Contractors shall develop a mechanism for ensuring the accuracy of the information entered into the MCD. This mechanism shall include, at a minimum, a process by which data that is entered into the database is reviewed and verified for accuracy within four days of appearing to the public on the Web.

13.8 - The LCD Advisory Process
(Rev. 71, 04-09-04)

13.8.1 - The Carrier Advisory Committee
(Rev. 99, Issued: 01-21-05, Effective: 03-24-04, Implementation: 02-22-05)

Carriers shall establish one CAC per State. Where there is more than one carrier in a State, the carriers shall jointly establish a CAC. If there is one carrier for many States, each State shall have a full committee and the opportunity to discuss draft LCDs and issues presented in their State. Carriers maintain a current directory of CAC members which is available to CO, RO (for PSCs, the GTL, Co-GTL, and SME) staff, and the provider community on request. Carriers that develop identical policies for their entire jurisdiction may establish a single CAC if they are granted a waiver from the CO (for PSCs, the GTL, Co-GTL, and SME). In order to obtain a waiver from the CO (for PSCs, the GTL, Co-GTL, and SME), contractors shall obtain agreement from CAC members within the jurisdiction.

13.8.1.1 - Purpose of the CAC
(Rev. 71, 04-09-04)

Visited 08/05/2015

The purpose of the CAC is to provide:

- A formal mechanism for physicians in the State to be informed of and participate in the development of an LCD in an advisory capacity;
- A mechanism to discuss and improve administrative policies that are within carrier discretion; and
- A forum for information exchange between carriers and physicians.

Carriers shall clearly communicate to CAC members that the focus of the CAC is LCDs and administrative policies and not issues and policies related to private insurance business. The CAC is not a forum for peer review, discussion of individual cases or individual providers. While the CAC shall review all draft LCDs, the final implementation decision about LCDs rests with the CMD.

The CMD jointly develops the agenda with the co-chair representing the CAC to include concerns about LCDs and local administrative issues.

13.8.1.2 - Membership on the CAC
(Rev. 71, 04-09-04)

The CAC is to be composed of physicians, a beneficiary representative, and representatives of other medical organizations. Each is individually described in Exhibit 3.

13.8.1.3 - Role of CAC Members
(Rev. 71, 04-09-04)

CAC members serve to improve the relations and communication between Medicare and the physician community. Specifically, they:

- Disseminate proposed LCDs to colleagues in their respective State and specialty societies to solicit comments;
- Disseminate information about the Medicare program obtained at CAC meetings to their respective State and specialty societies; and
- Discuss inconsistent or conflicting MR policies.

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

Visited 08/05/2015

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.

Visited 08/05/2015

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

Visited 08/05/2015

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.

13.8.2 - Durable Medical Equipment Regional Carrier (DMERC) Advisory Process (DAP)

(Rev. 71, 04-09-04)

The DMERC shall establish a forum of DME advisory workgroups in each region to discuss DME issues and concerns with physicians, clinicians, beneficiaries, suppliers, and manufacturers. Options for this forum should include ad hoc workgroups that are time-limited and/or topic specific. Advisory participants do not advise the Federal Government. Therefore, the rules governing open meetings of Federal Government committees do not apply to the DAP process. Encourage individuals who are concerned with the issues or processes pertaining to DME to attend.

The purpose of the DAP is to provide:

- A formal mechanism to obtain input regarding Regional LCDs (RLCDs) development and revision;
- A mechanism to discuss and improve administrative policies that are within the DMERCs' discretion; and
- A forum for information exchange between the DMERCs, physicians, clinicians, beneficiaries, suppliers, and manufacturers.

13.9 - Provider Education Regarding LCDs

(Rev. 174, Issued: 11-17-06, Effective: 10-01-06, Implementation: 10-06-06)

Contractors shall educate the provider community on new or significantly revised LCDs (e.g., training sessions, speaking at society meetings or writing articles in the society's newsletter). This function shall be charged to provider outreach and education (POE). Inquiries of a clinical

Visited 08/05/2015

nature, such as the rationale behind coverage of certain items or services, shall be handled within medical review (MR), the department responsible for the development of the LCD.

Carriers are required to publish DMERC summary policies, and other pertinent information supplied by DMERCs, as requested, as part of regular bulletin distributions.

13.10 - Application of LCD
(Rev. 71, 04-09-04)

Contractors should apply LCDs to claims on either a prepayment or postpayment basis. If a contractor decides to enforce an LCD on a prepayment basis, the contractor shall design an MR edit. (See PIM Chapter 3, §3.5) Contractors have flexibility to add, alter, or eliminate MR edits at any time. Contractors should not apply a LCD retroactively to claims processed prior to the effective date of the policy.

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

Visited 08/05/2015

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 Determinations (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

Visited 08/05/2015

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.

Visited 08/05/2015

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.)

13.13.2 - The LCD Record

(Rev. 71, 04-09-04)

The contractor shall, by June 2004, maintain an LCD record for each active LCD (both stand alone LCDs and LCDs within LMRPs). In order to fulfill this requirement, contractors shall develop and maintain an LCD record when any new LCD is developed. Additionally, the contractor will have 30 days to provide an LCD record to the ALJ when an LCD is challenged. Finally, contractors shall develop and maintain an LCD record for all other LCDs by June 1, 2004.

The LCD record sent to the aggrieved party consists of any document or material that the contractor considered during the development of the LCD, including, but not limited to, the following:

Visited 08/05/2015

(1) The LCD.

(2) Any medical evidence considered on or before the date the LCD was issued, including, but not limited to, the following:

(i) Scientific articles.

(ii) Technology assessments.

(iii) Clinical guidelines.

(iv) Documentation from the FDA regarding safety and efficacy of a drug or device with the exception of proprietary data and privileged information.

(v) Statements from clinical experts, medical textbooks, claims data, or other indication of medical standard of practice.

(3) Comment and Response Document (a summary of comments received by the contractor concerning the draft LCD).

(4) An index of documents considered that are excluded from the record provided to the aggrieved part but provided to the ALJ because of their proprietary nature. (See §426.418 of the final regulation)

The LCD record furnished to the aggrieved party **does not** include the following:

(1) Proprietary data or privileged information.

(2) Any new evidence.

The LCD record furnished to the ALJ will include the following

(1) All documents furnished to the aggrieved party.

(2) Privileged information and proprietary data considered that shall be filed with the ALJ under seal. This information shall be clearly marked as "proprietary" so the ALJ will know to keep it confidential. (See §426.419 of the final regulation).

Within 30 days of receiving the record, the aggrieved party shall file a statement explaining why the contractor's LCD record is not complete, or not adequate to support the validity of the LCD**.**

Upon the receipt of the aggrieved party's statement, the contractor will have 30 days to submit a written response to the ALJ in order to defend the LCD. Generally, the response should explain why the aggrieved party's statement is incorrect. These statements will become part of the record.

If the ALJ finds the record complete and adequate to support the validity of the LCD, the review process ends.

Visited 08/05/2015

If the ALJ determines that the LCD record is not complete and adequate to support the validity of the LCD, the ALJ will permit discovery and the taking of evidence (see §§426.432 and 426.440 of the regulation) and evaluate the LCD (see §426.431 of the regulation) This process shall apply when an LCD record has been supplemented.

Upon agreement of the parties, any conferences, arguments or hearings may be held in person, via telephone, or via any other means (See §426.405 of the regulation.)

13.13.3 - Ex Parte Contacts
(Rev. 71, 04-09-04)

No party or person (except employees of the ALJ's office) will communicate in any way with the ALJ on any substantive matter at issue in a case, unless all parties are given notice and an opportunity to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures. (See Section §426.406 of the regulation)

13.13.4 - Discovery
(Rev. 71, 04-09-04)

If the ALJ orders discovery, then he or she will establish a reasonable timeframe for completion of discovery. If the Contractor (or any party) feels that the discovery sought is irrelevant or unduly repetitive, unduly costly or burdensome, or will unduly delay the proceeding, he or she should file a motion for a protective order before the date of production of the discovery.

A party may obtain discovery via a request for the production of documents and/or via the submission of 10 written interrogatory questions relating to a specific LCD. The term "documents" includes relevant information, reports, answers, records, accounts, papers, and other data and documentary evidence. Nothing in the discovery section of the Regulation will be interpreted to require the creation of a document. Requests for admissions, depositions, or any other forms of discovery will not be used in the 522 appeals process. The ALJ will notify all parties in writing when the discovery period will be closed. (See § 426.432 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.

Visited 08/05/2015

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.

13.13.6 - Evidence

(Rev. 71, 04-09-04)

The ALJ is not bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence when appropriate, for example, to exclude unreliable evidence. The ALJ shall exclude evidence that he/she determines is clearly irrelevant, immaterial, or unduly repetitive. The ALJ may accept privileged information or proprietary data, but shall maintain it under seal.

The ALJ may permit the parties to introduce the testimony of expert witnesses on scientific and clinical issues, rebuttal witnesses, and other relevant evidence. The ALJ may require that the testimony of expert witnesses be submitted in the form of a written report, accompanied by the curriculum vitae of the expert preparing the report. Experts submitting reports shall be available for cross-examination at an evidentiary hearing upon request of the ALJ or a party to the proceeding, or the reports will be excluded from the record. Unless otherwise ordered by the ALJ for good cause shown, all documents and other evidence offered or taken for the record will be open to examination by all parties. (See Section 426.440).

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.

Visited 08/05/2015

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

13.13.8 - New Evidence
(Rev. 71, 04-09-04)

An aggrieved party may submit new evidence pertaining to the LCD provision(s) in question. New evidence is defined as clinical or scientific evidence that was not considered by the contractor before the LCD was issued. The ALJ will review the new evidence and decide whether this evidence has the potential to significantly affect the evaluation of the LCD provision(s) in question under the reasonableness standard provided for in BIPA 522. (See §426.340 of the regulation.)

The reasonableness standard is defined in the regulation as the standard that an ALJ or the Board shall apply when conducting an LCD review. In determining whether LCDs are valid, the adjudicator shall uphold a challenged policy (or a provision or provisions of a challenged policy) if the findings of fact, interpretations of law, and applications of fact to law by the contractor or CMS are reasonable based on the LCD or NCD record and the relevant record developed before the ALJ/Board.

If the ALJ determines that the new evidence does not have the potential to significantly affect the ALJ's evaluation of the LCD provision(s), this evidence will be included in the record of the hearing to prevent it from being resubmitted as new evidence at a later date, and the review will continue.

If the ALJ determines that the new evidence has the potential to significantly affect the ALJ's evaluation of the LCD provision(s), then the ALJ will suspend the proceedings and send the new evidence to the contractor for review. The contractor will have 10 days, generally, to review the new evidence and decide whether the contractor will initiate a reconsideration.

If the contractor informs the ALJ that a reconsideration will be initiated, then the ALJ will set a reasonable timeframe, generally, but not more than, 90 days, by which the contractor will complete the reconsideration as described in Section (13.11) of this chapter.

Visited 08/05/2015

The ALJ will lift the stay in proceedings and continue the review on the challenged provision(s) of the original LCD, including the new evidence in the record of the hearing, if the contractor:

(1) Informs the ALJ that a reconsideration will not be initiated; or

(2) The 90-day reconsideration timeframe is not met.

(a) If an LCD is reconsidered and revised within the 90-day timeframe allotted by the

The ALJ/Board, then the revised LCD and any supplement to the LCD record will be forwarded to the ALJ and all parties and the review will proceed on the LCD.

The contractor should review any new evidence that is submitted, regardless of whether the ALJ has stayed the proceedings, including but not limited to—

(1) New evidence submitted with the initial complaint;
(2) New evidence submitted with an amended complaint;
(3) New evidence produced during discovery; and
(4) New evidence produced when the ALJ consults with scientific and clinical experts.
(5) New evidence presented during any hearing.

The contractor should submit a statement regarding whether the new evidence is significant within such deadline as the ALJ may set. (See §426.417 of the regulation.)

13.13.9 - Contractor Options
(Rev. 71, 04-09-04)

A. Retiring the LCD

A contractor has the discretion to retire an LCD under review any time before the date the ALJ issues a decision regarding that LCD. Retiring an LCD under review has the same effect as a decision under §426.460(b) of the final regulation, which is described below.

B. Revising the LCD

A contractor has the discretion to revise an LCD under review to remove or amend the LCD provision listed in the complaint at any time before the date the ALJ issues a decision regarding that LCD through the reconsideration process. Revising an LCD under review to remove the LCD provision in question has the same effect as a decision under §426.460(b) of the final regulation, which is described below.

A contractor shall notify the ALJ within 48 hours of:

(1) Retiring an LCD that is under review, or
(2) Issuing a revised version of the LCD that is under review.

Visited 08/05/2015

If the contractor issues a revised LCD, they shall 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.)

13.13.10 - The ALJ Decision
(Rev. 71, 04-09-04)

Within 90 days from closing the review record to the taking of evidence, the ALJ is required either to issue a decision, including a description of appeal rights, or to provide notice that the decision is pending, and an approximate date a decision will be issued. (See § 426.447 of the regulation).

After the ALJ has made a decision regarding an LCD complaint, the ALJ will send a written notice of the decision to each party.

If the ALJ finds that the provision or provisions of the LCD named in the complaint is (are) valid under the reasonableness standard, the aggrieved party or parties may appeal that (those) part(s) of the ALJ decision to the Board. (See §426.465 of the final regulation.)

ALJ decisions may be written narrowly to hold specific provision(s) invalid as applied to specific clinical indications and for similar conditions.

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.

Visited 08/05/2015

(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.

13.13.12 - Appeals
(Rev. 71, 04-09-04)

A contractor has the discretion to appeal any part of an ALJ's decision that states that a provision (or provisions) of an LCD is (are) unreasonable to the Departmental Appeals Board (the Board). The appeal shall be received by the Board within 30 days of the date the ALJ's decision was issued, or it shall include a rationale stating why the late appeal should be accepted by the Board. An appeal to the Board stays implementation of the Contractor's decision until the Board issues a final decision.

To file an appeal described in paragraph (a) of this section**,** a contractor shall send the following to the Board:

(i) The full names and addresses of the parties, including the name of the LCD.
(ii) The date of issuance of the ALJ's decision.
(iii) The docket number that appears on the ALJ's decision.
(iv) A statement identifying the part(s) of the ALJ's decision that are being appealed.
(See §426.465 of the regulation.)

Visited 08/05/2015

13.13.13 - Board Review of an ALJ Decision
(Rev. 71, 04-09-04)

If the Board determines that an appeal is acceptable, the Board **will** do the following:

- Permit the party that did not file the appeal an opportunity to respond to the appeal.
- Hold an oral argument (which may be held by telephone) if the Board determines that oral argument would be helpful to the Board's review of the ALJ decision.
- Review the LCD review record and the parties' arguments.
- Issue a written decision either upholding, modifying, or reversing the ALJ decision, or remanding the case to the ALJ for further proceedings.
- Dismiss an appeal by an aggrieved party of an ALJ decision finding that an LCD was valid if the contractor notifies the Board that it has retired the LCD or revised the LCD to remove the LCD provision in question. (See §426.476 of the final regulation.)

A contractor has the discretion to retire or revise an LCD during the Board's review of an ALJ's decision. If an LCD is retired or revised to remove completely the challenged provision(s), the aggrieved party is entitled to individual claim relief provided under §426.488(b) of the regulation. (See §426.478 of the regulation.)

A party (contractor or aggrieved party) who filed an appeal of an ALJ's decision may withdraw the appeal before the Board issues a decision by sending the Board and any other party written notice announcing the intent to withdraw the appeal. (See §426.480 of the 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;

Visited 08/05/2015

- 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.

13.13.14 - Effect of a Board Decision
(Rev. 71, 04-09-04)

If the Board's decision upholds the ALJ decision that an LCD is valid under the reasonableness standard or reverses an ALJ decision that than LCD is invalid, the contractor or CMS is not required to take any action.

If the Board's decision upholds an ALJ determination that the LCD is invalid, then the contractor will provide individual claim relief and coverage determination relief as described above and at §426.460(b) of the regulation.

If the Board reverses an ALJ's decision dismissing a complaint, the Board remands to the ALJ and the LCD review continues. (See §426.488 of the regulation.)

If the Board remands a case to the ALJ, the Board will notify each aggrieved party at his or her last known address, the contractor and CMS of the Board's remand decision and explain why the case is being remanded and the specific actions ordered by the Board. (See §426.489 of the regulation.)

A decision by the Board (other than a remand) constitutes a final agency action and is subject to judicial review. Neither the contractor nor CMS may appeal a Board decision. (See §426.490 of the regulation.)

13.13.15 - Future New or Revised LCDs
(Rev. 71, 04-09-04)

The contractor shall not reinstate an LCD provision(s) found to be unreasonable unless the contractor has a different basis (such as additional evidence) than what the ALJ evaluated. (See §426.463 of the regulation)

If Contractors incorrectly receive a "Challenge" they shall forward the challenge to the appropriate office designated at http://www.medicare.gov/coverage/static/appeals.asp, notify the aggrieved party that the complaint has been forwarded, and initiate a reconsideration of the policy.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R510PI	04/11/2014	Clarification to Pub. 100-02, Medicare Benefit Policy Manual Regarding Antigens and Deletion of Section 13.14 from Chapter 13 of Pub. 100-08, Medicare Program Integrity Manual	05/12/2014	8665
R473PI	06/21/2013	Update to Pub. 100-08, Program Integrity Manual, Chapter 13	01/15/2013	7829
R443PI	12/14/2012	Update to Pub. 100-08, Program Integrity Manual, Chapter 13 – Rescinded and replaced by Transmittal 473	01/15/2013	7829
R253PI	04/25/2008	Local Coverage Determinations (LCDs) Responsibility Transition From Durable Medical Equipment (DME) Program Safeguard Contractor (PSC) to DME Medicare Administrative Contractors (MAC)	05/27/2008	5953
R186PI	01/26/2007	Durable Medical Equipment Medicare Administrative Contractors (DME MACs) Adoption or Rejection of Local Coverage Determinations (LCDs) Recommended by Durable Medical Equipment Program Safeguard Contractors (DME PSCs)	02/26/2007	5410
R174PI	11/17/2006	Transition of Medical Review Educational Activities	10/06/2006	5275
R170PI	11/03/2006	Transition of Medical Review Educational Activities – Replaced by Transmittal 174	10/06/2006	5275
R165PI	10/06/2006	Durable Medical Equipment Medicare Administrative Contractors (DME MACs) Adoption or Rejection of Local Coverage Determinations (LCDs) Recommended by Durable Medical Equipment Program Safeguard Contractors (DME PSCs)	10/26/2006	5301
R163PI	09/29/2006	Transition of Medical Review Educational Activities – Replaced by Transmittal 170	10/06/2006	5275
R147PI	05/19/2006	Evaluation of LCD Topics for NCD Consideration	06/19/2006	4233
R099PI	01/21/2005	Waivers Approved by the Regional Office (RO) by Replacing Regional Office with Central office (CO)	02/22/2005	3646
R071PI	04/09/2004	Rewrite of Program Integrity Manual (except Chapter 10) to Apply to PSCs	05/10/2004	3030
R063PI	01/23/2004	Conversion from LMRP to LCD	02/23/2004	3010
R044PI	07/25/2003	Replacing Contractor MR Web Sites with Medicare Coverage Database	10/01/2003	2592

Visited 08/05/2015

Rev #	Issue Date	Subject	Impl Date	CR#
R038PI	02/03/2003	Articles is deleted	02/14/2003	2120
R034PI	11/22/2002	LMRP Reconsideration	N/A	2435
R028PIM	07/10/2002	LMRP Reconsideration	10/01/2002	2196
R027PIM	07/02/2002	Contractor Review of LMRPs	10/01/2002	2141
R024PIM	04/05/2002	Moves the LMRP and related sections from Chap 1 and to Chap 13	10/01/2002	2061

Back to top of chapter