

POLICY DEVELOPMENT PROCESS

The use of a Local Coverage Determination (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.

LCDs may be developed when there has been identification of a service that is never covered under certain circumstances prompting establishment of an automated review in the absence of an NCD or coverage provision in an interpretive manual that supports automated review 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 services).
- 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.

In order to be covered under Medicare, a service must be reasonable and necessary. A service is considered to be reasonable and necessary if it is determined 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 service, in terms of whether it is:
 - o 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;
 - o Furnished in a setting appropriate to the patient's medical needs and condition;
 - o Ordered and furnished by qualified personnel;
 - o One that meets, but does not exceed, the patient's medical need; and
 - o At least as beneficial as an existing and available medically appropriate alternative.

There are exceptions to the requirement that a service be reasonable and necessary for diagnosis or treatment of illness or injury which 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.

When a new or revised LCD is required, the following occurs:

- The CMD facilitation contractor, other contractors, the local carrier or intermediary, the DMERC (if applicable), the Medicare Coverage Database or QIOs (formerly PROs) are contacted to inquire if a policy which addresses the issue in question already exists;
- Adoption or adaption of an existing LCD, if possible; or
- A policy is developed if no policy exists or an existing policy cannot be adapted to the specific situation.

The process for development of a draft LCD

The Contractor Medical Director reviews medical literature and local practice. Evidence is gathered to support LCDs by searching published scientific literature for any available evidence pertaining to the item/service in question. All available evidence is considered and its quality evaluated before a conclusion is reached.

LCDs are based on:

- Published authoritative evidence resulting from clinical trials or other studies, and
- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
 - o Scientific data or research studies published in peer-reviewed medical journals;
 - o Agreement of expert medical opinion (i.e., recognized authorities in the field); or
 - o Medical opinion derived from consultations with medical associations or other health care experts.

Comment and notice periods are provided 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 an error published in an LCD that substantively changes the reasonable and necessary intent of the LCD is identified, the comment and/or notice period will be extended by an additional 45 calendar days.

When a comment and notice period is unnecessary, a revised LCD is published electronically (e.g., Medicare Coverage Database, Contractor Web site, email). In the following situations, the comment and notice processes are unnecessary when a revised LCD:

- Expands the list of covered indications/diagnoses of an existing LCD. The revision effective date may be retroactive.
- Is issued for compelling reasons (with CMS approval, such as a highly unsafe procedure/device).
- Revision does not significantly change the LCD, for example, typographical or grammatical errors. The revision effective date may be retroactive.
- Makes a clarification, such as adding information that clarifies, but does not restrict, the LCD. The revision effective date may be retroactive.
- Is updated to reflect changes in NCDs, coverage provisions in interpretive manuals, payment systems, HCPCS, ICD-9 or other standard coding systems. The revision effective date may be retroactive depending on the effective date of the NCD, etc.
- Adds revisions that explain a coding issue as long as the revision does not restrict the LCD. The revision effective date may be retroactive.
- Is done to effectuate an Administrative Law Judge's decision on a BIPA 522 challenge.

When a new or revised LCD requires comment and notice a minimum comment period of 45 calendar days is provided on the draft LCD. After the contractor considers all comments and revises the LCD as needed, a notice period of at least 45 calendar days is provided on the final LCD.

Comments are solicited from the medical community including the Carrier Advisory Committee (CAC.) Comments are responded to either individually or via a comment/response document. When appropriate, the comments are incorporated into the final LCD and providers are notified of the LCD effective date. New LCDs are not implemented retroactively.

For LCDs that affect 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.

A minimum comment period of 45 calendar days is provided. Contractors have the discretion but are not required to accept comments submitted after the end of the comment period.

When a new or revised LCD requires comment and notice (See §13.7.2), comments and recommendations are solicited on the draft LCD and input is sought from, at least:

- Groups of health professionals and provider organizations that may be affected;
- Representatives of relevant specialty societies;
- Other intermediaries/carriers;
- Quality Improvement Organizations (QIOs formerly known as PROs) within the region;
- Other CMDs within the region;
- General public;
- The Regional Office, associate regional administrator, for distribution to the appropriate regional staff (e.g., coverage experts, reimbursement experts). The RO staff will review the LCDs for any operational concerns; and
- The appropriate Advisory process (CAC):

Open meetings are provided for the purpose of discussing draft LCDs prior to presenting the policy to the CAC. To accommodate those who can not be physically present at the meetings, other means for attendance (e.g., telephone conference) are provided and written or e-mail comments are accepted. 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 and 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) may be invited to participate in meetings at which a related LCD is to be specifically discussed.

All Draft LCDs are posted on the MarylandMedicare Web site and can be accessed by clicking on "Medical Review" (left side of page), "Local Coverage Determinations", "Draft LCD", and "Draft LCDs". To check on the status of a draft LCD, click on "Medical Review (as above), "Local Coverage Determinations", "Draft LCD", and "LCD Status".

A Summary of Comments received concerning the draft LCD are posted to the Web site with a response prior to or on the start date of the notice period and remains on the Web for at least a 6 month period.

When a new or revised LCD is issued following a comment period, the policy shall become effective following a minimum notice period of 45 calendar days. Final LCDs are made public via publication on the MarylandMedicare Web site with a follow-up ListServ bulletin.

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

All final LCDs are posted on the MarylandMedicare Web Site and in the MCD. The MCD can be accessed at www.cms.hhs.gov/mcd. The web site and MCD are updated when a new or revised LCD is issued or when an existing LCD is archived.

LCDs are applied to claims on a prepayment as an MR automated edit.

Annual Review of Policies

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

Reference: CMS Pub. 100-08 (PIM), Chapter 13
Error Validation Process - Chapter 3, §3.2A