

Medicare Decision-Making (Medicare Parts A and B):

Medicare Participation (Providers):

There is an annual Open-Enrollment period that allows and enables physicians to decide whether or not they want to participate in the Medicare program, and if so, to enroll. *For providers who are currently enrolled in the Medicare program, they can also opt to dis-enroll from the Medicare program during this time.*

Agreeing to participate means:

- Physician accepts assignment for all Medicare claims he/she submits
- Physician requests direct payment from Medicare
- Physician accepts Medicare's allowable amount as payment in full for the services rendered
- Medicare reimburses for 80% of the allowable amount (patient is responsible for remaining 20% coinsurance)
- Physician agrees to complete and file claim forms for the patient at no charge
- Physician agrees not to bill patient for services not determined reasonable and necessary by Medicare.

Medicare contractors recruit Contractor Medical Directors (CMDs):

CMD Requirements:

- Contractors shall have their Medicare contractor operations approved by the CMS Central Office (CO).
- Contractors must employ a minimum of one Contractor medical director and arrange for an alternate when the CMD is unavailable for extended periods. *(NOTE: Waivers for very small contractors may be approved by the CO.)*
- The CMD FTE must be composed of no more than two physicians, and all physicians employed or retained as consultants must be currently licensed to practice medicine in the United States.
- When recruiting CMDs, contractors must give preference to physicians who have patient care experience and are actively involved in the practice of medicine.

CMD's Leadership Duties in the Provider Community:

- Interacting with medical societies and peer groups,
- Educating providers, individually or as a group, regarding identified problems or Local Coverage Determinations (LCDs),
- Acting as "Co-Chair" for the Carrier Advisory Committee (CAC)

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

CAC Co-Chair Responsibilities:

- 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.)*
 - 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.)*
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- Providing the clinical expertise and judgment to develop LCDs and internal Medical Review (MR) guidelines,
 - Serving as a readily available source of medical information to provide guidance in questionable claims review situations,
 - Determining when LCD is needed or must be revised to address program abuse,
 - Assuring that LCD and associated internal guidelines are appropriate,
 - Briefing and directing personnel on the correct application of policy during claim adjudication, including through written internal claim review guidelines
 - Selecting consultants licensed in the pertinent fields of medicine for expert input into the development of LCD and internal guidelines;
 - Keeping abreast of medical practice and technology changes that may result in improper billing or program abuse;
 - Providing the clinical expertise and judgment to effectively focus MR on areas of potential fraud and abuse; and
 - Serving as a readily available source of medical information to provide guidance in questionable situations.

Other CMD duties include:

- Interacting with the CMDs at other contractors to share information on potential problem areas;
- Participating in CMD clinical workgroups, as appropriate; and
- Upon request, providing input to CMS Central Office (CO) on national coverage and payment policy, including recommendations for relative value unit (RVU) assignments.

To prevent conflict of interest issues, the CMD must provide written notification to both the CMS Central Office (MROperations@cms.hhs.gov) and the Regional Office (RO), as well as to the CAC, within 3 months after the appointment, election, or membership effective date if the CMD becomes a committee member or is appointed or elected as an officer in any State or national medical societies or other professional organizations. In addition, CMDs who are currently in practice should notify their RO of the type and extent of the practice.

The Carrier Advisory Committee

The CAC is to be composed of physicians of various specialties (including sub-specialties), a beneficiary representative, and other medical organizations.

The Purpose of the CAC:

- 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 must clearly communicate to CAC members that the focus of the CAC is LCDs and administrative policies, 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 must 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.

The Role of CAC Members:

CAC members serve to improve the relations and communication between Medicare and the physician community by:

- Disseminating 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 Medical Review policies.

CAC Structure and Process:

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 both the CMS Central Office and Regional Office, and also to 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*). **NOTE:** In order to obtain a waiver from the CO, contractors shall obtain agreement from CAC members within the jurisdiction.

Number of Representatives:

Each specialty shall have only one member and a designated alternate with approval of committee co-chairs.

(NOTE: Additional members may attend when policies that require their expertise are under discussion.)

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.**

Co-Chairs:

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

NOTE: Refer to the CMD section above for the list of Co-Chair responsibilities

Staff Participation:

The Director of Medicare Operations must assure that appropriate contractor staff attend to address administrative issues on the agenda.

Other staff may also be required to attend include:

- Professional Relations (PR) representative;
- Medical Review (MR) manager and
- *Medicare Fraud Information Specialist (MFIS)*

Location:

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

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 must notify the RO that this one time occurrence is taking place.

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 LCDs. Carriers solicit input from CAC members to help explain or interpret the data, and give advice on how over-utilization should be addressed.

NOTE: The use of data to illustrate the extent of problem billing (e.g., average number of services per 100 patients) may 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 individual provider's data as long as the provider's identification is not disclosed or cannot be deduced.

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.

Recordkeeping:

Carriers keep minutes of the meeting and distribute them to members. Carriers submit the following items from CAC meetings to the Regional Office Medical Review staff 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; and
- Tentative date of the next meeting.

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

Communication With CMS 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 the CMS Central Office (CO) from the CAC. CACs must send these letters through the Regional Office, however, where they will either be answered or forwarded to the appropriate department within CMS for response.

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.

National and Local Coverage Determination (NCD or LCD) Overview:

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

- Contact the CMD facilitation contractor, other contractors, the local carrier, intermediary, DMERC, MAC (if applicable), or Qualified Improvement Organizations (QIO, formerly called Peer Review Organizations) 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.

NOTE: 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.

Provider Education Regarding LCDs

Contractors must 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).

Application of LCD

Contractors may apply LCDs to claims on either a pre-payment or post-payment basis. If a contractor decides to enforce an LCD on a pre-payment basis, the contractor must design an Medical Review (MR) edit. Contractors have flexibility to add, alter, or eliminate Medical Review edits at any time. Contractors must apply LCDs pre-payment or post-payment prospectively when conducting MR-directed claim reviews with dates of service on or after the effective date of the policy. Contractors should not apply an LCD retroactively to claims processed prior to the effective date of the policy. However, if NCD, coverage provisions in the interpretive manuals and LCD fail to address an issue of coverage for a given claim, contractors can make coverage determinations based on the information provided.

Retired LCDs

Contractors must list the retired date on all retired LCDs. Contractors must have a mechanism for archiving retired LCDs. This mechanism may be hard copy, electronic or web-based. This mechanism must also allow the contractor to respond to requests and retrieve the LCD that was in effect on any given day. Contractors must post on their Web site information regarding how to obtain retired LCDs.

Multi-State Contractors

A contractor with LCD jurisdiction for 2 or more states is strongly encouraged to develop uniform LCDs across all its jurisdictions. However, carriers must continue to maintain and utilize CACs.

Least Costly Alternative

"Least costly alternative" is a national policy provision that must be applied by contractors when determining payment for all Durable Medical Equipment (DME). Contractors have the discretion to apply this principle to payment for certain medications or non-DME services as well.

LCD Requirements That Alternative Service Be Tried First

Contractors may incorporate into LCDs the concept that use of an alternative item or service precedes the use of another item/service. This approach is termed a "prerequisite." Contractors must base any requirement on evidence that a particular alternative is safe, more effective, or more appropriate for a given condition without exceeding the patients' medical needs. Prerequisites must 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 must 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..."

The Coverage Determination (NCD or LCD) Process:

CMS issues the National Coverage Determinations (NCDs), which are binding nation-wide on all A/B and Specialty MACs. **Local Coverage Decisions (LCDs) are issued through the A/B or Specialty MACs directly**, and only affect the local MAC jurisdictions (*LCD's were formerly called Local Medical Review Policies (LMRPs) until 2003*). The LMRP process changed officially on 12/7/03, and was renamed to LCD. Quality Improvement Organizations (QIOs) and Program Safeguard Contractors (PSCs) issue guidelines that are binding for all Medicare + Choice, or Medicare Part C organizations.

***NOTE:** CMS provides guidelines to base these determinations. The bulk of the decision-making is then left to the A/B MAC or Specialty MAC. A/B and Specialty MACs then create Local Coverage Determinations (LCDs).*

Driving forces, or reasons, for medical guidelines and coverage decisions:

- Provider requests
- Complaints from beneficiaries.
- Office of Inspector General (OIG) requests (*to prevent or investigate fraud*)
- High utilization of new or current drugs
- Recommendations from the Medicare Working Group (MWG)

The CMS Medical Director provides written medical guidelines regarding:

- Medical Necessity
- Utilization of Services
- Improper billing and abuse situations

Four Step Process (*Follows standards set forth by HIPAA*):

1) CMS, or an A/B MAC or Specialty MAC drafts a policy (30-45 days)

The policy department reviews many sources to gather background information to prepare a draft policy. These sources may be: the clinical compendia, peer-review journals, other carrier or fiscal intermediary policies, and applicable medical society guidelines.

2) The draft is published for comment solicitation (45 days)

Once the policy department has developed the draft, a series of reviews occur in which various parties are given the opportunity to comment on the draft. The draft is discussed and reviewed at the pre-Carrier Advisory Committee (CAC) meeting, then again at the Carrier Advisory Committee (CAC) meeting. Then, the draft is either posted on the CMS, A/B or Specialty MAC websites, depending on whether it is a National Coverage Determination (NCD) or Local Coverage Determination (LCD), whichever applies, as a draft policy so that providers and the general public may read it and provide comment.

NOTE: It is extremely important for providers to comment on policies during the comment period (if a comment is necessary). This is the provider's opportunity to influence local and national coverage decision-making.

Medicare Carrier Advisory Committee (CAC) Participants –

- Medical Directors and policy staff (Part A, B and Medicaid)
- Physicians from all specialties
- Administrative representatives
- Hospital society representatives

Note: CAC representatives (other than medical directors) are not employed by Medicare, nor receive compensation for participating

Medicare Carrier Advisory Committee (CAC) Responsibilities –

- Keep physicians in state informed of policy changes
- Allow physicians to be participants in policy development
- Discuss and improve administrative policies
- Provide a forum for information exchange between Medicare medical directors and providers
- Meet three to four times each year

3) Policy Change (30 days)

At the end of a typical 45-day comment period, all comments from the various parties are considered by the developers of the policy, and new applicable data is incorporated into the draft. CMS and/or A/B and Specialty MACs monthly bulletins will then carry a 30-day notice of the new policy and its effective date so that providers can update their systems.

4) Policy Implementation (30 days)

Finally, when the policy becomes effective, either CMS, or the A/B and Specialty MACs will accept claims under the terms of the new policy.

The NCD or LCD Reconsideration Process:

CMS has implemented a process for patients and providers to request revisions and updates to NCDs or LCDs *already finalized*. The NCD or LCD Reconsideration Process is a mechanism by which interested parties can request a revision to an already existing NCD or LCD. The whole NCD or LCD, or any part of the NCD or LCD, may be reconsidered (e.g. Benefit Category Provisions, Utilization Guidelines, Covered ICD-9 codes, etc.)

Some of the questions that patients and providers should address when sending in a formal Request for Reconsideration of an NCD or LCD are:

- Name and number of policy
- Section(s) where changes are desired
- What language is being questioned?

- How should the language be changed?
- What is the justification for requesting the change?
- How can we contact you if further information is needed?

CMS or CMS Contractor Reconsideration Process/Guidelines are:

- CMS or the local CMS Contractors must respond timely: They must first decide within 30 days if the request is valid, then follow up and make their decision in 90 days whether to retire the policy, make it more restrictive, make it less restrictive, or simply, do not revise it at all
- CMS or the local CMS Contractors may revise or retire either their NCDs or LCDs, whichever applies, at any time on their own initiatives
- CMS and/or CMS Contractors must add to their current web sites information and instruction on the NCD or LCD Reconsideration Process
- CMS and CMS Contractors MUST consider all reconsideration requests from beneficiaries residing or receiving care in a contractor's jurisdiction and providers doing business in a contractor's jurisdiction.
- CMS or CMS Contractors may only accept reconsideration requests for NCDs or LCDs published in FINAL form
- Requests must not be accepted for any other documents, including: Draft NCDs or LCDs, Retired NCDs or LCDs, Bulletins, articles, etc.
- 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.
- Requests MUST be submitted in writing, and must identify the language that the requestor wants added to or deleted from an NCD or LCD.
- Requests must include a justification supported by new evidence, which may materially affect the NCD or LCD's content or basis. Copies of published evidence must be included.
- CMS or CMS Contractors may consolidate valid requests if similar requests are received

LMRP to LCD Conversion, Changes and Updates:

Due to changes set forth under the Benefit Improvement and Protection Act (BIPA) of 2000, the Local Medical Review Policy (LMRP) process has changed, and LMRPs are now called Local Coverage Determinations (LCDs). The main difference is an LCD may include only "reasonable and necessary" information. Any additional information - including coding guidelines - may be included in a separate article to be published along with the LCD. The LCD will still include ICD-9 codes and payable CPT or HCPCS codes for a service, but not advice on how to code. Reconsideration is limited to what's in the LCD. Practices asking the MAC contractor to change an LCD may seek a reconsideration based only on the information in the LCD - not the coding guidelines or any other information included in the separate article. The same rule applies to LMRPs not yet revised - you can seek reconsideration of only the "reasonable and necessary" information in the LMRP that will eventually crosswalk to the new LCD.

It's up to the MAC contractor to determine how to present any separate information related to the LCD, and they are exploring ways to do it that are easiest for practices. Removing coding guidelines from the LCD could enable these contractors to speed the process of releasing draft and final coverage decisions because the medical director can focus on the medical necessity of the service addressed in the LCD. The Contractor Medical Director (CMD) shouldn't tell practices how to code or bill in a local coverage policy because coding education is not a specialty of CMDs. With the new LCDs, the section for the description of the service addressed has been removed. That information is now included in the section on indications and limitations of coverage and medical necessity.

Medicare Utilization Techniques:

1) *Focused Medical Review (FMR):*

FMR Goals:

- Reduce aberrant over-utilization
- Generate more streamlined claims submissions
- Decrease denials, medical review
- Eliminate fraud and abuse

FMR Process:

- Biannual utilization review data is prepared by Medicare
- Top 30 drugs and/or services are selected
- Local utilization levels are compared to national average
- Drugs and services above the national average are targeted
- A post-payment or pre-payment review will be implemented (Additional documentation of medical necessity)
- Medicare reviews all data and compares to available, published clinical literature

MAC Contractor Outcomes/Options:

- Coverage policy development or change
- Provider education
- Referral of provider(s) to fraud unit
- Nothing – conduct business as usual

2) Coding Audits:

A/B and Specialty MACs conduct audits to control or track utilization of drugs and services

ESRD Examples:

- Number and level of dialysis sessions
- Number and units of drug(s) administered
- ICD-9, CPT, HCPCS coding linkages