Understanding New Medicare Coverage Determinations

by Steve Cooper, RHIT

Recent legislation included in both the Benefits Improvement and Protection Act (BIPA) and the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 has affected the content and implementation processes for Medicare coverage determinations. This column reviews differences between local medical review policies and local coverage determinations, the mandated transition from the former to the latter, and the introduction of national coverage determinations.

Local Coverage Determinations and Local Medical Review Policies

A local coverage determination (LCD) is a decision by a Medicare contractor on whether to cover a particular service on a carrier-wide basis in accordance with section 1862(a)(1)(A) of the Social Security Act (e.g., a determination as to whether a service is reasonable and necessary). LCDs consist of only "reasonable and necessary" information; they do not contain any information pertaining to benefit categories or statutory exclusions, such as reasons for denial, the abstract or description, or coding guidelines.

Local medical review policies (LMRPs), on the other hand, may contain benefit category and statutory exclusion provisions. Medicare defines an LMRP as

> an administrative and educational tool to assist providers, physicians, and suppliers in submitting correct claims for payment. Local policies outline how contractors will review claims to ensure that they meet Medicare coverage requirements. The Centers for Medicare and Medicaid Services (CMS) requires that LMRPs be consistent with national guidance (although they can be more detailed or specific), developed with consideration of scientific evidence and clinical practice, and developed through certain specified federal guidelines. Contractor medical directors develop these policies. Reviewing local medical review policies assists in understanding why Medicare claims may be paid or denied.[1]

LMRPs may address any or all of the following issues:

- Coding
- Benefit category
- Statutory exclusions
- Reasonable and necessary services

However, LCDs may only address whether a service meets reasonable and necessary standards. Both diagnosis and procedure codes may be included in the discussion. Based on the statutory definition, an LMRP may contain no LCDs at all, or it may contain multiple LCDs.

Transitioning from LMRPs to LCDs

BIPA mandates that Medicare contractors must implement only new LCDs and not new LMRPs. In addition, it mandates that all existing LMRPs either be retired or converted to LCDs over the next two years.

BIPA section 522 mandates that only the reasonable and necessary information within either an LCD or an LMRP may be challenged. Therefore, during the conversion phase, the term *LCD*, for the purpose of coverage challenges, refers to both reasonable and necessary provisions of an LMRP and an LCD that contains only reasonable and necessary language.

The final rule was published on November 11, 2003, and effective December 7, 2003, CMS contractors began issuing LCDs rather than LMRPs.

Between now and October 2005 contractors will convert all existing LMRPs into LCDs and articles. Any language not related to reasonable and necessary issues that a contractor wishes to communicate to providers must be done through an article.

National Coverage Determinations

In addition to LMRPs and LCDs, Medicare has issued a number of national coverage determinations (NCDs). According to the Medicare coverage glossary, an NCD

> sets forth the extent to which Medicare will cover specific services, procedures, or technologies on a national basis. Medicare contractors are required to follow NCDs. If an NCD does not specifically exclude/limit an indication or circumstance, or if the item or service is not mentioned at all in an NCD or in a Medicare manual, it is up to the Medicare contractor to make the coverage decision (see LMRP). Prior to an NCD taking effect, CMS must first issue a manual transmittal, CMS ruling, or *Federal Register* notice giving specific directions to our claims-processing contractors. That issuance, which includes an effective date and implementation date, is the NCD. If appropriate, the agency must also change billing and claims processing systems and issue-related instructions to allow for payment. The NCD will be published in the *Medicare National Coverage Determinations Manual*.[2]

Following the date of issuance, the implementation deadline for an NCD can extend no longer than 180 days after the first day of the next full calendar quarter. CMS maintains a list of NCDs on its Web site (see "CMS Resources Online," below).

Each NCD page is comprised of the publication number, the manual section number (the section of the *Medicare Coverage Manual* where the determination is reflected), the effective and implementation dates, the benefit category, a description of the item or service, the indications and limitations of coverage, the transmittal number in which the decision was published, and a link to that transmittal. There may also be a revision history and a link to the applicable national coverage analyses.

National coverage analyses documentation includes public input reports on possible coverage issues, including expert testimony, the compilation of medical and scientific information currently available, any FDA safety and efficacy data, and clinical trial information. This information is considered prior to issuing an NCD. Thus, NCDs cover more than LCDs, which deal only with issues of reasonable and necessary services.

The MMA addresses the process for developing and changing the NCDs, streamlining the process and allowing for more public involvement. The following changes to the NCD process became effective January 1, 2004:

- For NCD requests not requiring an external technology assessment or Medical Coverage Advisory Committee review, the decision on the request shall be made no later than six months after the date the completed request is received.
- For those NCD requests requiring either an external technology assessment or Medicare Coverage Advisory Committee review and in which a clinical trial is not requested, the decision on the request shall be made no later than nine months after the date the completed request is received.
- A draft of the proposed decision shall be made available on the CMS Web site (or other appropriate means) for public comment no later than at the end of the six- or nine-month period described above. This comment period shall last 30 days. Comments will be reviewed, and a final decision issued no later than 60 days after the conclusion of the comment period. A summary of the public comments received and responses to the comments will be included in the final NCD.

An external technology assessment studies the medical, social, ethical, and economic implications of the development, diffusion, and use of technologies. In support of NCDs, technology assessments often focus on the safety and efficacy of technologies.

Challenges to LCDs and NCDs

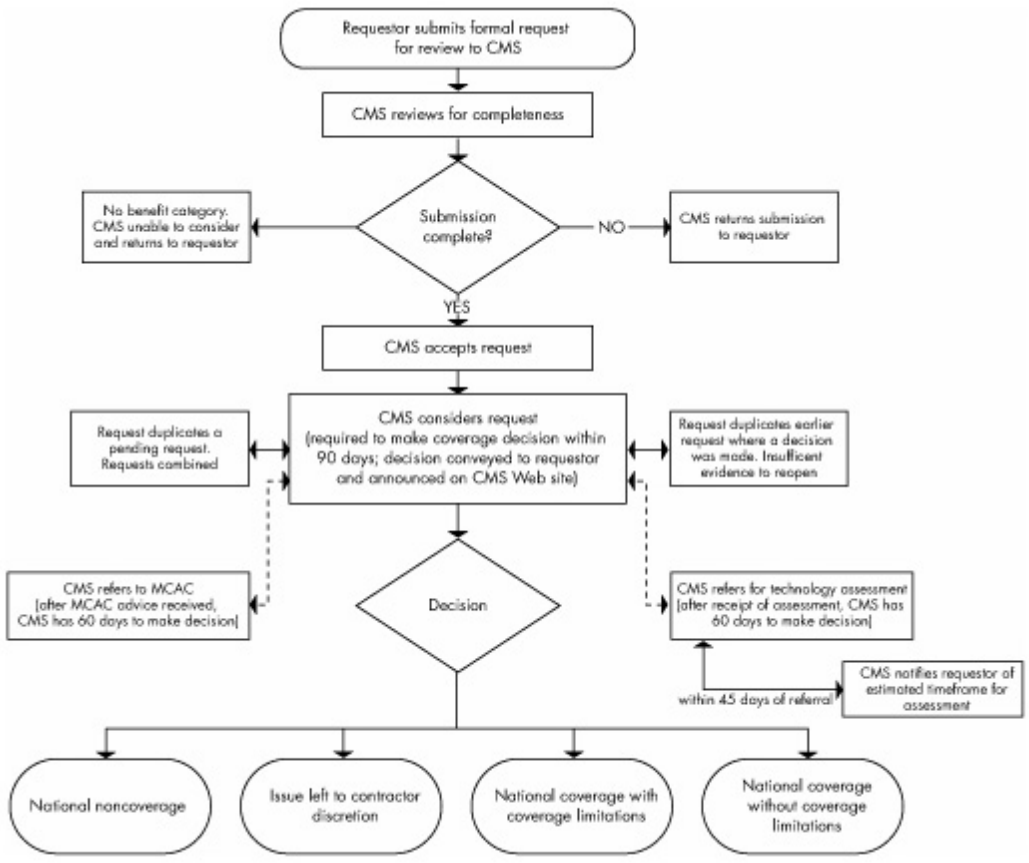
Section 522 of BIPA created a new review process that allows beneficiaries to challenge some portions of LCDs and NCDs. It does not affect requests for review of denied claims, which remain unchanged. Only individuals who are entitled to benefits under Medicare parts A or B, or both, who are in need of an item or service that is the subject of a coverage determination, and who have obtained documentation of need for this service from their treating physician may request review of an NCD or LCD. This individual is referred to as an "aggrieved party" in the legislation even if no negative determinations have yet occurred.

The individual may challenge the coverage determination either before or after services have been rendered and the claim has been denied on the basis of the coverage determination. Beneficiaries may not assign appeal rights to any other person, although they may request assistance in the process from others, including physicians, other healthcare providers, and attorneys. In addition, if a beneficiary dies after initiating the challenge but before adjudication, the estate may continue the challenge. A successful challenge to an LCD or NCD could result in either the retirement or withdrawal of the coverage determination in its entirety or revision of the policy.

Reviews of LCDs are conducted by administrative law judges, who are required to abide by any applicable NCDs. The Medicare Department Appeals Board conducts NCD reviews.

While only an aggrieved party can request a review of a coverage determination, any interested party, including a provider, may request a reconsideration of an NCD or LCD. CMS will consider a request if the requester presents documentation of material medical or scientific information not considered during the initial review that results from new clinical trails, new scientific literature, or new studies or if the requester presents arguments that the existing NCD materially misinterpreted the existing evidence at the time it was made. The diagram "Medicare National Coverage Process" below, summarizes the NCD approval process.

Medicare National Coverage Process



Innovations in medical technologies and procedures are increasing at an astounding rate. In conjunction, coverage decisions relating to these innovations will increase as well. Awareness of new and revised NCD and LCD policies is crucial for HIM professionals and their organizations.

CMS Resources Online

The Medicare coverage Web site is the official source of coverage information. The main page (www.cms.hhs.gov/ cover-age/default.asp) serves as a portal to the coverage database, the laboratory coverage determinations, the activities of the

Medicare Coverage Advisory Committee, and other topics. A glossary of coverage terms is available at www.cms.hhs.gov/coverage/glossary.asp, and an online version of the coverage manual can be found at www.cms.hhs.gov/manuals/06_cim/ci00.asp. The final rule on LCDs is available at www.cms.hhs.gov/regulations/coverage/3063f-10-30-03.pdf.

Acknowledgment

Catherine Coughlin, governmental operations support, HCA

Notes

1. The Centers for Medicare and Medicaid. “Medicare Coverage—Glossary.” Available online at www.cms.hhs.gov/ coverage/ glossary.asp.
2. Ibid.

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Article citation:
Cooper, Steve. "Understanding New Medicare Coverage Determinations." *Journal of AHIMA* 75, no.7 (July-August 2004): 62-64.