

403. Reimbursement and Finance: Using the National Coverage Decisionmaking Process for Investigational Products/Uses—

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Title: Medicare's National Coverage Process

- A. Coverage of Services, General **[slide 2]**
 - 1. Medicare is a defined benefit program
 - 2. Service must fit a benefit category
 - 3. Only services fitting benefit categories may enter process.

- B. HCFA's authority to make coverage decisions **[slide 3]**
 - 1. Restricts all coverage and payment to that found "reasonable and necessary"
 - 2. Gives HCFA and contractors authority to determine coverage

- C. Two general methods by which coverage decisions made **[slide 4]**
 - 1. By Medicare contractors, through Local Medical Review Polices (LMRPs)
 - 2. By HCFA's Coverage and Analysis Group (CAG), through national coverage decisions (NCDs)
 - 3. Differences—national coverage decision applicable to all claims, must be followed by contractors
 - 4. LMRP's only effective in contractor's area, may vary by area, may not conflict with national coverage decision

- D. HCFA's Process for Making National Coverage Decisions **[slide 5]**
 - 1. Revised process published in *Federal Register*, 4/27/99.
 - 2. Sought to make process more understandable, open and responsive to public
 - 3. Process has many avenues to coverage, with many branches

- E. General Outline of Process— **[slides 6 & 7]**
 - 1. Process begins with a "formal request," which can be generated internally or externally. For external requests, they must:
 - a. Be submitted in writing, and state it is a formal request
 - b. Define what the service is, and what benefit category it fits.
 - c. Include a compilation of all relevant medical evidence
 - d. Include a description of any clinical trials underway
 - e. If applicable, the FDA status of the drug or device

2. HCFA takes several actions when accepting a formal request:
 - a. Announcement of acceptance posted on HCFA's web site
 - b. Tracking sheet describes source and nature of request, expected decision time, and meetings or other relevant activities connected with consideration of request.
 - c. Tracking sheet updated to account for activities, such as request for technology assessment, or referral to MCAC.
 - d. When decision is reached, a decision memorandum, outlining the reasons for the decision, is posted on HCFA's web site.

3. If it accepts the formal request, HCFA promises to decide within 90 days, however:
 - a. 90 days does not begin until HCFA formally accepts request,
 - b. HCFA can refer for assessment, which suspends the 90-day clock;
 - c. HCFA can refer to MCAC, which suspends 90-day clock,
 - d. HCFA may re-start clock if they, or outside source, comes up with relevant information not submitted with formal request
 - e. HCFA may re-start clock if requester submits additional information, or asks request be broadened or narrowed.
 - f. HCFA may also delay decision if newly-discovered additional information will become available within reasonable time

4. HCFA's response to a formal request can take several forms:
 - a. Request is duplicate—may combine with other request or find insufficient information to re-open issue;
 - b. Issue referred for technology assessment.
 - c. Issue referred to MCAC
 - d. National non-coverage decision, precludes contractor payment
 - e. No national coverage decision, issue left up to contractor discretion
 - f. National coverage decision--usually limited by appropriateness criteria.

5. Referral for technology assessment
 - a. HCFA may use already-completed assessment, if appropriate one is available.
 - b. Usually there is no available assessment, so HCFA refers the issue to an outside body, usually a unit of the Public Health Service. (Currently, the Agency for Healthcare Research and Quality (AHRQ)).
 - c. Issue in turn referred to an approved AHRQ center for preparation of the assessment.

- d. Assessments not only suspend the 90-day clock, but also may take several months or longer, depending upon the complexity of the issue.
6. Referral to MCAC (Medicare Coverage Advisory Committee)
- a. Not only suspends the 90-day clock, but can take months or years
 - b. MCAC process struggling, no clear mandate or rules, although attempts are underway to revise
 - c. MCAC may also request assessment, thus adding more time to the consideration.
 - d. MCAC only makes recommendations, HCFA may not accept all or part of them.

F. MCAC Process Vague at this time **[slide 8]**

- 1. No clear reason for its creation
 - a. Many called for an open advisory committee to replace the Technology Advisory Committee (TAC), which held closed meetings.
 - b. While TAC had a defined role and met frequently, MCAC did not have clear role—charter and process descriptions were vague and not coordinated
 - c. Its Executive Committee expected to set standards and coordinate reviews, but absence of criteria regulation has delayed that work
 - d. Ex. Comm. working on interim guidelines, but not yet formalized
 - e. Meanwhile, panel recommendations are made in semi-vacuum, often do not pass Ex. Comm review.

G. Technology Assessments

- 1. HCFA either contracts for assessments or buys existing ones “off the shelf” if they are of acceptable quality and relevant to the issue being investigated
- 2. The MCAC can also request assessments on its own
- 3. The MCAC Executive Committee recently called for opening the assessment process to notice and comment from the public
- 4. This will probably delay both the assessment and the MCAC processes even more

H. Completion of review

[slide 10]

1. Decision memorandum posted on HCFA's web site
2. This includes all major factors bearing on the decision, including any assessments or MCAC recommendations.
3. If not covered, memorandum will give reasons and identify information required to reach different decision
4. National coverage decision will be published within 60 days of publication of decision memorandum
5. Payment of claims for service may take some additional time
 - a. Coding, claims processing changes, notifications of these changes take considerable time, and are only effective on a calendar quarter basis.
 - b. Consequently, payment changes will not begin until 180 days following the first day of the next calendar quarter following the date the national coverage decision is issued
 - c. Thus, payment may be from 7 to 9 months following coverage decision.
6. Reconsideration of decisions
 - a. HCFA will reconsider a national coverage decision at any time, however
 - b. The request for reconsideration must either furnish new evidence not considered, or an analysis of how HCFA "materially misinterpreted" the original information in making its decision
 - c. If accepted, this becomes a new formal request, and goes through the same process as an original request
 - d. The national coverage decision originally made remains in effect unless and until a change is made based on the new request.

I. Pitfalls in the process

[slide12]

1. This process will only work within a reasonable time frame if referrals for assessments or MCAC reviews are avoided.
2. This process permits others to tinker with a request by adding new information or requesting a broader or narrower scope
3. The existence of outside information, such as competitors clinical trials, assessments underway for other payers, etc., can result in delays and some confusion.
4. CAG is currently barred from interpreting or explaining policies unless they go through the entire coverage process—take care in what instruction says
5. The long delay between decision and actual payment must be factored in to budgetary and sales projections

J. Avoiding Pitfalls

[slides 13 & 14]

1. Talk to HCFA early on; if possible, even before research is underway.
2. Discussions as to the type and amount of information HCFA may want to see, the types of questions they will ask of the data, etc., will save both parties considerable time and frustration.
3. HCFA is responsive to informal discussions, willing to assist, and keeps such discussions strictly confidential.
4. Helps both parties work through any confusion or misunderstanding in a collegial manner and without artificial time limits.
5. HCFA and FDA willing to hold three-way conversations with potential requestors, both early on and during each agency's reviews.
6. Both agencies willing to explain the different legal requirements they work within, as well as the differing views they have regarding the effectiveness of services.
7. Discuss and question the draft manual instruction—no changes or interpretations can be made without going back through the process again

K. Latest Developments

[slide 17]

1. HCFA has rechartered the MCAC, but loose ends remain.
2. The Benefits Improvement Act (BIPA) allowed specialty committees to report directly to HCFA, rather than go through Executive Committee, but that change is not certain.
3. Allowing such a procedure may result in differing amounts and kinds of evidence being used for different types of services prior to completion of criteria regulation.

L. BIPA Provisions

[slides 18 & 19]

1. NCDs may be appealed to HHS Appeals Board
 - a. This is a new process, has not been tried before
 - b. Question of whether Appeals Board has time or expertise to handle this type of appeal
 - c. Could add more time and confusion to finalizing NCDs
2. LMRPs may be appealed to Administrative Law Judges (ALJs)
 - a. Could undermine attempts of contractors to handle abuse
 - b. Could undermine attempts of contractors to conform LMRPs though use of template policies
 - c. Adds another wild card to coverage questions

3. Medicare patients may request HCFA make coverage decision within 90 days.
 - a. Beneficiaries may request decision, but may not always be in favor of coverage
 - b. Mechanism for handling these requests not in place, nor forms, methods, etc., which could take considerable time to put in place
 - c. Unlikely to result in positive decisions—the quick answer is always no.
 - d. Will probably only add another layer of confusion to the process
4. HCFA must put together an annual report to Congress of all its coverage decisions, the time taken for each step, the evidence reviewed, and a host of other facts.
 - a. Does require coding and payment actions be reported as well, may result in some tightening up at that end.
 - b. However, adds another task for staff, keeping accurate records of time spent, reasons for delays, etc., detract from coverage work
 - c. Unlikely to be useful as a management tool—will be reporting past actions that are unlikely to repeat in same context
5. HCFA must provide public notice and comment prior to issuance of NCD.
 - a. Adds another needless delay—public notice on web site designed to allow comment prior to issuance.
 - b. Will allow competitors to delay coverage by raising trivial questions and comments
 - c. Notice and comment adds at least 6 months to processing regulations and notices, likely to add same amount here.
6. HCFA must put in public record all Advisory Council materials, evidence, comments and other materials prior to issuance.
 - a. Methodology and vehicle for performing this task unclear—currently all these materials are available for inspection at HCFA, publication in any form would take considerable time.
 - b. No apparent reason for doing this, other than to facilitate lawsuits.
7. Advisory Committee panels may report directly to HCFA, rather than to Executive Committee.
 - a. Certainly would speed up MCAC process
 - b. HCFA has taken no action to do this, nor has Executive Committee endorsed it in their actions or deliberations.
 - c. Raises possibility of varying standards of evidence and other requirements by each panel, especially since no coverage criteria are forthcoming

M. General Factors to Keep in Mind

[slides 20 & 21]

1. Coverage process is iterative—there are no “final” answers.
2. This is a coverage process, not a non-coverage process. It is intended to cover services that meet HCFA’s requirements.
3. HCFA struggling to make decisions based on limited evidence, with no practical way of reversing any mistakes.
4. Responsibility for understanding process is shared—HCFA can explain, but interested public must question and listen.
5. Knowing what HCFA wants is key to obtaining coverage promptly, and avoiding the pitfalls.
6. Best approach seems to be meet with HCFA early and often, be frank about problems, seek reasonable solutions.

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