
MTLF FORUM

Medicare Coverage Policy: The Balance Between Local and National Decision Making

JUNE 28, 2002

WASHINGTON, D.C.



MEDICAL  TECHNOLOGY
LEADERSHIP FORUM

GIVING NEW MEANING TO THE FUTURE OF MEDICAL TECHNOLOGY

WHAT IS THE MEDICAL TECHNOLOGY LEADERSHIP FORUM?

The Medical Technology Leadership Forum (MTLF) was founded in 1996 to educate its own members, policy makers, the general public, and the media about issues facing medical technology. MTLF has attracted an elite group of leaders from a wide spectrum of the medical technology community, including innovative bioengineers, physicians, research institutions and universities, manufacturers, and patient organizations. MTLF has held forums at leading institutions, including Duke University, the Johns Hopkins University, Indiana University, and Stanford University. Our White Papers and Forum discussions have made a significant contribution to the development of public policy on issues of concern to the medical technology community.

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INTRODUCTION

Coverage policy is a key component of the Medicare program. Beneficiary access to new therapies and Medicare's stewardship of the Trust Fund depend on appropriate coverage decisions. Medical technology innovators and practicing physicians have a stake in how these decisions are made. Underlying the discussion of coverage policy is the critical issue of how best to incorporate evidence-based medicine and utilization management into the practice of medicine.

There are two non-exclusive pathways to Medicare coverage of new technologies: (1) Medicare contractors (known as carriers and fiscal intermediaries) make local medical review policies (LMRPs) and 2) The Centers for Medicare and Medicaid Services (CMS) make national coverage decisions (NCDs). If no NCD or other national restrictions apply, each contractor has the flexibility to establish its own policies within its regional jurisdiction, resulting in potential variation in coverage policies at the local level. While CMS does not keep statistics on this matter, it has been asserted that local contractors make over ninety percent of the policy decisions on coverage.¹

In recent years, policymakers have shown renewed interest in the balance between local and national coverage processes. Some Members of Congress have supported legislation to strengthen the accountability of Medicare contractors by streamlining the number of contractors and allowing new kinds of entities to compete for Medicare contracts. In addition to proposed legislation, insurance market consolidations and other regulatory pressures have reduced the number of entities serving as contractors, and this consolidation raises questions about the future of decentralized coverage decisions.

The Medicare Payment Advisory Commission (MedPAC) recently criticized the variation among local coverage policies.² The General Accounting Office (GAO) has authored numerous reports on Medicare policy and is currently studying aspects of the local policy process. The report is expected in early 2003. CMS has surveyed its carriers to ascertain the extent of regional variation on coverage and payment policy for injectable pharmaceuticals and biologics. It found significant variation with respect to which medications were covered, sparking a new round of questions regarding the utility of carrier discretion. In the wake of this debate, interest groups have expressed concerns about the impact of any changes on their interests in the coverage process.³

On June 28, 2002, the Medical Technology Leadership Forum (MTLF) convened a Forum focused on the balance between the local and national pathways to coverage. The goal was to (1) review what is known (and not known) about local and

national coverage of new technologies; (2) build an understanding of the local processes; (3) identify issues related to the Medicare coverage policy process; and (4) discuss proposed options for change. A wide array of MTLF members and interested parties, including healthcare providers, a patient group representative, and innovative manufacturers and bioengineers, participated along with senior officials from CMS, representatives from Medicare contracting organizations, legislative staffers and health policy researchers. Dan Mendelson, Managing Director of The Health Strategies Consultancy LLC and Adjunct Professor at Duke University's Fuqua School of Business, facilitated the conference.

This paper is divided into three parts. Part I provides a brief overview of local and national coverage processes and was prepared by Health Strategies as background for the discussion. Part II summarizes the perspectives of stakeholder participants at the Forum, and Part III offers policy options that emerged from the Forum discussion.

PART I: CHARACTERISTICS OF THE LOCAL & NATIONAL COVERAGE PROCESSES

The Social Security Amendments of 1965 specified that any item or service must fit within an included benefit category and must be determined to be "reasonable and necessary" in order to be covered under Medicare. The term "reasonable and necessary" has never been defined in law or regulation, despite numerous efforts in the last three decades by CMS and its predecessor agencies to do so.⁴ Contractors follow informal directives from CMS and use limited discretion to interpret the statutory meaning.

The appropriate balance between local and national decision-making has become an area of concern among policymakers and interested parties. Many items and services are not the subject to coverage policies, but are covered or not based on whether the claims for individual patients are paid or denied. In fact, many new technologies obtain coverage seamlessly because they fall within existing codes and are integrated into stable DRG payment groups.

Exhibit 1 illustrates some of the major similarities and differences of the two systems. It is worth noting that the two systems share many similarities: both pathways require FDA approval, are subject to open and public processes, and must meet the "reasonable and necessary" standard. However, they also differ fundamentally in the mechanisms through which a coverage determination is made, the typical level of evidence required for coverage, timelines that are established for completion of review, and appeals processes.

EXHIBIT 1: COMPARISON OF LOCAL AND NATIONAL COVERAGE PROCESSES

	Local Process LMRPs	National Process NCDs
Responsible Groups	<ul style="list-style-type: none"> Fiscal Intermediaries – Part A. Carriers/DMERCs – Part B. 	<ul style="list-style-type: none"> The authority to make coverage decisions rests with Secretary. Increasingly, NCDs with significant consequences are being reviewed at the Secretary office level. The Coverage & Analysis Group (CAG) reviews all requests for NCDs for items and services under Part A or B. Other CMS divisions participate at times.
Policy Decision Tools	<ul style="list-style-type: none"> Contractors develop <i>draft LMRP</i> based on review of medical literature and understanding of local practice. Carriers may use input from Carrier Advisory Committee (CAC) and the DMERC Advisory Process (DAP). Contractors post <i>draft LMRP</i> on their website (and on www.draftLMRP.net) and circulate to providers and the regional office (RO) for comment. CMS RO reviews LMRP for conflicts with national policy, not for policy soundness. Contractors consider comments, revise as needed, notify providers and posts <i>final LMRP</i> on website (and on www.LMRP.net). 	<ul style="list-style-type: none"> CAG notifies public of new NCD reviews by posting issue tracking sheet on CMS website at www.cms.hhs.gov/coverage/8b3.asp. CAG develops Decision Memoranda (DM) detailing basis for NCD after careful review of scientific literature, recommendations from MCAC if applicable and Technology Assessment (TA) if available and posts DM on the website. DM are not considered NCDs and are not binding until fully implemented through program/manual instructions.
Timing & Target Deadlines	<ul style="list-style-type: none"> Post LMRPs and responses to comments within 45 days of posting draft. New LMRP reconsideration process requires contractor to determine if request is valid within 30 days and make a final decision within 90 days. 	<ul style="list-style-type: none"> Notifies public of plans to proceed (MCAC, Tech Assessment, coverage decision) within 90 days of receipt of NCD request or reconsideration. Issues change to formal policy within 60 days of decision memo. Implements payment changes within 180 days.
Evidence Standard	<ul style="list-style-type: none"> “Reasonable & Necessary” – no explicit criteria specified in regulation, however directives in the Program Integrity Manual (PIM) define it as “safe and effective”, “not experimental or investigational”, and “appropriate” in terms of duration and frequency. General assessment is: “Practice-based/bottom up”. Typically relies on review of the published literature, existing LMRPs developed in other regions and regional practicing physicians to inform LMRP. Manual language directs contractors to base LMRPs on “the strongest evidence available”. 	<ul style="list-style-type: none"> “Reasonable & Necessary” – no explicit criteria specified in regulation. General assessment is: “Evidence-based, top down”. Relies on evidence-based medicine (EBM) principles to determine reliability of evidence on clinical effectiveness in a specific, definable population.
Policy Scope	<ul style="list-style-type: none"> Regional: applies only in a single contractor’s jurisdiction. 	<ul style="list-style-type: none"> Nationwide: applies to all contractors.
Role of Physicians in Process	<ul style="list-style-type: none"> Local physicians participate on CACs; advise contractor. Identify new items or services and request local review to standardize claim submissions. 	<ul style="list-style-type: none"> Physician thought-leaders sit on MCAC; average practicing physician has little direct input. Anyone, including physicians, may submit an NCD request and provide evidence for review. Physician specialty societies may meet with CAG decision-makers – individual participation is rare.
Beneficiary Participation	<ul style="list-style-type: none"> Represented on CAC, and meetings open to public, but little communication between contractors and beneficiaries except in claim denials/appeals. Beneficiaries may appeal denied claims (8/22/02 Proposed Rule would enable beneficiaries to challenge coverage decisions before receiving a service). 	<ul style="list-style-type: none"> Consumer representative – generally affiliated with specific advocacy organization – sits on MCAC. MCAC meetings are open to the public and beneficiaries may comment, but only scientific evidence may be considered by the MCAC. Beneficiaries may not appeal NCDs, but can request an NCD review or reconsideration (8/22/02 proposed rule would grant beneficiaries <i>in need</i> the right to challenge coverage decisions).
Industry Participation	<ul style="list-style-type: none"> Informal participation on CAC. Meets with contractors and provides technology-specific information. 	<ul style="list-style-type: none"> Industry representative sits on MCAC. Often requestor of technology-specific NCD.

Source: The Health Strategies Consultancy LLC

A. THE LOCAL COVERAGE PROCESS

Fiscal intermediaries administer benefits provided by institutional providers (hospitals, skilled nursing facilities, and other institutional services), and carriers administer benefits provided by physicians and independent diagnostic testing facilities (IDTF). CMS identifies 30 fiscal intermediaries and 49 carriers nationally, however many of these contractors are affiliates of larger umbrella organizations, making the actual number of independent companies contracting with the government substantially less.⁵ If no NCD or other national restrictions apply, each contractor has the flexibility to establish parameters for determining coverage, often resulting in geographic variation in the types of services and indications that are covered.

There is consensus among Medicare analysts and policy-makers that Medicare contractors make the vast majority of coverage decisions, but the number of reviews, their character, and the basis for decisions has never been studied systematically. The GAO will report out results of its study of local decision making in 2003. In addition, researchers at the University of Minnesota, with a Robert Wood Johnson Foundation grant, are also studying the local processes with results to be published in 2003.

PROGRAM EVOLUTION

When Congress enacted Medicare, it recognized the importance of efficient claims administration for the new national health care program. Private organizations already engaged as third-party payers for private health care services were considered better equipped than government to perform necessary day-to-day administration, including receiving and reviewing bills from and making payments to providers, and were hired as contractors to process Medicare claims.⁶

The local contractors were also considered administratively necessary to protect the integrity of the Medicare program. Their role was to faithfully implement the legislatively created benefits. The contractors began developing automated systems to more efficiently process claims. In addition to national office system edits related to service volume and medical necessity documentation, contractors incorporated their own contractor-specific edits to trigger manual claims review.

The local coverage process allows contractors to evaluate whether the items and services provided meet the “reasonable and necessary” standard, and are medically necessary for the individual beneficiary. Contractors craft LMRPs taking into account local centers of excellence or other concerns unique to their region, which also gives newly developed items and services an opportunity to gradually penetrate the market.

The local process allows many decentralized decision-makers

to consider a new technology; success in any one area can result in usage, which ultimately assists in technology evaluation. Medical decision-makers must base local medical review policies (LMRPs) on the strongest evidence available. All evidence, including peer-reviewed journal articles and medical opinions derived from consultations with local medical associations and other health care experts, must be considered. Medical practice standards develop over time, indicating that medical customs are derived from a set of earlier experiences and subsequently develop into practice norms. Moreover, less stringent evidence is required for local contractors to make individual coverage considerations.⁷ At a 1999 hearing, the Chief Medical Officer of CMS stated: “There are places where we want local flexibility for technologies to be created, developed and diffused.”⁸

RECENT DEVELOPMENTS

Participants at the Forum identified a number of trends: (1) CMS interest in geographic variation resulting from individual carrier decision-making; (2) consolidation of carriers resulting from changes in insurance markets; (3) expansion in beneficiary rights to challenge coverage decisions; (4) efforts to update coverage policies and retire outdated policies; and (5) improved public access to and involvement in decision-making.

Increased focus on contractor variation has occurred from a variety of external and internal sources. For example, MedPAC’s recent report to Congress critiqued the variation resulting from the local coverage process. The GAO is also studying aspects of local decision-making. Earlier this year, CMS surveyed its carriers to ascertain the extent of regional or contractor variation on coverage and payment policy for Part B drugs. CMS also found significant variance in carrier policy when they conducted a survey regarding which Part B medications were covered. In the case of Part B drug coverage, CMS has not forced consistency across carriers through an NCD, but instead has asked that each carrier interpret a recent program memorandum containing greater specificity, as they deem appropriate. These reports have sparked a new round of questions regarding the utility of carrier discretion and whether this diversity in regional policies is warranted.

As a result of the rising health care costs and the added pressure on payers to limit spending, there has been a consolidation of private third-party payer organizations that has in turn created a consolidation in the contractor market. For example, one contractor, Noridian, is the Part B carrier in 11 states. How this affects the health services payer environment is not known, and raises important questions for the Medicare program. Some contractors with Medicare contracts for multiple states require consistent coverage policies across states. Those companies that also offer

commercial insurance products may additionally require that commercial coverage policies are comparable with their Medicare policies. In addition, CMS requires that before developing new LMRPs, carriers must review and take into consideration any LMRPs already in place in other regions. These policies would all tend to promote a homogeneous coverage environment, and vie against individualized local policy.

In light of patient empowerment and the currents generated by Congressional interest in the Patient Bill of Rights, CMS recently expanded a beneficiary's right to challenge underlying coverage decisions prior to receiving a particular item or service. Authorized in the Benefits Improvement and Protection Act of 2000 (BIPA), HHS promulgated a proposed rule on this issue in August 2002. Irrespective of the opportunities to challenge coverage decisions in BIPA, CMS has already launched a number of efforts to update and routinely assess local coverage policies. These efforts include retiring and archiving outdated or contradictory LMRPs and dating new LMRPs with expiration dates – requiring contractors to proactively review policies.

Increased participation of beneficiaries in their healthcare decisions and planning has been the focus of CMS interest for at least a decade. Direct-to-consumer advertising, Internet information services, and consumer awareness campaigns offer Medicare beneficiaries a wealth of information. To accommodate greater beneficiary interest and reinforce public confidence in program administration, CMS recently began requiring local contractors to have public advisory meetings to discuss draft LMRPs and to post their draft and final LMRPs on a centralized website. Contractors also have continued to post local coverage decisions on their own websites and have added website features including newsletters, FAQs, and other resources.

B. THE NATIONAL COVERAGE PROCESS

The national coverage process is administered through the Coverage and Analysis Group (CAG) at the CMS national office in Baltimore. There are 47 CAG employees, including nine physicians (medical officers), divided among four divisions: (1) Division of Items and Devices (DID), (2) Division of Medical and Surgical Services (DMSS), (3) Division of Operations and Committee Management (DOCM), and (4) Division of Information Management (DIM). DID and DMSS are directly responsible for conducting the reviews of individual NCD requests. Drugs, non-implantable medical devices, including durable medical equipment, and laboratory and diagnostic services are handled primarily by DID analysts, while all other clinical topics are assigned to DMSS, including physician services, surgical procedures, and

implantable devices. DOCM manages all public meetings (e.g., MCAC meetings) and rulemaking activities relating to coverage policy procedure. DIM, a recent addition to CAG following the last reorganization, handles correspondence, information requests, and website content.

DEVELOPMENT OF THE NATIONAL COVERAGE PROCESS

Following pressure from Congress and medical device companies, CMS began making major changes to the national coverage process in 1997 and 1998. In 1999, CMS announced formal procedures for making NCDs that included parameters for using the newly established advisory body, the Medicare Coverage Advisory Committee (MCAC)⁹ that would convene open meetings to discuss coverage issues under review.¹⁰ Shortly after, in May 2000, CMS published a Notice of Intent (NOI) to issue a proposed rule, in an effort to define how services and products in a statutorily defined benefit category are deemed “reasonable and necessary” for diagnosis and treatment of a patient. The agency also announced its intention to develop “sector-specific” guidance documents following development and publication of a proposed and, subsequently a final, rule on coverage criteria. As yet, the agency has not published a Notice of Proposed Rulemaking (NPRM) on coverage criteria.

The open NCD process enables any member of the public to submit a request for an NCD review. CMS may also internally generate NCD requests to review new technologies or medical services likely to have a great impact on the Medicare population, if there is wide variation in coverage at the local level, or if an item or service is at risk for over-utilization. Once an NCD is initiated, reviews are generally assigned a lead analyst (either in DID or DMSS), a medical officer, and an analyst in DOCM to aid in record-keeping and documentation efforts.

Coverage requests are first reviewed for completeness: appropriate FDA approval/clearance, statutory benefit, and scientific evidence. The CAG staff identifies all pertinent statutory, regulatory, and administrative/guidance policies; examines the scientific evidence in detail, contacting specialists and experts if necessary; and decides whether the evidence is sufficient to make a decision on the reasonableness and necessity of the particular item or service. If the reviewers feel that they are not equipped to immediately make a decision, they may refer the issue to the MCAC and/or request a technology assessment be conducted by an evidence-based practice center (EPC) through AHRQ.

CMS uses an evidence-based medicine (EBM) approach to evaluate items for coverage; decisions are based on the best available medical evidence according to the generally accepted hierarchy of evidence. For example, controlled clinical trials are not always available for new technologies

and may be impracticable for some medical devices, but granting positive coverage does require some evidence of added clinical benefit and improved clinical outcomes.

A national coverage determination, positive or negative, can often result in an “all or nothing” scenario in terms of patient access. However, since initiation of the new NCD process, CMS has frequently made delimited decisions that allow payment for specific populations for which efficacy of the procedure or technology has been proven.

RECENT DEVELOPMENTS

Several participants at the Forum identified important trends in the national NCD process, including: (1) increased scrutiny of the timing of decisions; (2) the establishment of several new methods of communicating with the public (i.e., routine posting of issue tracking sheets and the creation of an email listserv open to all interested in receiving updates and announcements on coverage policy developments); (3) the creation of new mechanisms to foster accountability to Congress; (4) the reformation of the appeals process; (5) the growth and evolution of CAG within CMS; and (6) an increased willingness and interest in reassessing existing NCDs.

The most notable trend, however, may not be found in any of the internal processes the Medicare program, either through Congress or administratively, has formally instituted, but the agency’s general efforts to reach out to interested parties for input and assistance in making coverage decisions. For example, a recent review on the use of positron emission tomography (PET) in diagnosing and managing Alzheimer’s disease eventually evaluated at an MCAC meeting illustrates CMS’ efforts to proactively engage outside groups. In preparation for the meeting, CMS staff engaged various patient groups and technically specialized organizations on the use of decision modeling and diagnostics in the treatment of Alzheimer’s.

In response to requirements in BIPA, CMS sent its first annual report to Congress on the NCD process in early June 2002. This report is intended to provide Congress with an annual update on CMS’ progress in making timely and thorough coverage policy decisions. The report found that decisions were, on average, implemented within the self-imposed timeframe of 180-270 days from the date of the decision memorandum to the date of instructions implementing the decision (Exhibit 2).

EXHIBIT 2: CMS REPORTED TARGET & AVERAGE TIMES FOR NCDs IMPLEMENTED IN FY 2001

	TARGET TIME (in days)	AVERAGE TIME (in days)
Days to Determination without a TA and/or MCAC	90	65-96 (with and without emergencies)
Additional Days to Technology Assessment	180	90
Additional Days to MCAC recommendation	180	108
Days to implement decision (from date of decision memorandum)	180-270	156

Source: HHS Report to Congress on National Coverage Determinations, June 2002; www.cms.hhs.gov/coverage/8a.asp

The report to Congress may be of limited usefulness in evaluating the amount of deliberative time CMS requires to issue a final NCD. Congress only required CMS to submit information on NCDs implemented within the past fiscal year that expand Medicare coverage to include items and devices not previously covered by Medicare. Decisions implemented before October 1, 2000 or after September 30, 2001, regardless of whether the decision memo was already posted, are not included in the report. Also excluded from the report are NCDs that retain non-coverage decisions or decisions with decision memos posted prior to October 1, 2000 even if they were not effective until FY 2001.¹¹

Although CMS reported on average meeting the self-imposed timelines, the report acknowledged that six of the ten decisions exceeded the target times and two of the four decisions that did not exceed the time limits were identified as “emergency” determinations. Although the emergency decisions lowered the average decision implementation time (156 days), without their inclusion the average time (195 days) still fell within the self-imposed target.

Moreover, while the report does fulfill CMS’ statutory requirement by notifying the Congress of how many decisions were made and in what timeframe, it does not detail the reason for the delays. In some cases, CMS may be responsible for the delay in making a decision. In others, it may be the requestors who are the cause of the delay. Once CMS reviews a request, it may decide that additional information is necessary to make a decision and it will contact the requestor for that information. A CMS official noted that in the case of the decision on the treatment of actinic keratosis, CMS forestalled making a decision for more than six months while the Academy of Dermatology gathered relevant evidence in support of its request.

On August 22, 2002 CMS published a proposed rule entitled “Review of National Coverage Determinations” which implements portions of §522 of BIPA that were intended by

Congress to provide beneficiaries with a more responsive Medicare program. The proposed rule provides beneficiaries with the opportunity to challenge not just individual claims denials, but actual coverage policies on which decisions are based. The details of the proposed rule were highly criticized, and it is expected that the proposal will be revisited.

Finally, the changes to CAG and efforts to make the coverage process more transparent and responsive to beneficiary needs have resulted in CMS' willingness to be proactive in modifying and prioritizing coverage reviews to better reflect changes and advancements in medical care. For example, the NCD on respiratory assist devices (RADs) for the treatment of chronic obstructive pulmonary disease (COPD) clearly states CMS' intention to reevaluate the decision in 1-2 years. CMS representatives at the Forum reiterated the agency's intentions to periodically and proactively reexamine NCDs as new information becomes available, and to select issues for review according to its potential impact on beneficiaries and the program.

PART II: MTLF FORUM DISCUSSION

Because of the controversies surrounding the balance between local and national coverage, the Medical Technology Leadership Forum brought a group of stakeholders and policymakers together to share their perspectives. Many of the participants had first hand experience with either the local or national processes, and MTLF wanted all views out on the table for review. MTLF also recognized that there was a lot that was not known about the local process. MTLF invited health policy researchers from public agencies and universities to participate in the discussion and share their research goals and preliminary findings. Brief synopses of the presentations of various stakeholders follow:

CMS DECISION-MAKERS

While coverage decisions are generally made at CAG, many other individuals and groups within CMS have a say in coverage policy. CAG is one group within the Office of Clinical Standards and Quality (OCSQ), which oversees all quality, clinical, and medical science issues and policies for the agency. The other groups within OSCQ can inform coverage decisions directly by sharing specific clinical expertise or more generally by aiding general quality improvement and the adoption of best practices in the medical community. In addition, the Center for Medicare Management (CMM) drafts and implements all Medicare payment systems and is generally responsible for defining benefit categories that can enable CAG to undertake a "reasonable and necessary" review. Concerns regarding Medicare reimbursement are often based on payment levels created in CMM rather than coverage policies. Also, the Program Integrity Group (PIG) is

responsible for providing local contractors with instructions and directives from the national office impacting the way local coverage policies are promulgated. MTLF was fortunate to have CMS representatives from CMM, CAG, and PIG join in the Forum as speakers and participants.

Medicare officials have an obligation to enforce fiscal discipline. CMS decision-makers participating in the Forum discussion believe it is reasonable to preferentially direct funds to items proven medically effective through standard methodological means and tests. They believe that there are inherent risks in performing medical procedures before accumulating conclusive evidence of benefit. Even in the event that a particular procedure does not directly harm a patient, any treatment of questionable benefit, delivered in lieu of a more effective treatment, could ultimately result in the patient's harm and divert limited Medicare funds. In fact, one CMS official remarked on the difficulty CMS faces in addressing all coverage requests as they emerge, rather than prioritizing issues by the potential impact or consequence to the program. CMS has not established a systematic method to allocate resources according to the complexity or applicability of a particular issue. Also, while CMS has wide discretion in undertaking new projects, it has much less control in easing off projects already in process.

Regulators believe that the industry should collect data about its products on which Medicare can base coverage decisions. A CMS representative compared FDA requirements for drug studies with those for 510K device approvals. Devices granted 510K approvals by the FDA only require that the product be "substantially equivalent" to a product already on the market. Such tests do not require a direct study measuring the effectiveness of the technology. Once on the market, physicians and beneficiaries may be reluctant to enter trials evaluating efficacy. Therefore, when providers and patients immediately embrace new technologies, Medicare and other payers may not have the type of evidence they need to evaluate whether a technology is "reasonable and necessary."

One CMS official also stated, however, that the standard of care in a community may not always indicate what is most effective. To support this, he cited examples of widely accepted medical treatments subsequently proven harmful: bone marrow transplants for breast cancer patients and carotid laser stenting – illustrating that well-informed hypotheses and early study results can later be proven wrong. Furthermore, dramatic variance in covered services or service intensity demonstrates a wide range of opinions in the medical community as a whole. If two practitioners hold widely divergent views on the best way to treat a particular patient or disease, at least one practitioner is likely to be wrong. However, without careful study no one will be able to definitively determine whether one pathway is truly the

better than another. Therefore, the medical policy decision-makers and all involved in the delivery of medical care should focus on what can be learned from the differences that have developed in medical practice, not simply the presence of geographical differences.

MEDICARE CONTRACTORS

There are a wide variety of insurance organizations that serve as Medicare contractors. Each contractor does, by definition, provide perspectives only from his or her own experience. Each Medicare contract includes a Medical Director who is a medical doctor. These individuals play an important role in the implementation of coverage policy at the local level.

The participants found that there is value to local decision making, but also recognize the need for national coverage policy as well. They found that there may be some medical technologies or services that are appropriately addressed at the local level. One example may be newer technologies that depend on the skill and specific interests of an individual physician or center of excellence. Another suggested that there is a greater likelihood that national decisions drafted too early in a technology's development will be out of date as new information is gleaned. Also, contractors have no discretion to make allowances for even well documented changes in practice patterns once an NCD is in place. The contractor or individual physician's only recourse is to request that the NCD be reconsidered by CAG.

However, it was also noted that it can be inefficient for many local contractors to develop LMRPs for established technologies. It was argued that while certain conditions may be susceptible to particular regional variations, Medicare patients nationwide tend to be more similar than different. Thus, in cases where there is general consensus in the medical community, the promulgation of national policy could be an effective way to ensure consistency across regions for beneficiaries.

INDUSTRY

Two industry representatives, one from a large medical device company and another from a small, one-product medical device company, voiced a number of concerns about centralization of coverage decision-making. They asserted that the local coverage process is integral to the diffusion of innovative medical technology as there is often a lag-time between the approval of breakthrough medical devices by the FDA and the issuance of national coverage determinations that make those devices available for the treatment of Medicare beneficiaries. These representatives stated that many advances in medical technology are incremental and evolutionary, although even slight improvements over existing technologies can have an important positive effect on outcomes. Moreover, the representative of the larger device

company emphasized that the rapid pace of innovation requires a flexible and responsive process.

The industry speakers believed that innovative technology gains acceptance in the medical community through gradual diffusion and knowledge sharing. The ability of innovators to introduce their new medical technologies into local markets enables practitioners to gradually increase their proficiency, resulting in measured preparedness and greater incorporation of technological advances. However, physicians' willingness to incorporate advances in their practice may largely depend on whether they can be reimbursed for the service.

Considerable resources are required to develop a new technology. It can take years, even decades, to develop a new technology and just as long to incontrovertibly prove its effectiveness. The expense of structuring and carrying out clinical studies can be prohibitive, especially for small companies with little influence in the marketplace. Thus, by allowing individual physicians acquainted early on with new technology, generally at centers of excellence or research facilities, to request coverage at the local level allows beneficiaries to benefit from the most advanced technologies available in the market.

In addition, participants suggested that smaller, one-product device companies view the NCD process as especially risky and more difficult, in that it relies more heavily on clinical evidence. Introducing a new technology to a few areas where studies have already taken place through local coverage requests enables small companies to build a core expert base. Larger companies can subsidize the research of new products with revenues from other product lines, while smaller companies are more dependent on early revenue generation. Thus, from this viewpoint, strict standards regarding the types of evidence that are adequate for coverage could hinder entrepreneurship and the successful development of innovative treatments.

PHYSICIANS AND PRACTITIONERS

Physician panel members indicated that they believe many of their colleagues have found the administrative burdens of insurance requirements overwhelming. Inconsistent Medicare coverage policies may be a source of confusion for medical professionals and patients, and inconsistent LMRPs and NCDs are not uncommon. They believed that NCDs created early on in a technology's development can be too limiting as use evolves and technologies mature, whereas LMRPs can be modified more quickly to accommodate newer applications of existing technologies.

One physician panelist pointed out that not all physicians are equally proficient in all medical arenas, and therefore, it is reasonable to give physicians latitude in prescribing treatment

protocols for their patients. Medicare patient demographics are similar throughout the country, but resources and technology penetration are not. Local policies provide physicians with the flexibility to use familiar techniques that have not had the time to be adopted by practitioners nationwide. Thus, NCDs may be useful for the consistent application of older technologies, but could inhibit the adoption of newer technologies. Moreover, while practitioners often support the use of evidence-based medicine, many are concerned that in the absence of clinical studies, the national process may not rely sufficiently on physician judgment.

Several physicians noted that the local coverage process was more responsive to physician interests, as the decision-makers were closer to local physicians. The consolidation of the carriers and the centralization of coverage decision-making would tend to erode this effect, assuming Medicare allows current trends to continue. Nevertheless, one physician association noted that physician opinion leaders are sometimes frustrated with the inefficiency of repeatedly reviewing and deciding the same issue in many forums.

BENEFICIARIES AND BENEFICIARY GROUPS

Only one participant from a beneficiary advocacy group was able to participate. In addition to this panelist's comments, audience members (researchers, CMS representatives, and technology companies) voiced issues of interest to beneficiaries. Repeatedly, concerns centered on the lack of true beneficiary involvement in the coverage process and access to Medicare policy decision-makers.

Various participants recited the steps CMS has taken to ensure that disease groups have timely information about coverage processes and decisions. All issues under consideration for both local and national coverage review are posted on the Internet, and beneficiary representatives sit on the Medicare Coverage Advisory Committee (MCAC) and the Carrier Advisory Committees (CACs). However, like industry representatives, beneficiary representatives on the MCAC are precluded from voting. The panelist representing a beneficiary advocacy group also shared her experiences as a participant on the MCAC as a beneficiary representative. The principal concern she had regarding her role and the MCAC more generally was that CMS always retains final decision-making power. While they are charged to examine the body of evidence as a whole, CMS officials responded dismissively to information presented by beneficiaries and other members of the public.

Some Forum participants also questioned whether those most deeply affected by coverage decisions have input into the system. The beneficiary representatives to both the national and local coverage processes are generally chosen from

advocacy groups that may not share the interests of other beneficiary groups or individual beneficiary members. Requests for public input on coverage issues under review generally result in the participation of advocates for individual issues, often without detractors being present – placing the regulators in the role of critic by default.

CONCLUSIONS AND POLICY ISSUES

The goal of MTLF Forums is to bring together participants representing multiple perspectives and engage them in a dialogue on challenging policy issues. This Forum accomplished the goal by assembling speakers and attendees with a variety of local and national coverage process experiences. While there was no clear consensus on how the coverage system should be structured that emerged from the meeting, there were a number of helpful suggestions pertaining to the local and national coverage processes, as well as some observations on relative balance between the two systems. Below we summarize these conclusions.

Improving the Local and National Coverage Processes

During our discussions, many suggestions were proffered on how the local or national process could be improved. These suggestions are discussed below.

CONSUMER PARTICIPATION

Several speakers noted the lack of meaningful participation by consumer and patient groups in Medicare coverage decisions. While there is a consumer representative on the MCAC, one speaker expressed concern that the consumer views were undervalued. Neither industry nor consumer representatives can vote on the MCAC at this time. While many contractor medical directors do reach out and consult patient groups at the local level, the practices vary among contractors, and consumers often lack the resources to track decisions. Several participants suggested improving information consolidation and dissemination at both the local and national levels in order to interact with beneficiaries and not just organized patient or consumer groups.

CONTRACTOR CONSOLIDATION & LOCAL RESPONSIVENESS

The participants who supported the widespread use of local decisions expressed concern that the consolidation of contractors, either through market forces or contractor reform legislation, would erode the local responsiveness of contractors, leading several participants to recommend:

- Separating the claims management role from the coverage decision-making role.
- Granting contractor medical directors (CMDs) the authority to make independent decisions based on the practices in their region and interaction with the medical community.

- Potentially creating positions for multiple CMDs operating under a single Medicare claims processor to ensure local responsiveness. Determining carrier regions based on geography and demographics to ensure equal power across individual contractors and the CMDs.

Some Forum participants voiced concerns over reforming the current contractor structure without more information and cited the consolidation of contractors for Medicare's durable medical equipment benefits into four regional carriers (DMERCs) as an example. The DMERC consolidation has resulted in the concentration of decision-making power and decision-makers seen by many in industry as unapproachable, however no systematic research on the effects of this consolidation has been conducted, and the issues associated with DME evaluation may differ from the evaluation of Class II and III devices. The DMERCs meet regularly for scheduled calls with no public participation and generally adopt identical policies in the four regions, providing consistency without the transparency and openness of the current national review process. Forum participants stressed the importance of retaining local medical directors who are required to act independently, provide coverage decisions through a timely, open and collaborative process, and permit coverage on a case-by-case basis.

DATA ON COVERAGE PROCESS OPERATIONS

While participants shared anecdotal experiences, little solid research actually documented and evaluated the local and national coverage processes. Participants noted how remarkable it was that a process so critical to the interests of beneficiaries and technology companies had not been previously studied in a systematic way. Fortunately, panelists agreed that the environment is now receptive to more information.

The U.S. General Accounting Office Health staff who participated in the MTLF Forum will issue a report on this topic in January 2003. The Medicare Payment Advisory Commission (MedPAC) is continuing its research into coverage and payment issues. Academic research, including the work presented by Susan Bartlett Foote of the University of Minnesota, and funded by the Robert Wood Johnson Foundation's Changes in Health Care Financing and Organization Initiative, will be disseminated in 2003. Conferences sponsored by ECRI, a technology assessment firm, and the National Institute for Healthcare Management, among others, will take place in 2002-2003.

FUNDING CLINICAL RESEARCH

There was substantial debate regarding the nature of the evidence that should be required for coverage of a new technology. Participants generally agreed that gathering additional evidence is costly and often necessary for Medicare

to make good decisions. However, there was no agreement on who should subsidize the costs of gathering data, and how such studies should be conducted. Several participants suggested, as a partial solution to the challenge of gathering evidence, that conditional or provisional coverage decisions be permitted to allow for the diffusion of a new technology contingent on the completion of clinical studies, particularly important for smaller companies. Others noted that requiring the Medicare program to subsidize research is only one possible solution.

FURTHER INTEGRATION OF THE LOCAL AND NATIONAL COVERAGE PROCESSES

As described above, there are currently a number of ways in which the local and national processes are connected. Local coverage policies are supposed to take into account other promulgated policies, and NCDs often rely on LMRPs as well. Some participants suggested that further integration of these processes could benefit the Medicare program. For example, administrative reforms could build on the efforts currently underway to standardize LMRPs, enabling both agency staff and public stakeholders to more easily identify trends in medical practice. Automatic trigger mechanisms could also be created to initiate a national review once a certain number of CMDs had reviewed a technology.

Changing the Balance Between Local and National Coverage Determinations

The Forum focused on the balance between local and national coverage. Forum participants generally agreed that there are essential differences in how the coverage process operates at the local and national levels, and that both play an important role in the current system. Participants also agreed that the current balance between the local and the national coverage processes likely shapes how new technologies diffuse among Medicare beneficiaries. Most observers characterized the local process as being relatively more responsive to physician practice norms, and the NCD process as being more focused on hard clinical evidence.

The current balance between the local and national coverage processes in many key respects defines the coverage process and the relative emphasis on local flexibility versus national consistency. However, the widely varying perspectives presented demonstrate that the participants could not reach clear agreement on the appropriate balance between the two processes and that key evidence on the true characteristics of the processes is lacking. Nonetheless, of concern to some participants was the risk that any reform efforts, such as proposed legislation on contractor reform or other proposed reforms to Medicare, would alter the current balance inadvertently or without adequate consideration of the consequences.

Note that the balance has already changed to some extent as a result of the efforts in the market to consolidate local carriers and decision-makers. Moreover, further changes to the current Medicare contracting structure are in the offing. For example, language in a Senate Medicare bill (September 30, 2002) provided for changes in contract bidding and assignments and required a set number of local decision-makers. Such provisions indicate that there is genuine interest in this area of policy and that policy-makers are engaging in an ongoing, active dialogue.

As with most Medicare issues where multiple stakeholders are affected, there are no easy answers in defining the balance between the local and national processes. Further, there is little hard evidence about the effects each pathway has on beneficiary access, the Medicare Trust Fund, or the speed with which new technologies diffuse. We hope that the Forum session and this report contribute to our knowledge base and serve as a guide towards rational policy choices.

¹*Medicare Coverage Decisions and Beneficiary Appeals: Hearing Before the Subcomm. on Health of the House Comm. on Ways and Means, 106th Cong. 23, at 5 (1999) (statement of Bill Thomas, Chairman).*

²Medicare Payment Advisory Commission. Report to Congress: reducing Medicare complexity and regulatory burden. Washington (DC). December 2001.

³*Medicare Coverage Decisions and Beneficiary Appeals: Hearing Before the Subcomm. on Health of the House Comm. on Ways and Means, 106th Cong. 23 (1999) (Statements of the American College of Physicians –American Society of Internal Medicine, the Medical Device Manufacturers Association, and the Health Industry Manufacturers Association).*

⁴S.B. Foote, “Why Medicare Cannot Promulgate a National Coverage Rule: A Case of Regula Mortis,” *Journal of Health Politics, Policy and Law* (October, 2002).

⁵See <http://www.lmrp.net/directory.asp>. Once consolidations are accounted for, there are 20 FIs and 28 Carriers, and the numbers are decreasing every year.

⁶*More Can Be Done to Achieve Greater Efficiency in Contracting for Medicare Claims Processing* (HRD-79-76, June 29,1979).

⁷HHS, CMS, *Medicare Program Integrity Manual*, Sec. 2.3.2.1, “Evidence Supporting LMRPs” (Baltimore, Md.: CMS, July 2001).

⁸*Medicare Coverage Decisions and Beneficiary Appeals: Hearing Before the Subcomm. on Health of the House Comm. on Ways and Means, 106th Cong. 23 (1999) (Statement of CMS).*

⁹The MCAC was established on December 14, 1998, 63 Fed. Reg. 68,780.

¹⁰Medicare Program; Procedures for Making National Coverage Decisions, General Notice, 64 Fed. Reg. 22,619 (April 27, 1999).

¹¹See NCD, CAG-00057, on Extracorporeal Immunoabsorption Columns Using Protein A Columns for Treatment of Rheumatoid Arthritis. Program Memorandum, Transmittal 127, CR 1005; CIM §35-90.

Agenda

Welcome: Senator David Durenberger: Why MTLF :8:00 a.m.

Introduction: The Current Role of Local & National Coverage. :8:05 a.m. - 8:30 a.m.

Dan Mendelson, *The Health Strategies Consultancy LLC*

This session will review the local and national Medicare coverage processes; and, describe recent congressional, CMS, MedPAC and GAO discussions on the local/national coverage dynamic, as well as academic research. The goal is to outline the questions most important to exploring Medicare coverage policy development from a variety of perspectives.

Conference Goals & Guiding Coverage Policy Principles. :8:30 a.m. - 8:45 a.m.

Immediately following the overview of how coverage policy is currently crafted, the moderator will elicit from the conference participants an initial list of conference goals, specific themes and relevant ideas to be posted for reference, review, guidance and structure throughout the day.

Stakeholder Perspectives I :8:45 a.m. - 9:50 a.m.

Michael Rapp, MD, *Co-Council Chair, Practicing Physicians Advisory Council*

Robert M. Zwolak, MD, *Dartmouth-Hitchcock Medical Center*

Phyllis Greenberger, *Society for the Advancement of Women's Health Research*

Elisabeth Bressee Brittin, *Parkinson's Action Network*

Physician and patient representatives will share their perspectives on the appropriate balance between local and national coverage. In addition to the questions below, panel members will be asked to explain how their experiences affect the themes and ideas outlined during the introduction.

Questions for patient group representatives will include:

- What is the role of national and local coverage in terms of patient outcomes and access to technology?
- Are patient groups involved in discussions of local and national coverage of medical technology?
Why? Why not?
- What are patient groups' primary concerns relative to local and national coverage?
- From patients' perspectives, what changes, if any, should be made to the local and national coverage processes?

Questions for providers and provider group representatives will include:

- What do you believe is the appropriate balance between decisions by individual physicians and national guidelines for coverage?
- What do you think will be the impact of the new (BIPA-mandated) appeals process on the coverage environment?

- In your experience, is there a role for variation in local coverage policy, i.e., early on in a technology’s development? If so, at what point does such variation become inappropriate?
- What are provider groups’ primary concerns relative to local and national coverage?
- From providers’ perspectives, what changes, if any, should be made to the local and national coverage processes?

BREAK9:50 a.m. - 10:05 a.m.

Stakeholder Perspectives II/Industry Experiences10:05 a.m. - 10:45 a.m.

Jayne Little, *Cryogen, Inc.*

Steve Kelmar, *Medtronic, Inc.*

This panel will provide two unique perspectives from companies with different products and outcomes with Medicare coverage.

Questions for industry representatives of companies with experience in both the local and national coverage policies will include:

- From your perspective, how does the structure of CMS coverage policy decision-making affect the testing and diffusion of new technologies?
- What role does variation in local coverage policy play in technology’s development?
- What do you see as the coverage dynamic between industry clinical study investigators and local coverage decision-makers and how do you believe that relationship affects local coverage of new technologies?

CMS Perspectives.10:45 a.m. - 11:30 p.m.

Tom Grissom, *Director, Center for Medicare Management*

This session will present the perspective of CMS’Center for Medicare Management. The balance between local and national decision-making is pertinent to all policy determinations, from contractor reform legislation to the inherent reasonableness authority.

Questions will include:

- How does the current balance between local and national coverage look from a Federal perspective?
- How does communication work between Central Office and contractors?
- What resources are needed to improve coverage processes?
- How does the local process really differ from the national process (e.g., timeframes, flexibility, level of evidence)?
- Would the Administration’s contractor reform initiative be expected to reduce the number of carriers or otherwise affect the balance between local and national determinations?
- Does the current survey of carriers relative to coverage of injectables under BIPA suggest precedential interest in national coverage decisions at CMS?

Coverage Perspectives.11:30 a.m. - 12:15 p.m.

Sean Tunis, MD, MSc, Director, CMS Coverage and Analysis Group

Building on the morning CMS session with CMM, this session will present the perspective of the Coverage and Analysis Group in CMS' Office of Clinical Standards and Quality.

Questions for the Coverage and Analysis Group will include:

- How does CAG communicate with contractors?
- Should CMS have the option to require that manufacturers study outcomes that result from a positive local coverage decision?
- Should there be an explicit authority -- like the 1115 Medicaid waiver authority -- to allow CMS to study the effects of a carrier's coverage decision in a segment of the country?
- Is there a role for variation in Medicare coverage policy - perhaps early on in a technology's development? At what point does that become no longer necessary?
- What is the effect of LCA and inherent reasonableness determinations at both the national and local level?
- What resources are needed to improve Medicare coverage decisions?

LUNCH12:15 p.m. - 1:00 p.m.

Carrier Perspectives.1:00 a.m. - 2:00 p.m.

Jenifer Levinson, The Health Strategies Consultancy LLC

Brigid Davison, Acting Deputy Director, CMS Program Integrity Group, Division of Medical Review

Laurence Clark, MD, Carrier Medical Director, Trailblazers

David Perez, MD, Carrier Medical Director, Trailblazers

Douglas Wayne, MD, Carrier Advisory Committee (Virginia)

The carriers have traditionally had a considerable degree of discretion in forming coverage policy and have typically built relationships with clinician advisors, including other carriers, to help navigate difficult issues. Also, prior to the formalization of the NCD process, the carriers frequently relied on CMS for informal discussion. The session participants will share their experiences concerning Medicare coverage at the local level and the recent modifications to the national process.

Questions will include:

- How do you work with Medicare contractors and/or CMS Central Office?
- What is your role of in developing LMRPs?
- According to your experience, how is evidence used in making local decisions?
- How do you feel about the timing of coverage decisions (both local and national)?
- What are your primary concerns relative to local and national coverage?
- From your perspective, what changes, if any, should be made to the local and national coverage processes?

Options for Change2:00 p.m. - 3:00 p.m.

Dan Mendelson

Susan Foote, *University of Minnesota*

Sheila Avruch, *Asst Director, GAO Program Administration & Integrity Issues*

Deborah Williams, *Staff, House Ways and Means Health Subcommittee*

Jon Blum, *Staff, Senate Finance Committee*

Session participants will discuss options for change that have been proposed to date. Options range from maintaining the status quo to a complete overhaul of the system.

Questions for panel will include:

- How can the Medicare program balance the need for speed and consistency in Medicare coverage with patient outcomes and beneficiary equity concerns?
- What additional research should be conducted to help CMS find such a balance?
- What existing legislative and administrative proposals (if any) offer promising reform options?
- What is the scope and purpose of the GAO study currently underway?

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