# Improving the Quality and Efficiency of the Medicare Program Through Coverage Policy

**Timely Analysis of Immediate Health Policy Issues**
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## Introduction

In the face of large and growing budget deficits, finding ways to bend the health care cost curve and improve the efficiency of the Medicare program has been a central focus of budget policy. Medicare spends more than $500 billion annually for more than 46 million senior and disabled beneficiaries,[1] and research suggests new medical technologies[2] such as drugs, devices, diagnostics and surgical techniques are a major driver of increasing costs. For example, some novel anti-cancer drugs now cost significantly more than older alternatives,[3] many new diagnostic technologies are additive rather than replacing outmoded or older services,[4] and advances in minimally invasive surgical techniques have substantially expanded the number of people who are now surgical candidates.[5] Within the fee-for-service environment, which makes up the vast majority of Medicare spending, there are few incentives to be efficient or economical. While some advances in medicine undoubtedly have contributed to reductions in morbidity and mortality, new technology and new uses of established technology are often adopted with little evidence that they work better than existing treatments. There is even less evidence about which patients might actually be harmed by their use.

Coverage policy examines the clinical evidence to decide which services and treatments should be paid for by insurance and under what circumstances. Medicare coverage determinations can act as a policy lever to influence both the appropriate use of medical technology and the creation of better evidence to support clinical and health policy decisions.

Currently, Medicare defers most coverage decisions to regional contractors who process claims on a daily basis. The emphasis of these contractors' work is on efficiently processing claims rather than accurately evaluating clinical effectiveness or appropriateness of the services provided. There is also a dearth of information available to the contractors about the details of these services, leading to missed opportunities to prevent ineffective, unproven and/or harmful technologies from widespread adoption, at a significant cost to the program. Even when national policies are developed, the Centers for Medicare and Medicaid Services (CMS) and the administrative contractors often lack the resources to assure that the policies are implemented as written. Dependent on research performed by other agencies, CMS often must make coverage policy decisions while lacking high-priority, clinical research relevant to the Medicare population. In essence, CMS is precluded from taking action to restrict the coverage of services that do not provide added value to patients when compared to available alternatives that are sometimes less expensive.

The four authors of this paper have each been senior officials at CMS with direct responsibility for core aspects of coverage and payment policy. The observations presented here reflect our consensus viewpoint on how things now work at CMS and how they might be altered. We support our observations and recommendations with evidence and opinion provided by other experts in this field.

This paper's premise is that the process for making coverage decisions in Medicare falls short of its potential to contribute to the recently articulated "Triple Aim" of the program to (1) improve the individual experience of care, (2) improve the health of populations, and (3) reduce per capita costs of care for populations.[6] Most Triple Aim attention has been focused on how organizations providing health services can be encouraged to become Triple Aim "integrators" on behalf of the populations they serve. That is the role of accountable care organizations, as envisioned by the Patient Protection and Affordable Care Act (ACA). However, payers can also play a decisive role in promoting Triple Aim objectives. While a broad policy audience may consider policy about coverage and

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payment of technology a technical aspect of program administration with little direct relevance to beneficiary well-being and the financial status of the Medicare program, the authors argue that Medicare coverage and payment policies for new technology represent a fertile mechanism through which to achieve the Triple Aim.

This paper provides a basic overview of the coverage policy process at CMS; explores particular operational deficiencies in current implementation; and discusses a few, selected opportunities to better align coverage policy with the Triple Aim. It concludes with high-priority recommendations for reform. Some changes could be relatively easy to implement with sufficient leadership, political will and adequate administrative resources. Other changes would require more significant and politically difficult actions dependent on affirmative congressional authority that does not now exist. These more ambitious recommendations are made anticipating that any fundamental reconsideration and possible restructuring of the Medicare program should thoroughly review the current limitations in the CMS coverage process.

This paper does not explore all aspects of Medicare's potential to influence the use of technologies. For example, many believe that patients should be more fully engaged than they are currently with their health professionals in shared decision-making about when and how to apply available technology in their particular circumstances. Approaches to achieving shared decision-making, such as with accountable care organizations and patient-centered medical homes, are beyond the scope of this paper. Nor does it explore provider payment incentives, which surely affect the use and the costs associated with technology. The decision on whether to employ an available technology is an inherently different decision than determining whether the technology should be made available and paid for by the program and whether any restrictions should be placed on that coverage. The focus of this paper is the process of making coverage policies, not Medicare's influence on health professionals and their patients' decisions to use covered items and services.

## How the Medicare Coverage and Payment Process for New Technology Works

The original statutory language that established Medicare in 1965 instructed what eventually became the CMS policy not to pay for services that were "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."[7] Although Congress determines the broad categories of services beneficiaries can receive—e.g., inpatient hospital services and durable medical equipment—CMS controls when to pay for specific items and services through its coverage process.

Operationally, coverage determinations are reserved for those services that are likely to have a major impact on cost or quality of care or when safety concerns arise. Most services provided in Medicare do not require a formal coverage determination.[8] One important reason is that Medicare's prospective payment systems for some providers—e.g., diagnosis-related groups for inpatient care and ambulatory service payment categories for outpatient hospital care—allow payment for incremental improvements relying on new technology.[9] In those cases, the recipient of the prospective payment assumes responsibility for deciding whether and how to provide specific services. In essence, the provider determines coverage within the constraints of the fixed prospective payment.[10] For example, pulse oximetry, a device that provides real-time information about the oxygen content of the blood and obviated the need for complicated blood tests with delayed feedback, was adopted rapidly by hospitals with no need for a coverage determination.

As noted previously, even for items bundled into a prospective payment system, CMS may choose to make a coverage determination for an individual service where there is a cost, quality or safety concern. As an illustration, lung-volume reduction surgery used for treating emphysema was initially used in some hospitals and paid for under a nonspecific billing code for multiple resections of the lung tissue. When evidence surfaced that the surgery might increase the risk of death, CMS initiated a formal coverage policy.[11] Other examples in recent years include implantable cardioverter defibrillators (ICDs), carotid artery stents and left ventricular assist devices. Still, only a small percentage of major new technologies are subject to explicit local or national coverage policies (described below).

### *Local Coverage*

Providers file claims through 14 local administrative contractors, which adjudicate them and often decide whether the items and services for which they are submitted are, in fact, eligible for payment.[12] As noted in the introduction, while CMS has

overall responsibility for determining which services to cover,[13] these regional, administrative contractors are commonly faced with making payment decisions that grant, limit or exclude items and services from Medicare on a day-by-day basis.[14] Depending on the service considered, local coverage determinations are made by the contractors with an evidence base that ranges from no evidence at all to peer-reviewed randomized controlled trials.[15] In addition, there has been considerable variation in local contractor coverage of services, although this variation may have been reduced as contractors have consolidated into fewer, regional administrators in recent years. While uneven coverage policies allow more rapid patient access and enable practitioners to gain experience with new technologies in some areas of the country, some argue that a national program should not allow significant geographic differences in which services beneficiaries can receive.[16] Whatever the merits of permitting geographic variation in coverage, Medicare's ability to establish scientifically based coverage of new technologies diminishes when they are considered ad hoc through local policy-making.

### *National Coverage*

CMS develops national coverage determinations (NCDs) on a relatively small subset of technologies. For example, CMS can initiate NCDs when there are particular concerns about technologies or services that may have significant quality or safety effects on the Medicare population, as was done when there were indications for increased mortality risk with the use of erythropoiesis-stimulating agents to promote red blood cell production in cancer patients. In addition, an individual or organization with a particular interest in a technology, including manufacturers, providers, beneficiaries and even Congress, may seek a policy to provide coverage nationally. For example, a manufacturer initiated the request to greatly expand the approved coverage of ICDs to include preventive use to protect patients from potentially fatal arrhythmias. Overall, the portfolio of topics that undergoes formal NCD review is a mixture of items and services for which there is no readily apparent programmatic or public health strategy. Over the past decade, CMS has issued 10 to 15 NCDs per year.[17]

CMS is required to use a formal and transparent process to make coverage determinations, with reliance on a review of the best available evidence about the effectiveness of the technology under consideration. It can also seek expert advice from the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC), which consists of 100 experts in medicine, biological and physical sciences, public health administration, patient advocacy, health care data and information management and analysis, health care economics, and medical ethics. CMS also convenes smaller groups of content experts for deliberation on specific topics.

Despite these procedures designed to improve CMS's ability to make informed decisions about the underlying value of a technology, researchers have found that most of the time, NCDs that contained a positive decision to provide coverage for a new service or new clinical indication for an established service were based on "fair" or "poor" evidence.[18] The reality is that CMS cannot simply defer a decision on technology while waiting for "good" or "excellent" evidence to be produced. In these cases, CMS staff has determined that the purported, potential benefits of proposed technologies and services to improve beneficiaries' health and well-being are adequate to support coverage even in the absence of satisfactory scientific evidence that the proposed technology works as claimed. This attitude stems in part from the desire to provide beneficiaries access to potentially beneficial technologies without the lengthy delays needed to design, fund and implement clinical studies after their regulatory approval. However, it sometimes derives from political pressure from affected stakeholders, such as device and drug manufactures, clinicians and patient advocacy groups.

The lack of high-quality evidence for making informed coverage decisions means that the vast majority of new technologies and services bypass any meaningful review. This is exacerbated by the absence of a coherent policy framework for activating the NCD process nationally. The relatively small number of issues that are addressed through NCDs do not reflect predefined policy priorities or public health objectives oriented to the core aim of improving population health. Further, the NCD process has only rarely been used proactively as a mechanism either to increase the use of high-value services that have been underused, such as when the CMS approved coverage of smoking cessation programs,[19] or to reduce the use of services that are obsolete or harmful, as in the case of an NCD that denied payment for wrong surgery or surgery on the wrong patient.[20]

In 2008, Medicare published a list of 20 technologies about which sufficient uncertainty existed, prompting CMS to consider a NCD review.[21] However, despite the substantial health and economic implications of the services identified on this list, action was taken on only a few items. Due to a lack of resources and changing leadership, the list has never been updated or expanded. Similarly, despite a few recent broad programmatic initiatives to promote the development and use of high-value innovations—including providing clearer guidance regarding coverage and payment for pharmacogenomic testing and initiating an effort to adopt a streamlined Food and Drug Administration (FDA)-CMS parallel review process (see box to the right)—these efforts have not signaled a sustained effort in any of these areas and there is little concrete evidence of positive impact.

### *Pricing for Covered Services*

Once an item or service is covered, the next step is to determine the appropriate price or method for reimbursement. The amount paid by Medicare for many services is determined by formulas that consider cost or resource use, meaning that CMS attempts to determine the average cost for provision of that service whether through prospective payment for an episode or fee-for-service-based retrospective payment for the actual services provided. CMS does not currently consider an item or service's relative effectiveness or its cost relative to alternative diagnostic and treatment options in its pricing. This would require a process involving considerations similar to that used in the coverage process. In short, with limited exceptions, Medicare currently does not factor a service's relative value to the program or to beneficiaries when setting provider prices.[22]

### *Conditions of Coverage*

When an NCD is published, rather than adopting universal coverage or denial of a service, CMS generally renders more nuanced judgments on coverage that place restrictions based on patient clinical characteristics and setting of care.[23] Coverage policy involves more than reviewing the rigor of the study design and granting a yes or no verdict. Rather, it means sifting through the multifaceted evidence base; balancing benefits and risks; and determining more finely when coverage is appropriate for which patients, under what conditions, and in what settings, with consideration of clinician expertise and facility requirements.[24]

This approach was pioneered in Medicare for solid organ transplantation in the 1970s.

## FDA-CMS Parallel Review

Over the past decade, individuals within the Department of Health and Human Services (HHS) and some advocacy organizations have observed that the federal government's processes for regulatory and reimbursement decision-making function independently of each other, and that this might lead to delays in the clinical adoption of some new health technologies, often because payment issues were not recognized until very late in the regulatory process or after the product had been approved by the FDA.[1] This has led them to explore the possibility of product developers working simultaneously with the FDA and CMS during clinical development.

Under consideration has been a voluntary FDA-CMS parallel review process, in which a Medicare national coverage review would be initiated while a specific technology is still undergoing regulatory review. The primary goal of parallel review is to shorten the total time required to complete FDA and CMS review, while ensuring that health technologies are acceptably safe and improve health outcomes for Medicare beneficiaries. A joint agency parallel review process could provide simultaneous marketing approval by the FDA and national coverage by CMS, with all relevant coding and payment issues identified and resolved during the review process. Another great potential benefit of this process would be the efficient use of the available clinical and scientific expertise available in both agencies.

In September 2010, CMS and the FDA issued a request for public comments on what products would be appropriate for parallel review by the two agencies, what procedures should be developed, how the parallel review process should be implemented, and other issues related to the effective operation of the process.

The comment period ended on December 16, 2010, and this input is currently under review. No specific timeline for future action on the parallel review process has been announced, though it is expected that one or more product developers may request that CMS and the FDA initiate an informal version of this process before any further formal plans are developed.

Conditions were set in three categories: patients had to meet certain clinical indications, only trained physicians were authorized to perform transplantations, and facilities had to be Medicare-approved and meet particular standards. For the most part, conditions on coverage did not expand beyond transplants until the late 1990s, when CMS added similar procedures to current transplant standards (ventricular assist devices in heart transplant facilities), required facilities to be Centers of Excellence (bariatric surgery), required specific facility accreditation (JCAHO accreditation for inserting ventricular assist devices), and established other Medicare-specific standards related to clinical indications and clinician and facility requirements (ICDs and carotid stenting).

Conditions of coverage have now become the norm. Of the 140 NCDs CMS completed between 1999 and 2007, it issued favorable decisions in 60 percent of the cases, almost always with specific conditions.[25] The new technology or procedure was covered without any restrictions or requirements in only 3 percent of coverage decisions. The following were the major conditions placed on favorable coverage decisions (not mutually exclusive): restricted to patients with defined disease severity (56 percent), coverage only within the context of clinical trials or other data collection (19 percent), diagnostic test restricted by specific test threshold (25 percent), restricted to patients who failed first-line therapy (19 percent), restricted to specified treatment regimen or interval (17 percent), restricted to patients receiving care in specific settings (17 percent), and other (16 percent). Between 2004 and 2007, fully 74 percent of favorable decisions were restricted to patients with defined clinical characteristics.

### *Deviations from Conditions*

Unfortunately, placing conditions on coverage does not guarantee that clinicians will actually adhere to those restrictions. A recent study measured use of services before and after the effective date of specific coverage decisions.[26] In seven of the eight cases, there were no measurable changes in use.[27] The study authors suggested that patients are receiving unapproved interventions that may not benefit them, but which come with a large cost to the program.

A more recent example involves

## Implantable Cardioverter Defibrillators

CMS's deliberation on the NCD for ICDs represents how technically and clinically complicated it can be to measure the value of coverage for the most expensive medical technologies. It is also a good example of how scientific uncertainty makes it very difficult to have an effective national discourse on such a topic. ICDs are indicated for patients with specific levels of heart failure and specific heart rhythm abnormalities and can be lifesaving. The cost to Medicare for implantation of the ICD is currently more than $40,000,[1] and about 100,000 are implanted annually.[1]

Before 2002, CMS had provided coverage for ICDs in patients who had survived a cardiac arrest, had an episode of ventricular fibrillation, had an inducible ventricular fibrillation, or had specific genetic abnormalities that placed them at high risk for sudden cardiac arrest. New evidence presented in 2002 suggested that an estimated 290,000 additional heart failure patients might benefit, leading Guidant, a manufacturer, to request that CMS expand its NCD to cover those patients. CMS chose to cover a smaller subgroup of heart failure patients: those with a wide "QRS complex" on the electrocardiogram who appeared to have the greatest benefit from ICD placement. This subgroup of patients was estimated at 90,000 of the 290,000 Guidant projected for eligibility. In 2005, additional data from another trial suggested a benefit in a larger group of patients, and CMS expanded its coverage to that larger group but required data collection to ensure only appropriate Medicare patients were being treated. Three ICD manufacturers—Guidant, Medtronic and St. Jude Medical—also agreed to assist in developing a registry of ICD users to expand the evidence base for future coverage of ICDs. Both these decisions were met with claims of "statistical homicide" and "rationing" from many sources.

The National Cardiovascular Data Registry ICD Registry's aim was to better identify subgroups of patients who would benefit most from ICD implantation. Efforts to secure sufficient funding to use the registry to conduct risk stratifications studies continued for more than four years, and the several million dollars needed to do this work has only been recently identified. Over this period, Medicare has spent between $10 billion and $15 billion on ICDs, without being able to obtain these vital data to inform coverage decisions. In a recent article using physician self-reports, Al-Khatib and colleagues[1] found that 25 percent of ICDs were implanted in patients who have contraindications to placements.

Medicare coverage of ICDs. As discussed in the previous text box, expanded coverage of ICDs was associated with use of Medicare's coverage with evidence development mechanism (discussed below), in this case with the establishment of the National Cardiovascular Data Registry ICD Registry. The availability of the registry permitted a recent study of the actual practice of ICD insertion compared with the recommendations in clinical guidelines. The study found that nearly 25 percent of ICDs were placed in patients who had contraindications to placement, according to the guidelines.[28]

In all likelihood, many insertions of the ICD also did not meet the conditions of the coverage, which was designed to protect patients from inappropriate use of a complex medical device with serious potential side effects. The study also found the rate of noncompliance with clinical criteria for ICD insertions has been increasing in recent years. Although there need to be exceptions to evidence-based criteria that allow physicians to individualize care to the particular circumstances of patients, the ICD experience reveals a broad disregard of coverage decisions at a large cost to the program. As noted, such behavior seems to represent the overall experience with current conditions of coverage.

CMS and the administrative contractors who review and pay claims lack the resources, clinically specific information and systems to ensure that conditions of coverage are actually followed. As a result, some beneficiaries receive services from which they do not benefit—along with the associated potential harms—at an excessive cost to the program.[29] In short, coverage with conditions could positively guide use to support the Triple Aim. However, because they can be simply ignored by clinicians, the approach falls short of its potential.

### *Prior Authorization*

Another potential approach that could help assure that patients receive appropriate care would be selective use of prior authorization for particular services. CMS has limited ability to review and recover payment that should not have been made when provided services were not appropriate and did not meet coverage conditions. Prior authorization would remove the need to deny payment after resources have already been committed.[30]

Yet, prior authorization has a mixed record of performance as administered by commercial insurers and has raised concerns about intrusion into care. If performed by Medicare, prior authorization should be narrowly applied and targeted to the application of technology and services that meet most or all of the following criteria: (1) have high unit cost; (2) are performed relatively infrequently; (3) are elective, such that the time to conduct the review would not affect patient outcomes; (4) rely on clinical judgment based largely on objective, validated and easily retrievable information; (5) have associated evidence of or reason to expect significant variations in use; and (6) would benefit from a review process to support quality as well as prudent use of resources.[31] As with the overall goal of Medicare coverage, the application of prior authorization would be based on the current, best scientific evidence.

Although questions have been raised about whether the Medicare statute provides a basis for prior authorization, CMS, in fact, engaged in prior authorization in the 1980s. Peer review organizations (now called quality improvement organizations) were required to perform prior authorization for 10 medical and surgical procedures, including cataract extractions and carotid endarterectomies.[32] The approach was abandoned because it was not successful, not because of lack of statutory authority. This earlier experience with prior authorization suggests the need for caution in adopting it as a way to improve the appropriate application of technology in Medicare.

Yet, the Medicare Payment Advisory Committee (MEDPAC) recently recommended the targeted use of prior authorization for office-based referrals for advanced imaging tests, relying in part on the reported success of the approach by commercial insurers in recent years.[33] Of note, the MEDPAC recommendations would apply prior authorization outside the coverage-making process for new services; the advanced imaging services to which it would apply prior authorization have long been covered for broad use in Medicare.

In summary, CMS routinely reviews available evidence as a guide to making coverage determinations and usually places restrictions on approved coverage based on patient characteristics or other factors. Yet, largely because of a lack of resources and systems, the clinical criteria accompanying coverage are often ignored by providers, sometimes to the detriment of patient well-being and at increased cost to the program. With additional resources, CMS and its administrative contractors could better monitor compliance with evidence-based coverage policies and be in a better position to implement additional approaches, such as selective application of prior

authorization, to permit more appropriate use of costly technical services.

### *Comparative Effectiveness Research*

Controversy continues around the role comparative effectiveness research (CER) should play in Medicare coverage and payment policy. The inclusion of funding for CER in both the American Recovery and Reinvestment Act of 2009 and the ACA encountered stiff opposition. Opponents argue that the use of CER could lead to rationing, and that federal funding might supplant private investment in clinical research. There was considerable push back to maintain patient and professional choice about treatment options. Some of the debate focused on whether and how often Medicare should use the information produced from federally funded comparative effectiveness research to deny coverage for its beneficiaries.[34]

Although CER has been variously defined,[35] most definitions recognize the following features:

- The research compares two or more alternatives.
- The focus is on relative effectiveness, or how alternative approaches work in practice, as opposed to relative efficacy, or how they work under ideal conditions.
- The goal is to produce findings that would help patients, clinicians, purchasers and policy-makers make informed decisions about health care choices, with the ultimate aim to improve patient outcomes.

The emphasis on producing findings that are relevant to decision-makers, including patients, clinicians and payers like Medicare, is a fundamental aspect of CER, implying the research should be useful for making sound coverage and payment policy, as well as other clinical and health policy decisions. As cited earlier, current Medicare coverage and payment policies are often made without strong evidence, often relying on a small number of poorly designed studies. Many studies lack any head-to-head comparisons with other treatment options and are conducted on too few patients or limited to too few centers or physicians to be able to draw valid conclusions that are generalizable to Medicare. Further, studies do not consistently examine the benefits and harms in a Medicare-relevant population.

As an illustration of how coverage policies are developed now, without evidence of comparative effectiveness, Medicare began paying for intensity modulated radiation therapy (IMRT) in 2002, essentially doubling prostate cancer treatment costs for those undergoing radiation therapy with little evidence about its relative effectiveness compared to existing standard care (brachytherapy).[36] Within six years, one-third of Medicare prostate cancer patients were receiving IMRT, and Medicare was spending approximately $1 billion a year on that therapeutic approach,[37] still without evidence of its comparative effectiveness. Recently, CMS opted to defer to local coverage policies rather than issue a national coverage determination on payment for a new alternative treatment, proton beam therapy. Once again, there was insufficient evidence on which to draw conclusions about its relative effectiveness[38] while, once more, treatment costs would potentially double.[39]

In another example, two high-quality randomized clinical trials were published in 2009 demonstrating that vertebroplasty for vertebral compression fractures (putting bone cement into a fractured vertebra through a skin incision to stabilize the spine) produced similar clinical outcomes to the simple local injection of anesthetic.[40] Such compelling results might reasonably have triggered a reconsideration of Medicare's existing policy on this procedure, which was essentially that regional administrative contractors could allow reimbursement for vertebroplasty with few restrictions. However, no such policy review was ever initiated, and the use of this procedure remains quite common in the Medicare program.

Patient-specific concerns have been raised that CER is oriented to producing evidence for an "average" patient, thereby neglecting important individual characteristics and patient preferences. However, in the prostate cancer example, CER could have helped Medicare better understand specific subsets of the population who might have benefited from IMRT, compared with the standard of brachytherapy. The agency considered restricting the use of the new technologies to those not likely to respond to brachytherapy but lacked the evidence basis to make this judgment. As physicians who own the radiation equipment stand to benefit financially from its use, there are strong incentives for inappropriate or overuse of IMRT, as has been recently reported.[41] Relevant comparative effectiveness research would also have provided information for physicians and patients to make better informed choices about which of the various treatment approaches to follow.

The ACA's establishment of the Patient-Centered Outcomes Research Institute (PCORI), which is devoted to CER, and the increased interest by the National Institutes of Health (NIH) to fund such studies offer the potential to support the types of research and infrastructure that could strengthen evidence-based coverage and payment policies within Medicare. Further, the ACA's statutory language does not prevent Medicare from considering CER studies generated by PCORI or other researchers for making coverage decisions, although it does impose some restrictions. Decision-making must be done in an "iterative and transparent process, that includes public comment and considers the effect on subpopulations" and cannot solely be based on CER results. Neither of these restrictions is inconsistent with the process Medicare currently uses for coverage decisions. Medicare is also prohibited from using results of CER in a manner that discounts the value of extending the lives of elderly or disabled persons relative to others, or uses a specific threshold for cost per quality-adjusted life year (QALY), a common metric in cost-effectiveness analysis.

Although Medicare would benefit greatly from relevant CER, the program's ability to influence CER priorities or the methods used in CER is limited. The agency does not have a seat on the PCORI Governing Board or Methodology Committee, which are charged with determining research priorities and methodological standards for CER, respectively. Clinical issues of importance to the elderly and disabled populations Medicare serves, especially related to chronic health conditions, appear to be inadequately emphasized by Governing Board members and external stakeholders called upon to voice their views about research priorities.

Medicare policy-makers face specific questions that timely and targeted CER could help answer, such as what is the relative benefit of using erythropoiesis-stimulating agents for chronic kidney disease or whether left ventricular assist devices should be used for "destination" therapy rather than as a bridge to heart transplants.[42] Yet, past efforts by CMS to influence NIH's research agenda to be more relevant to its needs and to the Triple Aim have not been consistently successful.

Currently, once FDA approval has been received, Medicare typically uses available evidence to make coverage policy. However, the available evidence often does not satisfy Medicare's expectations to help them make these decisions.[43] To generate the evidence desired to make these coverage decisions, studies done for regulatory approval should be designed to better address questions of importance to CMS. In addition, this type of evidence will sometimes be most appropriately collected under provisional coverage arrangements.

In short, CMS's coverage process has long been committed to thorough evaluation of available comparative effectiveness research. A major problem is that there are significant gaps in the available evidence bases, particularly as related to seniors and disabled beneficiaries in Medicare. A national commitment to CER could help fill evidence gaps to reduce the current overreliance on "fair" and "poor" evidence as the basis for CMS deciding whether to provide coverage for new services and new clinical indications for established services.

## Coverage with Evidence Development

Coverage with evidence development (CED) is a policy tool that links coverage of a technology with a requirement that patients receiving the service are enrolled in prospective clinical studies to inform future revisions to the coverage decision. The term was coined specifically for Medicare[44] but is now part of a growing array of options for insurers to share in the costs of data collection in order to support their collective interest in reducing uncertainty when making coverage decisions.[45] Under CED, Medicare reimbursement is contingent on a beneficiary's participation in a clinical study as part of a systematic data gathering exercise. Opponents argue that CED raises the threshold of evidence needed to obtain a positive coverage determination and slows access to medical advances. In face of the limited information on which Medicare now makes its coverage determinations, CED provides a mechanism for Medicare's views on study design to be considered in the development of clinical research protocols, such as ensuring the study enrolls a patient population reflective of Medicare beneficiaries or uses outcomes of relevance to Medicare beneficiaries.

CED remains a promising idea and its implementation has been done with great diligence, but there are still few unequivocally successful examples of CED leading to the generation of the type of relevant and reliable evidence originally envisioned. Although Medicare has applied CED in more than a dozen national coverage decisions in the past 15 years, data from the resultant studies have been used for policy in only two cases: for lung volume

reduction surgery to treat late-stage emphysema in 2003 and the use of positron emission tomography (PET) for cancer in 2009. In both cases, Medicare made positive coverage policies that have been viewed as more permissive than was justified by the evidence generated from the studies.[46] In many other cases, appropriate studies were never designed, funded or implemented for various reasons. In short, the promise of CED as a mechanism to support clinical research on urgent topics has not yet been realized.

### *Operational Problems*

Even when launched, many CED studies have had significant design flaws; received insufficient funding; lacked adequate data collection systems; or, for other reasons, have not produced the scientifically rigorous data needed to formulate sound coverage policy. For example, the National Oncologic PET Registry, which was developed to inform coverage policy on the use of fluorodeoxyglucose (FDG)-PET scans for diagnosing, staging and monitoring response to oncology treatment, relied on physician self-reports to determine whether the imaging changed their clinical approach to treatment practice. But physicians' financial interest in the study outcome may have influenced their behavior, undermining the value of the information gathered.[47] Some of these limitations are being addressed in the next generation of this registry, though there are no published results to date from this initiative. The National Cardiac Data Registry, which was developed to inform coverage policy on the appropriate use of ICDs, did not begin to gather critical data on device firing—a main outcome of interest for Medicare—until five years after the registry was launched.

The limited impact of CED as implemented by Medicare is not the result of inherent flaws in the concept of CED. Rather, the major barrier seems to be the absence of a clear statutory foundation for CED. A difficult aspect of using the "reasonable and necessary" authority to implement CED is that CMS decision memos have considered "reasonable and necessary" to mean that there is "adequate evidence to conclude that the item or service improves health outcomes."[48] If the purpose of CED is to generate that "adequate evidence," then the item or service cannot be reasonable and necessary under the standard statutory authority. Thus, Medicare currently relies upon the Agency for Healthcare Research and Quality's (AHRQ) legal authority to conduct research with respect to the outcomes, effectiveness and appropriateness of health care services and procedures for the Medicare population.[49]

Although CMS has issued guidance attempting to clarify the authorities for CED,[50] each application has involved much internal legal debate. Without a clear legal mandate to pursue CED, CMS's efforts have by necessity been ad hoc, with no formal process for selecting appropriate topics; little learning from one initiative to the next; and limited resources and lack of dedicated staff skilled in navigating the political and operational issues raised by CED, including CMS's ability to require provider and supplier compliance with CED reporting requirements. This experience has dampened CMS's enthusiasm for pursuing this policy tool, as it requires considerable staff time and resources just to get approval, resulting in the failure to apply the policy for technologies that would most benefit from additional study.

Another major barrier is the lack of resources for supporting studies the agency feels are important. Several CED policies have failed because NIH or other sources to support studies were not forthcoming in a timely fashion, if at all. Overcoming these limitations and creating a well-crafted, consistent policy framework is possible, but it will likely require senior-level policy support for CED in the HHS, specific statutory authority from Congress, and a dedicated funding stream to support the nonclinical costs of the research.[51]

Coverage with evidence development is a potentially important coverage tool in that it permits beneficiaries to receive services when evidence on effectiveness is lacking, while contributing to developing an adequate evidence base on which more definitive coverage decisions can be made subsequently. For practical reasons, the approach has not been effectively implemented. Perhaps most important is the need for a clear statutory foundation for coverage with evidence development.

## Costs and Cost-Effectiveness Analysis

Having the ability to somehow weigh costs in making coverage decisions is an area that is appealing to policy-makers. Clinical experts have suggested that sometimes new, expensive technologies offer little or no benefit to beneficiaries yet are very costly to Medicare.[52] For a program under fiscal pressure, even proven but limited benefits of a new technology may be viewed by some as insufficient to justify a large increase in spending.

The Medicare statute does not explicitly address costs, thus leaving room for ambiguity concerning legislative intent. While Medicare

currently does not formally consider costs in making coverage determinations, as a practical matter, costly new technologies receive comparatively greater scrutiny than other devices, procedures and services.[53]

In a recent example, the pivotal clinical trial of sipuleucel-T (Provenge) for use in hormone-refractory, metastatic prostate cancer demonstrated an improved survival of 4.1 months compared to placebo.[54] Studies comparing outcomes or side effects to other treatment alternatives have not been done. Yet, CMS reasonably undertook an NCD on this new therapy in early 2010 and convened a MEDCAC panel meeting in November 2010 to provide additional guidance. The panel suggested that evidence was sufficient to determine that sipuleucel-T was beneficial for its on-label use, but absence of evidence prevented it from drawing conclusions for off-label uses. In its final decision released on June 30, 2011, CMS affirmed the panel's recommendation.[55] Priced at $31,000 per treatment, with a usual course of three treatments, sipuleucel-T is one of the most expensive cancer therapies on the market. As is customary in NCDs, CMS did not consider the increased program costs as part of its evidence review.[56]

### *Failed Rule-Making*

Two administrations, one Republican and one Democrat, have proposed substantive rules that articulated how the agency would consider costs in the context of broader proposed rules that provided detailed guidance to the coverage process.[57] The first attempt to provide long-sought clarification of CMS's legal authority in the coverage area and to provide substantive criteria to guide how coverage would be made took place in proposed rules issued in 1989, as one of the last official acts of the Reagan administration. Those proposed rules described how cost-effectiveness analysis would be used in considering new items and services. They were criticized by some stakeholders, including the device manufacture industry trade association, as being the "foundation for rationing."[58] The final regulations were never issued.

A decade later in 2000, during the Clinton administration, CMS issued a notice of intent (NOI) to publish a proposed rule in which it did not mention cost-effectiveness per se, but the concept of "added value." The standards would have required that new technologies provide some benefit to beneficiaries beyond what was already available to them in the program. If a technology did not provide added value, Medicare would deny coverage. Clearly, considerations of the costs of alternative diagnosis and treatment modalities were being advanced as relevant to determining coverage. Again, a large number of negative comments on this notice of intent persuaded HHS and CMS to withdraw this proposal, and no further attempt has been made to address these issues through regulation.

In a number of ways, Congress has actually made CMS's interest in considering costs in coverage more difficult, suggesting that these occasional efforts to develop national policies that explicitly address costs or cost-effectiveness have in fact resulted in policy moving in the opposite direction.[59] For example, when CMS attempted to pay a single rate for products deemed "clinically equivalent," Congress expressly prohibited the agency from any future use of this equivalence standard involving payments to hospital outpatient departments. Given this record, both the Congressional Budget Office[60] and the Medicare Payment Advisory Commission[61] have recently asserted that regardless of legal interpretation of the current statute, CMS would require clear statutory authority to formally consider costs in its coverage policies.

That authority is unlikely to be given, at least in the short term. As discussed earlier, ACA prohibited Medicare from using a specific threshold for a cost per quality-adjusted life year, a standard technique in cost-effectiveness analyses, in making reimbursement and coverage decisions.[62] It also limited PCORI from determining cost-effectiveness using this technique.[63] In addition, limitations were placed on the ways comparative effectiveness research could be used.

A number of methodological issues make reliance on CEA using calculation of cost per QALY problematic for making coverage policy in Medicare.[64] There is controversy over how accurately QALYs reflect societal values around issues of distributive justice and equity[65] and about individual preferences for health care.[66] The National Institute for Health and Clinical Excellence (NICE), part of the National Health Service in the United Kingdom, does use thresholds of cost for QALYs to make coverage determinations. However, even then, NICE has established a 30-member citizens' council as a way to incorporate public views into its appraisal process to temper reliance on only the QALY calculation in some situations.[67]

NICE makes exceptions in certain cases, such as end-of-life care or care for small populations with incurable

illnesses, allowing for consideration of coverage where the cost per QALY exceeds the threshold range.[68] Further, the United Kingdom has recently proposed that future yes or no recommendations by NICE will not be strictly based on cost per QALY thresholds but will instead move toward value-based pricing.[69] For any application in Medicare, some suggest that formal CEA using QALYs should constitute one piece of data to inform decisions, but not to determine coverage. Countries other than the United Kingdom use CEA in this less formal, informational manner.[70]

Clearly, CMS is precluded from formal use of comparative effectiveness analysis, such as using approaches like calculating QALYs. Indeed, even the United Kingdom, which does formally use comparative effectiveness analysis in its coverage process, recognizes some limitations in relying solely on QALYs. The question for Medicare is whether costs should be considered in any way in the coverage process, recognizing that some new technologies or expanded application of existing technologies are very costly and provide little or no apparent benefit compared with other available diagnosis and treatment modalities.

## Least Costly Alternative as a Cost-Containment Strategy

As noted earlier, CMS generally does not attempt to factor an item or service's relative effectiveness or its cost compared to alternatives in setting the amount to be covered.[71] When CMS set the payment rate for a new anti-anemia drug equal to the rate for an existing drug on the grounds that the products were "functionally equivalent" in their clinical impact on patients, Congress expressly prohibited the agency from doing so.

However, local contractors have been highly selectively adjusting prices based on clinical effectiveness evidence for more than 15 years. This has been through their use of a least costly alternative (LCA) policy for certain types of items, including durable medical equipment and Part B drugs.[72] The policy's rationale is that Medicare, beneficiaries and taxpayers should not pay more for a service when a similar service can be used to treat the same condition and produce the same outcome at a lower cost.[73]

Using this reference pricing approach, Medicare contractors have not paid the added cost of a more expensive service if a clinically comparable one exists in particular categories of items and services. Examples include manual wheelchairs, power mobility devices, seat lift mechanisms, supplies for tracheostomy care and anti-androgen drugs for patients with advanced prostate cancer.[74] Beneficiaries are allowed to obtain the more costly item if they choose to pay the difference between the approved payment amount for the reference item and the amount for the one they choose.

There is no statutory provision giving specific authority or prohibiting the application of LCA. Again, CMS has considered the "reasonable and necessary" statutory language to provide the needed authority to adopt this approach for equivalent drugs and equipment. However, a recent court decision constrains Medicare's current use of LCA determinations. In a case involving LCA for inhalation drugs for asthma, the court found that because Congress did not specifically authorize LCA, CMS could not use its broad reasonable and necessary authority to do so for drugs.[75] In short, the court ruled that the specific payment policies contained in statute preempted the general statutory language on which it had been relying.

As a result of the court action, it appears that Medicare's administrative contractors have retired some LCA policies that were constraining spending, including the policy for paying the same for all anti-androgen drugs. As with the issue of whether CMS can consider costs in any way when making coverage determination, it appears again that the agency needs explicit legislative authority to engage in reference pricing policies such as LCA, at least for drugs. CMS has continued to apply LCA for durable medical equipment, which was not addressed in recent legislation.

### *Expanded Use of LCA*

In a recent paper, Pearson and Bach promoted an even more robust use of an LCA approach in Medicare.[76] In their proposal, after a suitable period needed for producing the requisite evidence, a service judged to be clinically comparable to its most relevant covered alternative would be assigned a payment level equal to the alternative. That is, rather than pay based on the actual cost plus a modest profit as Medicare does now, services with equivalent clinical effectiveness would be paid the reference price.

This proposal would go far beyond the LCA application CMS had been using until enjoined by the court, which involved very closely related products. The Pearson-Bach proposal goes further by considering certain interventions clinically equivalent even though they may be very different on a number of other

parameters, such as their mode of administration, biological mechanisms of action and patient preferences.

Continuing the example of prostate cancer, a longstanding alternative to anti-androgen drugs is orchiectomy, or removal of the testes to remove the production of androgens. Evidence suggests that this surgical approach is more effective than anti-androgen drugs with fewer side effects, and, if analyzed over a sufficiently long period, less costly.[77] Yet, while producing a comparable effect on reducing testosterone levels, the surgical removal of testes is obviously not equivalent to the use of drugs—certainly not from a patient perspective. Further, determining the pricing equivalence comparing a one-time, relatively high-unit cost service to a repetitive, lower-unit cost service would be quite challenging.

At the very least, a distinction would seem appropriate for different diagnostic and treatment modalities, such as surgery, chemotherapy, radiation therapy, etc., as the 2000 NOI proposed. However, extending the concept of equivalence, for example, to different drugs with the same biological effect but different routes or frequency of administration might also be a reasonable approach for application of LCA in cases where the pricing differences are substantial.

## Discussion and Recommendations

CMS has recently emphasized its programmatic Triple Aim as improving patients' experience of care, improving the health of a population and slowing the rise in per capita costs—an approach that reflects similar objectives inherent in the concept of value-based purchasing. Value-based purchasing emphasizes the desire to obtain higher quality with more prudent and, likely, lower spending.

To support value-based purchasing, Congress and CMS have emphasized measurement of provider performance and have begun to modify payment approaches to better align payment with demonstrated provider quality and efficiency. However, the leading cause of increased health spending[78]—adoption of new technology and increased use of existing technology—has not been a prominent focus of value-based purchasing initiatives, nor has there been any recent movement by Medicare to directly address the health effects or costs associated with the use of new technologies. In fact, Congress has occasionally challenged attempts by CMS to make coverage decisions based on a careful appraisal of available scientific evidence from peer-reviewed clinical journals, creating a very cautious environment at CMS. Further, CMS and its regional administrative contractors lack sufficient resources and will to appropriately implement the coverage decisions they do make.

As a result, some items and services that do not benefit Medicare patients are provided, often at high cost to the program, while other services that would improve patient health and well-being are underused, with no clear incentives to promote their adoption. The implication is that addressing some of the current programmatic deficiencies in coverage policy could improve care while reducing program spending.

ACA established the controversial Independent Payment Advisory Board (IPAB) to hold Medicare spending within legislated limits, with Congress required to either accept the board's proposals or come up with alternatives that achieve similar savings. If no legislative action is taken, the IPAB's recommendations would take effect.[79] Because of its specific legislative charter, policy analysts expect IPAB to focus mostly on payment rates and payment methods, not coverage policies and procedures. IPAB is specifically prohibited from making recommendations that would result in "rationing" of care, although the term is not defined in statute, and is also prohibited from making recommendations that would limit benefits. Some opponents of IPAB would surely argue that changes in how Medicare considers approval for coverage of new technology at least constitutes limiting benefits, if not overt rationing. In short, it is unlikely that IPAB, even if it survives current political efforts to prevent its creation, will play a significant role in supporting a stronger coverage process at CMS and the administrative contractors.

Nevertheless, Medicare's recent commitment to improving the patient experience of care and health outcomes at lower per capita cost could be more effectively supported through Medicare coverage policy by considering the following recommendations. These are organized based on their potential ability to improve the Medicare program and by the practical feasibility of adoption.

### *1. Improvements to the current CMS coverage policy approach*

CMS has become increasingly reluctant to use its existing "reasonable and necessary" statutory authority to make or modify national coverage decisions even when based on very high-quality evidence. The agency should seriously explore the policy and legal concerns behind this trend. As discussed earlier, even

when the agency had strong scientific evidence that casts doubt on the effectiveness of a technology or service to improve patient health and well-being, it did not move forward, partly because of a political environment that makes such evidence-based policy-making a target for affected stakeholders.

The MEDCAC could help CMS craft a more systematic approach to identifying topics for review as national coverage determinations. For CMS to become more active in reviewing technologies, it would be necessary to augment the size and expertise of the staff that conducts clinical and scientific reviews, most of whom are housed in the Coverage and Analysis Group. Additional resources would also be important to permit the agency and its contractors to monitor compliance with the clinical conditions described in local and national coverage decisions.

Selective use of prior authorization for high-cost items with demonstrated inappropriate use should also be considered as a way to improve adherence to evidence-based coverage conditions. If the additional resources were provided with accountability for their use, it is likely that the increased administrative costs would be more than offset with program savings resulting from reduction of services that do not benefit—or actually harm—Medicare beneficiaries.

Medicare could also use its existing coverage authority to more actively conduct national coverage reviews of new technologies that are likely to provide important health benefits for Medicare beneficiaries. While CMS took this approach with national coverage of smoking cessation therapy, there have been few other examples to date of specific high-value technologies being promoted through the coverage process, and no current policy strategy or mechanism exists to pursue this approach.

CMS should expand the use of national coverage decisions to actively promote adoption of high-value technologies that are underused, including interventions that may help reduce the need for costly subsequent interventions. CMS should seek opportunities to promote delivery system innovations that will be tested through the Center for Medicare and Medicaid Innovations that could be facilitated through NCDs on individual items and services that might be included in those demonstration programs.

With the advice of the MEDCAC, CMS could identify important needs and current gaps in services in the Medicare program to better support care for elderly and disabled beneficiaries, sending clear signals to product developers and providers about high-impact areas for investment to develop new products and services.

It would also be worth conducting a more careful review of the regional and local coverage process in order to identify how this critical aspect of Medicare coverage policy is conducted. Given the significant impact of these decisions and the uptake of new health care technologies, the effect of any proposed changes in national coverage policy will depend in part on a robust, consistent and evidence-based regional process with sufficient resources to monitor provider compliance.

### *2. Systematic approach to promoting high-priority research*

Medicare's ability to develop evidence-based coverage policy is severely restricted by its relatively limited capacity to ensure that its research priorities are weighed seriously in the allocation of public research funds. CMS has no budget to support clinical research. Additionally, the major public funders of research have little interest in ensuring that Medicare's programmatic needs are significant factors in the scientific review process.

CMS could make more deliberate use of the MEDCAC to help identify critical research priorities and then provide these recommendations to NIH, AHRQ, PCORI and private-sector research funders for consideration. Agencies within the federal government, including NIH in particular, should be more attentive to the practical needs of CMS for comparative effectiveness research relevant to the Medicare program. In addition to developing a process to articulate these research priorities, it will be necessary to establish HHS policies or other policy mechanisms to ensure that at least some CMS clinical research questions are given higher priority. Otherwise, the poor quality of evidence currently hampering Medicare's ability to make evidence-based clinical policy will continue.

### *3. New statutory authority*

Three specific statutory changes would contribute significantly to Medicare's ability to use the coverage process more effectively.

First, it would be useful to establish explicit legal authority that would allow CMS to apply "coverage with evidence development" to promising technologies that are particularly important to Medicare beneficiaries and require better evidence to answer important questions about their clinical effectiveness. The current authority is sufficiently ambiguous to prevent CMS from fully developing

and implementing coverage with evidence development consistently and systematically. The historical difficulty in addressing coverage policy through legislation and regulation suggests that statutory refinements will be challenging, though clearly critical to achieving essential programmatic goals.

Second, Congress should restore and expand Medicare's authority to apply LCA pricing to products that are similar in their biological and/or physical characteristics and that achieve comparable clinical outcomes.

Finally, statutory changes will be necessary to allow Medicare to explicitly consider costs as part of the national coverage process. This will almost certainly require explicit statutory authority, given the clear evidence that past efforts to accomplish this through regulatory action have been stymied. Consideration of costs should not be based on the formal cost-effectiveness analysis as embodied in QALY calculations. Instead, CMS should be allowed to deny coverage and/or reduce the pricing for technologies that provide health outcomes comparable to already covered, but less costly, technologies. More difficult to address will be technologies that provide small incremental benefits at significantly higher prices. In such cases, Congress may need to consider new pricing authorities for Medicare that allow CMS to link prices to incremental benefits. This approach will be necessary until payment reforms have been successfully implemented that create financial incentives for providers and/or patients to have some sensitivity to the relative benefits and costs of the technologies being used.

## Conclusion

As the Medicare program enters a new phase of rapid evolution following the passage of ACA, many new programs, demonstrations, pilots and policies are being pursued, all of which aim to improve the individual experience of care, improve the health of populations and reduce per capita costs of care. There is substantial room to improve the implementation of existing policy processes to achieve these aims, particularly with respect to Medicare coverage policy. Much can be achieved by more deliberate use of existing authorities and procedures, and further substantial gains would result from ACA's additional clarifications of CMS's authority. Although the main focus of Medicare reform has been to shift Medicare away from the underlying fee-for-service payment approach, significant benefits to the program and Medicare beneficiaries could also result from the improvements in CMS's activities in determining and implementing coverage of services that are recommended in this report.

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[72] Drugs that are not self-administrable or have been defined by Congress as drugs paid for under Medicare Part B. Coverage and payment systems for Part A, Part B and Part D drugs differ.

[73] *Report to the Congress: Aligning Incentives in Medicare*. Washington, DC: Medicare Payment Advisory Commission, 2010. www.medpac.gov/documents/Jun10_EntireReport.pdf.

[74] Ibid.

[75] A 2009 decision by the Court of Appeals affirmed the initial District Court's decision; CMS did not appeal further. Hays v. Sebelius, DC Circuit, 2009.

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