

Coverage Options For Promising Technologies: Medicare's 'Coverage With Evidence Development'

Medicare's CED program could reduce the logjam between innovation and evidence-based coverage policy.

by Sean R. Tunis and Steven D. Pearson

ABSTRACT: In April 2005 the Centers for Medicare and Medicaid Services (CMS) posted on its Web site a draft guidance document describing a new approach to coverage policy called "coverage with evidence development" (CED). CED offered an option for coverage of promising drugs, biologics, devices, diagnostics, and procedures that would not otherwise meet Medicare's evidentiary standards for being "reasonable and necessary." An updated guidance was posted 12 July 2006, clarifying several key statutory, regulatory, and operational issues. This paper traces the history of this policy approach, explains the rationale behind the policy, and describes the major challenges that will need to be addressed for CED to become an important advance in evidence-based coverage decision making. [*Health Affairs* 25, no. 5 (2006): 1218-1230; 10.1377/hlthaff.25.5.1218]

THE CHALLENGE OF MAKING COVERAGE DECISIONS for "promising" new medical tests and treatments, including biotechnology products, has long bedeviled insurers. The forces on the side of innovation, championed by patients and physicians and supported by manufacturers, have often conflicted with the demands for prudent use of resources and the principled arguments that coverage should be based on solid evidence of clinical effectiveness. In July 2006 the Centers for Medicare and Medicaid Services (CMS) posted on its Web site a revision of its April 2005 draft guidance document describing a new approach to coverage policy called "coverage with evidence development" (CED).¹ CED links

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Medicare coverage of specific promising technologies to a requirement that the patients participate in a registry or clinical trial. In the six months prior to the release of the draft guidance in 2005, this approach had been applied by the CMS to coverage of several biologics approved for colorectal cancer, implantable cardioverter-defibrillators (ICDs) for prevention of sudden cardiac death, and positron emission tomography (PET) scanning for patients with malignancies. The policy was framed as having a dual purpose: to assure at the time of service that care met the Medicare standard of being “reasonable and necessary” and, most notably, to provide the basis for longitudinal data collection that would ultimately “assist doctors and patients in better understanding the risks, benefits and costs of alternative diagnostic and treatment options.” CED offered a formal option for coverage of promising drugs, biologics, devices, diagnostics, and procedures that would not otherwise meet Medicare’s evidentiary standards for “reasonable and necessary.” The policy thus suggested one way to diminish the logjam between innovation and evidence-based medical policy—walking the fine line between competing visions of the role of evidence in coverage decision making by offering a third way between unlimited coverage and no coverage at all.

Although CED was not targeted to biotechnology products, its application to the off-label use of several biologics recently approved for treatment of colorectal cancer provoked intense public reaction, perhaps because the tension between the promise of technology and the perceived burden of evidence-based coverage policy was particularly vivid in the context of biotechnology and cancer. The prospect that Medicare coverage policy might limit clinical use of Food and Drug Administration (FDA)-approved biologics, or that Medicare might influence clinical research priorities through coverage policy, was of great concern to some product developers, professional organizations, and patient groups.²

But CED, while appearing to be a dramatic new development, has a long intellectual history both within and outside the CMS. This paper traces the development of CED; discusses its application to devices, procedures, and the new wave of biotechnology; identifies some recurring themes across all types of medical innovations; and discusses major ongoing challenges that will determine whether CED will remain an important feature of evidence-based coverage in the future.

Coverage Decisions And Evidence-Based Medicine

Health insurers, including Medicare, have long included a requirement that services within a covered benefit category must be medically necessary to be reimbursed. Over time, the concept of medical necessity became intertwined and often confused with benefit contract language that excluded coverage for “experimental or investigational” items, under the premise that health insurance was not intended to pay for care that had not passed FDA scrutiny or that was being provided in the context of research.³ The experimental and investigational coverage exclusions became virtually universal among public and commercial insurers.⁴

The tensions among evidentiary standards, experimental status, and coverage policy have become increasingly apparent as commercial insurers have moved rapidly toward a stronger emphasis on evidence from high-quality scientific studies and away from decisions based on expert opinion and community standards of care. In 1985 the Blue Cross Blue Shield Association (BCBSA) adopted criteria requiring that adequate scientific evidence be available to determine that a technology improves health outcomes. Other public and private payers, including Medicare, began to follow this approach to their interpretation of “medical necessity.”⁵

Although the intended result of applying rigorous principles of evidence in coverage decisions was to ensure that insurance payments were targeted to effective technologies, that outcome might not have been uniformly achieved. First, adoption of more rigorous evidence standards for coverage created a *de facto* double standard, in that new and emerging technologies were expected to meet evidentiary standards that were never applied to existing technologies; this became particularly awkward in attempts to interpret comparative trials that showed that a new technology produced similar results to existing alternatives for which no careful evaluation had been done. Second, although randomized controlled trials (RCTs) have proved technically and economically feasible for drugs and biologics, the practical implications of broadly applying the same evidentiary standards to medical devices, diagnostics, and procedures can be more challenging.

A third, and perhaps the most important, problem is that this evidence-based framework will usually exclude new technologies that have suggestive evidence of important benefits, but for which the quality of that evidence would not be considered “adequate” to justify coverage. This can be particularly problematic when a promising technology shows evidence of being a potential major clinical breakthrough, or of being highly cost-effective or even cost-saving. The increased adoption of the evidence-based medicine (EBM) framework without any reasonable way to accommodate promising technologies places payers between medical innovations and the patients and clinicians who want them. On the other hand, for health plans to retreat from the use of well-defined scientific standards in determining medical necessity would also not be ideal.

Linking Coverage To Clinical Research

Medicare, because it has a major role in public policy and is also a very large payer, has come under particular pressure to find ways to reconcile the tension between strict evidence-based coverage standards and being rapidly responsive to innovation and emerging technologies. The need to address this tension led to a series of coverage decisions over the past decade in which Medicare payment has been linked to a requirement for prospective data collection.

■ **National Emphysema Treatment Trial.** The first example of having Medicare coverage for a specific technology be linked to beneficiary enrollment in a clinical trial occurred in 1995 through a national coverage decision on lung volume reduc-

tion surgery (LVRS) for patients with severe emphysema.⁶ Noting enthusiastic adoption of this procedure in the absence of well-designed trials, Medicare and the National Institutes of Health (NIH) agreed to collaborate on the National Emphysema Treatment Trial (NETT), a seven-year RCT of 1,218 patients that compared the outcomes of comprehensive pulmonary rehabilitation with those of LVRS.

In support of this trial, Medicare issued a national coverage decision (NCD) that allowed payment for LVRS only for beneficiaries treated according to the NIH clinical trial protocol, explaining that this provided the assurance required to conclude that care was “reasonable and necessary.” Although this approach was unprecedented for Medicare, the CMS was probably aware of an earlier decision by several health plans to limit coverage for patients with advanced breast cancer undergoing high-dose chemotherapy with autologous bone marrow transplant to participation in clinical trials.⁷ Despite vigorous opposition from some members of Congress and provider representatives, the NETT was firmly supported by the NIH as well as by the American Thoracic Society and the American Lung Association, and this support was critical to allowing the study to go forward.

The study demonstrated that some patients were more likely to die if they underwent surgery rather than rehabilitation without surgery, while others achieved a slightly better quality of life or a small survival benefit from LVRS.⁸ Based on these results, Medicare revised its NCD to cover all patients who matched the characteristics of patients in the trial who experienced a survival or quality-of-life benefit.

The cost of conducting the NETT is not known with precision but has been estimated at about \$35 million for research costs and possibly \$100 million for the clinical costs paid by Medicare.⁹ The true incremental costs were probably much lower, since the clinical costs of caring for these severely ill patients in the absence of the trial would also have been high. Furthermore, findings appear to have greatly reduced clinicians’ and patients’ enthusiasm for the procedure: Although about 3,000 surgeries were done in 1996, only about 500 have been done since the coverage decision was expanded.¹⁰ Had the number of surgeries simply remained stable at about 3,000 per year, Medicare would have been paying about \$150 million annually for LVRS—more than the NETT’s aggregate clinical and research costs. Furthermore, without this trial (which presumably would not have been done without Medicare’s support), the true benefits and risks of LVRS would have remained unknown, thereby subjecting thousands of beneficiaries to unnecessary risks.

Medicare coverage of LVRS offered a model approach for addressing the simultaneous goals of rapid access to potentially high-impact technologies while also supporting their careful prospective evaluation. However, the experience also showed that these studies can be slow, expensive, and extremely complex politically, operationally, and scientifically. Perhaps for these reasons, the NETT model was not soon to be repeated, although the need to address the innovation/EBM

tension persisted, and Medicare continued to explore strategies to improve the quality of evidence for decision making through national coverage policy.

■ **Encouraging voluntary clinical research.** Beginning in 1999, Medicare began a series of major reforms to its procedures for developing coverage decisions.¹¹ Perhaps the single most important change was the development of written decision memos that provided a systematic review of the existing scientific evidence, along with a detailed description of why that evidence was or was not adequate to merit coverage. In part to maintain stakeholders' and political support for the recent reforms to the coverage process, the CMS chose in several cases to provide coverage for technologies supported by evidence that was marginally sufficient, while including specific statements in the decision memos that additional research would be desirable. In some cases, the decision memo indicated that the technology would be reviewed again in several years and that the agency would consider restricting coverage if no further evidence was produced.¹² However, the suggested research was never done, and the CMS did not pursue any effort to narrow coverage.

■ **Angioplasty of the carotid artery with stenting.** Recognizing the difficulty of encouraging product developers to conduct needed clinical research after obtaining Medicare coverage, the CMS explored additional mechanisms to support evidence development. Such an opportunity arose with another NIH clinical trial comparing two treatments for patients with carotid artery disease who were at high risk of stroke: balloon angioplasty plus carotid stenting versus carotid endarterectomy (the CREST trial). Medicare had no existing national coverage policy on carotid stenting but did have a national noncoverage policy in place for balloon angioplasty of the carotid artery, a procedure that was required for placement of the carotid stent. The carotid stent itself was eligible for coverage by Medicare under a policy that allowed coverage of certain investigational devices that the FDA considered to be refinements of existing approved devices.¹³ The CREST trial was able to go forward only after the CMS reconsidered the national noncoverage of balloon angioplasty, ultimately deciding that this procedure could be considered reasonable and necessary, and therefore covered, within the context of the CREST trial protocol.¹⁴

In the decision memo accompanying this policy change, the CMS articulated several key elements of the conceptual framework for CED: (1) The existing evidence had to be promising but insufficient to warrant unlimited coverage, (2) the potential population health benefit had to be significant, and (3) the research required to reduce the uncertainty would only be feasible with Medicare coverage.

■ **FDG-PET for suspected dementia.** The CMS applied the same basic rationale in deciding to provide limited coverage for fluorodeoxyglucose (FDG)-PET in the evaluation of patients with suspected dementia, although in this case, the technology under consideration was a low-risk (but expensive) diagnostic test. Medicare's original noncoverage for this use of FDG-PET was based on a decision analysis that showed that it would not provide net clinical benefit over standard neurological assessment.¹⁵ Because existing treatments are only modestly effective and have rela-

tively few serious side effects, the model concluded that treating patients based on clinical evaluation was a superior management strategy despite the fact that there was reasonably good evidence to show that FDG-PET was more accurate than clinical evaluation in diagnosing Alzheimer's disease.¹⁶ An expert panel convened by the National Institute on Aging also concluded that the evidence for the clinical utility of FDG-PET in the evaluation of dementia was promising but not conclusive and that well-designed real-world studies would be helpful.

Despite this assessment, the CMS faced sustained pressure for coverage of FDG-PET from product developers as well as from the clinical and patient communities.¹⁷ Given this complex landscape of factors—promising but not conclusive scientific evidence, a major burden of suffering for the Medicare population, and increasing demand from multiple stakeholders—Medicare reversed its non-coverage policy. The new policy allowed coverage for FDG-PET in evaluation of suspected dementia, with the requirement that patients receiving this test be enrolled in a “large practical clinical trial.”¹⁸

The primary intended purpose of the trial was to evaluate the short- and long-term impacts of the use of FDG-PET on the health and well-being of patients with suspected dementia, as well as on clinicians' and caregivers' decisions about the use of treatments and other diagnostic tests and the timing of changes in the setting of care.¹⁹ After extensive efforts over several years, a trial protocol has now been funded and deemed by the CMS to meet the requirements of the coverage decision. Given that broader coverage of FDG-PET for suspected dementia will not be in effect until a trial is under way, this example highlights the challenges of getting the necessary clinical research designed, funded, and implemented in a time frame consistent with the needs of clinicians, patients, and other decision-makers.

■ **Prophylactic use of the ICD.** The linkage of Medicare coverage to prospective data collection prompted limited public attention until this approach was applied to coverage of the ICD to prevent sudden cardiac death in high-risk patients. Major trials published in 2002 and 2005 demonstrated that hundreds of thousands of Medicare patients with cardiac dysfunction might be at high risk for sudden death and eligible for an ICD, at a potential cost of billions of dollars. Few technology issues in Medicare's history had comparable clinical and economic importance.²⁰

While published trials had led to broad consensus regarding the clinical benefit of ICDs in appropriately selected patients, there was also recognition that important questions remained about the benefits and risks in specific patient subgroups.²¹ Most notably, the clinical trials showed that only about 20 percent of implanted devices fired over four years of follow-up, and it was not yet possible to identify the majority of patients for whom the device was unlikely ever to fire. To address these and other remaining questions about the effectiveness of ICDs in real-world settings, Medicare issued an NCD that linked expanded coverage of ICDs to a requirement to submit data to a national data registry.²²

Medicare explained its primary motivation for mandatory participation in the ICD registry as supporting “the development of additional evidence that can help doctors and patients make more informed decisions.”²³ Yet the registry in fact was viewed as serving two functions: One was to use the registry data at the time of ICD implantation to ensure that patients met the clinical criteria in the NCD for appropriate use of ICDs; the second was to develop longitudinal outcome data to inform future clinical and coverage decisions.

The ICD registry experience highlights the tremendous complexity, but great potential value, of engaging a broad range of stakeholders in serious discussions about how best to develop evidence that will help clinicians, patients, and other decisionmakers. It would not have been possible to move forward with the CED policy on ICDs without the cooperation and financial support of the ICD manufacturers, which participated despite their reservations about the scientific value and business implications of the ICD registry. Also essential was the sustained support of the electrophysiology community, which supported the ICD registry primarily as a means to monitor and, they hoped, minimize procedure-related complications associated with ICD implantation. Private health insurers were also brought into the process and agreed to help fund the ICD registry and contribute ideas for what data elements would be useful for future coverage decisions.

■ **Off-label use of biologics approved for colorectal cancer.** Medicare had linked coverage to data collection for surgical procedures, devices, and diagnostic tests but had not yet applied this approach to an FDA-approved drug or biologic. One week after publication of the ICD coverage decision, Medicare finalized another NCD that linked coverage of off-label uses of drugs approved for colorectal cancer to the enrollment of patients in selected NCI-sponsored clinical trials. By law, Medicare is required to pay for FDA-approved uses of anticancer agents and for off-label uses listed in specified drug compendia, but the CMS has discretion regarding coverage of off-label uses not listed in these compendia. For these unlisted off-label uses, the NCD required coverage for patients enrolled in the NCI trials. The practical impact of this coverage policy has been questioned, given that the policy still allowed Medicare contractors to cover all off-label uses for patients not enrolled in the NCI trials; however, the policy impact of the decision was important because Medicare had not previously applied its national coverage authority to other biologic products or chemotherapeutic agents. The possibility that Medicare and other payers would begin using their coverage authority to restrict reimbursement of FDA-approved products prompted expressions of concern from the biotechnology community, as well as from some provider and patient groups.

Coverage With Evidence Development

■ **The April 2005 draft guidance: CED.** The combined effect of the ICD and colorectal cancer drug coverage decisions was to draw more attention to the frequency with which Medicare had chosen to link coverage decisions to prospective

clinical studies, and questions were raised about the rationale for this policy, how technologies were being selected for this approach, and the regulatory and legal basis. In response, Medicare developed a guidance document that was posted on its Web site 7 April 2005, in which the term “coverage with evidence development” was first publicly advanced.²⁴

In the draft guidance, the CMS was required to base its new CED policy upon its existing statutory authority. At the time of this first guidance, the only recognized statutory authority for linking coverage decisions to the collection of additional data was derived from Section 1862(a)(1)(A) of the Social Security Act, which states that Medicare may not provide payment for items and services unless they are “reasonable and necessary” for the treatment of illness or injury. This legal argument was asserted for the coverage policies on LVRS, carotid angioplasty, and FDG-PET for suspected dementia. Now that CED was going to be formalized as a policy tool, the CMS initially believed that this statute was the firm but narrow foundation upon which it would need to rest. Thus, as opposed to the language in the ICD coverage decision, which had stressed evidence development for future decision making, the 2005 CED draft guidance document emphasized that “the primary purpose of obtaining additional evidence through CED is for the agency’s use in making payment determinations, i.e., that a treatment is reasonable and necessary.”²⁵

To support its claim that extra data would be needed to decide whether a treatment was reasonable and necessary, the CMS presented two possible justifications: (1) The item or service was not reasonable and necessary unless the CMS could assure that it was provided in accordance with the clinical criteria specified within the NCD. Payments for inappropriate cases would be reviewed and potentially rescinded, making CED a method to assure appropriateness much like prior authorization functions among private insurers. (2) The additional oversight and other elements of human subject protections in clinical trials augmented the likelihood of clinical benefit. In other words, the argument was that participation in a federally sponsored clinical trial or long-term registry was by itself beneficial, raising the confidence in the clinical benefit to the patient, compared to receiving the item or service outside of these contexts. As the CMS said, “The additional care in clinical decision making and monitoring of the patient offers greater assurance that the benefits of receiving the service will exceed the risks.”²⁶ The validity of this justification emerging from the agency’s “reasonable and necessary” authority was challenged in a number of public comments on the draft guidance and in a detailed legal working paper.²⁷

■ **The July 2006 revised guidance: CAD and CSP.** As the CMS began to receive public comment on its April 2005 guidance and to work with stakeholders on implementing CED coverage decisions, the use of the single term “coverage with evidence development” to describe different situations and to reflect different goals proved complex and ultimately unsustainable. The public, likely responding to the

broader “secondary” goals of CED, has often understood the term to imply true longer-term evidence development through research as its major objective, while the CMS continued to emphasize its justification of CED as a short-term requirement to determine the appropriateness of the service at the time it was delivered.

After extensive input from the public, industry, and other stakeholders, the CMS released a revised version of the CED guidance document on 12 July 2006, more than a year after the earlier version. In the July 2006 guidance, the CMS clarified and separated the two different elements that had been entwined in the CED concept and presented an expanded statutory justification for each.

The new guidance made clear that CED included the function of gathering data to assure that an item or service was only being provided appropriately according to the clinical criteria specified in the coverage decision. This subtype of CED was newly labeled “coverage with appropriateness determination” (CAD), and its statutory foundation was reaffirmed as existing within the previously acknowledged 1862(a)(1)(A) provisions. Thus, with ICDs as a clear example, the requirement for additional data at the time of implantation could be seen as CAD, assuring that payment was made only when the service was provided to patients who had appropriate clinical indications.

The July 2006 guidance also provided a new name for the other subtype of the original CED concept. “Coverage with study participation” (CSP) was the term applied to those situations in which the evidence for an item or service was not adequate to meet 1862(a)(1)(A) standards but would be deemed reasonable and necessary if the patient was enrolled in a clinical study that would ultimately provide reliable evidence of the health benefits and risks of the item or service. The statutory authority for CSP is derived from 1862(a)(1)(E), a section of the Medicare statute created at the time of the founding of the Agency for Healthcare Research and Quality (AHRQ) that allows Medicare payment for items or services provided in studies determined by AHRQ to reflect the research needs and priorities of the Medicare program.

The July 2006 guidance thus addressed one of the key issues that had complicated the development and application of CED. CAD and CSP were presented as distinct subtypes of CED, with different goals, methods, and statutory authorities. The posting of the revised CED guidance reflects a sustained commitment on the part of the CMS to improving evidence for decision making while expediting access to promising technologies, and a clear statement that the agency believes that it has sufficient statutory authority to pursue these goals through the development of national coverage policies.

Challenges For Linking Coverage To Clinical Research

If the approach of linking coverage to prospective data collection is to achieve its stated goals, several ongoing challenges will need to be addressed.

■ **Clarifying standards of evidence.** First, the justification for CED rests on

greater clarification of the evidentiary standards used by coverage decisionmakers. In general, for CED to be justified, a given technology must fall between two clearly defined standards of evidence. The first standard is an “upper” standard for the strength of evidence, which, when attained, meets the standard for unlimited coverage. Technologies being considered for CED must fall below this standard. But there is also a corresponding lower standard of evidence below which a technology’s risks and benefits should be judged too uncertain for coverage at all, even under CED. The appropriate application of CED thus requires that an evidentiary “middle ground” be identified. Technologies whose supporting evidence falls into this category, making them eligible for CED, can be selected reliably only when clear evidentiary boundaries, both above and below, are presented in a transparent manner.

■ **Establishing a priority-setting process.** Second, it will be necessary to carefully establish criteria with which to identify technologies that are of the highest priority for application of the CED policy. Medicare’s approach to date has been somewhat ad hoc, reflecting to a large degree the technologies that happen to be under review for national coverage, which is not determined through a systematic priority-setting process. However, given the expense and effort involved in conducting prospective studies through CED, it will be important to have a robust approach to ensure that technologies are selected based on the quality of existing evidence, potential for reducing the burden of suffering for Medicare beneficiaries, and potential to produce savings for the program.

■ **Improving the quality of evidence.** Third, public comments on the draft guidance document on CED highlight the concern among some stakeholders that this approach will inhibit access to important new technologies and might create new uncertainties that reduce capital investments in health care technology innovation.²⁸ It is clear that various stakeholders have different views about which technologies require further study, what sorts of questions require answers, and what methods are necessary to answer those questions. It seems extremely important to maintain a clear focus on designing CED to improve the quality of evidence available to patients and clinicians in making health care decisions. This perspective will be necessary to ensure that CED fulfills its potential but will be a serious challenge, given the inevitability that this perspective will conflict with the interests and beliefs of other powerful stakeholders.

■ **Overcoming ethical concerns.** A fourth challenge to the linkage of coverage and research is posed by ethical concerns. The Office of Human Research Protection (OHRP), in its role as monitor of protection of human subjects in federally sponsored research, has argued that the CED project should be subject to the same regulatory requirements as all other clinical research, even when these technologies are already approved by the FDA and readily available for clinical use (except to the extent that their use is inhibited by lack of reimbursement). Some policymakers, patient groups, and other stakeholders have also questioned the ethics of the entire CED approach by suggesting that it is coercive to link insurance coverage to require-

ments for participation in patient registries and clinical trials. Future clarification of the two separate strands within CED, and the formal linkage of one of these strands to a new statutory authority that allows payment for research, might settle some of the questions related to the appropriate role of protecting human subjects in the context of CED. The concern about coercion may be mollified by new guidance delineating the CMS's evidentiary standards for CED, making clear that CED expands insurance coverage for new technologies that would not otherwise be available. However, the existing understandings of requirements for patients' participation in research and the appropriate models of informed consent for that research will likely continue to create tensions as innovative efforts look for new and better ways to gather evidence following introduction of new technologies.

■ **Funding and managing CED projects for the long term.** The fifth and perhaps most significant challenge will be operational and financial. Doing this right is likely to require substantial and sustainable funding, and to attract such funding from public or private resources (or both), it will probably be necessary to establish some organization with the scientific credibility, political independence, and technical expertise to manage these projects successfully and efficiently.²⁹

■ **Additional challenges.** In addition to the complex set of challenges described above, many other complex issues will need to be addressed, including the development of adequate and efficient methods to answer the research questions identified; how to ensure that adoption of health information technology supports the development of better evidence in routine practice; and how issues of privacy and informed consent will be balanced with the need to rapidly learn about the risks, benefits, and costs of new technologies.³⁰ The recently established Institute of Medicine Roundtable on Evidence-based Medicine will be addressing some of these issues, and a newly established foundation-funded Center for Medical Technology Policy is bringing together decisionmakers with other experts and stakeholders to develop efficient and reliable methods and strategies to conduct real-world evaluations of new health care technologies. The approach of linking coverage to requirements for data collection have been proposed in Australia and the United Kingdom, and many of the technical, strategic, and scientific issues might be constructively explored through international collaboration.³¹

THE CHALLENGE OF BALANCING THE DEMANDS for access to innovative new technologies with the need to establish clinical benefit, document risks, and spend prudently remains an important policy issue. The approach of linking coverage of these promising technologies to prospective data collection continues to face major challenges. However, Medicare and perhaps soon private payers in health care are likely to continue exploring the policy approach. It is unlikely to have a major impact until a more comprehensive and systematic policy approach is developed, although Medicare's efforts to advance this policy mechanism have triggered considerable discussion about how best to bal-

ance evidence-based decision making with rapid access to promising innovation.

It is unlikely that CED, or any other application of evidence-based decision making, will have much of an independent effect on health care spending trends. However, to the extent that CED provides a pathway for more rapid adoption of promising and high-value technologies and a mechanism by which better evidence about technologies is gathered over time, it will allow patients, clinicians, payers, and other decisionmakers to make better-informed choices about the relative value of alternative technologies as reforms to health insurance and financing make these economic trade-offs increasingly important.

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