ISSUE BRIEF

Coverage with Evidence Development (CED) in the Private Sector: Lessons in Design and Implementation

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INTRODUCTION

Patients, physicians, and health insurers are often faced with difficult decisions about the use of medical treatments that are considered "promising" but still lack important information about risks, benefits, and comparison to existing therapies. For most new treatments, substantial questions exist about their best use for many years after they are introduced, but the incentive to study whether a medical treatment works for a specific indication, for whom, and as compared to alternative options is substantially reduced once a health insurer has decided to pay for the treatment. Coverage with Evidence Development (CED) is a policy tool for health plans to offer provisional coverage for a promising but unproven intervention while data are being collected to generate the evidence needed to inform coverage and payment policy.

Previously, under a grant from the California HealthCare Foundation (CHCF), the Center for Medical Technology Policy (CMTP) identified key issues and developed benefit language for private plans that were interested in developing CED initiatives. For the current CHCF funded project, CMTP assembled a multi-stakeholder workgroup of representatives from private health plans, self-insured employers, patients, clinicians, researchers, and others to design a feasible research and implementation plan for a multi-payer collaborative CED project. This issue brief focuses on lessons learned based on the current project, prior work by CMTP[1], and the experience of other countries in implementing CED.[2] These insights focus on three major aspects of CED:

1) priority-setting and topic selection
2) stakeholder engagement in research design and implementation
3) operational/implementation challenges

SECTION 1: Priority-setting and Topic Selection

In order to select an appropriate technology for the CED pilot study, CMTP developed a structured process for identifying, assessing, and ranking medical technologies not widely disseminated or covered by private payers. CMTP elected to focus this pilot effort on technologies addressing cardiac disease, due to its significant disease burden and rapid proliferation of promising but costly technologies. Because there is often high demand from clinicians and patients for these emerging technologies, payers are subjected to significant pressure to cover them, often before they have been fully evaluated in clinical trials. In addition, these interventions may be good candidates for CED because they often have short term, measurable outcomes that can be largely attributed to a single technology. An initial list of candidate cardiac technologies was generated through a review of horizon-scanning literature and recent technology assessments, nominations by external stakeholders, and the

[1] CMTP Issue Brief - Coverage for Evidence Development: A Conceptual Framework. January 2009. www.cmtpnet.org

[2] Mohr PE, Tunis SR. Access with evidence development: the US experience. *Pharmacoeconomics*. 2010;28(2):153-62.

identification of technologies failing to receive widespread favorable coverage decisions via searches of available online databases of coverage decisions/clinical policy bulletins as well as suggestions by contacts at a number of health plans. Technologies were evaluated against a set of criteria generated by the workgroup in CMTP's previous CHCF-funded work.[3] These were then further refined by CMTP staff and consultants after additional research into priority-setting criteria and processes used by other health technology research organizations, including the Agency for Healthcare Research and Quality (AHRQ), the Centers for Medicare and Medicaid Services (CMS), the Canadian Agency for Drugs and Technologies in Health (CADTH), and the California Technology Assessment Forum (CTAF). These criteria included considerations of:

- the potential clinical benefit (both net benefit and benefit to individual patients)
- the state of current clinical evidence
- cost-effectiveness
- potential for unregulated diffusion
- demand for the technology within the health care community and
- feasibility of study design

Based on these criteria, CMTP staff narrowed an initial list of approximately 40 cardiac technologies to a list of ten. CMTP then convened a 6-person priority setting workgroup consisting of cardiologists, researchers, payers, and patient advocates. CMTP developed technology briefs for each of the ten candidate technologies for workgroup members to review prior to ranking the technologies. These briefs provided clinical and population health overviews of each technology, as well as details of the technology and alternatives, both clinical and cost-effectiveness information, and the current status of evidence and coverage for the technology. CMTP elected to use a combination of group decision-making techniques, such as the Delphi method[4] and nominal group technique[5] to prioritize the topics. To achieve this goal, the workgroup reviewed and ranked each of the ten technologies against the pre-determined set of criteria via a web-based survey and were then given the de-identified group results (Delphi method). The group then convened in-person to discuss each technology, including the reason for considering the topic to be high or low priority (nominal group methods). At the end of the meeting, workgroup members were asked to rank the topics in order of importance for CED, and a relatively high degree of consensus emerged.

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[3] CMTP Issue Brief - Coverage for Evidence Development: A Conceptual Framework. January 2009. www.cmtpnet.org

[4] **Delphi Method:** Participants are involved in an iterative process of responding to mail questionnaires and receiving feedback about the group's responses (and their own initial judgment). This process may be repeated several times, and the responses are aggregated and sometimes weighted for different levels of expertise. Participants do not interact directly. This method is relatively low cost, but it lacks the potential benefits of face-to-face interactions and exchanges of information.

[5] **Nominal Group Technique:** Initially developed for committee decision-making. The primary objective of this approach is to structure the group interaction by having each individual record his/her ideas independently, presenting each idea in a round-robin format, and discussing each idea in turn by the group. Additional discussion and/or voting may take place. This technique has the advantages of allowing all ideas to be presented and of potentially minimizing individuals' inhibition about sharing ideas.

The top three technologies identified through this process were:

1. catheter ablation for atrial fibrillation
2. genotype testing to guide initial warfarin dosing
3. percutaneous aortic valve replacement

The workgroup ultimately selected the "genotype testing to guide initial warfarin dosing" as the topic most appropriate for this CED project.

Based on this experience, CMTP identified a number of specific recommendations for priority-setting and topic selection for CED projects in the future.

- **Decision-maker input**: It is essential to utilize the input of decision-makers (i.e. end users of evidence like patients/patient advocates, providers, and payers) to identify potential topics for CED. These groups have unparalleled insight into the practical uses of emerging technologies, and their perspective is vital to identifying important unanswered questions about their use and diffusion. In particular, representatives from health plans can identify topics that generate the most pressure for coverage and are of the greatest interest to their organizations, and thus most likely to motivate participation in a CED study. In our project, payers, physicians and patients had a significant impact on the selection of a study topic.
- **Selection of patient/patient advocate participants**: In our workgroup, we had the input of one patient participant, but became quickly aware that it would have been preferable to have two participants to more broadly represent this critical stakeholder perspective.[6] Additionally, we recommend that at least one (if not both) of those patient representatives should be closely associated with a patient advocacy group in the disease area, so that they can draw upon the resources of their organization to present a well-rounded perspective of the spectrum of patients that might be affected by the technologies under review.
- **Scoping priority-setting efforts**: Our experience in priority setting in cardiology suggests that it would be very difficult to have a meaningful process if the range of technologies and conditions is overly broad. We believe that it is more manageable to start by selecting a disease condition (i.e. cardiology, oncology, etc.) in order to be able to engage relevant clinicians, researchers and patient advocates with sufficient knowledge of the topics being discussed. Additionally, even if focusing on a single disease condition, consider technologies for a range of "decision points", including screening, diagnostic, and treatment technologies.
- **CED specific criteria:** While there are a number of general criteria that might be common in any priority-setting project (i.e., the technology has a potentially large clinical benefit), it is important to ensure that workgroup members take into account priority-setting criteria that would be more specific to a technology that would be studied through CED.

[6] See "Patient and Consumer Engagement" in Section 2 of this issue brief for further discussion.

These criteria include:

- The technology is or is likely soon to be FDA approved.
- The technology is not the sole treatment for a life-threatening condition.
- There is great potential for widespread or highly varied dissemination with little evidence of clinical benefit.
- Payers are facing or are likely to face in the near future high demand for the technology
- The technology is discrete and has (or can be given) a unique billing code that can be used to determine when the technology is used, allowing the payer to accurately track its use during the study.

- **Use of technology briefs:** Workgroup members agreed that the technology briefs provided to them by CMTP were valuable in helping them prepare for the topic selection process. We recommend creating concise, relevant summaries of each technology for those involved in the technology prioritization process. We also prepared "consumer-friendly" versions of the briefs for use in final topic selection.[7] Because of different levels of technical expertise among the workgroup members, these simplified versions were helpful to the patient advocates.

- **Priority-setting methods**: While there are a wide range of options for priority-setting, including modeling techniques (i.e. expected value of information) and more informal public consensus forums, we recommend methods that engage multiple expert stakeholders, particularly end-users of these technologies. A combination of Delphi and nominal group techniques provides distinct advantages. The use of a pre-meeting independent survey ranking allows participants to set down their initial thoughts independently, and returning an aggregate of the rankings allows them to understand the overall group consensus without initially having to worry about dealing with strong personalities and differing opinions. However, we have found that while the Delphi surveys allow participants to formulate initial, personal opinions based on their experiences and stakeholder perspectives, holding an in-person meeting also provides valuable input into the topic selection process. Having workgroup members interact with each other provides a more complete picture of how each technology is or may be used in clinical practice, particularly with the participation of clinicians who are familiar with the technology, and often leads to different rankings by the end of the meeting. Participants at these in-person meetings have acknowledged that they gained valuable insight and knowledge on technologies from other participants, and that they felt more confident in the accuracy and comprehensiveness of their rankings post-meeting.

[7] Technology briefs available upon request to CMTP.

SECTION 2: Stakeholder Engagement

The engagement of stakeholders representing all relevant perspectives was extremely informative in our efforts to design and implement this CED project. End-users of evidence generated by a CED project- that is, payers who use evidence to make final coverage decisions, and providers and patients who use evidence to make clinical decisions- provide unique insights into the process of selecting the most appropriate technologies for a CED program. Their participation is also useful in identifying elements of the study design that would answer their key research questions and would be realistic in regard to patient accrual in the study. Throughout all stages of this project, the Center for Medical Technology Policy elicited input from patients, consumers, providers, payers (both public and private), employers, clinical researchers, government funders, and legal authorities. A number of preliminary insights derived from this experience (as well as other CMTP projects involving stakeholder engagement[8]) are listed below:

- **Balancing perspectives**: While certain stakeholder groups will be more difficult to recruit (in our experience, patient/consumer and employer representatives), it is important to ensure that a balance of perspectives is engaged from project initiation. At least two representatives from each stakeholder group should be included, and all representatives should feel sufficiently prepared to participate, which may involve the preparation of tailored materials before any group discussions.

- **Patient and consumer engagement**: Effective patient engagement is of particular importance, as other stakeholder groups will tend to dominate discussions, particularly when the material is highly complex from a clinical or technical perspective. It is especially important to ensure that more than one patient or consumer representative is present, as being significantly outnumbered by clinicians and others in a stakeholder group, may cause the patient to be reluctant to speak freely and openly. CMTP has found that it is preferable to find several public representatives, including patients, consumers, and general advocates with good background on the topic, so they can participate with the rest of the workgroup in detailed discussions of elements of research (i.e. inclusion/exclusion criteria, outcomes, topic selection). These individuals often work for formal patient advocacy groups that interact with clinical researchers on a regular basis. Including a patient with the disease and/or experience with participating in a clinical trial can bring a more informed viewpoint to the discussion. For example, patient representatives were particularly influential as the multi-stakeholder workgroup decided to use direct clinical endpoints like bleeding events for a warfarin trial, rather than INR score or other common indirect endpoints for research on this topic.

[8] *Unpublished manuscript*. Hoffman A, Montgomery R, Aubry W. Stakeholder Engagement in Comparative Effectiveness Research: Lessons from the Field.

- **Achieving stakeholder commitment**: CED is a relatively new and still-evolving concept. Stakeholders who have never been involved in the development of a CED program (or the design of a decision-maker driven research study) may not understand why they should participate, or why their perspectives are a significant and valuable contribution to the program. The key to commitment from all desired participants is reaching an understanding of the common purpose behind a CED program and the rationale for the involvement of stakeholders. It is helpful for a neutral party to lead this dialogue with participants in the stakeholder group so that they understand that the ultimate goal of their participation is to create a conditional coverage program to generate new evidence that meets the information needs of decision-makers. CMTP has played that role as neutral facilitator, but there are other entities that could also be effective.

- **Discussion-based stakeholder meetings**: The goal of stakeholder engagement is to engage a variety of perspectives and identify and resolve topics that produce conflicting views – a good facilitator can help draw out discussion from participants who are reluctant to speak, and allow researchers and CED program designers to listen more closely to the needs and views of all involved stakeholders. Meetings should be as discussion-based as possible, keeping didactic presentations to a minimum. Different stakeholder groups will have some conflicting viewpoints, which are important to acknowledge and sufficiently work though (possibly via smaller breakout groups) in order to move forward with any CED program. For example, we have found that stakeholders will have different views about how stringent the evidentiary threshold of coverage should be once the results of the CED study are available. Many health plans have expressed concerns that CED will lower the evidentiary bar for coverage without producing the robust information needed to make coverage decisions that are consistent with evidence required for other technologies not subjected to CED. In contrast, industry and patient representatives are concerned that involving health plans in the selection of the CED study design will mean that the study will be too rigorous, costly, and take more time, slowing the development of products and patient access to them. Differing views such as these have to be acknowledged and can only be resolved with a balanced proportion of stakeholder involvement.

- **Achieving ongoing stakeholder participation**: The design and implementation of a CED program can be lengthy and although there are many steps to the process, not all stakeholders need to be involved in every step. Nonetheless, it is important to ensure that all participants are informed of progress and have an opportunity to give input if needed. This can be done via periodic email updates, or through other means of communication. Stakeholders should also be encouraged to communicate among themselves outside of formal group meetings- with the exception of multi-payer communications that risk violating antitrust laws.

SECTION 3: Operational/Implementation Challenges

CMTP has also addressed a number of important operational and implementation issues that may be encountered when designing a collaborative CED initiative in the private sector.

- **Antitrust concerns**:
    - There are a number of antitrust related issues that must be addressed as any CED study moves forward with multiple private payer organizations. Particular issues to address include questions of what information can be shared (such as scientific information regarding the technology) and discussed by each plan, what decisions must be made independently, and what steps must be taken to ensure that multi-payer discussions are pre-decisional and recognized as such. Essentially, antitrust laws exist to prohibit anti-competitive behavior among competing entities, which in this context can include discussions or agreements related to coverage decisions, pricing, premiums, discounts, reimbursement to providers, etc. However, legal experts have stated that multi-payer CED programs do not raise complex antitrust issues, as long as the private health plans do not discuss the above issues together or have any undocumented discussions among themselves independently of official meetings that are moderated by a neutral body. It is also recommended that each health plan ensure that their own in-house legal counsel is kept up-to-date of all proceedings and provides legal advice to each plan as needed to ensure compliance with antitrust laws. If some of the private plans deem it necessary, the organizing body can request a formal review by the antitrust division of the Department of Justice, although this is likely to be a 6 month process.

- **Additional regulatory requirements**:
    - There are a number of issues to address in this area, including compliance with state laws surrounding coverage of qualifying clinical trials, compliance with the regulations and procedures related to state independent medical review laws, and notification of the state insurance commissioner's office, if required.
    - Health plans will need a procedure code to identify the CED service, and it may be necessary to obtain a new category 1 or new category 3 Current Procedural Terminology (CPT) code from the American Medical Association's CPT Editorial Panel (possibly with the help of CMS or BCBSA) if the selected technology does not have one for an appropriate CED study. In our experience with large health plans, it was noted that including only self-insured products would eliminate the need for lengthy and complicated state insurance commissioner notification and approval, but there would be other issues related to the Employee Retirement Income Security Act (ERISA) plans,[9] because employers that are self-insured are allowed under ERISA

[9] **ERISA plans:** The Employee Retirement Income Security Act of 1974 establishes minimum standards for non-government, private employer-sponsored health insurance coverage and other benefit plans. ERISA does not require employers to offer plans; it only sets rules for benefits, including conduct for managed care, reporting, accountability, and disclosures.

regulations to make certain independent decisions about coverage not subject to state approval.

- **Selection of benefit designs**:
  - There are a number of coverage model options outlined in our prior Issue Brief,[10] including: 1) adding language to the current "Experimental and Investigational" exclusion language, 2) using extra-contractual payments, and 3) creating a supplement to existing clinical trial language. Plans will generally prefer to create CED programs that are implemented outside of coverage language (as an extra-contractual benefit or special program).
  - Plans are required to have "Evidence of Coverage" (EOC) documents for their fully insured populations. As such, the plans generate their own language for insured products but are required to submit the language for approval to state regulators, which can take a significant amount of time. Self-insured clients can generate their own evidence of coverage documents because ERISA status is not subject to state regulation.
  - Large self-funded employers with a high percentage of union employees pose a unique situation if the CED program is created as a type of benefit. In these situations, coverage for the technology might be subject to union negotiations even if evidence from a study indicates that the health plans should not cover the technology. Thus, it might be difficult to discontinue or revoke coverage based on CED findings if the union wished to retain it. As such, each employer group under a health plan would have to individually agree to join the CED project, and agree to abide by the decision reached by the plan based on the results of the CED study. To comply with federal antitrust laws, a neutral multi-stakeholder planning committee should determine when the study is going to be concluded, and each plan would then make an independent decision about how to interpret and use the data for coverage decisions. Because of these complexities with union plans, health plans would be more likely to implement early CED projects with their self-funded, non-unionized clients, until the experience and clinical research under these programs becomes more attractive to insured and union clients.
  - Aetna has implemented programs (and called them 'programs' not 'benefits') where they offer weight scales under disease management programs and other types of research programs, thus providing a benefit through an extra-contractual payment mechanism.
  - Other problems identified in working with fully insured plans include the need to file a new Evidence of Coverage (EOC) certificate with the state insurance commissioner's office; the plan could cover unproven services in the context of a clinical trial while covering standard care routinely, or it could cover experimental treatments outside of a clinical trial as a defined benefit. For rare forms of cancer, a plan could cover a technology as part of a cancer care network's best practice guidelines, despite the lack of sufficient evidence of effectiveness, which is

[10] CMTP Issue Brief - Coverage for Evidence Development: A Conceptual Framework. January 2009. www.cmtpnet.org

sometimes done for rare forms of pediatric cancer. Because of the greater complexity of issues with insured plans, and the greater flexibility of working with health plans in their Administrative Services Only (ASO) role, our stakeholder group recommended starting the CED project with self-insured employers.

- **IRB approval**:
  - This is mostly relevant when conducting prospective clinical studies, although retrospective studies using patient records or databases are also subject to IRB approval to ensure patient informed consent and compliance with HIPAA regulations. Essentially, it is up to the co-investigators of whatever study is selected for a CED program to obtain IRB approval in their respective regions across multiple study sites that work with different participating payers. These researchers usually work with their own hospital IRBs even if the selected technology is delivered via outpatient treatment. Alternatively, outpatient research studies can be submitted to community IRBs for approval. In states with clinical trials mandates, researchers can seek pre-certification by health plans to determine if the CED study is considered a qualifying clinical trial already mandated for coverage. In general, private health plans participating in this study would not have to seek IRB approval. However, the plan should ensure that any approved CED study has secured IRB approval for the specific study site.

- **Informed consent**:
  - Payers, researchers, and patients are especially concerned with issues of informed consent, and it can be anticipated that health plan legal departments will require some time to carefully review the CED study program and ensure that it does not contradict established medical policy (e.g., if the technology is already covered, access only through CED could not be required), especially if it is not designed as an special program or extra-contractual benefit. If it is designed as an extra-contractual benefit and the technology is not covered by medical policy, then there is no inherent conflict, but rather an additional benefit not previously available and covered. Self-insured employers should check with the plan regarding current medical policy and any relevant contractual issues that may require modification to allow participation in the CED study (such as an explicit statement that the CED technology is not covered except in the context of the CED study). Individual subscribers would have to be made properly aware that they are in a study and that it is not part of their typical health care coverage. Additionally, the legal departments of each health plan have to independently determine their disclosure procedures.
  - As with any clinical trial, there is a risk of coercion/therapeutic misconception issues. It will be important to ensure that patients do not unknowingly choose to participate simply to get access to healthcare that they might otherwise not get, and this must be properly communicated in the informed consent procedures.

- **Additional liability issues**:
  - When designing and implementing a CED study, the health plan must consider if it poses undue risk to the patient and ensure that there is adequate disclosure to the patient of the risks and benefits of participation. It may be challenging to overcome patient and consumer suspicions that the primary motivation for the payers in creating CED programs is cost containment, rather than a genuine effort to create better information and grant access to promising treatments currently being evaluated. In general, plans will need to prevent any accusations of negligence in conducting CED studies or inconsistently making coverage decisions (including implementing a non-coverage decision based on the CED study results) without transparency or rationale based on evidence, as these types of claims can lead to substantial bad faith or punitive damages. While meaningful and transparent stakeholder engagement throughout the priority-setting and CED topic selection process can significantly alleviate these risks, they become more significant if the CED technology is something used to treat a life threatening or chronic and severely disabling condition. Therefore, if a technology for a less life threatening condition is chosen, the legal risk is likely to be reduced.

- **Recruitment of eligible providers and patients**:
  - Each of the participating health plans will undoubtedly choose independent means of identifying and recruiting providers and patients to participate, largely depending on their structure and the type of benefit or program under which they are offering the CED. Recruitment of self-insured employers to participate in the program will depend on finding those clients who want to participate in an innovative program and are willing to undertake some additional effort to make it work. If the study does not include an adequate number of facilities and physicians, the plan would need to develop those contracts.
  - If the plan and the employer are already paying for the test or intervention, it makes it easier to cover under CED, but the plans will need to notify the employer clients and allow them to opt out if that is their preference. Existing coverage of the technology, however, means that access under the plan does not *require* participation in the CED study. This will likely reduce accrual of patients to the CED study and may create some confusion.
  - If the CED study is created as an add-on to an existing study with pre-selected study sites, the plans will need to evaluate how many potential members their clients have at the study sites. This is not a simple task because plans will also need to determine how many of their regional members might go to the specific study site in the region, and how many might have the relevant condition within a reasonable study enrollment period.
  - It is important for plans to evaluate how many of their self-insured clients would be interested in participating in the CED study and how many members might be eligible for this program. The determination of enrollment numbers will be critical to the feasibility of participation of each group.

- **Coordinate data collection and management among different providers and testing labs**:
  - In general, health plans would want the study investigators to develop a method for identifying and tracking patients across different providers, plans, and labs. For them, the single most important issue is to make sure that claims are submitted properly and to avoid unlisted (-99) CPT codes, because claims with unlisted codes suspend for individual review, increasing costs and inconsistency while delaying payment. If possible, submission of claims and issuance of payment for covered CED services should be automated. Plans prefer to use the AMA-issued CPT codes or the CMS-issued Healthcare Procedural Coding System (HCPCS) codes to identify the technology instead of local codes.
  - If the CED study is designed as an observational trial and if the selected technology does not yet have a CPT code, CMS may be able to help assign an appropriate code if they also have an interest in the technology. This is a crucial issue in order to be able to use universal claims forms to identify and track patients. Regardless of the design of any CED study, a process for correctly identifying patients is required, thus ensuring that the claim will be correctly paid. Essentially, there are three areas on the claims form that can be used to identify and track participants in a CED study – the procedure code (e.g., HCPCS code), the trial identification number, and/or a trial-specific modifier. In the absence of a service specific code, prior authorization is an option, but would usually only be available to providers with contracts with participating health plans. Even if prior authorization is used, however, the subsequent claim will still need to be identified by the plan in some way to generate appropriate and timely payment.
  - If the selected technology is a laboratory test, one possibility is that plans with contracts with national labs that perform the tests could require identification of these tests for payment under the study protocol. However, using preauthorization without a specific code to identify patients again raises the problem of delayed and inconsistent payment. Providers dislike this and may not comply because it is a labor intensive process. Essentially, the provider and the lab (if relevant, depending on the selected technology) need to be contacted by the participating health plans to ensure smooth implementation of the CED project. It may also be worthwhile to include representatives from the national labs as part of the CED planning committee, as this will be a good way to have meaningful ongoing dialogue and correctly identify providers and patients.
  - It is important to ensure standards for data security and patient confidentiality. Patients are commonly referred to clinical trials who turn out to be ineligible, and providers don't always collect data or submit it accurately. For example, the common method of using fax-back forms to submit data is fairly cumbersome. One potential solution is to contract with a Contract Research Organization (CRO) to manage data collection for the study. Regardless of how data are collected, the study design submitted to the IRB should ensure patient confidentiality with stringency equivalent to that of federally funded clinical trials.

- **Research costs**:
  - Health plans expect to fund three costs when devising a CED policy: 1) the costs of the experimental treatment, 2) the costs of gaining acceptance among self-insured clients and developing a mechanism for them to 'opt-out' of the trial; and 3) the administrative costs connected to claims processing which might include the costs of modifying their claims processing system to identify an exceptions process for coverage under the trial if needed.
  - Plans do not expect to pay the research costs, including patient recruitment, informed consent counseling, data collection, and data analysis. Essentially, plan costs should not exceed the administrative costs they would pay for other covered technologies. Research funding may need to come from product developers or public research grants.
  - Additionally, plans will be reluctant to make public announcements about any CED policy for a new technology until funding is available for an approved study, and this is especially true if they need to recruit self-insured employer clients.

- **Clinical costs**:
  - If the health plans agree to cover the cost of a technology under the CED program, it is important to assure that they are getting the best possible price for the technology.
  - Although paying for research costs is more challenging than clinical costs, payers (including Medicare) do not want to allow billing for physician time to enroll participants. This activity may be folded into an "evaluation of management" code- i.e. the physician could bill more for the service to include the time it would take to talk to the patients, but the plan may not recognize the higher code and reimburse it. This is an issue that plans need to work out, both independently and in collaboration where possible.

- **Selection of CED-appropriate studies**:
  - CED by private payers requires each payer to deem a trial worthy of reimbursement of clinical care costs. Doing that individually for every CED project (assuming CED becomes more common) is quite burdensome and likely to be unsuccessful. However, it still needs to be done independently among participating health plans, and since many health plans do not have staff who can evaluate study design, the role of an independent third party becomes more crucial. Plans may be more interested in engaging a neutral organization like CMTP in a coordinator role that would certify study designs against a set of payer/stakeholder generated CED requirements.

CONCLUSION

CED has been conducted on a limited basis in the past, most often by CMS within the United States, but also on an ad hoc basis by individual private payers and increasingly in other countries.[11] Because of the ongoing high level of innovation in health technology, the increasing emphasis on more comparative effectiveness information, and increasing pressures on health care spending, we believe that CED will be an increasingly attractive policy mechanism. Life sciences companies generally believe that CED will become a more common tool in the near future and have been incorporating the impact of CED into models and pipeline projections. CED is widely discussed as a promising policy tool in CER discussions, though it is also widely recognized that the approach requires further refinement and proof of concept.

For CED to be effectively deployed in the private sector, it will be important to coordinate CED studies across multiple health plans. In order for multiple private insurers to work together in this way, an independent neutral entity is helpful to bring together the multiple plans, as well as experts and stakeholders needed to design and implement these projects.
If the private sector has a goal of taking the lead on technology decision making and being able to incorporate coverage policies relevant to their covered patient populations, rather than simply mirroring or reacting to CMS coverage decisions (whether or not generated through CED), coordination of technology information-gathering and decision-making activities is key. Over the past 18 months, CMTP has convened a broad group of stakeholders, selected a technology appropriate for CED (pharmacogenomic testing to guide initial warfarin dosing), identified and worked through operational and research design issues, engaged researchers interested in designing and securing funding for a CED study in the private sector, and obtained agreement in principle from multiple private payers to incorporate CED language that will allow the project to go forward. With support from the California HealthCare Foundation, CMTP is currently working on the final implementation phase of this CED project, which will include securing research funding for the genotype testing of warfarin dosing and enrolling multiple payers and self-insured employers in the project.

[11] Mohr PE, Tunis SR. Access with evidence development: the US experience. *Pharmacoeconomics*. 2010;28(2):153-62.