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Cost and Resource Burden of Coverage With Evidence Development

Under the Social Security Act, the Centers for Medicare & Medicaid Services (CMS) provides coverage for products and services that are deemed "reasonable and necessary" to patients over 65 and disabled populations. CMS may issue a National Coverage Determination (NCD) that establishes a single coverage standard on how a product or service approved by the Food and Drug Administration is covered (and, thus, reimbursed) in the Medicare Part B program. In 2005, CMS introduced the Coverage with Evidence Development (CED) paradigm that requires Medicare patients to enroll in a CMS-approved CED clinical study as a condition of coverage for that product or service. CED has never been explicitly authorized by Congress.

CMS imposes additional administrative, financial, and operational costs to healthcare providers (HCPs) to enroll patients in CED studies and facilitate data collection and monitoring to fulfill the CED requirements. Coverage for CED-restricted products or services is limited to patients willing and able to participate in CED-approved studies and who have access to a provider willing to do the same. This undue burden placed on patients disproportionately affects rural, lower-income, and lower-resourced communities, leading to widening gaps in healthcare disparity and delayed initiation to appropriate treatment for many patients.

The goals of this paper are to:

- Describe HCPs' awareness, utilization, and perception of CED
- Discuss CED's burden on providers and patients
- Recommend improvements to the CED paradigm should CMS continue to advance and implement the policy

Given the added burden of CED and the barriers to treatment confronting providers and patients, it is imperative that CMS consider the implications of CED to patient accessibility and evaluate the policy's purpose in its current form and application.

This paper aims to provide insights into the burdens and challenges associated with CED studies and draws from survey findings with HCPs and in-depth interviews with HCPs, patients, and policy experts who have experience with CED. In addition, should CMS continue to move forward with this paradigm, this paper offers recommendations on how the CED process must be improved to ensure it operates for the benefit of patients without factors that create barriers to access and care.

An Overview of the CED Policy and History

In 2006, the Centers for Medicare & Medicaid Services (CMS) formally issued the first guidance document of a new form of coverage restriction to National Coverage Determinations (NCDs) called Coverage with Evidence Development (CED).[1] CED is a process CMS uses when it believes certain products and services are promising but need further research to determine whether these treatments are "reasonable and necessary" for Medicare patients. When CMS invokes CED for an NCD, patients must enroll in a CMS-approved clinical study to obtain Medicare coverage for that product or service. CMS updated the CED regulatory guidance in 2014 indicating its intent to expand and advance CED coverage restrictions, and issued proposed guidance in 2023.[2,3]

However, CED has never been explicitly authorized by Congress.[4] This lack of clear authority is particularly troubling when coverage restrictions undermine or duplicate the authority of the Food and Drug Administration (FDA). Until recently, this policy had never been applied to an on-label use of an FDA-approved therapy. In April 2022, CMS issued an NCD with CED that covers FDA-approved monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease.[5] This action raises concerns about whether CMS is impeding access to FDA-approved drugs and entire classes of therapeutics. Thus, the CED policy may create an additional barrier that shrinks the pool of beneficiaries with access to certain treatments, weakening efforts to fulfill unmet needs and delaying patient access to innovative, FDA-approved drugs with established safety and efficacy.

Over the years, CMS has employed CED 27 times across 8 therapeutic areas.[6] The vast majority of those coverage restrictions have remained in place since inception. Only 7 of the 27 CED requirements have been removed; in 4 cases, the CED requirements were removed while the NCD remained in place, taking between 4 to 12 years for such a decision; 3 resulted in removal of the NCD and deferral of coverage decisions to local contractors and they took between 10 to 13 years to be removed.[6,7] The most recent was the removal of the NCD with CED for beta amyloid positron emission tomography (PET) in dementia and neurodegenerative disease in October 2023.

CMS retired the CED after a decade of extensive evidence generation and more than 30 published peer-reviewed manuscripts demonstrating the clinical value of amyloid PET, but rather than providing broad national coverage, CMS deferred coverage to local contractors, raising the specter of inconsistent coverage and still potentially raising access barriers for Medicare beneficiaries.[7,8]

Some of the 20 remaining CED policies have been in place for over 15 years, with little indication from CMS on when it plans to conclude its data gathering to satisfy the CED requirements. **Accordingly, CED ends up being a black hole for many products and services, from which full access is never addressed, discussed, or granted.** While these CED requirements remain in place, patients and providers face increased burdens to obtain coverage, potentially limiting patients' access to life-saving treatments.

Survey Findings on HCP Perceptions of CED

A survey was conducted between June 15 and July 10, 2023, among 400 healthcare providers (HCPs), which included specialists in neurology, dementia, cardiology, oncology, and radiology. The purpose of the survey was to understand the baseline awareness of, and participation in, CED among HCPs in select specialty areas. It should be noted that survey respondents do not represent all HCPs and were provider specialists with the ability to add capabilities to participate in CED. Respondents who were familiar with CED and had participated in a CED study were further probed on their perceptions of the challenges, benefits, and burden associated with CED. The mean years in practice of the HCPs ranged from 14 to 17 years. The majority of HCPs were located in urban areas (45%-56%), followed by suburban areas (38%-55%), and rural areas (0%-13%).

Table 1. Breakdown of survey participants, by specialty and number

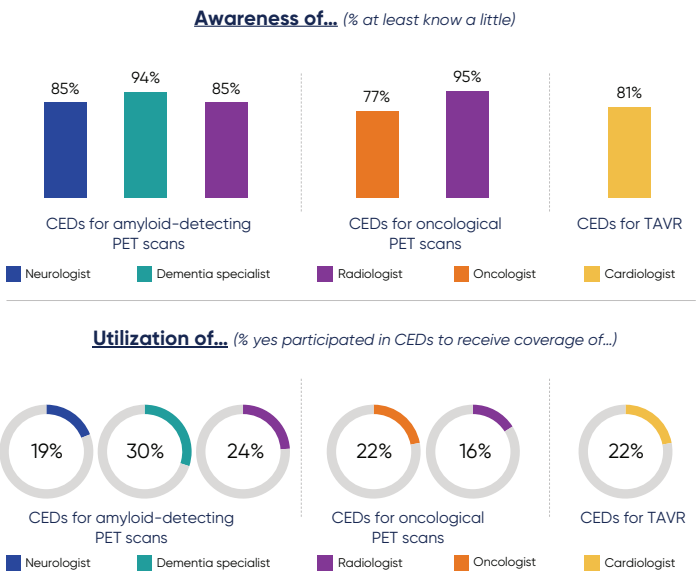
Specialty	Number of participants
Neurologists	110
Cardiologists	100
Oncologists	100
Dementia specialists	70
Radiologists	20

Awareness of CED

When asked about their awareness of CED, 30% of all HCPs who were surveyed (n=121) provided neutral coverage-based responses. Twenty-six percent (n=103) had a positive response to how CED incentivizes research and data collection, improves access to new treatments, drives innovation, and is helpful or appropriate. Seventeen percent (n=68) had a negative response, citing CED as bureaucratic and inefficient, and saw it as reducing coverage, reimbursement, and resources. The remaining 27% (n=108) had a range of miscellaneous responses from "unsure" to specific treatment mentions.

Regarding specific CED policies, 89% of neurologists, dementia specialists, and radiologists (n=177) were aware of the CED for amyloid-detecting PET scans. Likewise, 81% of cardiologists (n=81) were aware of the CED for transcatheter aortic valve replacement (TAVR), and 80% of oncologists and radiologists (n=96) were aware of the CED for oncological PET scans. However, only 24% of surveyed HCPs (n=42) who were aware of the CED for amyloid-detecting PET scans had participated in the CED process to receive coverage. Similarly, 22% of respondents (n=18) who were aware of the CED for TAVR and 21% (n=20) who were aware of the CED for oncological PET scans had participated in a CED. In other words, **many of the surveyed HCPs were aware of CED coverage requirements for the specific procedures but had low participation in the CED trials.**

Figure 1. Survey participants' awareness of, and participation in, CED policies



Increased access to healthcare with a wide range of resources but associated paperwork barriers.

– Neurologist

Limited access to advanced medical treatments for Medicare/Medicaid patients.

– Neurologist

This might deny more coverage but also save money.

– Radiologist

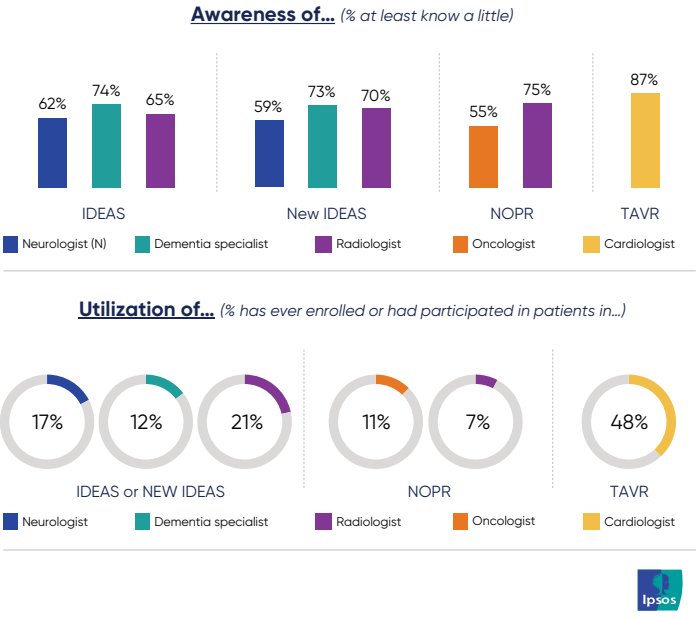
A bunch of people sitting around talking about how to cut costs at the expense of patients.

– Cardiologist

Neurologists (n=110) and dementia specialists (n=70) were also asked for their views on CED restrictions on the use of FDA-approved amyloid-targeting therapies. Overall, HCP reactions were negative, stating the CED restriction overcomplicated the process and led to additional steps on top of an already burdensome insurance process that included additional paperwork and time spent away from direct patient care. Many said they lack the resources needed to manage the additional burden of this process. HCPs also thought the CED restrictions would prolong the time it took for patients to get treatment and would restrict patient access.

Respondents were then surveyed on their awareness of specific clinical trials and registries that are part of the CED policies for amyloid-detecting PET scans, oncological PET scans, and cardiology TAVR procedures. Of neurologists, dementia specialists, and radiologists, 67% (n=133) and 65% (n=130) were aware of the Imaging Dementia-Evidence for Amyloid Scanning (IDEAS) and New IDEAS clinical trials, respectively, for amyloid-detecting PET scans. Eighty-seven percent of cardiologists (n=87) were aware of the TAVR registry, while 58% of oncologists and radiologists (n=70) were aware of the National Oncologic PET Registry (NOPR).

Figure 2. Survey participants' awareness of, and participation in, specific CED trials/registries



I think that this would decrease the utilization of amyloid-targeting therapies.

– Neurologist

This would unnecessarily restrict a lot of patients not enrolled in CED.

– Neurologist

I think it would probably worsen urban/rural healthcare disparities.

– Neurologist

Frustrated as this again undermines clinical judgment of physicians and increases administrative burden. Another demonstration of governmental intervention in medical care.

– Dementia specialist

HCP awareness of specific CED trials and registries was lower than their knowledge of the general CED policy, but participation in the trials and registries varied. Only 16% of surveyed HCPs (n=21) who were aware of the IDEAS or New IDEAS clinical trials had patients enrolled. Even fewer participated in NOPR, with only 10% (n=7) of oncologists and radiologists who were aware of the registry had patients enrolled. Participation was much higher for the TAVR registry, with 48% of cardiologists (n=40) who were aware of the national registry had patients enrolled.

Experiences with CED reimbursement

Respondents with patients enrolled in one of the specific clinical trials or registries were asked about their experiences with the CED reimbursement process. Of surveyed HCPs who had patients enrolled in the amyloid-scanning IDEAS or New IDEAS clinical trials, 48% (n=10) had a positive experience with the reimbursement process. Similarly, 48% of surveyed cardiologists with patients enrolled (n=19) responded positively to the TAVR registry reimbursement process, and for NOPR, 71% (n=5) of respondents who had participated had positive reactions. **While HCP reactions were varied, respondents acknowledged the challenges endemic to working with CMS to receive reimbursement.**

Attitudes towards CED

When asked about the rationale for not participating in a CED, surveyed HCPs said the main reasons were lack of information, insufficient staff to support the additional burden, and patient hesitancy to enroll in clinical trials. HCPs would consider participating if more information on CED (including reimbursement) was available, eligibility criteria for patients were expanded, and CMS simplified the process.

Surveyed HCPs who had participated in a CED were further asked about their perceptions of the CED process; specifically, ease of enrollment and initial setup, need for additional staff, timeliness of reimbursement, perceived burden, and hesitancy of patients to participate in a clinical trial. Overall, many HCPs indicated the initial setup enabling their practices to participate in the CED was difficult. While HCP reactions toward the reimbursement process were mostly positive, some indicated they were not receiving reimbursement in a timely manner. However, many HCPs who overcame the initial hurdles of participating do believe the benefits of CED outweigh the burden, though this is likely due, in part, to the additional staff they added to help facilitate the process.

It's a novel trial with useful implications, but it is hard to work with CMS.

– Radiologist on IDEAS or New IDEAS clinical trial

Reimbursement has not been great for TAVR, but it has not been limited, per se, because of its requirement for participation in a registry.

– Cardiologist on TAVR registry

Overall, feelings around participation were split, with surveyed HCPs having both positive and negative comments about participating in CED clinical trials. **Respondents said the support of additional staff helps make the CED process manageable. Otherwise, many HCPs claimed the paperwork and increased data collection required for CED would be too cumbersome and a barrier to patient enrollment in CED trials.** The survey results highlight that while HCPs appear to be aware of CED and understand the purpose of CED in receiving coverage for select products and services, few HCPs enroll patients in any CED clinical trials or registries due to the increased burden on HCPs, staff, and patients.

Figure 3. Survey participants who strongly or somewhat agreed regarding statements about specific CED trials or registries

Strongly/somewhat agree	IDEAS/New IDEAS (n=21)	NOPR (n=5)	TAVR (n=40)
I had to add additional staff to help facilitate the process	67%	57%	65%
I found the process of communicating patient progress and results straightforward	62%	100%	45%
The CEDs are burdensome to me and my staff	62%	57%	55%
The benefits of the CEDs outweigh the burden	62%	86%	58%
The enrollment process was easy	62%	71%	48%
The enrollment process was fast	52%	71%	38%
I received my reimbursement in a timely manner	48%	71%	43%
I am not able to enroll patients I believe should receive a test due to the procedural burden	48%	57%	30%
The initial setup for my practice to participate in the CED was easy	38%	100%	40%
My patients are hesitant to participate in a CED because it is a clinical trial	29%	57%	33%

Participation in CED initiatives may require significant investments of time and resources, which can be challenging for individual clinicians to achieve on their own.

– Dementia specialist

Not enough administrative support in the office.

–Neurologist

The paperwork burden.

–Cardiologist

Costly initial expenses.

–Radiologist

Provider, patient, and policy perspectives on the burden of CED

A series of in-depth interviews were conducted to help shed light on particular aspects of CED that may present challenges for providers and patients alike. Select HCPs who responded to the survey and said they participated in a CED were chosen for interviews. Patients and policy experts were also consulted to explore what changes could be made, by CMS or other stakeholders, to help alleviate and address these barriers and burdens.

Administrative burden of CED on HCPs and staff

The administrative requirements needed to participate in a CED study involve the initial setup of the CED clinical trial or registry at the provider's facility, patient enrollment, continued monitoring and data collection, additional paperwork, and reimbursement from CMS.

The burden on HCPs and administrative staff can vary depending on whether the CED requires the setup of a traditional clinical trial or a registry. When the CED requires data collection in the context of a clinical trial, only select facilities may be an approved site, and patients must be referred to that facility to participate. Selected facilities can receive an overwhelming number of patients, depending on the demand and the availability of other clinical trial sites nearby.

Depending on where they live, Medicare beneficiaries will have uneven access to facilities where they can participate in a CED trial. Patients, particularly individuals in underserved communities, may have to travel long distances, well beyond the 30-minute standard, to access clinical trial sites.[9] According to a policy expert, "When data are collected via a registry, that makes it far more accessible. [For] facilities or physicians or practitioners who deliver CED-covered therapies that require registry enrollment, that burden is far lower and tends to involve a lot more places that makes access much better for Medicare beneficiaries. So there's a huge spectrum of burden, depending on what kind of data are necessary and how it's collected." Yet, there are still significant steps that must occur to establish a registry, during which time patients have no Medicare coverage. On average, the process to set up a registry takes between 18 and 24 months to complete.[10]

I stopped advocating once we learned the burdensome process of CED.

– Radiologist

I was all in on CED, then when I saw what the hurdle was, I was all out.

– Radiologist

There is extra work, working through a clinical trial coordinator, etc. There is only so many personnel we have. It's more resource-intensive than having it outright approved by CMS overall.

– Cardiologist

Facilities may also have to establish data repositories and compare the inclusion and exclusion criteria to determine if patients would benefit and qualify to be enrolled. According to a neurologist, "[There is] increased discussion between coordinator and providers and making sure patients are not missed that should be enrolled. That is all particularly challenging." In addition, certain outcomes must be followed under CED, introducing increased regulatory oversight and coordination with CMS. **Therefore, for many HCPs, the enrollment process may not be simple and involve additional coordination.**

The data-collection mechanism impacts the degree of CED burden on HCPs. Data collection via electronic health records can save staff hours compared to paper forms. For example, to enroll a patient in the TAVR registry, doctors must fill out an 11-page form for each patient. Moreover, CEDs may continue into perpetuity resulting in continuous data collection, monitoring, follow-up, and increased burden on HCP and staff for an unspecified amount of time.

To participate in some CED trials, HCPs may need additional staff to facilitate the process and help complete the administrative requirements under CED. One cardiologist said, "In order to allow patients to go forward under this structure, you yourself have to have clinical trial coordinators and other personnel to support it being carried out. The alternative would be not as palatable. It's another layer of requirements needed for us to be able to utilize technology."

To comply with CED requirements, HCPs may need staff to support the additional data collection required for enrollment into the CED study and to obtain reimbursement. These added burdens can siphon support from another drug, device, area of investigation, or patient. In addition, more paperwork tends to prolong the reimbursement process. One radiologist said, "The amount of paperwork required under CED is more than is needed for a conventional Medicare or Medicaid patient." **CMS needs to consider the impact of CED on the productivity of providers and staff and on an already burdened and overwhelmed healthcare system.**

Financial and operational burden of CED on providers and innovators

The potential need for additional resources to hire staff to address the administrative burden of CED presents both financial and operational costs to HCPs. Larger facilities with the infrastructure to support additional clinical trials may find it easier to enroll patients in CED studies, whereas smaller community hospitals may have more challenges, resulting in drained resources or an inability to provide new technologies to patients.

As noted by one cardiologist, "We have often thought about this through the lens of: Is this clinically valuable, is this a financially viable opportunity, what is likely to come from participation? But we've been less cognizant on operational impact. We already have a backlog of time for people to get in, so does it have other operational downstream concurrent or future impacts? Many times, the answer is yes."

If CMS continues to consider placing more CED coverage restrictions on FDA-approved therapies, it is important to evaluate the impact this will have on system operations, their ability to allocate resources to invest in patient care, and which systems will even consider taking on this burden.

Furthermore, it is not always clear who should bear the costs of participation, developing systems to collect and input data, or sharing with data registries. A policy expert noted, "There's a lot of additional payment that goes into this whole process to set up these systems to make sure that the specialists and the facilities are adequately paid. Industry has to pay for the registry data if a registry is the data collection method for that CED, or they may sometimes have to pay for the clinical studies. If you're a smaller company, you may not have the resources to do all of that."

In the example of the TAVR CED, an annual enrollment fee of $25,000 per hospital site in 2019 was required to participate in the registry hosted by the Society of Thoracic Surgeons and the American College of Cardiology.[11] Larger manufacturers may have more resources to help pay for registries for data collection or sponsor clinical trials, whereas smaller companies may find the additional barrier of CED on top of gaining FDA approval overly burdensome, potentially deterring investment in therapeutic areas where CED may be deployed.

In addition, **without clear guidance from CMS on a set time frame, manufacturers may be unsure of what requirements must be met to "graduate" from CED and what events may trigger failure leading to an adverse coverage determination by CMS or even threaten FDA licensure.** As exemplified by the recent removal of the NCD with CED for amyloid PET, even with extensive evidence generated over the past decade, CMS did not establish national coverage and instead transitioned to local coverage discretion, potentially leading to further coverage delays and variability in coverage across Medicare beneficiaries.[7] The CED process requires significant capital on top of the already substantial investment needed to undergo FDA approval for manufacturers, and often with no end in sight when coverage for these life-saving therapies will be fully accessible to all Medicare patients.

Undue burden of CED on patients

CED is disproportionately burdensome on rural communities, lower-income communities, and lower-resourced communities and can increase disparate healthcare in underrepresented patient groups. There is concern that CEDs are restricting coverage for therapies that have existing inequitable access to care. One survey showed rural areas had double the rates of Alzheimer's disease deaths compared to urban areas, likely due to the lack of access to healthcare professionals and providers with experience treating Alzheimer's disease and related dementias.[12] In 2018, a study on TAVR demonstrated only 4% of patients receiving TAVR in the United States were African American.[13] CEDs, such as those placed on TAVR, that require participation in a clinical trial as a condition of coverage further restrict access for patients and increase the geographic inequity of care.

"It sort of widens the haves and the have-nots in the Medicare program. It's really geared towards people who are better resourced and better informed, people who live in wealthier urban areas near academic research centers. For folks who don't fit into those categories, it's a losing situation. It's ironic because it's exactly those communities that are more dependent on Medicare coverage and reimbursement, and those folks are going to be less likely to have the ability to self-insure or to have rich supplemental plans that could help them in some other way, even if the base item or service isn't covered," said a policy expert.

The economics for this do factor in, they're not the only factor, but they are a factor that informs decision-making of whether we participate or not.

– Cardiologist

I think the problem is with CED that the incentives are not always aligned. It's when there's this problem of lack of consolidation of resources and misaligned incentives that we end up with these policies that just go on and on without really actually developing the data that was the intention to begin with.

– Policy expert

Patients may live in rural areas, hours away and sometimes even in different states from a clinical trial site, with less access to public and private transportation. One analysis showed how a clinical trial CED requirement could severely limit treatment for virtually all Americans living outside of major cities.[9] Many patients may not have the economic means to commute or take time out of daily tasks and change their routine to participate in a study. CED restrictions can increase the burden on patients by requiring a specific site of care or ongoing monitoring and data collection to fulfill CED requirements.

Minority groups are often underrepresented in clinical trials, and CED requirements can further expand these disparities.[14] As one policy expert noted in an interview, "With both the PET CED and the TAVR CED, [CMS] kind of weaponized the issue of equity by stating that the CED clinical studies didn't have enough diverse participation in the first round, and they've used it as a rationale to extend the CED further. The sort of paradigm that set up inequitable access in the first place is continued to be justified because it wasn't diverse enough. It creates a loop of inequity."

After CMS initiated the NCD requiring CED for TAVR in 2012, an analysis using 2012-2018 TAVR registry data demonstrated that higher proportions of socioeconomically disadvantaged, Black, and Hispanic populations had significantly lower rates of TAVR compared with more affluent and White populations.[15] In 2019, CMS acknowledged that there was insufficient evidence for minority populations, yet rather than lift the CED to potentially broaden access, it left the TAVR CED in place, further perpetuating disparate access.[4] Similarly, the original IDEAs CED registry for amyloid-detecting PET scans showed approximately 92% of patients who used the registry were White. In an effort to enroll a more diverse patient population, the New IDEAS study was established. However, despite efforts to recruit a majority diverse patient population, only 27% of New IDEAS study participants identified as Black, Hispanic, or Latino as of June 2022, 18 months after recruitment began.[16] **CED operates to limit access to underserved patient populations by restricting access only to patients who are able to enroll in CED studies.**

Patients may be hesitant to participate in a clinical trial and may lack awareness and understanding of the CED process. The extra steps needed to commit to the study as well as complications that may come from language barriers, preexisting discomfort with healthcare providers, and the investigational nature of CED studies can deter patients from participating.

One radiologist commented on his experience with a patient: "It takes longer because of the fact many times there is a care partner with them, so it's 2 people you're talking to and the discussion is longer. For the second appointment, if they decide to move forward, I bring up the registry and sometimes they get confused. Just to make the decision to go on it or not could take 2-3 visits." Even after explanations from HCPs, patients may struggle to understand the benefit of participating due to lack of health literacy or may not see value in the added effort needed due to previously failed treatments. **A patient's decision to undergo treatment can already be difficult, and adding the additional decision to participate in a clinical trial can lead to further delays, or even the decline, in patient initiation of appropriate care.**

> ***That decision is totally taken out of the doctor's hand and the patient too, for that matter, if it has to go for somebody else to determine if it's reasonable and necessary. If it's not reasonable and it's not necessary, the doctor wouldn't have prescribed it. I think the 'reasonable and necessary' should come from the treating physician and what the patient's wishes are. It's just kind of turned upside down as far as helping the patient.***
>
> **– Patient**

The barriers created by CED also add to the complexity of decision-making between patients and providers. In addition to helping patients understand their treatment, providers must ensure patients understand what participating in a CED trial entails. As one radiologist noted, "Patients don't really get it or what it really means. Some don't want their data out in that way. They also say let me think about it. That gives them a little caution because they think it may increase premiums, report to their job, etc. There are a lot of variables and hesitancy from the patients. Some are not educated and don't like the fact they have to go through clinical trials and don't understand the term." Patients want to understand how their data is being collected and used by CMS. They also want to know whether their participation will create any barriers to receiving care. Shared decision-making between patients and providers must address whether the benefits outweigh the burden for patients.

Improvements to CED

The fundamental question of whether CED, in its current form and application, accomplishes the stated goal of efficiently providing patients access to new products and services while continuing to learn about them should be scrutinized. However, if CMS continues to use CED, then improvements must be made to alleviate the burden on providers and patients.

The following recommendations outline solutions to improve CED:

1. CMS must implement better communication and more transparency in the CED process, specifically around timelines and data needs for reassessment. Clearer guidelines are needed to articulate when data collection is deemed sufficient, such that a device or therapy may "graduate" from the CED program.
2. CMS should provide more direct guidance for HCPs and staff on enrolling patients in CED clinical trials, along with education on what to expect, how to fulfill CED data collection requirements, and how to file for reimbursement to avoid delays.
3. CMS should strive to alleviate provider burden by increasing the availability of information (specifically on reimbursement), expanding eligibility criteria, increasing support from hospital systems, and simplifying both the enrollment process and the methods for collecting data.
4. Ongoing data collection should not operate as a barrier to access. Rather than limit access through restrictive CED studies, CMS should explore how to leverage claims data to better understand how medicines and services operate outside clinical trials.
5. CMS should involve patients in the CED process and enhance engagement by seeking input from patient advocacy groups, patient representatives, caregivers, and individuals with lived experiences when evaluating and updating CED policy and criteria. This involvement can help ensure that patient perspectives, needs, and preferences are considered in CED programs and requirements.
6. CMS should ensure that the CED policy supports and supplements the FDA approval process rather than generates an evidentiary gap between what the FDA wants and what CMS wants. Patients and providers depend on the FDA as the authority to determine the safety and effectiveness of approved therapies. CED, as it stands, causes confusion on the validity of the FDA's decision, potentially duplicating the FDA's efforts to assess therapies, while also interfering with patient/provider decision-making regarding the most appropriate care for patients.

Having a streamlined protocol adopted across the country would be easier. Each center has different regulations if their board wants increased oversight. That is the case for us, and it makes it a bit more challenging. Having that standardized process would be helpful.

– Neurologist

"[CMS] could be more transparent in asking for public comment. Letting the patients know exactly what they're up against, and then listen to them. Making it more available for public comment so that their voices can be heard. They're the ones that this is affecting."

– Patient

It puts hesitancy on patients as it makes it seem the FDA approved but CMS doesn't approve, so it causes hesitancy that those agencies don't agree. If FDA and CMS can't come to a conclusion, does that mean it's safe and effective? It's a point for confusion depending on patients' understanding and left to interpretation and even more education on my part.

– Radiologist

Conclusion

CMS continues to wield CED as a tool to restrict coverage to FDA-approved treatments without fully considering the burden placed on HCPs and patients to adhere to its requirements. Increased use of CEDs has the potential to exacerbate inequalities in access to healthcare and overwhelm HCPs and staff with additional layers of clinical studies, strict coverage requirements for sites of care, and prolonged mandates for data collection of health outcomes. CMS should examine the CED policy and evaluate whether required data collection is, in fact, providing beneficial impact to beneficiaries rather than perpetuating gaps in access and care. CED in its current use places undue burden on both HCPs and patients to access innovative, FDA-approved treatments.

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