

# Coverage With Evidence Development: Where Are We Now?

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The coverage with evidence development (CED) program is a mechanism whereby CMS covers promising therapeutics and services for Medicare beneficiaries on the condition that they are furnished in a setting of ongoing data collection.<sup>1</sup> When employed, CEDs constitute a National Coverage Determination (NCD) that applies to all Medicare beneficiaries; NCDs are relatively rare, with an average of 8 issued per year over the past decade.<sup>2</sup> Most decisions about Medicare coverage are made by third-party administrators with regional impact only; dozens of local coverage determinations are made each year, which vary from one region to the next.<sup>2</sup> Typically, NCDs are based on evidence generated during premarket trials for therapies and services designed to meet standards of the FDA, including efficacy or effectiveness for the labeled indication, reasonable assurance of safety, and benefits greater than risks. An NCD with a CED component is developed like any other NCD: It can be initiated internally by CMS or by an external party by submitting a “complete, formal request” based on publicly available rules, and the process includes a period of public comment. However, the standard for coverage by Medicare is “reasonable and necessary,” and this standard may not be met by these premarket data alone. For example, premarket trials may not adequately evaluate real-world use in typical Medicare populations including older patients and those with multiple comorbidities, both of whom tend to be poorly represented in clinical trials. Generating data through CEDs is one solution for closing this evidentiary gap.

The precursor to the CED program was created in a 1995 regulation by CMS’ predecessor, the Health Care Financing Administration, which established coverage for therapies furnished in the setting of an investigational device exemption trial that incorporates FDA oversight. In the subsequent 10 years, the CED program evolved with experience from programs like lung volume reduction surgery (1996) and left ventricular assist device for destination therapy (2003). In 2006, CMS issued the first guidance document of the modern CED program, which formally began in 2005.<sup>3</sup>

A CED decision implies that the therapy or service may be beneficial for Medicare beneficiaries but insufficient data exist.<sup>4</sup> In this way, a CED may make promising therapies and services

## ABSTRACT

**OBJECTIVES:** CMS’ coverage with evidence development (CED) policy allows Medicare beneficiaries to access promising therapies and services while additional data are collected. CED program characteristics are mostly unreported, and qualities associated with retirement of CED data collection requirements are unknown. We aimed to review and systematically describe CED program history and components and report programmatic elements correlated with retirement of CED data collection requirements, while identifying areas for policy improvement.

**STUDY DESIGN:** Systematic review.

**METHODS:** We extracted CED information from the CMS website, ClinicalTrials.gov, PubMed, internet searches, and communication with CMS.

**RESULTS:** There were 27 CED determinations from 2005 to 2022 in 8 therapeutic areas, with the most for cardiovascular diseases (8/27; 30%). Duration of CED programs (range, 1-16 years) and the number of related registries and clinical trials (range, 0-34) were widely variable. Only 4 CEDs have had data collection requirements with continued National Coverage Determination (NCD); 3 relate to cardiovascular therapies, and all have some public availability of findings resulting from CED-related data collection mechanisms. There were 2 instances of NCD revocation and deferral to local coverage decisions.

**CONCLUSIONS:** Changes in the CED program through improving program predictability and transparency with regard to outstanding questions, roles of relevant stakeholders, and requirements for reporting and reevaluation would strengthen the program’s effectiveness. Ultimately, these improvements would provide incentives for stakeholder participation in data collection to achieve the goal of increasing access to beneficial therapies and improving clinical outcomes.

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available to Medicare beneficiaries while facilitating ongoing data collection to prove reasonableness and necessity. For example, the Watchman left atrial appendage occlusion device (Boston Scientific) for the reduction of stroke risk in patients with atrial fibrillation initially failed to meet the primary clinical trial end point of equivalency with the standard of care, therapeutic anticoagulation. Although it was eventually approved by the FDA based on subsequent clinical evaluations, this technology may not have survived the regulatory gauntlet without a CED program.

In practice, CED data collection has been performed through CMS-approved clinical registries and trials designed to meet outstanding questions but without the intention to “duplicate or replace the FDA’s authority in assuring safety [and] efficacy” nor to “assume the [National Institutes of Health]’s role in fostering, managing, or prioritizing clinical trials.”<sup>11</sup> Although not specifically stated as part of the CED program, it is presumed that data collection, as a condition of coverage, will eventually be retired if benefit is demonstrated or the NCD will be revoked. Indeed, CMS guidance states that evidence produced by CED trials “will lead to revisions to Medicare coverage policies” to better align beneficiary access with the “reasonable and necessary” threshold for coverage.<sup>1,3</sup> These revisions to coverage policy are triggered like any NCD revision: internally by CMS or by request by any external party.

There are various versions of postmarket evidence development programs globally that differ based on payer structures and other factors.<sup>5-9</sup> There have been critiques of CMS’ specific CED program related to funding for postmarket evidence development, developing evaluation criteria, and harnessing the power of existing data sources,<sup>4,10,11</sup> with some evidence suggesting

**TAKEAWAY POINTS**

Efforts to increase coverage with evidence development (CED) program predictability could improve the likelihood of addressing outstanding clinical questions and improve access to beneficial therapies.

- ▶ Twenty-seven therapies have been subject to CED requirements since the program’s inception to make promising therapies available to Medicare beneficiaries while collecting clinical information.
- ▶ There has been wide variability in CED requirements among therapies including how requirements have been addressed by stakeholders and over what time period; some therapies have no data collection mechanisms.
- ▶ Few programs have achieved retirement of data collection requirements, suggesting that barriers remain to accessing CED therapies.

that the process of moving from CED designation to evidence development has improved.<sup>12</sup> Other investigators have explored postmarket evidence development programs more broadly and identified a number of challenges, including ethical ones, to the paradigm in general.<sup>6,8,13,14</sup> In this paper, we provide a contemporary systematic review of the CED program, report those programmatic elements that appear to predict retirement of CED requirements, and identify areas for policy improvement to better align the CED program with the intended goal of making promising therapies and services available to Medicare beneficiaries in a timely and evidence-based way.

**METHODS**

Data were collected by 2 investigators (E.P.Z. and L.G.G.) in 3 phases with 3 goals: First, to assemble the complete list of all CED programs past and present, including prespecified program components, listed in [Table 1](#)<sup>15-39</sup>; second, to identify relevant clinical trials and registries; and, third, to identify publicly available results from relevant clinical trials and registries.

**TABLE 1.** Therapies Subject to CED Since Program Inception<sup>15-39,a</sup>

Therapy identification	Year of CED	Therapeutic area	Status (No. of years of active program if retired)	Approved evidence development mechanisms		Total No. of trials + registries	Specific questions in memo	Any publicly available results?
				Registries	No. of clinical trials			
FDG PET and other neuroimaging devices for dementia <sup>16</sup>	2004 <sup>b</sup>	Neurology	Ongoing CED	No	1	1	Yes	Yes
Carotid artery stenting <sup>17</sup>	2005	Cardiology	Converted to NCD without CED (4)	Yes	3	4	No	Yes
Cochlear implantation <sup>18</sup>	2005	Otolaryngology	Ongoing CED	No	5	5	No	Yes
ICD for primary prevention <sup>15</sup>	2005	Cardiology	Converted to NCD without CED (12)	Yes	0	1	Yes	Yes
Off-label use of colorectal cancer drugs <sup>19</sup>	2005	Hematology/ oncology	Ongoing CED	No	11	11	No	Yes
Home oxygen for COPD <sup>20</sup>	2006	Pulmonology	Ongoing CED	No	1	1	No	Yes

(continued)

# CLINICAL

**TABLE 1.** (Continued) Therapies Subject to CED Since Program Inception<sup>15-39,a</sup>

Therapy identification	Year of CED	Therapeutic area	Status (No. of years of active program if retired)	Approved evidence development mechanisms			Specific questions in memo	Any publicly available results?
				Registries	No. of clinical trials	Total No. of trials + registries		
Artificial hearts <sup>21</sup>	2008	Cardiology	NCD revoked; coverage deferred to local contractors (12)	No	6	6	Yes	Yes
CPAP for obstructive sleep apnea <sup>22</sup>	2008	Pulmonology	Ongoing CED	No	0	0	Yes	No
Pharmacogenomic testing for warfarin response <sup>23</sup>	2009	Pharmacology	Ongoing CED	No	2	2	Yes	Yes
Allogeneic HSCT for myelodysplastic syndrome <sup>24</sup>	2010	Hematology/oncology	Ongoing CED	No	2	2	Yes	Yes
NaF-18 PET for bone metastasis <sup>25</sup>	2010	Radiology	Ongoing CED	Yes	0	1	Yes	Yes
Home oxygen for cluster headache <sup>26</sup>	2011	Neurology	NCD revoked; coverage deferred to local contractors (10)	No	0	0	Yes	No
MRA and MRI in patients with CIED <sup>27</sup>	2011	Cardiology	Converted to NCD without CED (7)	Yes	9	10	Yes	Yes
TENS for chronic low back pain <sup>28</sup>	2012	Neurology	Ongoing CED	No	0	0	Yes	No
Extracorporeal photopheresis for bronchiolitis obliterans syndrome following OLT <sup>29</sup>	2012	Pulmonology	Ongoing CED	No	1	1	Yes	Yes
Transcatheter aortic valve replacement <sup>30</sup>	2012	Cardiology	Ongoing CED	Yes	33	34	Yes	Yes
Autologous blood-derived products for chronic nonhealing wounds <sup>31</sup>	2012	Other	Limited NCD without CED (9)	No	13	13	Yes	Yes
Beta amyloid PET in dementia <sup>32</sup>	2013	Neurology	Ongoing CED	No	4	4	Yes	Yes
Transcatheter edge-to-edge repair <sup>33</sup>	2014	Cardiology	Ongoing CED	Yes	4	5	Yes	Yes
Percutaneous image-guided lumbar decompression for lumbar spinal stenosis <sup>34</sup>	2014	Neurology	Ongoing CED	No	3	3	Yes	Yes
Percutaneous LAA closure therapy <sup>35</sup>	2016	Cardiology	Ongoing CED	Yes	5	6	Yes	Yes
Allogeneic HSCT for sickle cell disease <sup>36</sup>	2016	Hematology/oncology	Ongoing CED	No	2	2	Yes	Yes
Allogeneic HSCT for myelofibrosis <sup>36</sup>	2016	Hematology/oncology	Ongoing CED	No	1	1	Yes	No
Allogeneic HSCT for multiple myeloma <sup>36</sup>	2016	Hematology/oncology	Ongoing CED	No	1	1	Yes	No
Leadless pacemakers <sup>37</sup>	2017	Cardiology	Ongoing CED	No	6	6	Yes	Yes
Vagus nerve stimulation for treatment-resistant depression <sup>38</sup>	2019	Psychiatry	Ongoing CED	No	1	1	Yes	No
Monoclonal antibodies against amyloid for Alzheimer disease <sup>39</sup>	2022	Neurology	Ongoing CED	No	0	0	Yes	No

CED, coverage with evidence development; CIED, cardiac implantable electronic device; COPD, chronic obstructive pulmonary disease; CPAP, continuous positive airway pressure; FDG, fluorodeoxyglucose; HSCT, hematopoietic stem cell transplantation; ICD, implantable cardioverter defibrillator; LAA, left atrial appendage; MRA, magnetic resonance angiography; NCD, National Coverage Determination; OLT, orthotopic lung transplantation; PET, positron emission tomography; TENS, transcutaneous electrical nerve stimulation.

<sup>a</sup>Data reflect the state of the CED program through July 1, 2022.

<sup>b</sup>Decision date predates the 2005 initiation of the CED program, but the associated clinical trial was approved after 2005 thus qualifying as a CED.

## Identification of CED Services and Therapies

The primary source of data for this analysis was the CMS website.<sup>40</sup> The set of CED therapies and services listed there was refined through direct communication with the Coverage and Analysis Group at CMS. The list of CED programs and associated registries and clinical trials, which was assembled based on information from the public CED website, was reviewed directly by the CMS Coverage and Analysis Group; they provided edits and clarifications because there were some programs with elements of CED but not formally considered to fall under CED authority. For example, coverage for the left ventricular assist device for destination therapy was provided via an NCD that required participation in a national registry, but this decision predated the 2005 implementation of CED so was not included in this analysis. Prespecified characteristics of each CED program were collected. Therapeutic area was assigned based on assessment by 2 investigators, with discrepancies resolved by consensus.

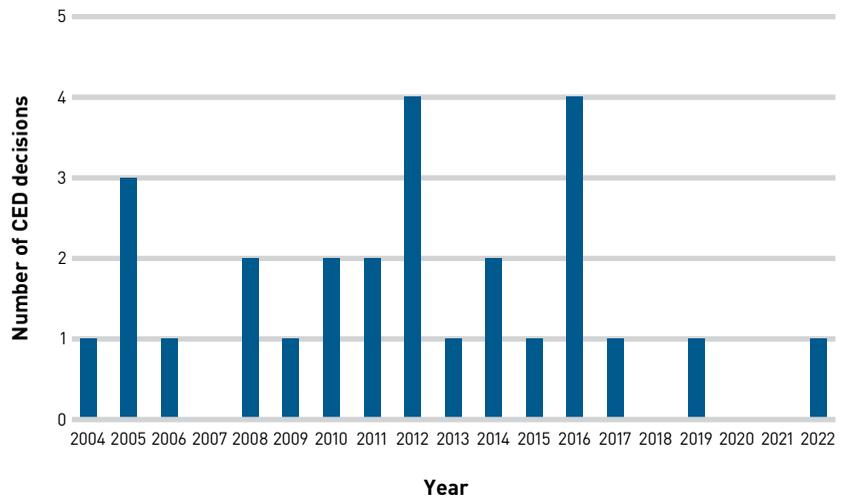
## Identification of Relevant Clinical Trials and Registries

For each therapy or service identified, the CMS website served as the primary source for identifying clinical trials or registries approved by CMS to support evidence collection.

## Identification of Publicly Available Clinical Evidence

In the third phase of data collection, publicly available data resulting from CMS-approved registries and clinical trials were sought in a stepwise fashion. CMS-approved registries and clinical trials that support evidence collection for CED must be registered at ClinicalTrials.gov, and each is given a unique identification number. Using these unique identification numbers, ClinicalTrials.gov was searched directly, and in some cases results were available there. If not, the ClinicalTrials.gov identification number was used to guide searching in PubMed along with the study or registry title(s) as listed on the CMS website. If no results were available, the scientific literature was searched using combination terms from the approved registry or clinical trial name along with the device or service name, if relevant. If no results were available at this point, the gray literature was searched, including, for example, websites from relevant manufacturers, professional societies, and trade literature using Google.com. Finally, after this stepwise search, if no results were available, the Coverage and Analysis Group at CMS was queried for any additional guidance; however, no additional results were identified through this direct communication. At this point, if no results were found, the CED program was labeled as having no publicly available results.

FIGURE 1. CED Therapies Over Time



CED, coverage with evidence development.

Study data were collected and managed using REDCap electronic data capture tools hosted at Duke University.<sup>41</sup> Because no patient data were collected or stored for this analysis and only publicly available data were gathered, review by an internal review board was not sought.

## RESULTS

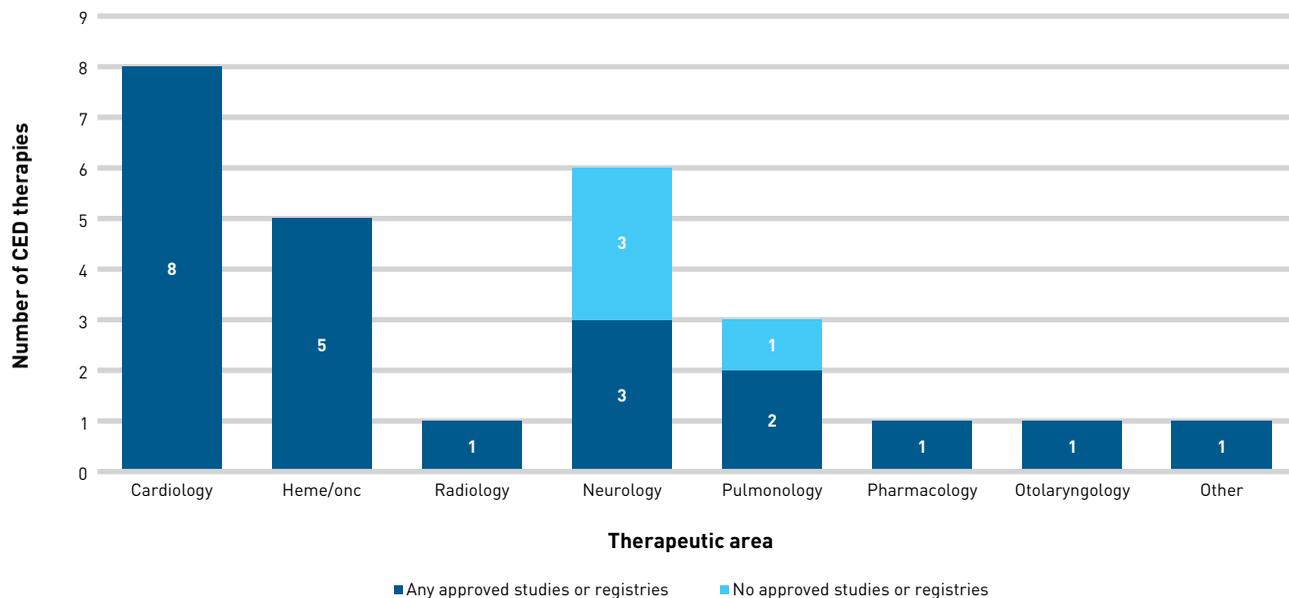
### Program Description

**Therapy and coverage characteristics.** Twenty-seven CED programs were identified including retired programs (Table 1<sup>15-39</sup>). Of the 27 CED programs, 74% provide coverage to new populations and 26% cover novel therapies. Four CED programs (15%) were diagnostic and 23 (85%) were interventional. CEDs were from 8 therapeutic areas, with the greatest number related to cardiovascular medicine. The number of CEDs in a year ranged from 0 to 4 (Figure 1). CED program duration has varied by therapy or service, with a range of 1 to 16 years (Table 1<sup>15-39</sup>).

In 23 of 27 CED NCDs, specific outstanding questions related to the therapy were listed in the CED decision memoranda and were typically focused on medium-term to long-term clinical outcomes or comparative effectiveness in the Medicare population. Four CED NCDs had no specific outstanding questions (Table 1<sup>15-39</sup>), and all of these were from the first 2 years of the program (2005-2006).

**Registries and clinical trials.** The number of registries and clinical trials per therapy or service ranged from 0 to 34 (Table 1<sup>15-39</sup>). There were 7 CED NCDs with 1 approved registry each; no CED NCD had more than 1. Of these, 5 were related to cardiovascular therapies, of which 4 had a registry administered by the American College of Cardiology's National Cardiovascular Device Registry (NCDR)

**FIGURE 2.** CED Therapies With at Least 1 Approved Registry or Clinical Trial



CED, coverage with evidence development; heme/onc, hematology/oncology.

suite. Compared with other therapeutic areas, cardiovascular CEDs were more commonly subject to a registry (6/8 [75%] vs 2/19 [11%]).

Twenty-one of the 27 CED therapies had at least 1 approved clinical trial (range, 0-33 trials), and 5 therapies had both approved registries and trials (Figure 2). In 4 cases, there were no associated registries or clinical trials: transcutaneous electrical nerve stimulation for chronic low back pain, home oxygen for cluster headache, continuous positive airway pressure for obstructive sleep apnea, and monoclonal antibodies for Alzheimer disease (Table 1<sup>15-39</sup>).

Of the 23 CEDs for which registries and/or trials existed, there were 20 (87%) with some publicly available results, including 7 in which results were posted on ClinicalTrials.gov.

### Instances of CED Retirement

There have been 4 instances in which the evidence development requirements were retired when the evidence was deemed to be adequate: carotid artery stenting, implantable cardioverter defibrillator (ICD) for primary prevention of sudden cardiac death, magnetic resonance angiography/MRI in patients with a cardiac implantable electronic device, and autologous blood-derived products for chronic nonhealing wounds. The retired CEDs share some characteristics. First, all 4 therapies had at least 1 associated trial or registry. Second, some portion of the results from the trials and registries associated with these CEDs was publicly reported.

There were also some important differences among the 4 programs with retired evidence collection requirements. First, 3 of the 4

programs were cardiovascular interventions or therapies. Second, time from initiation to retirement of CED requirements varied from 4 to 12 years. Third, 3 of these therapies, magnetic resonance angiography/MRI in patients with a cardiac implantable electronic device, ICDs for primary prevention, and autologous blood-derived products for chronic nonhealing wounds, had specific questions to address as part of the CED and, thus, clear goals for CED-related trial and registry design. Fourth, they varied considerably with regard to level of risk of the device or therapy and severity of the underlying disease. Performing carotid artery stenting, for example, may treat a life-threatening disease whereas MRI for patients with an implantable cardiac device is a diagnostic intervention for which alternatives exist.

There were 2 CEDs, artificial hearts and home oxygen for cluster headaches, that resulted in revocation of the NCD and deferral of coverage decisions to local contractors. These 2 therapies differed from each other in important ways. For example, there were 6 CED-related clinical trials evaluating artificial hearts, with publicly available results, whereas home oxygen for cluster headaches had no associated trials or registries. Furthermore, there were specific questions to be answered by the CED for artificial hearts, but no specific questions were outlined in the decision memorandum for home oxygen for cluster headaches.

In summary, on review of the 6 therapies with CED requirements removed, there were no clear programmatic characteristics suggesting greater or lesser likelihood of progressing to an NCD without CED requirements vs revocation of the NCD.

**TABLE 2.** Recommendations for a More Predictable and Transparent CED Program

Current status	Recommendation
Tools for data collection are designed around regulatory requirements.	Data collection mechanisms, including registries and clinical trials established to meet CED requirements, should be designed to minimize workflow disruption and administrative burden in order to efficiently collect data and reduce barriers for potentially eligible Medicare beneficiaries.
Evidence development requires substantial logistical and financial investment, and it may not be clear which entity (or entities) should share this burden. When no champion emerges, the therapy or service in question is unavailable to Medicare beneficiaries.	Existing and future CED programs should be designed with collaborative input from relevant stakeholders, including patient groups, professional societies, regulators, and others. This collaborative design process should identify a priori how data collection mechanisms will be funded, executed, and maintained, with contingencies for reconsideration as needed.
The expected duration of a CED clinical trial or registry is uncertain, and there is no clear timeline for reassessment.	Measures of progress and an assessment timeline should be identified a priori with a plan to address delays on a regular basis.
Some CED programs have no clearly stated outstanding questions, making it difficult for stakeholders to build consensus around evidence development.	Outstanding research questions should be clearly, transparently, and collaboratively developed and communicated at the time of a CED decision to direct the development of meaningful and informative evidence generation tools.
A CED can be reconsidered in response to public or internal request, but there is no prespecified rubric for retirement of CED data collection requirements.	A clear therapy-specific rubric for retirement of CED data collection requirements should be established a priori to enhance the authority of CMS to reconsider CEDs if criteria are not met and offer transparency and predictability to patients, providers, and other data collection stakeholders.

CED, coverage with evidence development.

## DISCUSSION

In this review of the CED program, we uncovered significant variation in its use over the past 15 years. In most cases, CED was employed to cover promising therapies and services in previously uncovered populations with specific outstanding questions, but there was tremendous variability in execution of the program across therapies and services. We explored this variability and uncovered some important themes, which inform recommendations for policy changes (Table 2).

There have been 4 CED NCDs for which data collection requirements have been retired as part of the NCD. However, even these CED programs have had serious challenges. For example, the CED for ICDs for primary prevention was established in 2005, and data were collected to meet this coverage requirement through the NCDR ICD Registry for more than 12 years. However, despite the registry’s long tenure and high profile, data collection for this registry was never systematically incorporated into clinical workflow. As such, substantial burden was shouldered by participating groups; this created a compelling motivation for facilities to cease data collection and withdraw from registry participation when it was no longer required for coverage in 2018. Data collection mechanisms, including registries and clinical trials using de novo or extant data sources established to meet CED requirements, should be designed to minimize workflow disruption and administrative burden in order to efficiently collect data and reduce barriers for potentially eligible Medicare beneficiaries.

On the other hand, CED therapies without any mechanisms for evidence development are essentially unavailable to Medicare beneficiaries despite a determination by FDA and CMS that they may in fact be beneficial. One barrier to evidence development

is the requirement for substantial logistical and financial investments, and it is not always clear what entity (or entities) should share this burden. For example, home oxygen for cluster headaches was covered with CED requirements in 2011, but no registries or trials were developed to facilitate data collection. Upon reconsideration of this NCD in 2021, CMS determined that “while well intentioned, [CED clinical study requirements] are challenging to implement for this treatment due to patient characteristics and care setting.”<sup>42</sup> This reality, plus lack of scientific equipoise and diffuse commercial interest with limited expected commercial gains, contributed to stagnation of this CED program. Thus, after 10 years, CMS concluded that there would be no CED protocols submitted to support evidence collection for this therapy. The NCD was revoked, and coverage was deferred to local contractors. Issues like these might be uncovered in a transparent predecision collaborative exchange, and an efficient alternative mechanism to address outstanding clinical questions could be identified when appropriate. Existing and future CED programs should be designed with collaborative input from relevant stakeholders, including patient groups, professional societies, regulators, and others. This collaborative design process should identify a priori how data collection mechanisms will be funded, executed, and maintained, with contingencies for reconsideration as needed.

Currently, data collection mechanisms for the CED program are designed and implemented without a specific and transparent timeline for coverage reconsideration by CMS. This is exemplified by the wide range of program duration for the 4 programs with retired data collection requirements (4 to 12 years) and the long duration of CED programs resulting in NCD revocation (10 and 13 years). Thus, potential sponsors of CED registries or trials may be reluctant to fund these initiatives due to anxiety about the program’s duration,

what constitutes “success,” and the possibility of “failure” that may eliminate any form of CMS coverage or even call FDA clearance or approval into question. Although prescribing specific trial or registry design may be counterproductive, a timeline for reevaluation could offer the predictability necessary for collaborators to confidently invest resources in data collection infrastructure. Moreover, from the perspective of CMS and Medicare beneficiaries, a stalled program means either a potentially beneficial therapy is being withheld or a potentially harmful therapy is being furnished to beneficiaries. Measures of ongoing success could be in the form of clinical trial or registry milestones such as protocol design, enrollment initiation, data analysis, and the like. Regardless of the specifics, measures of progress and an assessment timeline should be identified a priori with a plan to address delays on a regular basis.

Facilitation of a high-quality registry or trial requires a champion—including, for example, a commercial entity, a patient group, or a scientific community—and this champion is best identified at the time of the CED decision. This point is illustrated by the CED for ICDs for primary prevention with its few device manufacturers, each with substantial commercial interest in successfully developing a data collection mechanism to make ICDs available to a new large population of Medicare beneficiaries. The incentives of these commercial entities along with those of the scientific community concerned with sudden death aligned around specific outstanding questions stated in the decision memorandum to develop a meaningful data collection mechanism through the NCDR ICD Registry.<sup>15</sup> In the absence of clear potential for commercial success, organized patient advocacy groups, and meaningful scientific equipoise, a champion may not emerge. Specific outstanding questions can help establish organizing principles for 1 or more of these groups to serve as champion especially if relevant stakeholder groups are involved in framing these questions during the development and drafting of the CED decision. Outstanding research questions should be clearly, transparently, and collaboratively developed and communicated at the time of a CED decision to direct the development of meaningful and informative evidence generation tools.

According to CMS guidance, the CED cycle is complete when the CED requirement is removed from the NCD, and this can follow a reconsideration of the CED in response to public or internal request.<sup>1</sup> As with any NCD, this reconsideration includes a period of public comment. However, with only 4 CED programs having had data collection requirements retired from the NCD (as opposed to NCD revocation), it is difficult to identify generic characteristics of a CED “success.” For example, transcatheter aortic valve replacement is an interventional cardiovascular therapy with a small number of dominant manufacturers, many approved clinical trials and registries, publicly available results, and outstanding questions proposed in the decision memorandum. For these reasons, this therapy appears similar to those that have had data collection requirements retired, but CED requirements remain in place. Alternatively, the artificial heart is a high-risk cardiovascular therapy with a single manufacturer, many approved studies, and publicly available results, making it

similar to those therapies with CED requirements retired. Instead, after a period of 13 years, in response to manufacturer request for reconsideration, CMS revoked the NCD because it was “no longer necessary or appropriate.”<sup>43</sup> A clear therapy-specific rubric for successful retirement of CED data collection requirements should be established a priori to enhance the authority of CMS to reconsider CEDs if criteria are not met; such a rubric would offer transparency and predictability to patients, providers, and other data collection stakeholders while better aligning access to therapies and services with the available evidence in a timely manner.

### Limitations

Although input was sought and received from CMS to confirm accuracy and completeness for the background and analyses presented, it is possible that there are additional CED decisions or revisions that have inadvertently been omitted or were eligible for addition after the drafting of this manuscript. In addition, for those CED therapies included in this analysis, extensive review of the literature was performed to identify publicly available results, but there may be undiscovered reported results or results made available after the period of investigation.

## CONCLUSIONS

The CED program is a powerful tool wielded by CMS when more data are required to make an assessment of whether a therapy or service is “reasonable and necessary” for Medicare beneficiaries. This systematic review of the CED program reveals variation in the program that leads to uncertainty among stakeholders whose partnership is fundamental to CED program success. Making the program more transparent and predictable may improve stakeholder engagement in a process that could ultimately bring promising therapies and services to Medicare beneficiaries in a timely way while offering a mechanism to restrict access to those therapies that are not beneficial. Changes to the CED program to improve transparency and predictability can be applied to future and existing CED NCDs. Furthermore, lessons learned may inform future policies to more expeditiously provide coverage for promising breakthrough devices<sup>44</sup> or for therapies that fall outside the scope of the CED program, such as self-administered drugs.

Retirement of CED requirements to best align access to therapies and services with the available evidence is rare but possible. The public availability of results from CED-related data collection is a necessary but insufficient achievement for retirement of CED requirements. There remains opportunity to improve the predictability of the CED program through more concrete evidence requirements and rubrics for success, more inclusive program design, and straightforward timelines for reassessment. ■

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