The Value of Accelerated Medical Device Reimbursement[1]

by

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Abstract

Expediting breakthrough medical device reimbursement has become a recent public policy issue. This paper provides evidence of the value of faster reimbursement of new medical devices using a comprehensive dataset of past approved devices. The estimation considers the cost and patient health impacts of delays from FDA approval to CMS reimbursement and relying on existing evidence indicating an average delay of 4.7 years. We find that observed postponements of reimbursement and coverage for devices approved between 2010 and 2022 had the delays in health improvements valued about 11 times larger than the savings in spending.

Section 1: Introduction

Expediting breakthrough medical device reimbursement has become a recent public policy issue. In January 2021, the Medicare Coverage of Innovative Technology (MCIT) was launched (Federal Register, 2021). As stipulated in the Cures 2.0 Act, the MCIT ensures the coverage of breakthrough medical devices for Medicare patients within a specific time frame following FDA approval (Al-Faruque, 2021). Though the MCIT provision has been praised for enabling quicker access to innovative technologies, the initiative was eventually rescinded in November 2021 due to safety concerns. The final rules provided were not deemed sufficient to protect Medicare patients (CMS, 2021).

Before the MCIT was initiated, bills that provided expedited access of breakthrough medical devices to seniors were introduced in 2019 (H.R. 5333, 2019) and 2021 (H.R.4033, 2021). The Ensuring Patient Access to Critical Breakthrough Products Act mandated CMS to cover the medical devices that are approved under the Food and Drug Administration (FDA) Breakthrough Devices Program during a four-year transition period. These bills inevitably influenced the Cures 2.0 package and have been included through some wording in the package (DelBene, 2021). In 2023, Wenstrup/DelBene introduced similar bills to promote Medicare patients' access to breakthrough medical devices. Accordingly, in the Ensuring Patient Access to Critical Breakthrough Products Act of 2023, CMS would be mandated to cover such devices for four years while it decides the permanent decision for the devices' coverage (Wenstrup, 2023).

The CMS has proposed the new Transitional Coverage for Emerging Technologies (TCET) pathway to provide timely and predictable access to new medical technologies for Medicare beneficiaries. By utilizing existing coverage determination processes such as national coverage determination (NCD) and coverage with evidence development (CED), TCET aims to streamline the Medicare coverage process for breakthrough devices (CMS, 2023). The Congressional Budget Office (CBO) is currently in the process of analyzing its impact on the federal budget.

In this paper, we present evidence of the value of faster reimbursement of new medical devices using a comprehensive dataset of past approved devices. The estimation considers the cost and patient health impacts of delays from FDA approval to CMS reimbursement. We find that observed postponements of reimbursement and coverage for these devices can lead to losses in health improvements for patients valued between $1.90 million to $2.80 million annually as a unit measure for the yearly cohort of new devices, which we find is approximately eleven times larger than the savings in spending, which is valued between $0.15 million and $0.23 million, considering an average delay of 4.7 years between FDA approval and Medicare reimbursement.

The paper is structured as follows: Section 2 discusses the evidence on the cost- and health effects of past medical devices approved in the US. Section 3 calculates the impact on costs and patient health from observed reimbursement delays between FDA and CMS approval. Section 4 provides concluding remarks.

Section 2: Evidence on the cost- and health effects of past medical devices in the US

Section 2.1: Current policies on medical device reimbursement

Streamlining the regulations and approval process for breakthrough technology is important for encouraging innovations and ensuring timely access to patients. Currently, Medicare's process for getting new medical devices covered is lengthy and complex. In line with the goal of improving healthcare access, the CMS has proposed the TCET pathway to provide timely and predictable access to new medical technologies for Medicare beneficiaries. Under the proposal not yet finalized, by utilizing existing coverage determination processes such as NCD and CED, CMS indicates that TCET would streamline the Medicare coverage process for breakthrough devices and better ensure that patients can benefit from innovative medical technologies in a clear and consistent manner (CMS, 2023).

To participate in the TCET pathway, manufacturers may self-nominate their devices 12 months prior to the expected decision from the FDA. At minimum, eligible devices should be designated as breakthrough devices by the FDA and be within the benefit coverage of Medicare. CMS will examine the application by conducting an Evidence Preview (essentially a literature review) to provide feedback to the manufacturers regarding the state of available evidence and any notable evidence gaps. On being accepted and gaining marketing approval from the FDA, the CMS will continue the NCD process and manufacturers will be required to propose an Evidence Development Plan (EDP) when evidence gaps are identified. TCET NCD will cover the medical devices as long as needed to facilitate the timely generation of evidence, which is expected to be around three to five years. After the TCET pathway concludes, the CMS will update the evidence review within six months of the date specified in the EDP. This review will determine the continuation of the devices' coverage (ibid).

The TCET is meant to be the evolution of the Trump Administration's MCIT initiative published in 2021. MCIT would have ensured the coverage of breakthrough medical devices for Medicare-eligible patients within a specific timeframe following FDA approval (Al-Faruque, 2021). The MCIT provision has been praised for expanding access to innovative technologies. However, the provision was finally rescinded in November 2021 due to safety concerns (CMS, 2021).

Section 2.2: Health and cost impacts of new device innovation

In this section, we analyze the impact of innovative devices on health care spending and health outcomes using the largest existing database on this subject.2 We analyze the Cost-Effectiveness Analysis (CEA) Registry by Tufts University which collected such analysis across

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[2] The current evidence base on new medical devices is deficient in addressing how they affect total health care spending through potential cost offsets that may lower other forms of spending more than device spending rises. Some studies have shown cost offsets ranging from $42.57 to as high as $257.76 associated with the use of specific medical devices (Zhang and Soumerai, 2007; Miller et al., 2005). This is in contrast to a larger literature for such cost offsets for drug innovation (see e.g. Philipson and Di Cera, 2022).

the literature up to 2020. This database thus tracks the cost-effectiveness literature on medical products including devices.

To arrive at our estimates for the impact of new devices, we imposed several filters on the data. First, in order to obtain sufficient sample size, we defined medical devices to include all products labeled "Screening", "Diagnostics", and "Medical Device" in the dataset. Second, we restricted the literature to studies published after 2000, with trials conducted in the US, and where the results were reported in US dollars. For each device we obtained its health improvement (defined in Quality-adjusted Life Years (QALYs)), its impact on health care spending, and one estimate for the Incremental Cost-effectiveness Ratio (ICER). QALYs are defined as a life year adjusted for its quality so that the impact of patient use of a medical device that results in less disability or improved health gets a higher quality score ranging from 1 0 to 1. ICERs are the standard metric used in the cost-effectiveness literature and represent the new incremental spending of a device per unit of health the device generates. For example, if a device has an incremental cost of $20,000 and extends the health outcomes by 2 QALYs, the ICER is $20,000/2=$10,000.

In compiling the studies, several assumptions were made. First, given that different trials have different treatment designs and target populations, we took the average across both for a given device. Second, different studies report different perspectives in evaluating ICERs (e.g. societal vs healthcare payer), as well as different types of cost (e.g. caregiver vs out-of-pocket) which we averaged over.

To make all monetary estimates across time comparable, we used the CPI inflation calculator by the Bureau of Labor Statistics3, and adjusted all reported values to be in 2023 January dollars. We removed the outliers of the sample by retaining 1% to 98% interval of the QALY improvements, which resulted in a range of -2.98 QALY to 33.86 QALY improvements.

QALYs aim to measure the quality of a life year ranging from 0 to 1. Assuming the value of a full QALY of 1 is the same as the value of a statistical life year (VSLY) is a conservative approach to valuing QALYs as the VSLY measures may capture non-perfect health. Using this approach, we estimate the devices had QALY impacts with a range from -$1.4 million to $16.6 million. We drop outliers and focus on the samples in the 1% to 99th percentiles, which yields ICER estimates ranging from -$0.49 million per QALY to $3.29 million per QALY. With the outliers removed, we ended up with 356 devices reporting lifetime health and spending effects. Their summary statistics can be seen in Table 1, and their ICER distribution can be seen in Figure 1.

Table 1 Summary Statistics - Lifetime Estimates

Metric	N	Min	25% Percentile	Median	75% Percentile	Max	Mean	St. Dev.
QALY	356	-2.98	0.00	0.03	0.25	33.86	0.47	2.22
Value of QALY ($ Thousand)	356	-1,461.83	2.05	14.77	121.03	16,591.40	229.72	1,087.69
Cost ($)	356	-44,307.58	184.73	1,197.69	6,829.52	637,780	19,992.41	67,402.15

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3 https://data.bls.gov/cgi-bin/cpicalc.pl

| | ICER ($ Thousand) | 356 | -487.24 | 1.25 | 39.71 | 109.43 | 3,288.09 | 106.02 | 323.08 |

Figure 1 ICER Distribution Plots - Lifetime Estimates
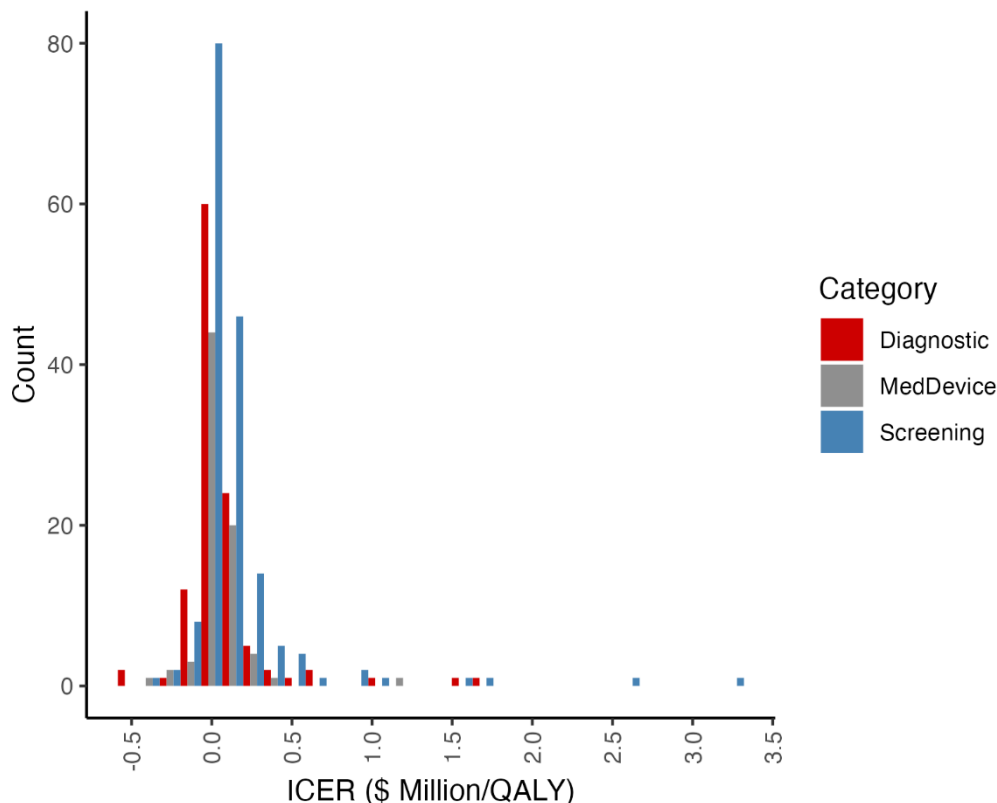
We find that the median improvement in QALY is 0.03, and the average improvement is 0.47 due to large values above the median driving up the mean. These improvements are equivalent to $10,000 and $230,000, respectively when valued at the average findings of VLSY in the literature. We assume that one QALY is valued similarly to a statistical life year. In comparison to a QALY valued at $490,000 per VSLY (Philipson and Durie 2021). Furthermore, it's important to note that the losses resulting from missed QALY improvements may represent only a conservative estimate, as we have not factored in the additional benefits of improved health, such as a reduced caregiver burden.

However, these gains in QALY are associated with increased costs of $1,197 at the median and $19,992 on average. The ICERs are therefore almost negligible at the median, and slightly over $0.1 million per QALY for the average. These values are influenced differently by the removal of outliers; the mean values change, but the median values remain the same. Since ICER is a measure of the cost per QALY gained, it suggests that, on average, gaining one QALY costs between $39,708 and $106,024.

Section 3: The costs and patient health impacts from observed reimbursement delays of medical devices

This section analyzes the implications of observed reimbursement delays for medical devices given the evidence base on their cost- and health impacts analyzed in Section 2. To avoid the effect of outliers biasing the mean, we only use the median estimates from above in our calculations.

Section 3.1: Evidence base on the delays in CMS reimbursement after FDA approval

In the past, delayed payment from the CMS for innovative technologies posed significant challenges for developers and investors, leading to a focus on established technologies and discouraging the pursuit of novel approaches (Ackerly et al. 2009). The prevailing perception among investors and innovators is that the existing Medicare coverage barriers hinder the advancement of innovative technologies. Recent studies focused on delayed payment and reimbursement from the CMS analyze the CED pathway. Moreover, CED studies are expensive and demand extensive data collection from clinicians, which may be feasible only for cost-justified technologies.

Tunis et al. (2022) examined devices that received FDA breakthrough designation and found that the majority achieved Medicare reimbursement without undergoing a formal CMS coverage determination process. Of the 35 devices they analyzed, only seven were subject to national or local coverage policies, indicating that 28 devices were not directly affected by Medicare NCDs or LCDs. Nonetheless, the researchers found evidence of reimbursement for the 28 devices without coverage. These findings suggest that the absence of formal coverage policies does not preclude Medicare reimbursement, potentially due to the underlying medical procedures already having CMS coverage. However, the authors state that the lack of NCDs or LCDs might have created uncertainty for patients, providers, and product developers regarding claims of reimbursement. Consequently, developers tend to prioritize technologies like those already covered, leading to a dearth of truly novel and superior approaches to diagnosis and treatment. This unintended consequence of the current policy framework does not encourage groundbreaking alternatives that carry higher risks of payment delays or lack of reimbursement.

In another study, Sexton et al. (2023) conducted a comprehensive analysis that went beyond just measuring the time it takes for new technologies to attain coverage milestones. Their work delved into the nuanced aspects of coverage attainment, coverage probability, and the various factors that influence the process. Notably, they found that within their cohort of novel technologies, 28% successfully reached at least nominal coverage, marking a significant milestone in the journey to reimbursement. Among these achievers, 50% secured explicit coverage through mechanisms such as NCDs, Molecular Diagnostic Services (MolDx) decisions, or LCDs. 79% attained implicit coverage through the assignment of new billing codes. Notably, 29% managed to achieve both implicit and explicit coverage, showcasing the multifaceted nature of the reimbursement process. Furthermore, the study revealed valuable insights into the temporal dynamics of coverage. At the 3-year mark post-FDA authorization, the apparent coverage probability for a novel technology stood at 25%, indicating the initial progress in the coverage journey. This probability steadily increased to 40.60% at the 5-year milestone, underscoring the

evolving landscape and opportunities for technologies seeking reimbursement. These findings shed light on the complex interplay of factors impacting the path to coverage and provide valuable data for stakeholders in the healthcare innovation ecosystem.

Lastly, Ruggles et al. (2022) studied surveys from innovators and investors about the time to each reimbursement milestone. They determined that the length of time to establish coding, the process where products receive specific alphanumeric codes, ranged from 1.1 to 4.1 years, and the length of time to obtain local Medicare Administrative Contractor (MAC) coverage ranged from 1.3 to 5.7 years. Innovators with expertise in diagnostics reimbursement indicated that the reimbursement timeline was up to 1 year shorter for diagnostic products. For important breakthrough therapeutic technologies, however, it takes 1.9 to 7.5 years to establish nationwide coverage. Ruggles et al. (2022) also reports an average delay of 4.7 years to obtain national Medicare coverage, which we focus on in the following analysis. The impact of such a 4.7-year delay on a single device can be seen in Table 2 below.

Table 2 Value of QALY and Cost Increase Delayed by 4.7 Years per Device

Value of QALY	Cost Increase	Value of QALY delayed	Cost Increase delayed
$14,700	$1,197.69	$69,090	$5,629.14

Note: Value of QALY is calculated using $490,000 VSLY and a median improvement of 0.03.

Section 3.2: Aggregate impacts on patient health and spending from coverage delays

In this section we calculate the aggregate value of faster reimbursement by year of approval using all devices approved in that year using results from Table 2. Using data from FDA,[4] we gather the number of approved devices each year from 2010 to 2022, as in in Table 3 below. For each year, to obtain the aggregate impact we multiply the number of new devices approved in that year with the per-device impacts discussed earlier. The per-device impact is the yearly impacts being pushed up from the observed delay of 4.7-years. This aggregate measure the impacts of one user per device for each new device. This measure can this be scaled up to any size of the patient population of interest when evaluating the health and cost impacts of new devices.

Across each year of approval the annual improved health ranges from $396,900 to $602,700, corresponding to $1.90 million to $2.80 million considering the 4.7-year average delay. For the cost-impacts, delaying the cohort induces cost-savings ranging from $33,337.63 to $49,105.29, corresponding to $0.15 million to $0.23 million considering the 4.7-year average delay. As for the ICER data on individual devices, these cost data came from the definitions of costs used in the entry in the CEA registry. On average, a 4.7-year delay would lead to a loss of $2.80 million from forgone health improvements, and a cost-saving of $0.23 million. In each year, the QALY loss is valued more than approximately eleven times the cost-savings, regardless of whether the 4.7-year delay is considered. With the 4.7-year delay, the trends across years can be seen in Table 3 and Figure 3. Similarly, although we do not consider discounting and inflations, this ratio between health improvement values and cost savings would remain constant.

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[4] https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/recently-approved-devices

Table 3 Aggregate Impact of Reimbursement Delays by Year of FDA Approval

Year	Number of Approved Devices	Total Delayed Value of QALY ($ Mil)	Total Delayed Cost ($ Mil)
2010	27	1.87	0.15
2011	51	3.52	0.29
2012	48	3.32	0.27
2013	33	2.28	0.19
2014	41	2.83	0.23
2015	42	2.90	0.24
2016	26	1.80	0.15
2017	27	1.87	0.15
2018	54	3.73	0.30
2019	46	3.18	0.26
2020	63	4.35	0.35
2021	28	1.93	0.16
2022	41	2.83	0.23
Average	40.54	2.80	0.23

Note: Lifetime estimates only; QALY valued at $490,000.

Figure 3 Trends of Cost Savings and Value of QALYs Lost by Year
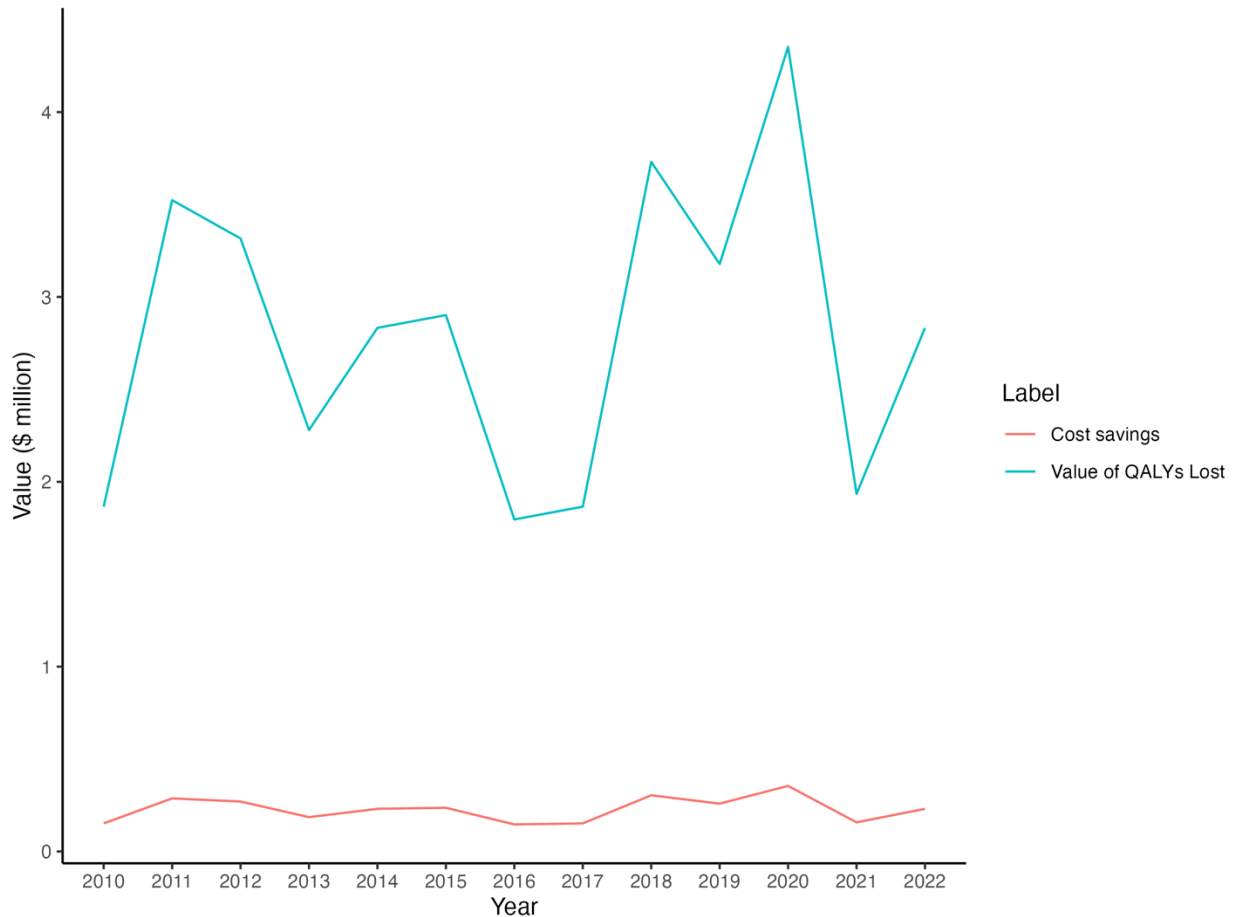
If we use the VSLY of $150,000 more commonly seen in policy-making bodies, the 4.7-year average delay would yield delayed values from QALY improvements ranging from $0.55 million to $1.33 million, while the delayed cost remains unchanged. Across the years, the 4.7-year average delay leads to a mean delayed value of $0.86 million from QALY improvements. Using this VSLY, values from QALY improvements are almost four times the cost. Though this VSLY is more commonly used in policy documents, we note that the scientific literature review by Philipson and Durie (2021) finds an average VSLY of $490,000 across literature, which we therefore rely on in our analysis.

Section 4: Concluding Remarks

The CMS recently proposed a new policy called TCET that would expedite the coverage of certain breakthrough medical devices for Medicare patients. This policy brief calculates the impact of the current 4.7year delay in Medicare reimbursement following FDA approval for breakthrough medical devices for patients, manufacturers, and government spending. There are three metrics observed to determine such impacts: Quality-adjusted Life Years (QALYs), total costs, and Incremental Cost-effectiveness Ratio (ICER).

Previous studies show that the uncertainty associated with reimbursement for new innovative medical technologies in many cases has led to manufacturers preferring to develop similar technologies with already proven features rather than developing entirely new innovative technologies.

Our research indicates that delaying the reimbursement for medical devices has a negative impact on patients' health and total costs. An average delay of 4.7 years in reimbursement and coverage of breakthrough medical devices results in a substantial loss in health improvements valued between $1.90 million to $2.80 million annually. While such a delay can result in savings in federal spending between $0.15 million to $0.23 million, those cost savings are offset by the positive changes in patient health. When we consider the impact on patient health, the value of the health improvements lost due to the delay is eleven times the corresponding cost savings.

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