Documents for the Record – 9/19/23 Health Subcommittee Hearing

Majority:

- September 18, 2023, letter from national organizations on H.R. 3842
- September 4, 2023, "Insulins and the Evolving Landscape of U.S. Prescription Drug Pricing"
- September 19, 2023, statement of Harbinger Health
- August 4, 2023, JAMA Health Forum article on "Time From Authorization by the US Food and Drug Administration to Medicare Coverage of Novel Technologies"
- Congressman Brad Wenstrup statement for the record (document submitted by Rep. Bilirakis)
- September 15, 2023, Obesity Care Advocacy Network letter on H.R. 4818
- September 19, 2023, statement from Geneoscopy
- September 19, 2023, National Grange Letter on Obesity
- March 17, 2023, letter from Congressional Budget Office on federal health care spending (document submitted by Rep. Burgess)

Minority:

- September 18, 2023 letter from diabetes organizations
- August 15, 2023 letter to CMS from members of Congress
- September 18, 2023 letter from Healthcare Leadership Council

September 18, 2023

The Honorable Cathy McMorris Rodgers
Chair
Energy & Commerce Committee
2188 Rayburn House Office Building
Washington, DC 20515

The Honorable Brett Guthrie
Chair
E&C Subcommittee on Health
2434 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Energy & Commerce Committee
2107 Rayburn House Office Building
Washington, DC 20515

The Honorable Anna Eshoo
Ranking Member
E&C Subcommittee on Health
272 Cannon House Office Building
Washington, DC 20515

Dear Chair McMorris Rodgers, Ranking Member Pallone, Chair Guthrie, and Ranking Member Eshoo:

Diabetes is a serious, costly chronic condition affecting roughly one in four Medicare beneficiaries and requiring access to a range of medications and services to help treat the disease. The undersigned national organizations support the bipartisan Expanding Access to Diabetes Self-Management Training Act (H.R. 3842) and thank you for including the bill in the upcoming Subcommittee on Health hearing, *Innovation Saves Lives: Evaluating Medicare Coverage Pathways for Innovative Drugs, Medical Devices, and Technology.*

Diabetes self-management training (DSMT) is an evidenced-based service that has been covered under Medicare Part B since 2001 to give beneficiaries the tools to manage their diabetes, reduce their risk of complications, and improve their quality of life. Even though DSMT has been consistently shown to help participants achieve lower hemoglobin A1c, weight loss, improved quality of life, and healthy coping skills, only 5 percent of Medicare beneficiaries with newly diagnosed diabetes utilize the service due to myriad barriers—many of which Congress can remove or reduce. This legislation is critical to improving outcomes for Medicare beneficiaries living with diabetes and, therefore, generating savings for the Medicare program.

The *Expanding Access to DSMT Act* would improve access to the DSMT benefit by–

- Excluding DSMT services from Part B cost-sharing and deductible requirements;
- Allowing beneficiaries the flexibility to access their initial 10 hours of DSMT services when needed rather than having hours expire after one year;
- Permitting DSMT and Medical Nutrition Therapy to be provided on the same day avoiding arbitrary waiting periods;
- Permitting all physicians and qualified nonphysician practitioners working in coordination with the beneficiaries treating provider to refer for DSMT services; and
- Establishing a CMS Innovation Center demonstration program to test the coverage of virtual DSMT within Medicare.

The *Expanding Access to DSMT Act* is bipartisan legislation led by Representatives Bilirakis (R-FL-12) and Schrier (D-WA-8). There is a companion bill in the Senate led by Senators Shaheen

(D-NH) and Collins (R-ME). Importantly, this legislation is also supported by the Diabetes Caucus.

Thank you again for including the bill in your upcoming hearing. As the 118th Congress proceeds, we also encourage you to consider this important legislation for markup and passage.

Sincerely,

Academy of Nutrition and Dietetics
Association of Diabetes Care & Education Specialists
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Endocrine Society
National Kidney Foundation
Omada Health, Inc.

Annals of Internal Medicine

Insulins and the Evolving Landscape of U.S. Prescription Drug Pricing

Mariana P. Socal, MD, PhD; and Ge Bai, PhD, CPA

The pricing of U.S. prescription drugs is complex. A drug's list price, determined by its manufacturer, is generally higher than its net price, the amount ultimately collected by the manufacturer. This is because manufacturers usually provide price concessions (rebates, discounts, and fees) to pharmacy benefit managers (PBMs), health insurers, and other supply chain entities (1). For cash-paying patients and insured patients in the deductible phase, list prices typically are aligned with their out-of-pocket expenditures (OOPs); for insured patients subject to coinsurance, list prices usually serve as the basis for calculating patients' OOPs (2, 3). Because price concessions are not passed on to patients, patients rarely benefit from lower net prices negotiated by insurers and PBMs (1, 2). The opaque pricing structure of drugs in the United States penalizes patients by exposing them to higher OOPs, limiting treatment affordability and access which, in turn, places patients at risk for poorer health outcomes and potentially higher downstream health care spending (4).

Recently, 3 major insulin manufacturers—Sanofi-Aventis, Eli Lilly, and Novo Nordisk—announced steep cuts to the list prices of their insulin products. Before this, list prices of insulin glargine were up to 5 times higher than its net prices (5). Therefore, a patient in the deductible phase would pay OOPs 5 times more than the net price that their insurance plan pays after rebates; a patient paying 20% coinsurance based on the list price would in effect pay the entire net price. For example, at a list price of about $28 per 100 U for glargine, a patient paying 20% coinsurance would pay $5.60 OOP when the net price to the insurer was approximately $4 (5). Because the insurer and/or the associated PBMs gets and keeps the rebate, in this case, the insurer and/or PBM makes a profit of $1.60 per each 100 U from the patient's OOP ($5.60 minus $4), a profit of about 40% over the net price ultimately due to the drug manufacturer.

Drug manufacturers have long been questioned as to why they maintain high list prices despite decreasing net prices. During congressional testimonies, drug manufacturers pointed to the critical role of PBMs in incentivizing this phenomenon (6). Drug manufacturers rely on PBMs for market access because PBMs negotiate prices with manufacturers on behalf of health insurers and influence which drugs an insurance plan will cover. Health insurers typically pay PBMs a small fee or no fee at all for managing their prescription drug benefits, with the understanding that PBMs cover costs and generate profit primarily from retaining rebates and other price concessions. This revenue structure incentivizes PBMs to favor drugs with high list prices and high rebates, such as insulin glargine (5, 7). Although PBMs also attribute high drug prices to drug manufacturers, both parties benefit from high list prices and high rebates (6). This dynamic explains why list prices of many prescription drugs have been stable or increasing even when net prices decrease. Unfortunately, this nontransparent pricing practice penalizes and shifts costs to patients through higher OOPs.

Against this backdrop, recent reductions in list price implemented by insulin manufacturers may seem counterintuitive. One potential driver is the recent passage of federal legislation capping Medicare beneficiaries' OOPs for insulin products at $35 per month, which—together with OOP caps for insulin for commercially insured patients implemented by several states—has restricted PBMs' ability to shift insulin costs to patients. This disincentivizes PBMs to cover insulin products with high list prices. This decision may have also been influenced by the lifting of the Medicaid rebate cap (to take effect in January 2024). Medicaid rebates are calculated through a complex formula that, among other factors, accounts for how rapidly drug list prices increase relative to inflation. Under certain scenarios, increases in drug prices that outpace the rate of inflation can result in rebates that exceed the average price of the drug (8). The rebate cap ensures that rebates to Medicaid cannot be greater than 100% of the average drug price. Given the historical trajectory of insulin prices, removing the Medicaid rebate cap might lead to insulin manufacturers having to pay state Medicaid programs substantial sums, negatively affecting manufacturers' revenues (8). Lowering list prices could help insulin manufacturers avoid paying such high rebates after the cap is lifted. Moreover, biosimilar insulin options, including some with low list prices and low or no rebates, are increasingly available. Assuming net prices remain stable, this strategy of reducing list prices would translate to insulin manufacturers paying lower rebates to PBMs and state Medicaid programs while potentially increasing manufacturers' total net revenues (through a potential increase in volume) without necessarily jeopardizing the likelihood of having their products covered.

Insulin list price reductions and reductions in rebates could disrupt the revenue and business practices of PBMs. Lower list prices align with the interests of plan sponsors. Although plan sponsors theoretically benefit from rebates passed on by PBMs, their concern is that PBMs may retain too much of the rebates. Pharmacy benefit managers rarely provide transparency on transaction details or allow insurers auditing rights, exacerbating this concern. Lower list prices and lower rebate amounts help mitigate this concern. Most importantly, lower list prices would improve drug affordability and lower OOP burden among cash-paying patients, insured patients during the deductible phase, and those subject to coinsurance. The insulin market has some unique features that may not apply to other drug markets, including a large patient population, high public

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awareness of pricing issues, and OOP caps. However, similar progress has also been seen for some other high-cost drugs, such as proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors and hepatitis C treatments.

Lower list prices should be welcomed news for prescribing clinicians, as affordability for the patients whose OOP expenditures are tied to drug list prices is likely to improve. However, high list price and high rebates are not changing for all drugs, especially not for most high-cost specialty drugs. The effect of this pricing model on patient OOP may not be fundamentally resolved until drug list prices are delinked from PBMs' compensation. The recently introduced bipartisan Patients Before Middlemen Act in the U.S. Senate Committee on Finance aims to accomplish this goal for the Medicare Part D program (9). Achieving a similar policy in the commercial market can be politically challenging, but a fee-based PBM business model—in which PBM compensation is disconnected to list prices—is emerging. Several other bills recently introduced in the House and Senate focus on improving transparency in the contracting process between PBMs and plan sponsors in the commercial market (10). Although these transparency proposals do not directly delink PBM compensation from drug list prices, they have the potential to enhance plan sponsors' ability to compare options, reduce entry barriers for fee-based PBMs, and encourage incumbent PBMs to adapt to the new model. Ultimately, if the fee-based PBM model gains market share by delivering value to employers and patients, it can mitigate PBMs' preference for high rebates and manufacturers' incentive to maintain high list prices.

Reforming the current opaque and rebate-based pricing structure of the U.S. pharmaceutical market should benefit patients by protecting them from cost shifting; improving medication affordability, treatment adherence, and health outcomes; and reducing preventable downstream health care spending and use.

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Statement of Harbinger Health
to the Subcommittee on Health, Committee on Energy and Commerce
U.S. House of Representatives

Legislative Hearing Examining Policies to Improve Seniors' Access to Innovative Drugs, Medical Devices, and Technology
September 19, 2023

Chairman Guthrie, Vice Chair Buschon, Ranking Member Eshoo, and Members of the Subcommittee on Health:

Thank you for the opportunity to share support for H.R. 2407, the Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act, introduced to improve equitable access to innovative cancer screenings in order to increase early detection and treatment of cancer. Harbinger Health commends the bipartisan support to create a covered benefit for multi-cancer early detection (MCED) screening tests to ensure Medicare beneficiary access to these tests without unnecessary delay once approved or cleared by the U.S. Food and Drug Administration (FDA).

Detecting cancer early can be the difference between life and death. As the risk of cancer increases with age, Medicare beneficiaries comprise the majority of individuals diagnosed with cancer and are especially vulnerable to the disease. The impact of late-stage cancer diagnosis is magnified in underserved communities where racial, socioeconomic, and geographic disparities persist.

Founded by Flagship Pioneering in 2018, Harbinger Health is transforming the detection, diagnosis, and treatment of cancer for everyone. The company is pioneering next-generation early cancer detection with high-resolution blood-based assays that combine recent genomic and epigenomic discoveries of early cancer and biology-informed artificial intelligence (AI). Unlike prior approaches that are purely statistical to identify informative biomarkers, Harbinger Health's approach is informed by insights into specific biological events early during tumorigenesis and is therefore optimized for detecting cancer in patients with very low levels of circulating tumor DNA. Harbinger Health is pushing into new frontiers of cancer screening guided by core principles ensuring that the technology is affordable, accessible, precise, and highly predictive.

Early cancer detection has the potential to significantly improve patient outcomes and reach the Cancer Moonshot goals of reducing the death rate from cancer by at least 50 percent over the next 25 years. "**At Harbinger, we know that early detection is the first line of defense against cancer**," said Stephen M. Hahn, M.D., CEO of Harbinger Health and former FDA Commissioner, in relation to the company's abstract, "*Novel blood-based assay for detection of early stage multi-cancer*," published in the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting Proceedings. By identifying cancer signals before an individual shows visible symptoms, Harbinger Health is pioneering the detection of early cancer through its biology and AI-driven platform, *HarbingerHx*, to design leading-edge cancer screening tools and to create a new pathway for cancer diagnosis.

MCED tests have the potential to find more than one type of cancer from a single blood sample. Given the low prevalence of individual cancers in an asymptomatic, average-risk population, the test must not only be highly specific, but it must also have a high positive predictive value (PPV) in order to reduce the number of tested individuals who receive false positive results. By testing across several cancer types, the specificity of the data would guide the physician's next step, for example, to determine the primary site of a tumor and allow for early intervention. For an effective MCED test, a critical step is identifying the biological signature of circulating tumor DNA (ctDNA), or certain pieces of DNA or proteins from cancer cells. ctDNA is tissue-specific and presents more significantly in the patient's blood than other types of biomarkers. The tests are developed through blood-based assays used to find certain biological signals and to measure the amount of a specific substance in a sample such as a liquid biopsy. Several innovators are currently developing MCED tests given the profound potential benefits to patients by finding cancer early, including in people without any symptoms of cancer.

Harbinger Health aims to differentiate itself in blood-based cancer testing on multiple fronts. To achieve this, the company is developing tools that address major constraints which are inhibiting the cancer detection field. For example, Harbinger Health is focused on performance and clinical informativeness for physicians by improving PPV (the percent of cancer signal detected results that were confirmed to be cancer). While accuracy of the predicted cancer signal origin is a key milestone, Harbinger Health understands that physicians make decisions also informed by the patient population, that is, PPV measures. While data from other MCED tests indicate their PPV is 30-40 percent, Harbinger Health aims to increase PPV for MCED tests to 70 percent or greater. This goal is critical to avoid large numbers of false positive tests, which would typically result in unnecessary follow-up testing and burdens on both individuals and health program budgets.

In addition to the accuracy and precision of analytical tools developed using the HarbingerHx platform, the company is focused on developing MCED tests that are affordable, so that the offering can be similar to a cholesterol test or other test routinely ordered. To advance technology for efficient product development and clinical testing, Harbinger Health is developing genomic libraries as templates to increase the abundance of reference samples from which development, optimization, and validation studies can be iteratively performed. The Archived Reference Samples (AReS) platform was formed based on such genomic libraries with the goal of expanding the availability of patient-derived samples for experimentation, accelerating assay development and regulatory submissions.

In July 2023, Harbinger Health announced results from an early development study demonstrating overall sensitivity of early cancer detection using the Harbinger blood-based assay was 82 percent at 95 percent specificity; specific cancer detection rates include colorectal (96%), lung (85%), prostate (82%) and breast (73%). In addition, the data demonstrate overall accuracy to predict tissue of origin (TOO) was 86% when the tumor fraction was greater than 0.1%, in the top three most prevalent cancer types (breast, colorectal and lung). The findings are published in the 2023 ASCO Annual Meeting Proceedings, a Journal of Clinical Oncology supplement. The data demonstrate that Harbinger's assay shows high technical precision and reproducibility, as well as extremely low tumor content limit of detection. This is important given that ctDNA analysis is challenging due to the low amounts and highly fragmented

nature of ctDNA. Therefore, the data support the precision of the blood-based assay and its ability to perform early-stage multi-cancer detection.

As a next step in product development, Harbinger Health has partnered with the Sarah Cannon Research Institute (SCRI) and announced the launch of a clinical trial to validate Harbinger's blood-based MCED test. The study, *Development and Validation of Harbinger Health Test for Early Cancer Detection* (CORE-HH, NCT05435066), is a prospective, multi-center, observational study with a collection of biospecimens and clinical data from approximately 10,000 participants from up to 40 clinical network sites and locations in the United States. The objective of this study is to collect blood samples, tissue samples, and associated clinical data from participants with a variety of solid tumor and hematologic cancers as well as cancer-free participants for testing and the development of a MCED screening test. Currently on target to complete enrollment by year-end, the study will evaluate the ability of the Harbinger Health test to detect cancer using blood-based biomarkers in a large cohort of patients with cancer and matched asymptomatic controls.

Beyond early detection and early intervention, MCED screening tests using different technologies to detect cancer-associated biomarkers, such as ctDNA, tumor DNA and other analytes, can assist physicians with decisions regarding a symptomatic patient population. For example, detectable levels of ctDNA can be used as a predictive indicator of response to a therapeutic regimen, and potentially as an intermediate endpoint that is predictive of survival outcomes. In addition, when captured and analyzed appropriately, ctDNA could be used in early phase clinical trials to aid in signal finding of drug activity and to potentially accelerate drug development.

If enacted, the Multi-Cancer Early Detection Screening Coverage Act will increase seniors' timely access to MCED technology by creating a pathway to Medicare coverage. This legislation will encourage companies such as Harbinger Health to continue to pioneer early cancer detection capacities to improve health outcomes while ensuring that our most vulnerable citizens are not left behind.

These tools introduce a significant shift in the cancer screening landscape. Ensuring seniors have timely access is essential since age is the primary risk factor for cancer, and more than 70 percent of cancer diagnoses are in the Medicare population. New MCED screening tools will complement existing screening and significantly improve early detection capabilities. Currently, we are only able to commonly screen for five cancers and just 14 percent of cancers are found through these screenings.

The Multi-Cancer Early Detection Screening Coverage Act would expand Medicare coverage to MCED tests approved or cleared by the FDA "insofar as the Secretary determines coverage of such tests is appropriate, furnished to an individual for the purpose of earlier detection of cancer across many cancer types (such as described in the National Cancer Institute's Annual Report to the Nation on the Status of Cancer)." We appreciate that the Act would grant broad authority to the Secretary to determine appropriateness and expect that CMS would use an evidence-based process with opportunities for public participation to determine coverage parameters for these new MCED tests as it does for other items and services under the Medicare National Coverage Determination (NCD) Process. That said, some

unique considerations are necessary in order for MCED tests to deliver their full potential to Medicare beneficiaries.

For example, in the past CMS has focused on specific sensitivity and specificity percentages to grant coverage for blood-based screening tests for colorectal cancer., For MCED tests, Harbinger Health believes that minimum levels of PPV are more appropriate to demonstrate clinical informativeness; that is, the percent of cancer signal detected that were confirmed to be cancer. Because MCED testing has the potential to shift cancer diagnoses to earlier stages, we believe that the number of cancers detected at an earlier stage by MCED testing will have the greatest impact on health outcomes and projected survival.

In addition, although cost is not a factor CMS considers in making "reasonable and necessary" determinations for purposes of Medicare coverage, decreasing costs while improving the quality of care is imperative for the health of our nation. Harbinger Health's biology-informed AI is constantly learning and improving, delivering ever-better results while driving down costs. Again, our goal is to ensure our technology is affordable, accessible, precise, and highly predictive.

We appreciate the Subcommittee's leadership on this legislation and encourage passage of the Act to ensure that Medicare beneficiaries, and their health care providers, have access to transformative new early cancer detection tests. Done right, MCED testing can save lives and money, especially by catching cancers earlier when treatment costs are much lower and treatment results are much better.

Sincerely,

/s/

Harbinger Health
A Flagship Pioneering Company
https://www.harbinger-health.com/

JAMA Health Forum™

Original Investigation

Time From Authorization by the US Food and Drug Administration to Medicare Coverage for Novel Technologies

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Abstract

IMPORTANCE A wide variety of novel medical diagnostics and devices are determined safe and effective by the US Food and Drug Administration (FDA) each year, but to our knowledge the literature lacks evidence documenting how long it takes to establish new Medicare coverage for these technologies.

OBJECTIVE To measure time from FDA authorization to at least nominal Medicare coverage for technologies requiring a new reimbursement pathway.

DESIGN, SETTING, AND PARTICIPANTS In this cross-sectional study, public databases were used to associate each technology to billing codes, determine the effective date of each code and Medicare coverage decisions, and stratify by the maturity of the Medicare coverage. At least nominal coverage was defined as achievement of explicit coverage milestones through a national coverage determination, local coverage determinations by Medicare administrative contractors, or by implicit coverage aligned to a new billing code. Characterization by product type (acute treatment, chronic or ongoing treatment, diagnostic assay, and diagnostic device), manufacturer size, and evidence level were assessed for association with coverage achievement. The study included new product applications authorized by the FDA through the premarket approval pathway, the de novo pathway, or with breakthrough designation in the 510(k) pathway from January 1, 2016, to December 31, 2019. Data analysis took place between May 1, 2022, and December 31, 2022.

MAIN OUTCOME MEASUREMENT Time from FDA authorization to the first coverage milestone.

RESULTS Among 281 identified technologies in the total sample, 64 (23%) were deemed novel technologies based on the absence of coverage determinations and/or the use of temporary or miscellaneous billing codes. Twenty-eight of 64 technologies (44%) successfully achieved explicit or implicit coverage following FDA authorization. The median time to at least nominal coverage for the analysis cohort was 5.7 years (90% CI, 4.4-NA years). Analysis of time-to-coverage data highlighted company size (log-rank $P<.001$) and product type (log-rank $P = .01$) as significant covariates associated with coverage achievement. No association was observed for technologies with level 1 evidence at FDA authorization and subsequent coverage milestone achievement (log-rank $P = .40$).

CONCLUSIONS AND RELEVANCE In this cross-sectional study of 64 novel technologies, only 28 (44%) achieved coverage milestones over the study timeline. The several-year period observed to establish at least nominal coverage suggests existing coverage processes may affect timely reimbursement of new technologies.

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Key Points

Question How long does it take to establish Medicare coverage for novel medical technologies?

Findings In this cross-sectional study, 64 devices and diagnostics authorized by the US Food and Drug Administration through premarket approval and de novo pathways between 2016 and 2019 required establishment of new Medicare coverage; at least nominal explicit or implicit Medicare coverage supportive of patient access was achieved by 28 (44%) within a median of 5.7 years.

Meaning Lengthy processes to establish Medicare coverage warrant attention; timelines for coverage achievement can be used to inform new policy strategies.

+ Supplemental content

Author affiliations and article information are listed at the end of this article.

Introduction

In 2022, more than 3000 medical devices and diagnostics were introduced into the US health care system through the US Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH).[1] Analysis of medical device development has often focused on timelines to FDA authorization.[2] Although achieving FDA authorization provides a manufacturer legal authorization for market access, uptake of these technologies and therefore meaningful patient access, is dependent on achieving reimbursement by health insurers.

The reimbursement process is how the insurer makes a determination of whether and how it will pay for a health care service. This determination involves 3 steps: coverage, coding, and payment. Coverage asks the question of whether the novel technology meets criteria established in the insurance contract as a covered benefit for patients. By statute, the coverage standard for the Medicare program is that services must be "reasonable and necessary" and fall within a benefit category defined by law. Coding is a process of creating a unique identifier in the claims system for the technology. Generally, coding of medical procedures is developed by the American Medical Association (AMA), whereas coding for medical devices is developed by the Centers for Medicare & Medicaid Services (CMS). Each year, more than 200 new codes are created to accurately reflect changes in the health care landscape.[3] The creation of these new codes requires advocacy by physician societies and a review and publication process that lasts between 12 and 15 months.[4,5] Payment assigns a monetary amount for the provision of covered (and coded) medical items and services.

The most influential coverage decisions are often made by CMS because they often precede private health plans.[6] These CMS coverage determinations may be explicit, implicit, or made through claim-by-claim adjudication. National coverage determinations (NCDs) are explicit coverage decisions made at the national level by Medicare. These determinations are infrequent, with only 3 to 4 NCDs initiated annually in 2018 to 2021.[7] Medicare administrative contractors (MACs) make explicit coverage determinations at the regional level through local coverage determinations (LCDs). Both NCDs and LCDs must be followed by traditional and Medicare Advantage organizations. Manufacturers typically initiate these coverage determinations through requests to CMS which include assessments of clinical evidence and indications for use. .

Medical technologies lacking an NCD or LCD can still have implicit coverage if the technology aligns with an established code that describes its use in clinical practice. However, reimbursement of novel medical technologies is unreliable when no coverage determinations exist, and when implicit coverage cannot be linked to an appropriate code. In these situations, temporary common procedural terminology (CPT) codes, unlisted codes, or miscellaneous codes are used to submit claims, and case-by-case adjudication may be necessary. Using these codes introduces hurdles to reimbursement and may require physicians to navigate lengthy administration processes to receive payment. Meanwhile, patients are more likely to incur out-of-pocket costs.[8-11]

Beyond Medicare, different reimbursement paradigms exist for Medicaid or private insurers owing to the nature of state-based and employer-sponsored insurance. Coverage determinations through employer-sponsored private insurance plans vary widely; only roughly half of private determinations align with NCDs, a quarter are more restrictive, and a quarter are less restrictive.[12] In addition, Medicaid and the Children's Health Insurance Program (CHIP) cover more than 40% of births, more than 41 million children, and more than 50 million adult beneficiaries, yet generally lack explicit policies for considering new devices and diagnostics.[13,14] Thus, policy initiatives focused on Medicare also affect these programs and populations.

Although a recent survey of investors and manufactures found that time to national Medicare coverage following FDA authorization is on average 4.7 years, to our knowledge, there is little to no literature objectively quantifying timelines of the reimbursement process.[15] The objective of the current study was to provide contemporary evidence about the progress to Medicare coverage for a cohort of new FDA-authorized technologies for which a reimbursement pathway has not already been established.

Methods

In this cross-sectional study, a convergent parallel design methodology was used consisting of objective analyses for all technologies meeting specific FDA regulatory pathways and authorization year criteria, and qualitative interviews with a convenience sample of market access experts at 25 manufacturers (eMethods in Supplement 1). This design provided insight into coverage, coding, and payment achievement while retaining an inclusive analysis set. Based on the information provided, the Stanford University School of Medicine institutional review board determined that this research did not involve human participants as defined in 45 CFR 46.102(f) or 21 CFR 50.3(g), and therefore did not require written informed consent. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines were used to ensure the reporting of this study (Supplement 1).[16]

The FDA database was screened for original applications that received market authorization during the enrollment period between January 1, 2016, and December 31, 2019. The cohort included technologies approved or cleared through the FDA's premarket approval (PMA) and de novo pathways, as well as 510(k) devices with breakthrough designation, resulting in 153, 124, and 4 products, respectively, for a total initial cohort of 281 technologies. These 3 FDA pathways for authorization were considered likely to contain the most novel technologies based on the lack of comparable device predicates. The follow-up period extended from January 1, 2016, to December 31, 2022, such that all technologies in the analysis set were at least 3 years from FDA authorization. Three milestones were determined as the transition from claim-by-claim adjudication to at least nominal coverage: a new NCD, positive LCDs from a plurality (3/7) of MACs, or implicit coverage through 1 or more new Healthcare Common Procedure Coding System (HCPCS) level 1 or level 2 codes specific to the technology (**Box**).

For all technologies in the analysis cohort, associated billing codes were established via online billing and coding forums, clinical labratory submission instructions, and manufacturer-provided reimbursement information. Codes were reviewed for accuracy by 2 study authors (Z.A.S. and S.W.R.). Technologies were excluded if they had no associated code, were billed with tracking codes (eg, *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision [ICD-10]*-PCS or C-code), had an indication for use restricted to inpatient care, or were capital equipment, software, or consumer-facing products otherwise lacking a Medicare benefit category. Using the Medicare Coverage Database, a designated coding database (Find-A-Code), and FDA documentation on authorized indications, the identified CPT and HCPCS codes were used to locate all CMS coverage literature through Medicare LCDs, billing and coding articles, and NCDs.[17-22] Revision history information was reviewed to determine accurate time point association of coding and coverage. Additional technologies were excluded from analysis when at least nominal coverage was effective before FDA authorization.

Clinical evidence included in the FDA authorization materials was reviewed independently by 2 study authors (Z.A.S. and J.R.P.) on clinicaltrials.gov to ensure consensus in assessing level 1 evidence. Authors referred to the Oxford Center for Evidence-Based Medicine evidence standards for level 1 evidence definitions concerning interventional and diagnostic technologies.[23] Level 1 evidence for diagnostics is generally defined by validation (as opposed to exploratory) studies with clear reference standards, whereas for devices it is defined by randomized clinical trials evaluating technology performance over the existing clinical standard or a sham control. Technology types were defined as 4 broad categories including diagnostic assays, diagnostic devices, acute treatments, and chronic or ongoing treatments, which were determined from indications for use statements in FDA authorizations. To facilitate subanalyses by manufacturer size, company size was researched from current public data sources and classified into small (<200 employees) and large manufacturers.

Box. Definition of Milestones That Establish at Least Nominal Medicare Coverage[a]

1. Explicit coverage through
   - National Coverage Determination (NCD)
   - Local Coverage Determinations (LCDs) via
     - ≥3 of 7 MACs
     - ≥2 of 4 durable medical equipment (DME) MACs
     - MolDx
2. Implicit coverage when billed with
   - HCPCS Level 1 codes (CPT I Codes)
   - HCPCS Level 2 codes (excluding C-, K-codes)

Abbreviations: CPT, common procedural terminology; HCPCS, Healthcare Common Procedure Coding System; MACs, Medicare administrative contractors; MolDx, molecular diagnostic services.

[a] Thresholds of at least nominal Medicare coverage include multiple coverage milestones defined from data collected during interviews with industry experts and from the authors expertise with coding, coverage, and payment of novel technologies (eMethods in Supplement 1).

Statistical Analysis

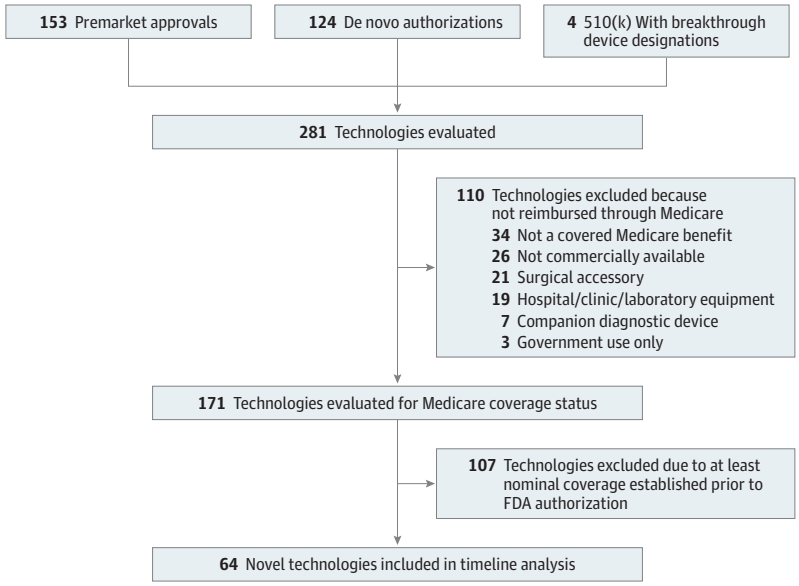
Coverage probabilities at 1, 3, and 5 years were estimated using the standard 1-sample method for population proportions. Time to coverage was computed as the difference between date of FDA authorization and date at which an at least nominal coverage milestone was reached; if no such milestone was achieved by the close of the study period (December 31, 2022), the data were considered lost to follow-up at that point (right censored at that time). Kaplan-Meier curves were estimated to demonstrate achievement of coverage over time. The log-rank test was used to assess factors associated with time to coverage, including strength of clinical evidence, type of technology, and size of commercial manufacturer. All tests were conducted using a standard $\alpha = .10$ type I error rate. All statistical analyses were performed using R statistical software with survival package (version 4.2.3, R Project for Statistical Computing).

Results

The total study cohort included 281 technologies (**Figure 1**). Products spanned 20 FDA advisory committees with cardiovascular (n = 66, 23%) and microbiology (n = 33, 12%) accounting for the largest number of product authorizations (eTable 1 in Supplement 1); products were distributed among 4 categories: diagnostic assays (n = 75, 27%), diagnostic devices (n = 47, 17%), acute treatment devices (n = 86, 30%), and chronic or ongoing treatment devices (n = 73, 26%) (eTable 2 in Supplement 1).

One hundred ten technologies (39%) were not directly reimbursed by Medicare. These included surgical supplies and supplies for in-patient hospitalizations such as intubation kits and surgical sealants, capital equipment or software associated with broad patient use cases, companion diagnostics for cancer therapeutics, and consumer-oriented technologies that are noncovered benefits such as hearing aids. Among these technologies were also those that did not fall under an established Medicare benefit category. One hundred seventy-one technologies (61%) were evaluated for coverage status. One hundred seven technologies (38%) used coding and coverage pathways that were established prior to the FDA authorization. These technologies often represent improvements to technologies that have established clinical value such as diagnostic assays for viral infections and stents. The remaining 64 technologies (23%) did not have at least nominal coverage

Figure 1. Flowchart of Medicare Coverage for Technologies in the Analysis Set

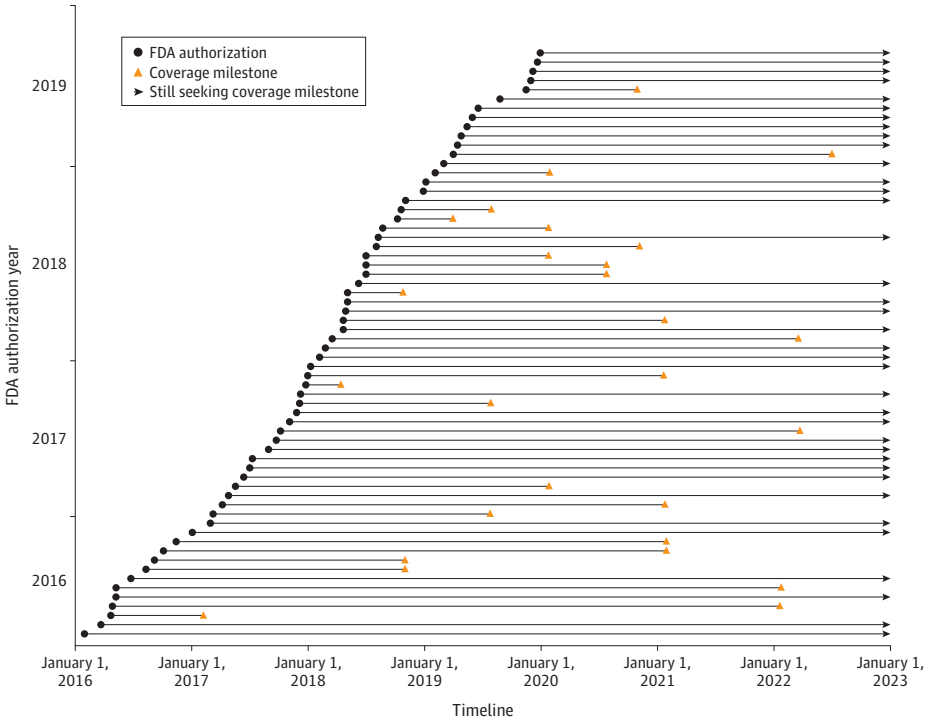


and were considered novel. These novel technologies were further analyzed for timing to coverage milestones. Manufacturer reimbursement information listing temporary CPT category 3 codes, miscellaneous, or unlisted codes were indicators of a technology requiring coverage.

For the 64 novel technologies, timelines from FDA authorization to at least nominal coverage are shown in (**Figure 2**). The shortest time to achieve a coverage milestone was 91 days and the longest within the limited study period was about 7 years (2546 days). Two technologies were evaluated through the Coverage with Evidence Development (CED) and CMS-FDA Parallel Review programs. Overall, 28 (44%) of the novel technologies in the cohort reached at least nominal coverage by the conclusion of the study period. Of those that achieved nominal coverage, 14 (50%) reached explicit coverage through an NCD, Molecular Diagnostic Services (MolDx) decision, or a minimum of LCDs; whereas 22 (79%) reached implicit coverage through assignment of a new billing code. Overall, 8 (29%) achieved both implicit and explicit coverage (**Figure 3**).

Across the 64 novel technologies seeking new coverage, 18 (28%) reached a coverage milestone within 3 years of FDA authorization. The apparent coverage probability for a novel technology at 1, 3, and 5 years after FDA authorization was 10.9% (90% CI, 5.48%-19.9%), 25.0% (90% CI, 16.6%-35.6%), and 40.6% (90% CI, 30.4%-51.7%), respectively. The time at which 50% of the sample had achieved at least nominal coverage was 5.7 years (90% CI, 4.4-not applicable [NA] years) after FDA authorization, where the upper bound of the confidence interval could not be estimated given the limited number of novel technologies that achieved coverage during the study period (**Figure 4**A). Potential covariates for coverage milestone achievement were also investigated including strength of clinical evidence, type of technology, and size of commercial manufacturer. For clinical evidence, most technologies (n = 39, 61%) had level 1, gold-standard, clinical evidence at FDA authorization; the remaining technologies had lower levels of clinical evidence (eg, nonrandomized or single-arm trials). Evaluating the 3- and 5-year coverage milestone achievement probabilities, we observed similar 3-year coverage probabilities 25.6% (90% CI, 15.0%-39.8%) and 24.0% (90% CI, 11.5%-42.4%) for technologies with and without level 1 evidence, respectively. Five-year coverage probabilities trended

Figure 2. Time Spent Seeking a Coverage Milestone Is Variable



FDA indicates US Food and Drug Administration. Among 64 analyzed technologies that required establishment of new Medicare coverage, the time spent seeking a coverage milestone varied from less than 91 days to about 7 years. The data represented by the arrowheads are right-censored because a coverage milestone was not achieved within the follow-up period.

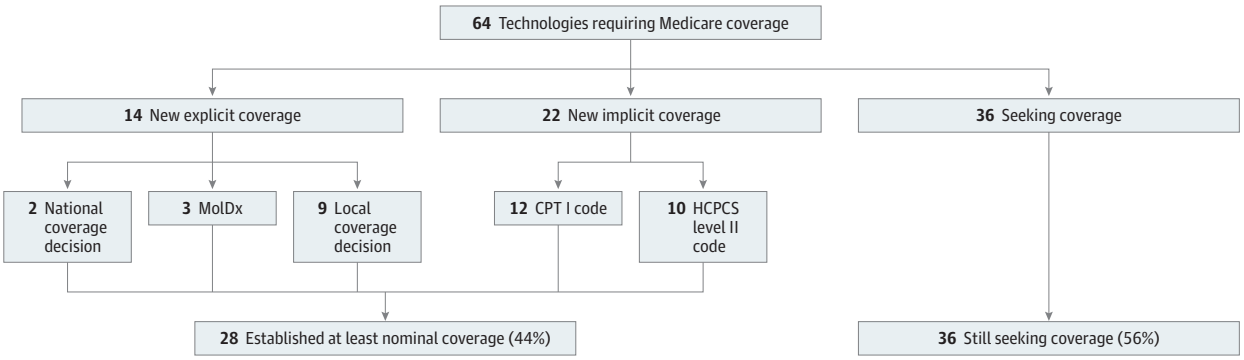
toward greater difference with 48.7% (90% CI, 34.9%-62.7%) and 28.0% (90% CI, 14.4%-46.4%) for technologies with and without level 1 evidence. However, there was no statistically significant difference in time to coverage comparing technologies with and without level 1 evidence (log-rank, $P = .40$) (Figure 4B). For diagnostic assays, diagnostic devices, acute treatments, and chronic or ongoing treatments, we calculated the coverage probabilities at 3 and 5 years after FDA authorization. Three-year coverage probabilities were 38.9% (90% CI, 20.5%-60.6%), 20.0% (90% CI, 6.33%-44.4%), 38.5% (90% CI, 17.3%-64.2%), and 5.56% (90% CI, 0.38%-25.2%), respectively. At 3 years, diagnostic assays and acute treatments trended toward greater coverage than diagnostic devices and chronic or ongoing treatments. This was further pronounced at 5 years where probabilities were 55.5% (90% CI, 34.3%-75.1%), 26.7% (90% CI, 10.4%-51.2%), 61.5% (90% CI, 35.8%-82.7%), and 22.2% (90% CI, 8.58%-44.3%), respectively. Time to coverage was statistically different across product types (log-rank, $P = .01$) (Figure 4C). Last, manufacturer size showed strong association with time to coverage (log-rank, $P < .001$) (Figure 4D). Post FDA authorization, coverage probabilities were 5.56% (90% CI, 1.19%-17.3%), 16.7% (90% CI, 7.89%-30.7%), and 19.4% (90% CI, 9.88%-33.8%) for small manufacturers and 17.9% (90% CI, 7.76%-34.4%), 35.7% (90% CI, 21.2%-53.0%), and 67.9% (90% CI, 50.5%-81.7%) for large manufacturers at 1, 3, and 5 years, respectively.

Discussion

This study examines 281 technologies approved or cleared through the FDA's PMA and de novo pathways, as well as 510(k) devices with breakthrough designation between January 1, 2016, and December 31, 2019. Of the 281 technologies included in the sample, 171 were technologies that required distinct reimbursement. Of these, 107 used existing reimbursement processes, whereas 64 technologies were novel and required establishment of a new reimbursement process. For this later subset, at least nominal Medicare coverage supportive of beneficiary availability was achieved by only 28 (44%), with a median of 5.7 years (90% CI, 4.4-NA years). Just 6 (9%) novel technologies had achieved a coverage milestone within 2 years, and 18 (28%) within 3 years.

This study also found considerable variability in time to coverage milestone achievement. Among 3 hypothesized factors for such variability, manufacturer size showed the most striking difference and suggests a disproportionate burden for small manufacturers. This could be for several reasons, including the financial ability for larger manufacturers to hire individuals with expertise navigating the path to milestones or to design and undertake additional analysis suitable for health technology assessment. Another striking difference was that diagnostic assays reached at least

Figure 3. Establishing Implicit Coverage Is a More Frequent Path to a Coverage Milestone

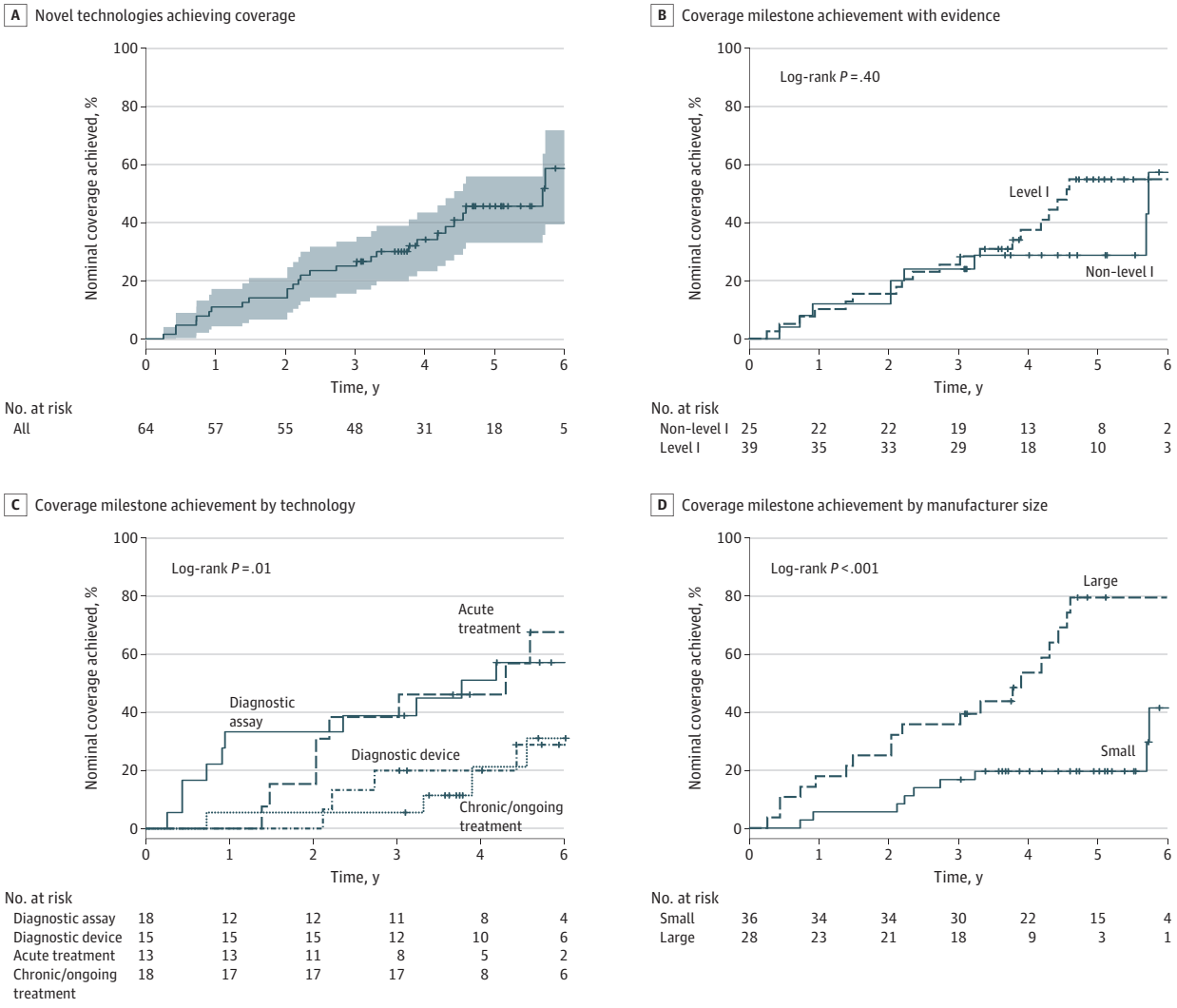


CPT 1 Indicates common procedural terminology; HCPCS, Healthcare Common Procedure Coding System; MolDx, molecular diagnostic services; Among 281 technologies in the analysis set were US Food and Drug Administration authorized during the enrollment period through the premarket approval and de novo pathways. A small subset of these technologies (n = 64) did not have appropriate billing codes or coverage available, thus new coverage was sought. Explicit coverage through new coverage determinations covered reimbursement of 14 technologies; implicit coverage through new codes supported reimbursement for 22 technologies. Of the 28 technologies that reached at least nominal coverage, 8 (29%) achieved both implicit and explicit coverage milestones.

nominal coverage more rapidly than other types of devices. This could be reflective of the effects of the MolDx Program. The MolDx Program was established to make coverage determinations specifically for molecular diagnostic tests and establishes coverage for 6 MAC jurisdictions at one time. Finally, there was no association between coverage milestone achievement and level of evidence developed for FDA authorization. This finding suggests that it is not necessarily the clinical evidence that is responsible for the lengthy time to coverage and perhaps points to other factors such as the coverage determination process itself, limited resources at CMS to support timely review, or some aspect within the level 1 studies that did not satisfy CMS' reasonable and necessary standard. Certainly, as supported by other investigators, the lack of clear and predictable evidence criteria required by CMS for coverage determinations is a known issue for new devices and diagnostics.[24,25]

Over the past few decades, government agencies including the FDA and CMS have developed acceleration programs designed to close the gap between FDA authorization and new Medicare

Figure 4. Factors Associated With Time to Achieve at Least Nominal Coverage



A, Probability of achieving coverage among all technologies requiring new Medicare coverage. The median time to achieve new coverage was 5.7 years (2077 days). The shaded area represents the 90% CI. B, Analysis of coverage milestone achievement among technologies with level 1 (dashed lines) gold-standard clinical evidence and non–level 1 (solid lines) evidence at FDA authorization (log-rank P = .40). C, Analysis of coverage milestone achievement by technology type. Diagnostic assays (solid lines), acute treatments (dotted lines), diagnostic devices (dashed lines), and chronic/ongoing treatments (dot-dashed lines) (log-rank P = .01). D, Analysis of coverage milestone achievement by commercial manufacturer size. Small manufacturers (<200 employees; solid lines) and large manufacturers (≥200 employees; dashed lines) (log-rank P < .001). For all curves, tick marks "+" within curves represent right-censored dropouts of technologies at the cut-off of the study window (December 31, 2022).

coverage. Programs like CED, the FDA Payer Communication Task Force, and Parallel Review have been implemented to facilitate greater access to emerging technologies. However, recent reviews suggest that these current programs fall short of their intended goals, with effects limited by low utilization and lack of clarity on CED program completion.[26,27] We note that the Parallel Review and CED programs were only used in 2 of the 64 novel technologies examined in this cohort, corroborating review findings.

A recent CMS rule proposal for Medicare Coverage of Innovative Technologies (MCIT) offered an approach in which selected technologies would be guaranteed temporary coverage for up to 4 years after FDA authorization.[28] Although the MCIT pathway was repealed, it inspired subsequent conversations and bipartisan legislative proposals, including the Transitional Coverage of Emerging Technologies (TCET) program. Many stakeholders have supported a new pathway that will support accelerated Medicare coverage for novel medical technologies linked to specific clinical evidence collection for Medicare beneficiaries. Such programs would provide support for clinicians to determine benefits, risks, and efficacy in the complex Medicare population. The results of this study suggest there is a need for a dedicated pathway that closes the substantial coverage gap demonstrated herein and provides a process for early communication between CMS and manufacturers that informs evidence development resulting in final coverage determinations.

Strengths and Limitations

Among the strengths of the current analysis is its reliance on a timely and comprehensive set of data including a cross-section of technologies receiving FDA authorization in recent years and a range of different reimbursement pathways.

At the same time, this study is subject to several limitations. First, the analysis and interpretation of data largely adopted the perspective that access to technologies authorized by FDA—and therefore deemed safe and effective—is a desirable objective for both patients and society. This perspective is supported by ongoing initiatives intended to create an accelerated approval pathway.[28] Nevertheless, additional postauthorization clinical evidence may be necessary for the Medicare population, and it is appreciated that such evidence collection takes time that might be well justified. Second, despite its size, the studied sample did not include the full scope of FDA 510(k) technologies, which represent the bulk of technologies authorized by the FDA each year. As such, the findings apply primarily to true novel technologies as opposed to technologies that are deemed substantially equivalent to technologies already authorized. Third, although industry experts provided information for the definition of coverage milestones associated with at least nominal coverage, their direct involvement with the studied technologies could have introduced potential bias. Fourth, calculation of time to coverage was based on a Kaplan-Meier survival analysis as opposed to direct measurement of time-to-coverage milestones for each technology. However, this is a well-established approach to account for right-censored data, while capturing the full analysis cohort. Finally, technologies that require a new Medicare benefit category, such as digital therapeutics, were excluded from analysis as were technologies that used temporary supplemental payment programs administered through C-codes, such as the Transitional Pass-Through payment and New Technology Add-on Payment.

Conclusions

In this cross-sectional study, 64 medical devices and diagnostics among 281 technologies authorized by the FDA from 2016 to 2019 required new Medicare coverage. The median time to at least nominal coverage was 5.7 years (90% CI 4.4-NA years). The time required to establish at least nominal coverage results in uneven beneficiary availability and stretches longer than the time to average FDA authorization.[2] These data highlight the need for establishment of a more efficient and timely reimbursement process for novel FDA-authorized medical devices and diagnostics.

ARTICLE INFORMATION

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Author Contributions: Mr Sexton, Dr Makower, and Dr Ruggles had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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Acquisition, analysis, or interpretation of data: Sexton, Perl, Saul, Trotsyuk, Pietzsch, Ruggles, Nikolov, Makower.

Drafting of the manuscript: Sexton, Perl, Trotsyuk, Pietzsch, Ruggles, Makower.

Critical revision of the manuscript for important intellectual content: All authors.

Statistical analysis: Sexton, Saul, Trotsyuk, Nikolov.

Administrative, technical, or material support: Sexton, Trotsyuk, Ruggles, Schulman, Makower.

Supervision: Sexton, Trotsyuk, Ruggles, Makower.

Conflict of Interest Disclosures: Dr Pietzsch reported personal fees, employment and stockholding from Wing Tech, Inc, outside the submitted work; and ongoing nonfinancial relationships with individuals trained at the Stanford Byers Center for Biodesign and others involved in advancing new medical technologies into patient care (eg, venture investors, corporate leaders, industry associations, and service providers). Dr Ruggles reported personal fees from Summit Rock Strategy Consulting, Inc (consulting employment and ownership), minority equity from 3NT Medical, BioTrace Medical, Orthini, LLC, and employee stock grants from Acclarent/Johnson & Johnson outside the submitted work; and ongoing nonfinancial relationships with individuals trained at the Stanford Byers Center for Biodesign and others involved in advancing new medical technologies into patient care (eg, venture investors, corporate leaders, industry associations, and service providers). Dr Schulman reported board membership from GRID Therapeutics, Updoc, Medeloop, and is a managing member at Faculty Connection; in addition, Dr. Schulman reported passive investment from Altitude Ventures and Excellerate Health Ventures, advisory board fees from Prealize, and is president at Business School Alliance for Health Management outside the submitted work. Dr Makower reported personal fees from New Enterprise Associates, minority equity and board membership with ExploraMed, Willow Innovations, Revelle Aesthetics, Moximed, X9, Allay Therapeutics, Setpoint Medical, minority equity and former board membership with Intrinsic Therapeutics, minority equity and board membership with Magenta Medical, minority equity in Moon Surgical, Cardionomic, Cala Health, CVRX, Ancora, Starlight Cardiovascular, Candescent Biomedical, iRhythm, former minority equity and former board membership with NeoTract/Teleflex, Acclarent/JNJ, Vesper Medical, Intact Medical, former minority equity from Ivantis and minority equity and former board member with Eargo and DOTS Devices outside the submitted work; in addition, Dr Makower has more than 300 US patents issued in a wide array of fields related to the companies listed above—no additional financial consideration is associated with these patents. The authors are further supported by unrestricted donations to Stanford University, Stanford Byers Center for Biodesign, Stanford Biodesign Policy Program, and the Clinical Excellence Research Center from multiple donors. Further, Dr Makower had ongoing nonfinancial relationships with individuals trained at the Stanford Byers Center for Biodesign and others involved in advancing new medical technologies into patient care (eg, venture investors, corporate leaders, industry associations, and service providers). No other disclosures were reported.

Data Sharing Statement: See Supplement 2.

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SUPPLEMENT 1.

eMethods. Determination of at Least Nominal Medicare Coverage
eTable 1. Distribution of Technologies by FDA Reviewing Committee
eTable 2. Type of Technology in the Total and Analysis Cohorts

SUPPLEMENT 2.

Data Sharing Statement

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Statement for the Record, House Energy and Commerce Subcommittee on Health, Hearing on Improving Seniors' Access to Innovative Drugs, Medical Devices, and Technology.
Brad R. Wenstrup, D.P.M.

Thank you to Chair Rodgers, Ranking Member Pallone, Chairman Guthrie, and Ranking Member Eshoo for holding this important hearing on Improving Seniors' Access to Innovative Drugs, Medical Devices, and Technology. I would also like to thank all the witnesses who are in attendance today for helping Congress examine a variety of policies that would ensure that seniors have better access to the best treatments, medical devices, and technology available. Policy discussions like the one occurring today are an important opportunity to evaluate how Congress can make the United States the healthiest nation on the planet.

Medicare provides millions of Americans with access to life-saving treatments and care. Unfortunately, outdated policies continue to interfere with patients' ability to access the latest innovations that the American scientific community has to offer. The purpose of today's hearing is to give members an opportunity to discuss policy improvements aimed at ensuring that seniors have better access to the newest and most effective treatments available.

There is a substantial gap between the time it takes the U.S. Food and Drug Administration (FDA) to authorize a novel medical technology and the time it takes for that product to gain new Medicare coverage. The Centers for Medicare and Medicaid Services (CMS) recently issued the Transitional Coverage for Emerging Technologies (TCET) proposal, which is an important first step in closing the gap between the time it takes a breakthrough product to receive CMS coverage after its FDA authorization. However, it is vital that we establish a new and distinct coverage pathway for life-saving breakthrough devices by enacting the Ensuring Patient Access to Critical Breakthrough Products Act of 2023 (H.R. 1691).

H.R. 1691 removes unnecessary barriers that prevent seniors from accessing the most innovative and cutting-edge treatments and ensures clear and accountable timelines. I would like to thank my Energy and Commerce Colleagues, Chairman Guthrie, Ranking Member Eshoo, Congressman Bilirakis and Congressman Cardenas for co-leading this important piece of legislation with me and I look forward to working with you all to ensure that this bill becomes law.

I am also pleased that the Treat and Reduce Obesity Act (H.R. 4818) has been included for discussion in today's hearing. This legislation, which I am leading with Energy and Commerce members Doctors Ruiz and Miller-Meeks, would allow medications that are FDA-approved to treat obesity to be covered under Medicare Part D. Expanding treatment options for obesity will help prevent additional diseases such as

heart disease and diabetes, lengthening Americans' health spans while saving Medicare dollars over the long run.

Patients should be empowered to have access to the latest innovations and treatments that our scientific community has to offer. I thank my Energy and Commerce colleagues for their work with me to provide patients with innovative treatments, and encourage the committee to advance my bills H.R. 1691 and H.R. 4818 in a future committee markup.

Sincerely,

Brad R. Wenstrup, D.P.M.
Member of Congress

OBESITY CARE ADVOCACY NETWORK

September 15, 2023

WASHINGTON, DC – The Obesity Care Advocacy Network (OCAN) applauds the House Energy and Commerce Health Subcommittee for including HR 4818, the Treat and Reduce Obesity Act (TROA), as part of the upcoming September 19th hearing on "Examining Policies to Improve Seniors' Access to Innovative Drugs, Medical Devices, and Technology." The purpose of the hearing is to examine ways that improve older adults' access to life-saving health care. Unfortunately, access to obesity treatment and care is limited for Medicare beneficiaries and we are pleased that the Committee has chosen to discuss TROA during this hearing. The passage and enactment of TROA would be an important step toward achieving the hearing's goal.

TROA is legislation designed to effectively treat and reduce obesity in older Americans by enhancing Medicare beneficiaries' access to healthcare providers that are best suited to administer intensive behavioral therapy (IBT) and by allowing Medicare Part D to cover Food and Drug Administration (FDA)-approved anti-obesity medications (AOMs).

The obesity epidemic has damaged our nation's health. Among older adults (aged 60+), the prevalence of obesity is 42.8%, similar to the level among younger and middle-aged adults. The prevalence of severe obesity among those aged 60+ is 5.8%. More than 20% of the population will be 65 years of age or older by 2030, up from 15% today, highlighting the importance of addressing obesity among older Americans. Congress must take steps to address this crisis now.

Currently, intensive behavioral therapy is restricted by the types of healthcare providers that can deliver services (only primary care physicians, nurse practitioners, and physician assistants) and it also limits the settings of care to primary care clinics. These restrictions leave many qualified specialty providers, like registered dietitians, clinical psychologists, and specialty physicians, as well as those community-based organizations providing evidence-based health interventions, unable to deliver this important lifestyle intervention.

Unfortunately, Medicare beneficiaries do not have access to all evidence-based treatments for obesity, such as AOMs. When Medicare Part D was passed in 2003, it included language that restricted coverage of "weight loss" medications. Medicare wrongly interpreted this restriction as a full exclusion. Because of this error, today Medicare Part D continues to preclude older Americans, and a number of dual eligible beneficiaries, from receiving updated, safe, and effective clinical standards of care reflecting FDA-approved pharmacotherapy to treat obesity.

The members of OCAN support and endorse the Treat and Reduce Obesity Act. Obesity is the number two cause of preventable death in the United States and it is critical that Congress pass this important legislation to improve and save patient's lives—now and into the future.

Obesity Care Advocacy Network Members

Academy of Nutrition and Dietetics
Am College of Occupational and Environmental Medicine
American Gastroenterological Association
American Society for Metabolic and Bariatric Surgery
Association of Diabetes Care & Education Specialists
ConscienHealth
Diabetes Leadership Council
Eli Lilly and Company
Gerontological Society of America
HealthyWomen
National Consumers League
National Hispanic Medical Association
Novo Nordisk
Obesity Medicine Association
STOP Obesity Alliance
WW International
American Academy of PAs
American Diabetes Association
American Psychological Association
American Society for Nutrition
Boehringer-Ingelheim
Currax Pharmaceuticals
Diabetes Patient Advocacy Coalition
Endocrine Society
Global Liver Institute
Intuitive Surgical
National Council on Aging
National Kidney Foundation
Obesity Action Coalition
Ro
The Obesity Society
YMCA of the USA

About OCAN

The Obesity Care Advocacy Network (OCAN) is a diverse group of organizations that have come together with the purpose of changing how we perceive and approach the problem of obesity in this nation. The mission of the coalition is to unite and align key obesity stakeholders and the larger obesity community around key obesity-related education, policy, and legislative efforts in order to elevate obesity on the national agenda. For more information, visit https://obesitycareadvocacynetwork.com/

Geneoscopy Written Testimony Regarding Policies to Improve Seniors' Access to Innovative Drugs, Medical Devices, and Technology
House Committee on Energy and Commerce
Subcommittee on Health
September 19, 2023

Submitted by
Geneoscopy, Inc.
St. Louis, MO

Thank you for the opportunity to provide written testimony regarding policies that increase seniors' access to medical devices that improve health and saves lives. Geneoscopy is a start-up biotech company based in St. Louis, MO, and our first product is a stool-based colorectal cancer (CRC) screening technology that is currently under review by the FDA. Like many small biotech companies, we worry about the time we will have to wait for revenue flow between approval by the FDA and coverage for our test by the Centers for Medicare and Medicaid Services (CMS) and private insurance. We believe the bureaucratic hurdles that companies like ours encounter are burdensome and unnecessary to our efforts to bring life-saving technology to patients.

About Geneoscopy

Geneoscopy was founded in 2015 with a vision to improve how gastrointestinal diseases are prevented, detected, and treated. Geneoscopy was started by an MD/PhD candidate at the Washington University School of Medicine in St. Louis, MO who developed a groundbreaking technology to isolate and interrogate RNA. As mentioned, Geneoscopy's initial product is a non-invasive CRC screening test that detects CRC and high risk pre-cancerous polyps – advanced

adenomas (AA).[1]

The Promise of New Technology

As technological innovations in the field of preventive screening and diagnostics advance for the country's deadliest diseases, more effective screening modalities become available. For example, Geneoscopy's non-invasive, at-home CRC screening test using novel mRNA technology has demonstrated the potential to improve the detection of CRC and AA above and beyond existing tests on the market. Geneoscopy's CRC-PREVENT pivotal clinical study demonstrated 94% sensitivity for CRC and 46% sensitivity for AA, representing the highest sensitivity profile reported for any non-invasive CRC screening test in a prospective clinical study.[2] When it comes to screening, more choice is better as it leads to greater compliance. Geneoscopy's clinical trial showed that the new technology worked successfully for people across demographic groups all over the country and has the real potential to advance the vital goal of increasing access to critically needed screening for historically underserved populations. In Geneoscopy's trial, 30% of participants had annual household income below $50,000 and 9% were on Medicaid.[3]

Colorectal Cancer is the Problem: Screening and Early Detection are the Solution

CRC is the third most diagnosed cancer and the second leading cause of cancer death in our country.[4] This year alone, the American Cancer Society estimates there will be 153,020 new cases and about 52,550 deaths nationwide.[5] Everyone is at some risk for developing CRC, however, some groups are at an elevated risk. Of particular concern, African Americans have

[1] https://pubmed.ncbi.nlm.nih.gov/11916153/
[2] https://www.prnewswire.com/news-releases/geneoscopys-non-invasive-colorectal-cancer- screening-test-demonstrates-high-sensitivity-and-specificity-in-large-pivotal-clinical-trial- 301717145.html
[3] https://doi.org/10.1158/1940-6207.CAPR-20-0294
[4] https://www.cdc.gov/cancer/colorectal/statistics/
[5] https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21772

the highest CRC incidence and mortality rates of all racial groups in the U.S. African Americans are approximately 20% more likely to develop CRC and an estimated 40% more likely to die from it than most other populations.[6]

CRC is also one of the most preventable cancers if people get screened for it regularly. CRC almost always develops from precancerous polyps (abnormal growths, also called adenomas) in the colon or rectum. If these pre-cancerous polyps can be detected and removed through CRC screening, CRC can be prevented before it develops. Moreover, every 1% increase in adenoma detection leads to a 3% decrease in CRC incidence and a 5% decrease in CRC mortality risk.[7] Screening can also identify early-stage cancer. When found at an early stage before it has spread, CRC is more treatable, and the five-year relative survival rate is about 90%. The percentage of individuals diagnosed with advanced-stage CRC has increased from 52% in the mid-2000s to 60% in 2019.[8] Survival rates are lower when cancer has spread outside the colon or rectum.[9]

Unfortunately, many patients avoid screening, and their cancer is diagnosed at later stages. Approximately 40% of patients fail to get screened in part because they do not want to have a colonoscopy, which is the gold standard for CRC screening in the U.S. A colonoscopy is frequently met with patient aversion due to its required bowel preparation, sedation, and potential time away from work.[10] Non-invasive screening tests that can be used at home, such as Geneoscopy's test, serve as important alternatives to colonoscopy for average-risk patients.

[6] https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21772
[7] https://jamanetwork.com/journals/jama/fullarticle/2792977
[8] https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21772
[9] https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/detection.html
[10] https://www.sciencedirect.com/science/article/pii/S2211335519300750

Access to Screening for Patients

A key hurdle to bringing life-saving screening tests to patients is CMS coverage and appropriate reimbursement. Additionally, many commercial insurance providers refuse to cover a test until after CMS has done so. Start-up companies like Geneoscopy take risks when developing new technologies and face the "valley of death" when coverage does not come quickly after FDA approval. Unfortunately, many innovative companies such as Geneoscopy fail to survive the valley of death because of undue delays in coverage. To keep pace with biotech innovation, CMS should offer a new predictable pathway for coverage for new technologies. In particular, we support the Committee's consideration of H.R. 1691, the Ensuring Patient Access to Critical Breakthrough Products Act of 2023, and H.R. 5389, the National Coverage Determination Transparency Act. If enacted, these bills would provide the predictable pathway we seek for coverage and would expedite patient access to novel cancer screening tests like ours.

Conclusion

New technology and screening tools like Geneoscopy's CRC screening test hold the exciting promise of improving CRC screening rates, enabling early-stage detection of CRC and AA, and, in turn, reducing morbidity and mortality associated with CRC. We strongly support the establishment of a coverage pathway for FDA-approved breakthrough designated products and we are grateful that this committee is working on this important issue. Patients cannot wait to get access to the latest advances in cancer screening; delays by CMS can make the difference between life and death.

We appreciate your consideration of our testimony as you explore ways to support access to innovative technologies for patients. We stand ready to be a resource to you and the committee. Thank you.

NATIONAL GRANGE

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American Values. Hometown Roots.

September 19, 2023

The Honorable Cathy McMorris Rodgers
Chair
Committee on Energy and Commerce
2125 Rayburn House Office Building
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The Honorable Frank Pallone
Ranking Member
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The Honorable Brett Guthrie
Chairman
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The Honorable Anna Eshoo
Ranking Member
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Dear Committee Leadership:

The National Grange is America's oldest agricultural and rural life advocacy organization. We have 140,000 members in 38 state chapters and 1,400 local chapters across the country. Grange members are the grassroots voice of rural America.

Obesity is related to multiple health issues which can be life threatening as well as require extensive treatment. These include high cholesterol, hypertension, diabetes and cardiovascular disease. Rural residents are more likely than their urban counterparts to die from multiple chronic diseases linked to obesity, heart disease and cancer.

Obesity is more prevalent in rural communities than in urban populations. Various factors likely contribute to rural obesity. These include low levels of income, an older population, lower levels of education, less emphasis on a healthy diet, limited access to health care, low rates of insurance coverage, and distance from services in general.

Because of these demographics, the Grange supports the passage of the Treat and Reduce Obesity Act (TROA). Rural residents truly are an underserved population. TROA is a giant step forward to allow older adults in greatest need access to anti-obesity medications.

Respectfully submitted,

Betsy Huber
President

CONGRESSIONAL BUDGET OFFICE
U.S. Congress
Washington, DC 20515

Phillip L. Swagel, Director

March 17, 2023

Honorable Sheldon Whitehouse
Chairman
Committee on the Budget
United States Senate
Washington, DC 20510

Re: CBO's Projections of Federal Health Care Spending

Dear Mr. Chairman:

You asked the Congressional Budget Office to gauge the accuracy of its projections of federal health care spending over time. In particular, you would like information about several aspects of the agency's work: how CBO's 2010 projections compare with actual spending and the agency's current baseline; why the 2010 projections overestimated or underestimated actual spending; how health outcomes and spending on health care in the United States compare with those measures in other countries; and how CBO incorporates past errors into its current and future baseline projections and estimates of the costs of legislation. This letter addresses those questions. In brief, these are the agency's findings:

- CBO overestimated mandatory spending for health care in its projections for the 2010–2020 period. Over that period, mandatory outlays for the two broad budget categories covering the major health care programs (mostly Medicare and Medicaid) were 9 percent lower than CBO projected in 2010.

- Most of the overestimate for the Medicare and Medicaid programs stemmed from an overestimate of spending per beneficiary, not an overestimate of the number of beneficiaries. Less-than-anticipated spending for prescription drugs in Medicare Part D and for long-term services and supports (LTSS) in Medicaid were two significant sources of error in CBO's 2010 projections.

- The rate of growth in federal mandatory spending on health care per beneficiary has slowed sharply since 2005. For example, Medicare spending per beneficiary grew at an average annual rate of 6.6 percent between 1987 and 2005, 3.1 percent between 2007 and 2012, and 2.2 percent between 2013 and 2019. Several developments may have contributed to that slowdown in spending growth, and the findings of several research papers do not fully account for that trend, in CBO's assessment.

- The United States spends a larger share of its gross domestic product (GDP) on health care than other advanced economies and performs worse on various measures of health outcomes than many of those same countries. In 2019, U.S. health expenditures were 17.6 percent of GDP, nearly 7 percentage points higher than the average of other comparably wealthy countries.

- By examining the accuracy of its past projections, CBO identifies opportunities to improve its current and future projections and cost estimates. The agency regularly publishes reports explaining how it has assessed the accuracy of its projections and the changes it has made as a result.

Fuller explanations for each of those findings is provided below.

How do CBO's August 2010 baseline projections of federal health care spending compare with actual spending over the 2010–2020 period?

CBO's baseline projections from August 2010—the first projections published after enactment of the Affordable Care Act—spanned the period from 2010 to 2020. At that time, the agency estimated that mandatory outlays for the two broad budget categories covering the major health care programs—function 550 (Health), mostly for the Medicaid program, and function 570 (Medicare, net of premiums and other offsetting receipts)—would be $11.7 trillion over the 2010–2020 period (see Table 1 on page 11).[1] Actual mandatory outlays for those categories turned out to be $10.6 trillion over that period, or 9 percent less than the amount CBO

[1] Congressional Budget Office, *The Budget and Economic Outlook: An Update* (August 2010), www.cbo.gov/publication/21670. CBO's analysis of spending in this letter focuses on mandatory, or direct, spending. Such outlays are generally governed by statutory criteria and are not normally constrained by the annual appropriation process. For discretionary spending (which stems from authority provided in annual appropriation acts), differences over time between projected and actual outlays result largely from differences between projected funding and actual appropriations.

projected in 2010; the difference between projected and actual mandatory outlays was 12 percent for function 550 and 7 percent for function 570. For 2019, the last year covered in the agency's August 2010 projections that was unaffected by the coronavirus pandemic, mandatory outlays for budget functions 550 and 570 turned out to be $1.2 trillion, which was 17 percent lower than the agency had projected in 2010.

Changes to CBO's baseline projections are grouped in three categories: legislative changes, which result from enactment of new laws; economic changes, which stem from updates to the agency's economic forecast; and technical changes, which reflect all other updates to the agency's projections. Of the $232 billion difference between projected and actual mandatory outlays in 2019, only $16 billion is attributable to legislative and economic changes. The rest of the difference ($216 billion) stems from technical changes: $123 billion in function 550, and $94 billion in function 570.

Disentangling the reasons that estimated spending has differed from actual spending since the August 2010 projections is difficult. In a previous analysis, CBO discussed how the slowdown in the growth of health care spending and an overestimate of the number of people receiving premium tax credits through the health insurance marketplaces contributed to downward technical revisions to CBO's projections.[2] For this analysis, CBO looked in more detail at trends in Medicare and Medicaid spending since the 2010 projections. For both programs, the agency estimates that most of the projection errors resulted from an overestimate of spending per beneficiary and not an overestimate of the number of beneficiaries. In 2019, the actual number of Medicare and Medicaid beneficiaries turned out to be only 1 percent higher and 2 percent lower, respectively, than CBO estimated in its August 2010 projections.

For the Medicare program, the largest difference between CBO's August 2010 baseline projections of net spending in 2019 and actual net spending was an overestimate of net spending for Medicare Part D (the program that covers the cost of beneficiaries' outpatient prescription drugs). In a 2014 report, CBO identified two reasons for the slower-than-expected growth in prescription drug spending, both nationally and in Part D. First, as existing brand-name drugs lost their patent protection, they faced new competition from generic drugs, and a significant share of prescriptions shifted to less

[2] Congressional Budget Office, Answers to Questions for the Record Following a Hearing Conducted by the Senate Committee on the Budget on CBO's Budget Projections (December 2020), p. 13, www.cbo.gov/publication/56908.

expensive generic formulations.[3] Second, fewer new brand-name drugs, which would have been relatively more expensive, were introduced than CBO had anticipated.

For the Medicaid program, identifying the precise causes of the differences between CBO's August 2010 baseline projections of spending in 2019 and actual spending in that year is more difficult—mainly because of the major changes to Medicaid during that period. One contributing cause is less-than-anticipated spending for long-term services and supports, which help people with functional or cognitive limitations perform routine daily activities for an extended period. LTSS can be provided in an institutional setting (such as a nursing home) or a noninstitutional setting (such as a person's home or an adult day care center).

From 2000 to 2010, growth of LTSS spending averaged 5 percent annually; that growth was largely driven by 11 percent average annual growth in noninstitutional LTSS. Between 2011 and 2020, average annual growth of LTSS spending fell to 1 percent, and average annual growth in spending for noninstitutional LTSS declined to 4 percent. The slower growth in spending since 2010 has been driven by two factors. First, the number of users of noninstitutional LTSS grew more slowly than it did from 2000 to 2010. Second, states have increasingly shifted patients from institutional to noninstitutional settings (in which care is provided at a lower cost), and more institutional services have been delivered by managed care plans (which actively seek to control costs). Both of those alternative care-delivery mechanisms are generally less costly on a per user basis. As a result, spending for institutional LTSS in 2019 was lower than such spending in 2010.

How do CBO's 2010 long-term projections of federal health care spending for the 2021–2033 period compare with actual spending in 2021 and 2022 and with current baseline spending projections?

CBO's 2010 projections of federal outlays for the major health care programs beyond the 2010–2020 period were presented in its 2010 *Long-Term Budget Outlook*.[4] Federal outlays for the major health care programs consist of outlays for Medicare (net of premiums and other offsetting receipts), Medicaid, the Children's Health Insurance Program (CHIP), and

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[3] Congressional Budget Office, *Competition and the Cost of Medicare's Prescription Drug Program* (July 2014), www.cbo.gov/publication/45552.

[4] Congressional Budget Office, *The Long-Term Budget Outlook* (June 2010), www.cbo.gov/publication/21546.

premium tax credits.[5] The health care projections in the *Long-Term Budget Outlook* reflect the agency's forecast for the next 30 years under the assumption that current laws governing taxes and spending generally remain the same. (The 2010 *Long-Term Budget Outlook* focused on projected health care outlays over the next 25 years, but CBO changed the length of its projection period to 30 years beginning in 2016.)

CBO's 2010 projections of federal outlays for the major health care programs in 2021 and 2022 can be compared with actual outlays for those years. In the long-term projections it made in 2010, CBO estimated that federal outlays for the major health care programs would account for 6.5 percent of GDP in 2021 and 6.6 percent of GDP in 2022. Actual outlays for those programs turned out to be 5.7 percent of GDP in both years.

Additionally, CBO's 2010 projections of federal outlays for the major health care programs over the 2023–2033 period can be compared with CBO's current baseline projections. In its long-term projections made in 2010, the agency estimated that those outlays would increase from 6.8 percent of GDP in 2023 to 8.5 percent of GDP in 2033. CBO now expects federal spending on those programs, measured as a percentage of GDP, to grow more slowly over that 10-year period, increasing from 5.8 percent of GDP in 2023 to 6.9 percent of GDP in 2033 (see Figure 1 on page 12).

Those sets of comparisons show that the rate of growth in federal spending on the major health care programs has slowed significantly since 2010 and that growth is expected to remain slower (relative to CBO's 2010 projections) over the next decade.

What factors account for the recent slowdown in federal health care spending?

In recent years, the growth of federal health care spending per beneficiary has slowed substantially. Between 1987 and 2005, for instance, Medicare spending per beneficiary grew at an average annual rate of 6.6 percent. But between 2007 and 2012, that rate was 3.1 percent.[6] The average annual

[5] Those major health care programs are mandatory. That scope of spending is narrower than the spending reported for 2010 to 2020 in Table 1, which comprises all of mandatory spending in budget functions 550 and 570.

[6] CBO omitted the growth rate for 2006 from the comparisons because that was the year in which Medicare Part D was introduced.

growth rate in the years that followed (before the pandemic began in 2020) was even lower, at 2.2 percent.[7]

To better understand what factors contributed to that slowdown, CBO reviewed several research papers. The findings from those papers do not fully account for the widespread slowdown in federal health care spending, in CBO's assessment.[8] The agency previously pointed to two factors—both of which are discussed in the research papers—that are known to have contributed to that recent trend.[9] Those factors are decreases in the growth of Medicare's payment rates, which are set through laws and regulations, and reduced spending on patients with cardiovascular diseases. The latter outcome stems from better management of such conditions, including greater use of medications to control risk factors, such as hypertension and diabetes.[10]

Recent research has suggested a potential third reason for the slowdown: a shift in the relative importance of technology in fueling the growth of health care spending. Historically, the pace of diffusion and the adoption of new technology have been key drivers of increases in health care spending,

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[7] CBO calculated those amounts using data through 2019 from the Centers for Medicare & Medicaid Services. In particular, see the entries for "growth rates," "per enrollee," and "Medicare" in Centers for Medicare & Medicaid Services, National Health Expenditure Data, Historical, Expenditures, "Table 21: Enrollment and Per Enrollee Estimates of Health Insurance: United States, Calendar Years 1987–2021" (accessed March 9, 2023), https://tinyurl.com/23tm6xdf.

[8] See, for example, Melinda B. Buntin and others, "Trends in and Factors Contributing to the Slowdown in Medicare Spending Growth, 2007–2018," *JAMA Health Forum*, vol. 3, no. 12 (December 2022), pp. 1–12, https://tinyurl.com/5n8ay43e; Laura M. Keohane, Lucas Stewart, and Melinda B. Buntin, *The Slowdown in Medicare Spending Growth for Baby Boomers and Older Beneficiaries: Changes in Medicare Spending Levels and Growth by Age Group, 2007–2015* (Commonwealth Fund, December 2019), https://doi.org/10.26099/sy0d-xs78; David M. Cutler and others, "Explaining the Slowdown in Medical Spending Growth Among the Elderly, 1999–2012," *Health Affairs*, vol. 38, no. 2 (February 2019), pp. 222–229, https://tinyurl.com/y4nau678; Amitabh Chandra, Jonathan Holmes, and Jonathan Skinner, "Is This Time Different? The Slowdown in Health Care Spending," *Brookings Papers on Economic Activity* (Fall 2013), pp. 261–323, https://tinyurl.com/3vz5k35c; Michael Levine and Melinda Buntin, *Why Has Growth in Spending for Fee-for-Service Medicare Slowed?* Working Paper 2013-06 (Congressional Budget Office, August 2013), www.cbo.gov/publication/44513; and Alexander J. Ryu and others, "The Slowdown in Health Care Spending in 2009–11 Reflected Factors Other Than the Weak Economy and Thus May Persist," *Health Affairs*, vol. 32, no. 5 (May 2013), pp. 835–839, www.healthaffairs.org/doi/full/10.1377/hlthaff.2012.1297.

[9] Congressional Budget Office, Answers to Questions for the Record Following a Hearing Conducted by the Senate Committee on the Budget on CBO's Budget Projections (December 2020), p. 13, www.cbo.gov/publication/56908.

[10] David M. Cutler and others, "Explaining the Slowdown in Medical Spending Growth Among the Elderly, 1999–2012," *Health Affairs*, vol. 38, no. 2 (February 2019), pp. 222–229, https://tinyurl.com/y4nau678.

but one recent study found that their contribution from 2009 to 2019 was notably smaller than it had been over a longer period starting in 1970.[11] That finding is consistent with a shift toward the diffusion of cost-saving technologies—such as those used to treat cardiovascular diseases.[12]

How do health outcomes and spending on health care in the United States compare with those measures in other countries?

Despite the recent slowdown in health care spending, the United States continues to spend a higher share of its GDP on health care—as it has for many decades—than other advanced economies. In 2019, U.S. health expenditures were 17.6 percent of GDP. That amount was nearly 7 percentage points higher than the average of other comparably wealthy countries and 5.9 percentage points higher than health care spending in Germany, the country with the next-highest spending among that group of wealthy nations.[13] Spending is much higher in the United States despite similar inputs and levels of health care utilization, which indicates that the prices paid for health care in the United States are higher.[14] Those higher prices reflect a mix of factors, including higher prices for labor, medical devices, and prescription drugs, as well as higher administrative costs (such as those related to processing claims and updating patients' medical records).[15]

Other high-income countries perform similarly or better on many—but not all—health outcome measures. For instance, among a group of nine high-

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[11] Shelia D. Smith, Joseph P. Newhouse, and Gigi A. Cuckler, *Health Care Spending Growth Has Slowed: Will the Bend in the Curve Continue?* Working Paper 30782 (National Bureau of Economic Research, December 2022), www.nber.org/papers/w30782.

[12] Congressional Budget Office, Answers to Questions for the Record Following a Hearing Conducted by the Senate Committee on the Budget on CBO's Budget Projections (December 2020), p. 13, www.cbo.gov/publication/56908.

[13] Matthew McGough and others, "How Does Health Spending in the U.S. Compare to Other Countries?" (Peterson-KFF Health System Tracker, posted February 9, 2023), https://tinyurl.com/bdf6pdzv. For information about how differences in the prices paid for health care services by country affect differences in countries' spending for that care, see Congressional Budget Office, *Policy Approaches to Reduce What Commercial Insurers Pay for Hospitals' and Physicians' Services* (September 2022), www.cbo.gov/publication/58222.

[14] Congressional Budget Office, *Policy Approaches to Reduce What Commercial Insurers Pay for Hospitals' and Physicians' Services* (September 2022), www.cbo.gov/publication/58222.

[15] Gerard F. Anderson, Peter Hussey, and Varduhi Petrosyan, "It's Still the Prices, Stupid: Why the U.S. Spends So Much on Health Care, and a Tribute to Uwe Reinhardt," *Health Affairs*, vol. 38, no. 1 (January 2019), pp. 87–95, https://doi.org/10.1377/hlthaff.2018.05144; and Irene Papanicolas, Liana R. Woskie, and Ashish K. Jha, "Health Care Spending in the United States and Other High-Income Countries," *JAMA*, vol. 319, no. 10 (March 2018), pp. 1024–1039, https://doi.org/10.1001/jama.2018.1150.

income countries, the United States had the highest maternal mortality rate and lowest life expectancy at birth.[16] The United States also lagged behind other nations on performance measures related to access to care and avoidable hospital admissions. For other measures, like those related to 30-day mortality rates for acute myocardial infarction and stroke, the United States landed near the top of the rankings among those same countries.[17] In general, using summary health outcome measures to assess the efficiency of national health systems is difficult because many outcomes are affected by other factors that are not attributable to the health care system and that cannot easily be controlled for in most available measures.

How does CBO review the accuracy of its projections and incorporate observed trends into current and future projections and cost estimates?

CBO frequently analyzes its projections of spending and its analyses of legislation to identify errors and opportunities to improve. Every year, the agency compares its projections for the most recent fiscal year with actual outlays and analyzes the extent of and sources of errors. CBO publishes a document summarizing that analysis.[18] Periodically, the agency also analyzes its projections over a longer period; that type of analysis was most recently published in 2019.[19]

Using the findings from those analyses, CBO identifies opportunities to refine its methodology and improve its projections. For example, in its March 2020 baseline, CBO updated its projections of spending growth under different parts of the Medicare program; as a result, the agency decreased its projection of the program's outlays by 1.3 percent over the 2021–2030 period. That revision in part reflected the agency's examination of actual spending during the early part of the 2020 fiscal year and growth

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[16] Nisha Kurani and Emma Wager, "How Does the Quality of the U.S. Health System Compare to Other Countries?" (Peterson-KFF Health System Tracker, posted September 30, 2021), https://tinyurl.com/374m998e.

[17] Organisation for Economic Co-operation and Development, *Health at a Glance 2019: OECD Indicators* (November 2019), https://doi.org/10.1787/4dd50c09-en.

[18] Congressional Budget Office, *The Accuracy of CBO's Budget Projections for Fiscal Year 2022* (January 2023), www.cbo.gov/publication/58603.

[19] Congressional Budget Office, *An Evaluation of CBO's Past Deficit and Debt Projections* (September 2019), www.cbo.gov/publication/55234.

rates in spending for various medical services—both of which were lower than expected.[20]

Assessing estimates of legislation can be challenging for various reasons. In some cases, for example, the agency cannot isolate the effects of legislation in administrative data from other underlying changes affecting outcomes. Despite those challenges, at times CBO has been able to compare its estimates with actual outcomes. In 2017, for instance, CBO published a report discussing how projected marketplace subsidies and spending for Medicaid beneficiaries made eligible by the Affordable Care Act differed from actual amounts.[21] Two other examples are a report that the agency published in 2012 on the relationship between increased use of prescription drugs and decreases in spending on medical services for the Medicare population and a report from 2014 analyzing why CBO's estimate of outlays for the Medicare Part D program differed from actual outlays.[22] CBO used the findings from the 2012 and 2014 reports in its later estimates of legislation (including the 2022 reconciliation act) that affected utilization of prescription drugs.

By examining actual spending and evaluating the experiences of other programs, CBO is sometimes able to discern what adjustments to make to key estimating inputs to improve its projections. For instance, when CBO analyzed the reasons underlying the difference between its cost estimate for the Medicare-Eligible Retiree Health Care Fund and actual expenditures from the fund, it found that fewer eligible military retirees and their dependents initially used some of the benefits covered by the fund.[23] On the basis of that experience, as well as experience with other federal programs (including Part D), CBO expects that full participation in new government programs will happen with a longer delay.

In addition to routinely updating the baseline by reviewing and incorporating the latest data on Medicare spending, CBO reevaluates its long-term projections by examining historical spending trends over an

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[20] Congressional Budget Office, *Baseline Budget Projections as of March 6, 2020* (March 2020), www.cbo.gov/publication/56268.

[21] Congressional Budget Office, *CBO's Record of Projecting Subsidies for Health Insurance Under the Affordable Care Act: 2014 to 2016* (December 2017), www.cbo.gov/publication/53094.

[22] Congressional Budget Office, *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services* (November 2012), www.cbo.gov/publication/43741.

[23] Congressional Budget Office, *A Review of CBO's Estimate of Spending From the Department of Defense's Medicare-Eligible Retiree Health Care Fund* (October 2020), www.cbo.gov/publication/56653.

extended period. That process, together with changes to CBO's projection methods, resulted in the agency's revising downward its estimate of additional cost growth at the end of the 30-year projection period used in the 2022 *Long-Term Budget Outlook*. (Additional cost growth is the amount by which the growth rate of nominal health care spending per person, adjusted to remove the effects of demographic changes, exceeds the growth rate of potential GDP per person.) Using that revised growth parameter, CBO projected that federal spending on Medicare as a share of GDP would be about one-half of one percentage point lower in 2052 than what the agency would have projected using its earlier estimate of additional cost growth.[24]

I hope this information is helpful to you. If you have any additional questions, please contact me.

Sincerely,

Phillip L. Swagel
Director

cc: Honorable Chuck Grassley
Ranking Member
Senate Committee on the Budget

[24] Congressional Budget Office, *The 2022 Long-Term Budget Outlook* (July 2022), www.cbo.gov/publication/57971.

Table 1.

Comparison of CBO's August 2010 Projections and Actual Amounts of Mandatory Outlays for Budget Functions 550 and 570, by Fiscal Year

Billions of Dollars

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	Total, 2010–2020
Functions 550 and 570												
Actual amounts	750	790	752	793	859	966	1,043	1,064	1,072	1,163	1,338	10,590
August 2010 projections	751	798	778	831	930	1,026	1,148	1,224	1,287	1,395	1,489	11,656
Differences												
Legislative changes	0	12	20	16	3	-1	5	4	-1	-10	74	121
Economic changes	0	1	2	4	7	4	-2	-11	-4	-6	-3	-8
Technical changes	-1	-21	-48	-57	-80	-63	-108	-153	-210	-216	-223	-1,179
Total Differences	**-1**	**-8**	**-26**	**-38**	**-71**	**-60**	**-105**	**-160**	**-215**	**-232**	**-151**	**-1,066**
Function 550—Health (mostly Medicaid)												
Actual amounts	304	310	286	301	354	426	455	473	490	519	569	4,486
August 2010 projections	304	315	299	309	380	449	522	574	612	657	700	5,121
Differences												
Legislative changes	0	0	2	1	-2	-5	-5	0	3	-4	24	15
Economic changes	0	0	0	3	6	6	0	-6	-9	-11	-11	-23
Technical changes	0	-5	-15	-12	-30	-23	-63	-95	-116	-123	-145	-627
Total Differences	**0**	**-5**	**-13**	**-8**	**-26**	**-23**	**-67**	**-101**	**-122**	**-138**	**-132**	**-635**
Function 570—Medicare												
Actual amounts	446	480	466	492	505	540	588	591	582	644	769	6,104
August 2010 projections	447	483	479	522	550	577	626	650	675	738	788	6,535
Differences												
Legislative changes	0	11	18	14	4	4	10	4	-4	-6	50	106
Economic changes	0	1	2	1	1	-1	-2	-5	5	5	8	15
Technical changes	-1	-15	-33	-45	-50	-40	-45	-57	-94	-94	-78	-553
Total Differences	**-1**	**-3**	**-13**	**-30**	**-45**	**-37**	**-38**	**-59**	**-93**	**-94**	**-20**	**-431**
Memorandum:												
Percentage Difference												
Functions 550 and 570	0	-1	-3	-5	-8	-6	-9	-13	-17	-17	-10	-9
Function 550	0	-2	-4	-3	-7	-5	-13	-18	-20	-21	-19	-12
Function 570	0	-1	-3	-6	-8	-6	-6	-9	-14	-13	-2	-7

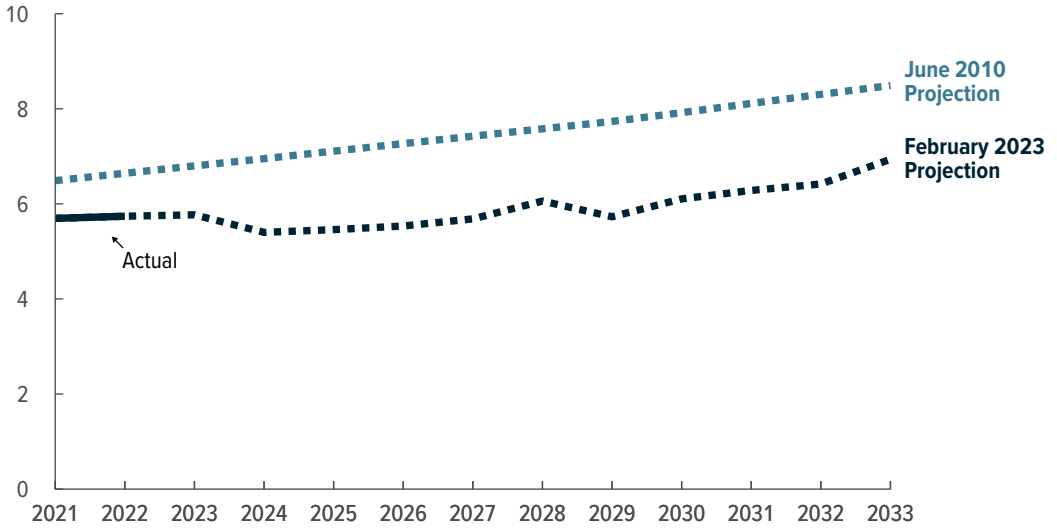
Data source: Congressional Budget Office.

CBO's analysis of spending in this letter focuses on mandatory, or direct, spending. Such outlays are generally governed by statutory criteria and are not normally constrained by the annual appropriation process. For discretionary spending (which stems from authority provided in annual appropriation acts), differences over time between projected and actual outlays result largely from differences between projected funding and actual appropriations. Outlays for function 570 are net of premiums and other offsetting receipts.

Figure 1.

CBO's Projections of Federal Outlays for the Major Health Care Programs

Percentage of Gross Domestic Product



Data source: Congressional Budget Office.

The June 2010 projection values for 2021 to 2033 reflect CBO's past projections as published in *The Long-Term Budget Outlook* (June 2010), www.cbo.gov/publication/21546. Actual amounts are reported through 2022; the February 2023 projection values for 2023 through 2033 reflect CBO's current projections as published in the *Budget and Economic Outlook: 2023 to 2033* (February 2023), www.cbo.gov/publication/58848. Outlays for the major federal health care programs consist of federal spending for Medicare (net of premiums and other offsetting receipts), Medicaid, and the Children's Health Insurance Program, as well as subsidies for health insurance purchased through the marketplaces established under the Affordable Care Act.

September 18, 2023

The Honorable Cathy McMorris Rodgers
Chair
Energy & Commerce Committee
2188 Rayburn House Office Building
Washington, DC 20515

The Honorable Brett Guthrie
Chair
E&C Subcommittee on Health
2434 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Energy & Commerce Committee
2107 Rayburn House Office Building
Washington, DC 20515

The Honorable Anna Eshoo
Ranking Member
E&C Subcommittee on Health
272 Cannon House Office Building
Washington, DC 20515

Dear Chair McMorris Rodgers, Ranking Member Pallone, Chair Guthrie, and Ranking Member Eshoo:

Diabetes is a serious, costly chronic condition affecting roughly one in four Medicare beneficiaries and requiring access to a range of medications and services to help treat the disease. The undersigned national organizations support the bipartisan Expanding Access to Diabetes Self-Management Training Act (H.R. 3842) and thank you for including the bill in the upcoming Subcommittee on Health hearing, *Innovation Saves Lives: Evaluating Medicare Coverage Pathways for Innovative Drugs, Medical Devices, and Technology.*

Diabetes self-management training (DSMT) is an evidenced-based service that has been covered under Medicare Part B since 2001 to give beneficiaries the tools to manage their diabetes, reduce their risk of complications, and improve their quality of life. Even though DSMT has been consistently shown to help participants achieve lower hemoglobin A1c, weight loss, improved quality of life, and healthy coping skills, only 5 percent of Medicare beneficiaries with newly diagnosed diabetes utilize the service due to myriad barriers—many of which Congress can remove or reduce. This legislation is critical to improving outcomes for Medicare beneficiaries living with diabetes and, therefore, generating savings for the Medicare program.

The *Expanding Access to DSMT Act* would improve access to the DSMT benefit by–

- Excluding DSMT services from Part B cost-sharing and deductible requirements;
- Allowing beneficiaries the flexibility to access their initial 10 hours of DSMT services when needed rather than having hours expire after one year;
- Permitting DSMT and Medical Nutrition Therapy to be provided on the same day avoiding arbitrary waiting periods;
- Permitting all physicians and qualified nonphysician practitioners working in coordination with the beneficiaries treating provider to refer for DSMT services; and
- Establishing a CMS Innovation Center demonstration program to test the coverage of virtual DSMT within Medicare.

The *Expanding Access to DSMT Act* is bipartisan legislation led by Representatives Bilirakis (R-FL-12) and Schrier (D-WA-8). There is a companion bill in the Senate led by Senators Shaheen

(D-NH) and Collins (R-ME). Importantly, this legislation is also supported by the Diabetes Caucus.

Thank you again for including the bill in your upcoming hearing. As the 118th Congress proceeds, we also encourage you to consider this important legislation for markup and passage.

Sincerely,

Academy of Nutrition and Dietetics
Association of Diabetes Care & Education Specialists
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Endocrine Society
National Kidney Foundation
Omada Health, Inc.

Congress of the United States

Washington, DC 20515

August 15, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Brooks-LaSure:

As Members of Congress, we write to express our concern with the recent actions taken by MolDX on behalf of the Centers for Medicare and Medicaid Services (CMS) to restrict access to non-invasive, post-transplant testing for patients with a transplanted heart, lung, or kidney. We believe that protecting and expanding access to innovative, non-invasive diagnostic tests is vital to post-transplant organ health and the long-term outcomes of transplant patients.

Organ transplantation is a crucial treatment for end-stage organ failure, but organs are the scarcest medical resource, with over 100,000 people on waiting lists and 17 dying each day while waiting for an organ. The cost of kidney, lung, and heart transplants are staggering at $400,000, $1.2 million, and $1.6 million, respectively. It is estimated that within five years following transplant, 1 in 2 lung transplants will fail, as will 1 in 3 hearts and 1 in 5 kidneys. These failures are most commonly due to organ rejection by the recipient's immune system, an ever-present risk in post-transplant care that requires a balance of immunosuppression medication. It is crucial to conduct post-transplant surveillance to identify organ rejection early on.

Non-invasive diagnostic tests, including donor-derived cell-free DNA (dd-cfDNA) and gene expression profiling (GEP), have emerged as crucial tools for post-transplant care. Through rigorous clinical validation and evidence-based research, these tests have demonstrated their effectiveness in improving the surveillance of transplanted organs for potential subclinical rejection, the treatment of which is demonstrated to improve patient outcomes. By reducing reliance on traditional, invasive biopsies, these innovative diagnostic methods significantly alleviate patients' physical and emotional burdens while providing an accurate and timely assessment of transplant organ health.

MolDX's recent decision to issue a new billing article that restricts access to these essential tests could potentially compromise the health and well-being of transplant patients. Early detection of organ rejection or injury is critical to initiating prompt interventions that can preserve the transplanted organ's function and ensure the long-term success of transplant recipients. Furthermore, this restriction may disproportionately impact marginalized and under-resourced populations, who already confront significant barriers to healthcare access. These populations may have less access to specialized transplant centers, making non-invasive diagnostic tests even more critical for their ongoing post-transplant care.

We are concerned that MolDX's new billing article contradicts the applicable local coverage determinations (LCDs). We are also troubled by how the billing article was issued with only a 30-day timeline before the effective date and without allowing public comments. This approach effectively silenced the voices of the transplant community, including patients, healthcare providers, and experts in the field.

Transplant patients depend on a future that supports innovation for advancement in their care, including coverage for non-invasive diagnostic tests. We urge CMS to review the recent actions taken by MolDX and consider the potential harm to transplant patients, particularly under-resourced populations. Specifically, we seek answers to the following questions:

1. How did the CMS and MolDX assess the potential impact of these coverage policies on patient access to care, prior to publishing the March 2023 billing article?

2. Considering the potential impact on transplant patients, how does CMS anticipate the new restrictions on non-invasive diagnostic tests will affect the Medicare End-Stage Renal Disease (ESRD) program?

3. What oversight measures does CMS have to ensure that MolDX and other contractors do not use billing articles to bypass the local coverage determination process and, consequently, fail to seek public comment as required by the Medicare Program Integrity Manual? Specifically, what guidance has CMS given to Medicare Administrative Contractors like MolDX on appropriately using billing articles?

4. Would CMS consider directing MolDX to rescind the March 2023 billing article and reinstate the previous interpretations of the LCDs? Furthermore, should MolDX implement any additional coverage policy changes, will CMS ensure compliance with the legal requirement that MolDX engages in a public process to gather input from patients, healthcare providers, and field experts?

We appreciate your attention to this matter and look forward to your quick response to these important concerns.

Sincerely,

Michael C. Burgess, M.D.
Member of Congress

Anna G. Eshoo
Member of Congress

Jefferson Van Drew
Member of Congress

Donald G. Davis
Member of Congress

Larry Bucshon, M.D.
Member of Congress

Katie Porter
Member of Congress

Nancy Mace
Member of Congress

Terri A. Sewell
Member of Congress

Maria Elvira Salazar
Member of Congress

Jason Crow
Member of Congress

Don Bacon
Member of Congress

Jerrold Nadler
Member of Congress

Eleanor Holmes Norton
Member of Congress

Stephen F. Lynch
Member of Congress

September 18, 2023

The Honorable Brett Guthrie
Chairman
Energy and Commerce Committee
Subcommittee on Health
Washington, D.C. 20515

The Honorable Anna Eshoo
Ranking Member
Energy and Commerce Committee
Subcommittee on Health
Washington, D.C. 20515

Dear Chairman Guthrie and Ranking Member Eshoo:

The Healthcare Leadership Council (HLC) appreciates the opportunity to provide comments in advance of your hearing, "Examining Policies to Improve Seniors' Access to Innovative Drugs, Medical Devices, and Technology."

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, homecare providers, group purchasing organizations, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach. Innovation leading to improved patient outcomes is at the core of HLC's work.

Thank you for holding a hearing to examine the immense value new innovative drugs and medical technologies bring to Medicare beneficiaries. HLC and its member organizations bring tremendous expertise to this issue. HLC has long championed ensuring seniors have access to innovative treatments and was instrumental in the creation of the Part D program. We look forward to working with Congress and the administration to provide access for seniors to certain medical devices that have already been designated as Breakthrough Devices by the Food and Drug Administration.

HLC supports the Centers for Medicare & Medicaid Services' (CMS) proposed Transitional Coverage of Emerging Technologies (TCET) pathway as an important step in providing expedited access to potentially transformative breakthrough devices for seniors and those living with disabilities. We appreciate that the proposed TCET pathway is voluntary for manufacturers, prioritizes safeguards for beneficiaries, and allows fit-for-purpose studies to appropriately address evidentiary gaps in a manner that aligns the study design with the aim of the study.

As this pathway is implemented and other innovative coverage avenues explored, we urge Congress and CMS to continue to closely collaborate with stakeholders to ensure the coverage process is truly transparent, predictable, and centers on patient clinical outcomes and safety in a manner that is not overly burdensome for stakeholders or beneficiaries.

HLC and its member organizations stand ready to work with you and your colleagues on the critical issue of ensuring access to innovative treatments and technologies to seniors. If you have any questions, please do not hesitate to contact Debbie Witchey at dwitchey@hlc.org or 202-449-3435.

Sincerely,

Mary R. Grealy
President