EYE ON CANCER CARE

Medicare Coverage of New Oncology Technology

American Cancer Society Cancer Action Network

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Issue

Cancer is the second most common cause of death in the United States, responsible for one in every six deaths, and the leading cause of death in people younger than 85.[1,2] However, prevention and robust clinical innovation is accelerating progress across the care continuum by enabling earlier, more effective interventions and minimizing unnecessary treatment. Advances in medical devices have the potential to improve patient outcomes, reduce beneficiaries' overall cost of care, and lower potential costs to the Medicare program. As cancer risk increases with age, it is critical to understand how the Centers for Medicare & Medicaid Services (CMS) ensures access to cutting-edge oncology technologies under Medicare – the primary insurer for individuals over 65.

Significant research is being conducted that is revolutionizing oncology care for patients in the United States. For example, researchers are exploring the use of artificial intelligence (AI) to analyze tumors to help better predict breast cancer growth and prognosis.[3] There is other work on developing programmable messenger RNA (mRNA) therapeutics, which will help improve health outcomes and lower patient cost barriers.[4] Molecular diagnostics are rapidly advancing in both technology, including through the integration of AI, and clinical uses, such as earlier detection and treatment monitoring.[5] Additionally, new technologies are being designed that can enhance care and expand patient access in rural areas, such as remote patient monitoring systems and robotic-assisted surgical platforms. Medicare coverage policies and payment pathways play a critical role in shaping the availability and timeliness of beneficiaries' access to these advances.

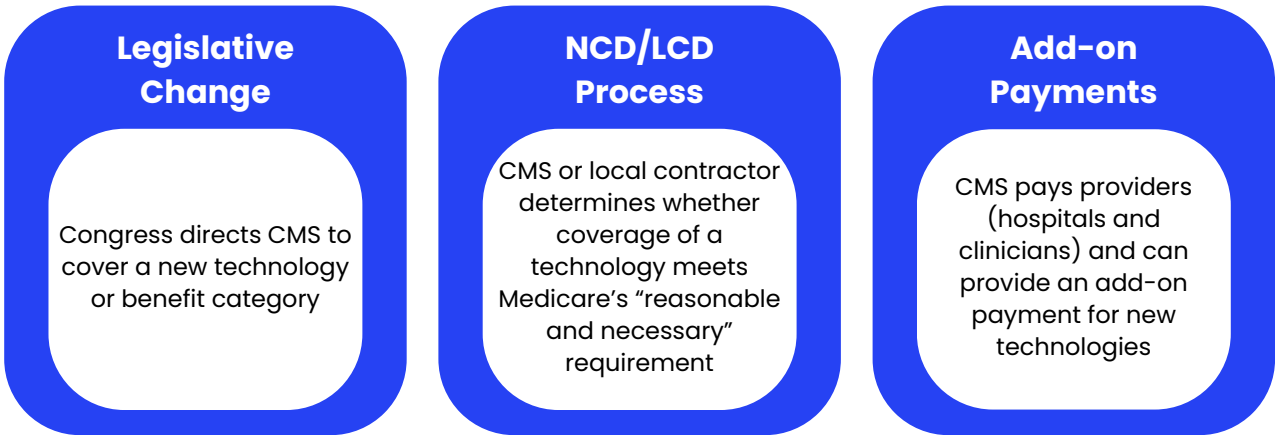
With cancer incidence increasing and national cancer costs projected to rise approximately 11 percent from 2025 to 2030, Medicare access to innovative solutions is increasingly urgent.[2,6] Debate surrounds the effectiveness of current Medicare's policies and processes for determining coverage and payment of new medical technologies and how they influence beneficiary access and innovation.[7] These concerns stem from CMS's narrowly defined authority to determine coverage and resource-intensive processes, which can be ill-suited to keep pace with the fast-moving development of emerging technologies. As a result, Medicare beneficiaries may face delays or inconsistent access to innovative technologies. It is crucial that Medicare evolves its coverage processes to ensure that there are viable, timely pathways for coverage and reimbursement to prevent cost from becoming a barrier for patients and to avoid inadvertently disincentivizing the development of promising new technology that can deliver critical clinical advancements to Medicare beneficiaries.

Cost of care for Medicare beneficiaries vary considerably depending on services being covered. With the introduction of any healthcare technology innovation in the marketplace, ultimate costs to the Medicare program are part of a complex coverage landscape. CMS has a duty to its beneficiaries, who pay cost sharing under the Medicare program, and the taxpayers who finance the program to ensure that any product or service it covers provides a meaningful clinical benefit. Although CMS generally does not consider the cost of a product or service when determining Medicare coverage, it can significantly influence real-world adoption by providers and access for beneficiaries.

Although cutting-edge technologies may impact Medicare outlays, the program was created to provide reasonable and necessary services to beneficiaries. These technologies have the potential to improve beneficiaries' long-term health outcomes and reduce cancer's financial burden on the Medicare program over the long-term. This paper analyzes Medicare's coverage determination process and proposals to expedite beneficiaries' access to new oncology technologies[i] and presents policy recommendations for reform.

The Path from Device Approval to Medicare Coverage

Medicare Coverage of New Technologies Pathways



The Food and Drug Administration (FDA) approval process helps to ensure that new devices are safe and effective for patients. This process requires devices to undergo several stages of clinical trials – including laboratory and patient testing – and the evidence required for approval depends on the devices' novelty and associated risk (e.g. life supporting devices).

Following FDA approval, Medicare coverage requires, regardless of the coverage pathway, that a device must fall within a statutorily-defined Medicare benefit category (including, but not limited to, inpatient hospital services, home health services, durable medical equipment, physicians' services, drugs and biologicals, and preventive services)[8], not be explicitly excluded by statute, and be "reasonable and necessary" for diagnosis and/or treatment of illness or injury, or improvement of bodily function as determined by CMS and its contractors.[9]

CMS's strictly defined authority and resource-intensive coverage processes are not well-equipped to handle the rapid development of technological innovation, often resulting in a delay in Medicare beneficiaries accessing the latest clinical advancements. The Medicare statute grants CMS limited, prescriptive authority, often requiring congressional action to expand coverage.[9] If a device does not fit within an existing benefit category, CMS lacks authority to cover it nationally because the agency cannot override statutory benefit exclusions even as clinical evidence evolves. As a result, stakeholders must advocate for Congress to enact individual statutory changes – either by explicitly requiring Medicare to cover a new technology or by establishing a new benefit category – before Medicare can cover certain novel technologies that lack an existing category. Congress has done so in the past by creating new benefits, such as the prescription drug benefit (Part D), and by expanding existing benefits to cover additional services, such as certain physician or therapy services delivered via telehealth. Enactment of legislation is a challenging and lengthy endeavor and thus coverage via the legislative pathway is relatively rare.

Medicare has existing authority, within the statutorily-defined parameters for explicit coverage decisions – local coverage determinations (LCDs) and national coverage determinations (NCDs) – that typically are made through a coverage determination process.[10] Most determinations are made using the LCD process in which Medicare administrative contractors (MACs)[ii] in a geographic area determine that the product meets Medicare's "reasonable and necessary" standard. When technology could affect a large number of beneficiaries and significantly impact the program, CMS may make an

[i] For the purposes of this paper, "technologies" refers to medical devices, not medical services or prescription drugs. Coverage of these devices is provided under Parts A and B of the Medicare program.
[ii] More information about the Medicare Administrative Contractors (MACs) including a map and list of current contractors is available at https://www.cms.gov/medicare/coding-billing/medicare-administrative-contractors-macs.

NCD, a process undertaken by the agency; NCD determinations are binding nationwide. Although stakeholders – including manufacturers, providers, and beneficiaries – and CMS may initiate an NCD, CMS may only initiate the process in circumstances of significant medical advances, inconsistent local coverage, controversial services, or overuse concerns. Through an NCD, CMS may fully cover a technology, cover it with special conditions (such as clinical trials or limited populations), or deny coverage altogether. NCDs ensure that all Medicare beneficiaries have equal access to covered products and services regardless of geography, including new oncology technologies.

Any stakeholder or MAC may initiate the LCD process. Manufacturers utilize the LCD process most often because LCDs are easier to obtain due to their narrower scope and review process, and because the risk of unfavorable NCDs pose to beneficiary access given Medicare's large market share.[10] However, the LCD process results in a patchwork of coverage, meaning that some new technologies are covered by Medicare – and therefore accessible to beneficiaries – in only certain regions of the country. In regions without an applicable LCD, Medicare may not cover the technology, so coverage is inconsistent nationwide. For instance, molecular syndromic infectious disease pathogen identification panel tests, a type of biomarker testing that has revolutionized diagnostics, is only covered under an LCD, meaning that only beneficiaries in a specific geographic area have access.[11]

Comparison of NCD and LCD Processes

	NCD Process	LCD Process
Policy set by	CMS	Local Medicare Administrative Contractor (MAC)
Scope	Nationwide	Only within the MAC jurisdiction
Who can request	Any stakeholder or CMS	Any stakeholder or MAC
Applicable to	All providers	Only those providers in the geographic area in which the MAC operates
Hierarchy	NCDs supersede LCDs	Only applicable if no NCD

Additionally, new technologies may be covered by Medicare without going through a coverage process. Depending on the product, Medicare may pay a provider in the form of a bundled payment when part of a broader service. Also, Medicare reimbursement for hospital inpatient and outpatient services allows for an additional payment for certain new technologies. However, despite the administrative burden of initiating explicit coverage determinations, manufacturers may choose to undergo these processes because they are more permanent – with an NCD providing binding national coverage – while some add-on payments are only temporary in nature. For beneficiaries, temporary coverage means a technology may be covered for only a limited period, and unless it ultimately receives an LCD, which can vary by region, or NCD, they could later experience reduced or discontinued coverage for a product upon which they depend.

Proposals to Accelerate Medicare Coverage

The rapid development of technologies is an impactful opportunity for people with serious conditions like cancer; however, the path to Medicare coverage – and access for beneficiaries – often is uncertain, even for new technologies that receive FDA approval. During the coverage determination

process, evaluating whether a service is "reasonable or necessary" requires CMS to apply different evidence standards than the FDA (which reviews the technology for safety and effectiveness). In other words, when CMS evaluates technologies for purposes of coverage, it is making a determination on whether the technology is appropriate for the Medicare population, which is generally older and has more comorbidities than typical clinical trial participants. The extent to which a technology will benefit this population from a coverage standpoint can be less clear.[12] As a result, CMS payment pathways must address this tradeoff between earlier access and uncertainty of benefit.

Evidence Requirements

FDA	CMS
Is the item or service safe and effective?	Is the item or service appropriate ("reasonable or necessary") for the Medicare population?

The evidence requirements for coverage determinations are also extensive, including a formal NCD request that identifies the benefit category, outlines supporting documentation and benefit for the Medicare population, and explains the purpose of the item or service; an important public comment process is provided; an internal technology assessment is made; and an external technology assessment and/or Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) meeting is held when there is a limited body of evidence or disagreement among experts.[13] Additionally, CMS cannot cover services that do not fit into an existing benefit category without a change in law from Congress, which may delay beneficiary access to innovative cancer technology, including devices. Even where coverage is permitted by law, the process for CMS coverage decisions – especially for some novel technologies that do not already have or qualify for nominal coverage[iii] – is often prolonged, with novel technologies facing a 5.7-year average wait for Medicare coverage.[14]

When the Medicare program began, many of today's technologies were not even imaginable. For instance, under existing statutory frameworks, AI tools – like AI-enabled medical imaging and machine learning models to identify cancer biomarkers – do not fit into traditional statutory benefit categories to qualify for coverage, potentially slowing beneficiary access to advanced technologies that could improve early diagnosis and personalized treatment. There have been efforts to encourage Congress to create a new benefit category for AI. There have also been efforts by CMS to speed up reviews and shorten the time to Medicare coverage, including proposing guidance on study protocols using real-world data for coverage decisions[15] and developing a systematic pathway for coverage of molecular diagnostic tests.[16] There are also longstanding methods used by CMS to encourage clinical adoption of costly innovative technologies that show substantial benefit over existing technologies, such as new technology add-on payments.[17] Despite efforts to improve coverage, it remains challenging to design policies that balance earlier access to new technologies with greater uncertainty about their benefits for the Medicare population.[18]

[iii] This study defines nominal coverage as when a technology has a new NCD, receives positive LCDs from majority of MACs, or is implicitly covered through one or more new Healthcare Common Procedure Coding System (HCPCS) codes specific to the technology.

Recent Medicare Policies Related to the Coverage of New Technologies

Policy	Year	Description	Uptake
New Technology Add-on Payment (NTAP)[17]	Established 2001	Provides supplemental payments to inpatient providers when the costs of new technologies that offer substantial clinical improvement exceed existing payment rates.	During 2021-2024, 59 technologies were approved, including 28 medical devices.[19]
Coverage with Evidence Development (CED)[20]	Established 2005	Allows CMS to provide coverage for items and services in the context of approved clinical trials or with the collection of additional clinical data.	CMS has only issued 27 NCDs with CEDs over the last two decades. Only four of the technologies have been converted to full coverage, and two of the 27 later had their coverage restricted or withdrawn.[21]
Molecular Diagnostic Program (MolDX)[16]	Established 2011	Administered on behalf of CMS and several MACs, it establishes coverage and reimbursement for molecular diagnostic tests, a process that includes assignment to a diagnostics and exchange registry, a technical assessment, and a coverage determination.	Approximately 1,200 to 2,400 tests are evaluated per year.[22]
Parallel Review[23]	Pilot established in 2011 and fully implemented in 2016.	Allows FDA and CMS to simultaneously review new technologies.	Only four technologies have completed this pathway.[18]
Medicare Coverage of Innovative Technology (MCIT)[24]	Published in federal regulation January 2021 and rescinded November 2021.	The pathway would have provided four years of transitional Medicare coverage for breakthrough devices approved by the FDA to enable manufacturers to develop additional evidence.	Not applicable.
Transitional Coverage for Emerging Technologies (TCET)[25]	Established 2024	Shortens timelines for CMS coverage decisions for FDA breakthrough devices and allows for greater engagement between developers and CMS reviewers during FDA review.	This pathway is new, so there is limited data on uptake. The pathway only applies to a narrow set of breakthrough devices and excludes drugs and almost all diagnostics.
Real World Data (RWD) Payment Protocol[15]	Proposed in January 2025 but not yet finalized.	Proposes use of a standard RWD study protocol template for CED that has been adapted from established observational study protocols.	Not applicable.
ACCESS (Advancing Chronic Care with Effective, Scalable Solutions) Model[26]	Begins July 2026	Tests a payment model that supports technology-enabled care through outcome-based payments for managing qualifying conditions. Allows FDA Technology-Enabled Meaningful Patient Outcomes (TEMPO) pilot manufacturers to provide care covered by the model.[27]	Not applicable.

The Need for New Pathway Options

These more recent payment pathways show promise, by shortening CMS review timelines, allowing for earlier feedback from CMS on necessary data for coverage determinations, and enabling potential cost savings for manufacturers by reducing the need for separate evidentiary studies. However, to date, relatively few technologies have received full national coverage under any of these pathways. Each of these pathways have narrow and differing eligibility, partially due to the limited statutory authority Congress provided CMS, and are only available to specific types of technologies, like the TCET pathway which excludes almost all diagnostics. Due to the inherent risk of these investments, companies investing in emerging technologies may be hesitant to undergo a process that has few proven results.

Those that choose to embark on these new pathways still face significant administrative challenges. Although these pathways offer shortened review timelines and earlier communication with regulators, manufacturers still must navigate and accommodate the different FDA and CMS evidence requirements. Even if their product receives a favorable coverage determination, under any of the pathways, except for add-on or bundled payments, manufacturers would still need to go through a separate reimbursement process to determine how much Medicare will pay for the product.[iv]

Changing the Medicare program to more nimbly adopt new technologies and expedite beneficiary access will not be easy, but CMS and Congress have opportunities to improve pathways for coverage of innovative technologies, particularly in the oncology space, while still safeguarding beneficiaries and maintaining program integrity. Some existing proposals focus on ensuring timely access by providing transitional coverage for FDA-market authorized breakthrough technologies utilizing CMS's existing regulatory authority. These proposals aim to reduce delays between FDA approval and Medicare coverage and provide greater certainty for manufacturers. Other proposals seek a legislative change to statutory limitations in Medicare's coverage authority that would direct CMS to create new benefit categories for emerging technologies – such as software-as-a-service – or expand existing benefit categories to better accommodate innovative devices.

Policy Recommendations

Medicare beneficiaries today are living longer and are more active relative to their predecessors at the turn of the century, and they should have access to new and innovative technologies that can improve their health outcomes and quality of life. This is thanks in part to all the advances in medical technology from which all Americans have benefitted. In order to best serve its beneficiaries into the future, Medicare must be reformed to allow the program to adopt new and innovative technologies, particularly those in the oncology field to address the cancer burden of Medicare beneficiaries. ACS CAN recommends that:

- *Congress* streamline the review process between FDA and CMS to improve the pathway to coverage of groundbreaking technologies while ensuring that CMS maintains authority to determine the appropriateness of technologies for the population it serves, including enacting the Ensuring Patient Access to Critical Breakthrough Products Act (H.R. 5343/S. 1717), bicameral, bipartisan legislation sponsored by Senators Todd Young (R-IN) and Alex Padilla (D-CA) and Representatives Blake Moore (R-UT) and Suzan DelBene (D-WA). This legislation would provide transitional coverage for new technologies – ensuring beneficiaries more timely access to treatments. Congress should also examine on a holistic basis the existing Medicare categories of coverage to ensure they reflect new technologies and consider creating new benefit categories to expedite coverage.

[iv] Medicare's reimbursement process is complex and varies depending on the product and service being covered. Except as otherwise noted, reimbursement issues are outside the scope of this paper.

- *Department of Health and Human Services (HHS)* publish an annual report detailing the number of applications and approvals for coverage of new technologies, including the pathway utilized for coverage. Additionally, an independent evaluation should assess the effectiveness of new pathways and identify whether changes are needed, given that many of the existing pathways are not being utilized to the extent[v] that they could be.
- *CMS, through the Centers for Medicare & Medicaid Innovation (CMMI)*[vi], create a demonstration focused on new oncology care technology – either as a track in an existing model like ACCESS or as a standalone demonstration – to test providers' adoption of innovative technologies and assess their impact on beneficiary health outcomes. These demonstrations could complement the existing CED framework by evaluating the effectiveness of care delivery models that incorporate these devices and expanding the evidence base for their use.
- *Congress and CMS* ensure the agency is adequately resourced to strengthen existing pathways and develop new policies for coverage of innovative technologies. Additionally, they should collaborate to maintain affordable beneficiary cost sharing for those products and services as Medicare covers new and innovative technologies.

[v] See the table 'Recent Medicare Policies Related to the Coverage of New Technologies' above for data on uptake of existing pathways.
[vi] CMMI models are alternative payment models (APMs) which are designed to reward health care providers for delivering high-quality and cost-efficient care. APMs can apply to a specific health condition (like end-stage renal disease), a care episode (like joint replacement), provider type (like primary care providers), community (like rural areas), or innovation within Medicare Advantage or Part D.

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