Crossing the Valley of Death, Part 1

The Innovation Imperative and Medicare Coverage Reform

Ted Cho and Brian J. Miller

With an estimated 45 percent of Medicare beneficiaries[1] suffering from impairments in activities of daily living and nearly nonexistent labor productivity growth in the hospital industry[2] manifesting in a frustrating care-delivery experience, healthcare delivery has an imperative to improve efficiency and lower cost through technological innovation. Pharmaceutical product development faces similar challenges, with rising development costs estimated at just under $1 billion to bring a drug from bench to bedside[3] and over six thousand rare diseases lacking treatments,[4] emphasizing the need for further innovation in the treatment of innumerable diseases.

While the American innovation ecosystem uniformly faces basic scientific and clinical barriers, life sciences and technology innovators must face the additional challenges of an antiquated US Food and Drug Administration (FDA) review process followed by an anachronistic technology assessment and coverage analysis at the Centers for Medicare & Medicaid Services (CMS) to achieve Medicare coverage and payment. In addition to these two regulatory barriers to market entry and payment, the FDA and CMS have differing statutory mandates, resulting in a so-called Valley of Death, with the median time from FDA approval of a novel technology to Medicare coverage supportive of patient access averaging 5.7 years.[5]

While critics denote attempts to realign regulatory standards as lowering the evidentiary standard[6] or providing corporate handouts,[7] regulatory reform can expand access to and lower the cost of innovation, driving improved convenience in care delivery and better outcomes. This policy brief reviews the innovation imperative along with historical CMS reform efforts. Then the Medicare coverage process is examined in conjunction with opportunities to improve transparency, efficiency, and meaningfulness of technology assessment, all with the aim of traversing the Valley of Death.

2025 and Beyond: Health Policy Challenges on the Agenda

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THE INNOVATION IMPERATIVE

Public perception of the US pharmaceutical industry is at an all-time low[8] while patients still face innumerable chronic, progressive, and debilitating diseases, and healthcare delivery suffers from inconvenience, outdated processes, and a litany of unsolved operational problems.[9] Patients still face innumerable challenges in achieving independence—a primary goal of many patients suffering from chronic, progressive, and debilitating diseases—with declining functional status associated with increased risk of hospitalization.[10]

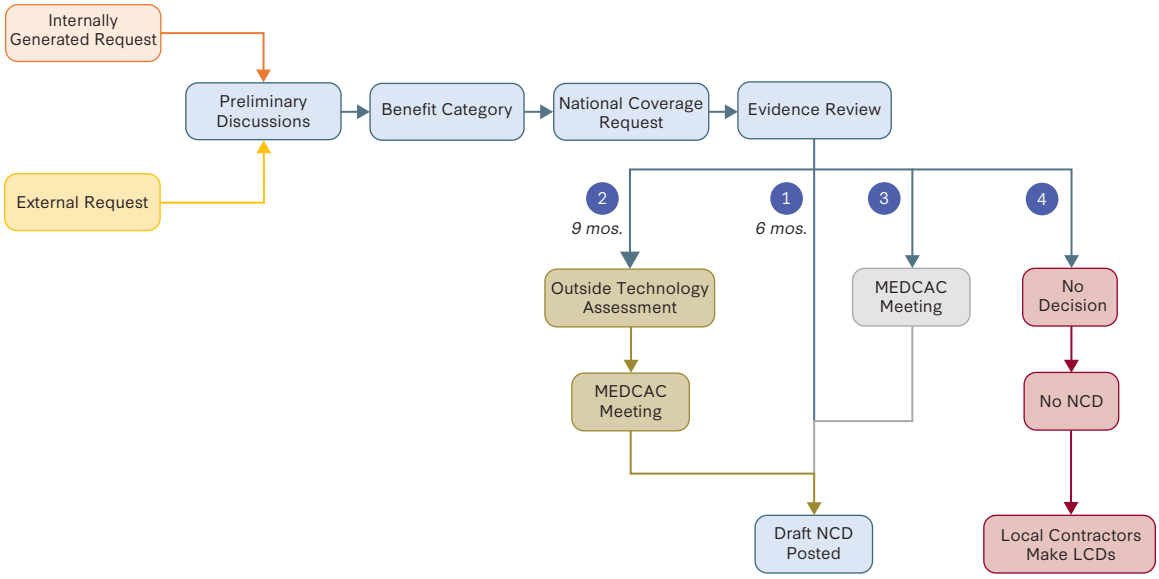
However, the current state of affairs belies the fact that the United States has a strong history of innovation. Over the past sixty years, the life sciences industry has developed over twelve hundred new drugs,[11] driving changes in clinical practice such as the development of goal-directed medical therapy in heart failure and the transformation of HIV from a death sentence into a chronic disease.[12] In other cases, device innovation has transformed surgical and procedural care and reduced morbidity and mortality, as is the case with cardiac surgical procedures such as aortic valve replacements increasingly becoming interventional cardiology procedures.[13] From an economic perspective, these massive transformations in care for patients and reduced morbidity and mortality have come at a modest price, with retail prescription drug spending representing just 9 percent of national health expenditures[14] while medical device expenditures represent 5.2 percent.[15]

Despite this track record, pursuing efficiencies to facilitate innovation should continue to be a policy imperative. An estimated ten million children suffer from rare diseases, only 5 percent of which have treatments.[16] Chronic insulin-dependent diabetes affects over five million Americans,[17] bringing with it the inconvenience and pain of checking one's blood sugar and injecting insulin multiple times daily for life. Unsurprisingly, adherence is around 55 percent,[18] with weekly basal insulin representing a potential revolutionary innovation.[19] Complications from inadequately controlled diabetes include limb amputations[20] and vision loss[21] resulting in significant functional impairment and downstream economic losses in productivity and workforce participation.[22] The economic impact of disease is significant, with the impact of diabetes estimated at $412 billion.[23]

MEDICARE COVERAGE REFORM

Technology assessment and coverage assessment in the Medicare program have remained an important pillar necessitating reform. In 1999, under the leadership of Administrator Nancy-Ann DeParle during the Clinton administration, CMS undertook regulatory policy reform and overhauled the Medicare coverage analysis group, addressing staffing, process, and transparency concerns while simultaneously creating the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC).[24] Nearly two decades later, persistent, long gaps between FDA approval and CMS coverage motivated the Trump administration, through administrative rulemaking under existing statutory authority, to grant temporary automatic coverage for up to four years for breakthrough medical devices[25] via the

FIGURE 1 CMS coverage analysis process



Medicare Coverage of Innovative Technologies (MCIT) pathway. Unfortunately, shortly after entering office, the Biden administration repealed this rule[26] and issued its own narrower pathway in the Transitional Coverage for Emerging Technologies (TCET) pathway,[27] which accepts only five devices annually and excludes diagnostics.[28] Given the limited scale and scope, the Ensuring Patient Access to Critical Breakthrough Products Act[29] was introduced in 2023 to mirror the MCIT pathway and establish a four-year transitional Medicare coverage period for devices designated as breakthroughs. While still making its way through the legislative process, this bill has the potential to bridge the gap that the TCET pathway has been unable to fill after the sunsetting of the MCIT pathway.

The technology assessment and coverage process often defines the time lag inherent to the Valley of Death, in part due to Medicare's muscles for core health plan functions having atrophied over the past decade. Medicare coverage is tied to an item or service being legal, having a benefit category and code, and being "reasonable and necessary,"[30] with the agency issuing guidance under existing statutory authority regarding the coverage process.[31] Medicare coverage can be granted through a variety of pathways (see figure 1). Requests for coverage can originate internally or externally, with evidence review occurring internally through CMS staff efforts, externally via an outside technology assessment, and potentially involving the MEDCAC as an outside advisory body to answer specific technical, clinical, and population health questions. Alternatively, coverage decisions can be devolved to the twelve local Medicare area contractors (MACs) that run the Fee-for-Service Medicare administrative operations.

Created twenty-five years ago, the MEDCAC serves as a robust outside advisory body and met six times in calendar year 2000 alone. Over the past decade, however, CMS has deferred or avoided coverage decisions, with MEDCAC meeting only fourteen times over that period.

In the same vein, the number of National Coverage Determinations (NCDs) issued has also declined, from a peak of twenty final coverage determination memorandums in 2003 to just four in 2022.[32]

CMS has also avoided definitive coverage decisions including increased usage of Coverage with Evidence Development (CED), which requires additional clinical trials on top of those conducted for the FDA. These requirements, originally designed to accelerate innovation, functionally can span decades and drain resources. The impact on patients of CMS's avoidance of coverage decisions is real. For example, the Independence iBOT Mobility System, a powered wheelchair that lets users navigate stairs and live a more normal life, took more than three years to gain CMS coverage after FDA approval.[33] Of the twenty-six devices or procedures subjected to CED from 2005 to 2023, only three had CED terminated and transitioned to routine national Medicare coverage, with only ten receiving any reconsideration of coverage decision at all after initiation of CED in the nearly twenty-year lifespan of the program.[34] A moratorium on new CED programs is needed until it can be fixed through the provision of defined clinical measurement milestones and completion criteria, coupled with predetermined timelines with defined NCD to follow within twelve months.

Finally, in addition to process concerns, CMS increasingly demonstrates hostility toward drugs receiving FDA accelerated approval. These drugs receive expedited review due to their potential to help an unmet medical need based upon surrogate endpoints. Under the Biden administration, CMS built a policy platform to consistently second-guess the FDA's marketing decisions, floating a model to cut reimbursement for accelerated-approval drugs.[35] The state of Oregon, for instance, applied for a Medicaid waiver[36] to deny coverage for accelerated-approval drugs, and a congressional Medicaid advisory committee suggested requiring higher Medicaid rebates for these drugs.[37]

CMS reform is necessary in order to ensure that new services, pharmaceutical products, and technologies are fairly and rapidly evaluated for the Medicare program. The statutory reason for coverage or the "reasonable and necessary" standard should be defined in rulemaking in order to standardize coverage decisions and provide clarity to market innovators seeking Medicare coverage. Currently, the "reasonable and necessary" standard is defined in the *Medicare Program Integrity Manual* as (1) safe and effective, (2) not experimental or investigational, and (3) appropriate for Medicare beneficiaries.[38] Since the creation of the Medicare program in 1965 that first conceived the "reasonable and necessary" standard,[39] there have been many failed pushes to statutorily define this standard.[40] This includes an attempt in 1989 to add "cost-effectiveness" to this standard that was challenged in court in 2008 and subsequently struck down,[41] as well as more recent efforts to establish the MCIT pathway that included a codified definition of "reasonable and necessary"[42] that was subsequently terminated[43] along with the MCIT pathway itself.

In the absence of a national definition established in statute or rulemaking, CMS makes determinations of what is "reasonable and necessary" through a combination of NCDs,

guidance letters, and documents for Medicare Administrative Contractors (MACs). MACs are private insurers that process Medicare Parts A and B claims. If there is no NCD from CMS, these MACs make coverage decisions, known as local coverage determinations (LCDs), through application of CMS "reasonable and necessary" guidelines[44] and key business process steps.[45] Because these LCDs are being made locally without standardization of core evaluative principles, there is substantial variation in state-by-state coverage,[46] resulting in arbitrary geographic boundaries dictating uneven access to care for Medicare beneficiaries.

While there is some merit to allowing CMS flexibility in denying coverage when there is a question of effectiveness or appropriateness specifically for the Medicare population, allowing a diffusion of responsibility to continue is inequitable to patients who may be denied care simply because of where they live. Instead, regulators should look to provide clarity of coverage for patients, clinicians, and innovators through clear delineation of both scope and processes for local and federal coverage decisions, while simultaneously driving pragmatic improvements.

First, having a federal-level "reasonable and necessary" standard defined in rulemaking through the provision of broad core guiding evaluative principles[47]—which can be updated or adjusted over time in response to technological innovation and market shifts—will not only help to even out coverage decisions nationwide, but will also give innovators more certainty about how to build new products and services in a way that provides the most value for CMS beneficiaries. Additionally, CMS should clearly define both guidelines and pathways for MACs to exercise flexibility in coverage decisions, preserving and promoting local positive customization when clear federal coverage decisions are absent or, alternatively, are in need of reevaluation.

Additional simultaneous improvements to the LCD process can provide regulatory certainty. For example, policymakers through statutory change and CMS rulemaking or MAC contracting should require hard and transparent time frames for all key steps in the LCD process, noting that the primary statutory requirement from the 21st Century Cures Act as part of LCD modernization[48] is the posting of the LCD forty-five days[49] prior to its effective date. MAC Contractor Advisory Committees (CACs) should be able to pull technical experts from the one hundred–member MEDCAC and ideally include clinicians with specific technical expertise or even experience with the product or procedure in question. CMS should also implement administrative process improvements for CAC meetings, modeling off the best practices of MEDCAC meetings, and require MACs to post the names of CAC members and technical questions at least thirty calendar days in advance of the meeting. Finally, noting that MACs are contractors for the $400 billion Fee-for-Service Medicare program, CMS should hold public meetings at least annually highlighting the policy and operational opportunities and lessons learned from MACs.

CONCLUSION

Promoting life sciences and technological innovation is an economic imperative to improve care delivery and unlock the positive impacts of improved functional status and return to work across the broader economy. Innovation is also a moral imperative: The human cost is real, as every patient is someone's spouse, child, or friend. Operational and policy changes in the Medicare coverage process can thoughtfully expand access to innovation, helping to solve clinical and population-level challenges in a nonpartisan fashion.

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