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ONE HUNDRED NINETEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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September 16, 2025

MEMORANDUM

To: Subcommittee on Health Members and Staff
From: Committee on Energy and Commerce Majority Staff
Re: Subcommittee on Health Hearing on September 18, 2025

I. INTRODUCTION

The Subcommittee on Health will hold a hearing on Thursday, September 18, 2025, at 9:30 am (ET) in 2123 Rayburn House Office Building. The hearing is entitled "Examining Policies to Enhance Seniors' Access to Breakthrough Medical Technologies." The Subcommittee intends to discuss the following pieces of legislation:

- H.R. 842, Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act (Rep. Arrington)
- H.R. ____, [Ensuring Patient Access to Critical Breakthrough Products Act of 2025]
- H.R. ____, [To amend title XVIII of the Social Security Act to ensure transparency in the national coverage determination process under the Medicare program and to make certain adjustments to Medicare local coverage determinations.]
- H.R. 3826, Expanding Access to Diabetes Self-Management Training Act of 2025 (Rep. Schrier)

II. WITNESSES

- **Dr. Todd Brinton, MD,** Corporate Vice President, Advanced Technology, and Chief Scientific Officer, Edwards Lifesciences
- **Stephen Ezell**, Vice President, Global Innovation Policy, and Director, Center for Life Sciences Innovation, Information Technology and Innovation Foundation
- **Roger Royse**, Patient Advocate and Partner, Haynes and Boone, LLP
- **Dr. Diana Zuckerman, PhD**, President, National Center for Health Research
- **David Lipschutz, JD**, Co-Director of Law and Policy, Center for Medicare Advocacy

III. BACKGROUND

More than 68 million Americans rely on Medicare for timely access to critical medical services and items.[1] The Centers for Medicare and Medicaid Services (CMS) is responsible for administering the Medicare program, including implementing and overseeing coverage policies for specific items and services furnished to beneficiaries. This legislative hearing will focus on several policies related to Medicare's coverage of innovative devices and technologies, as well as the processes through which the agency makes determinations about whether to cover, limit, or exclude Medicare Part A or Part B coverage of particular items or services. This legislative hearing builds on the Committee on Energy and Commerce's work during the 118th Congress to provide oversight of Medicare coverage policies and processes and to enhance beneficiaries' access to breakthrough advances that have the potential to improve patient outcomes.[2]

The Medicare statute and program regulation generally provide for Medicare coverage of items and services under Part A or Part B that are included in a Medicare benefit category, not otherwise statutorily excluded, cleared or approved by the Food and Drug Administration (FDA), as appropriate, and considered "reasonable and necessary."[3] This latter criterion—the "reasonable and necessary" standard—is stipulated by section 1862(a)(1)(A) of the Social Security Act, which prohibits the Secretary from providing payment under Medicare Part A or Part B for items and services that are not "reasonable and necessary for the diagnosis or treatment of a malformed body member."[4] The Social Security Act provides the Secretary certain authorities to determine what is "reasonable and necessary."[5]

As a result of the "reasonable and necessary" standard, Medicare coverage for certain preventive services and screenings is effectively excluded. Over several decades, however, Congress has codified coverage for many of these services and a process whereby the Secretary may allow for coverage of certain services recommended by the U.S. Preventive Services Task Force. Preventive and screening services currently covered by Medicare include screenings for breast, cervical, prostate, and colorectal cancers and a "welcome to Medicare" physical exam during a beneficiary's first year of Part B enrollment, as well as an Annual Wellness Visit each year, among other services.[6]

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[1] CTRS. FOR MEDICARE & MEDICAID SERVICES (CMS), Medicare and Medicaid Reports, *Medicare Monthly Enrollment* (May 2025), https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-monthly-enrollment.

[2] *See* the following Committee activity: *Innovation Saves Lives: Evaluating Medicare Coverage Pathways for Innovative Drugs, Medical Devices, and Technology: Hearing before the Subcomm. on Health of the H. Comm. on Energy and Com.,* 118th Cong. (Jul. 18, 2023); *Examining Policies to Improve Seniors' Access to Innovative Drugs, Medical Devices, and Technology: Hearing before the Subcomm. on Health of the H. Comm. on Energy and Com.,* 118th Cong. (Sept. 19, 2023); *Markup of 21 Pieces of Legislation before the Subcomm. on Health of the H. Comm. on Energy and Com.,* 118th Cong. (Nov. 15, 2023); *Markup of 44 Bills before the H. Comm. on Energy and Com.,* 118th Cong. (Dec. 5, 2023).

[3] Medicare Payment Advisory Commission (MPAC), *June 2024 Report to the Congress: Medicare and the Health Care Delivery System, Chapter 4: Paying for software technologies in Medicare* (Jun. 13, 2024), https://www.medpac.gov/wp-content/uploads/2024/06/Jun24_Ch4_MedPAC_Report_To_Congress_SEC.pdf.

[4] 42 U.S.C. § 1862(a)(1)(A).

[5] *Id.*

[6] Patricia A. Davis, CONG. RSCH. SERV. (CRS), R40425, Medicare Primer (2020).

Medicare coverage of particular of items and services can ultimately take several forms—such as by its inclusion in an existing billing code or bundled payment system; through a National Coverage Determination (NCD) or Local Coverage Determination (LCD); as required by CMS program memorandums or manuals; or through claim-by-claim adjudication at the Medicare Administrative Contractor (MAC) level.[7]

National Coverage Determinations

The Secretary can establish nationwide coverage policies through the NCD process, defined in section 1862(l)(6)(A) of the Social Security Act as "a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title."[8] NCDs can be requested by a variety of entities or initiated internally by CMS.[9] The process is comprised of opportunities for public comment; an internal evidence review; a technology assessment or Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) meeting if applicable; the publishing of a proposed decision memorandum with an opportunity for public comment; and the publishing of a final decision memorandum.[10]

Section 1862(l) of the Social Security Act requires that this NCD process be completed over a 9–12-month period once action on an NCD request is initiated by the agency.[11] A September 2025 report from the Government Accountability Office (GAO) found that CMS met this timeline for 83 percent of its analyses between October 2012 to February 2025.[12] For determinations that exceeded this timeframe, delays ranged from six to 351 additional days.[13] As a result of its report, GAO made two recommendations to CMS—that the agency "1) identify the causes of national coverage determination delays to better ensure that analyses are finalized within specified time frames, and 2) make available to the public the criteria it uses to prioritize its coverage analyses."[14] The Department of Health and Human Services (HHS) concurred with both recommendations. GAO also noted that identifying the causes of delays may allow CMS to better monitor performance and improve the timeliness of its analysis, which "in some cases, could help Medicare beneficiaries access new or enhanced evidence-based items and services."[15]

In some circumstances, CMS may issue an NCD involving Coverage with Evidence Development (CED), whereby Medicare covers items or services only in the context of approved clinical studies or under the condition that certain additional clinical data is collected. CMS notes in its CED guidance that "[when] the available evidence is insufficient to demonstrate that the items and services are reasonable and necessary under section 1862(a)(1)(A), CMS may use authority under section 1862(a)(1)(E) to provide [CED]."[16] Over the last two decades, CMS has

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[7] MPAC, *supra* note 3.
[8] 42 U.S.C. § 1862(l)(6)(A).
[9] GOVERNMENT ACCOUNTABILITY OFFICE (GAO), *National Coverage Determinations Are Generally Timely, but Improvements Are Needed* (Sept. 2025), https://www.gao.gov/assets/gao-25-107623.pdf.
[10] *Id.*
[11] 42 U.S.C. § 1862(1).
[12] GAO, *supra* note 9.
[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] CMS, *Coverage with Evidence Development* (Aug. 7, 2024), https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=38.

issued 27 NCDs requiring CED.[17] Some researchers and stakeholders have raised concerns about Medicare's CED policy, including issues related to a lack of clarity as to when CMS will apply CED requirements, opaque timelines for ending CED, and the burdens the policy may place on providers, along with broader concerns that CED has, at times, failed to improve access to new technologies.[18]

Local Coverage Determinations

In addition to other activities they perform, MACs also play an important role in the Medicare coverage process by establishing LCDs and managing claim-by-claim adjudications of particular items or services furnished in their respective geographic jurisdiction. LCDs are defined in section 1869(f)(2)(B) of the Social Security Act as a "determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under such parts, in accordance with section 1862(a)(1)(A)."[19]

LCDs only apply in the geographic region in which the contractor issuing such determination has jurisdiction. MACs develop LCDs based on guidelines in the Medicare Program Integrity Manual (PIM). The PIM requires that when establishing an LCD, the contractor determine whether an item or service is "reasonable or necessary," including whether the item or service is safe and effective, not experimental or investigational, and appropriate.[20] The PIM also provides additional guidelines regarding LCD process timelines, opportunities for comment, and advance notice of new LCDs.[21]

Medicare Coverage of Innovative Technology

In September 2020, CMS issued a proposed rule titled Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" in response to the October 2019 Executive Order (EO) 13890, *Protecting and Improving Medicare for Our Nation's Seniors*.[22] This proposed rule was finalized in January 2021 and would have provided a four-year Medicare coverage pathway for FDA-designated Breakthrough Devices as early as the day of FDA market authorization.[23] The rule was intended to address the "valley of death," wherein

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[17] *Id.*
[18] Darius Lakdawalla et al., *A Roadmap for Improving Medicare's Application of Coverage With Evidence Development*, VALUE IN HEALTH (Jun. 21, 2024), https://www.valueinhealthjournal.com/article/S1098-3015(24)02368-4/fulltext?_returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS1098301524023684%3Fshowall%3Dtrue#secsectitle0020.
[19] 42 U.S.C. § 1869(f)(2)(B); *see also* 42 U.S.C. § 1862(a)(1)(A).
[20] CMS, *Medicare Program Integrity Manual: Chapter 13: Local Coverage Determinations* (Dec. 18, 2024), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c03.pdf.
[21] *Id.*
[22] CMS, *Proposed Medicare Coverage of Innovative Technology (CMS-3372-P)* (Apr. 31, 2020), https://www.cms.gov/newsroom/fact-sheets/proposed-medicare-coverage-innovative-technology-cms-3372-p (for the proposed rule, *see* Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary," 85 Fed. Reg. 54327 (proposed Sept. 1, 2020)).
[23] CMS, *Medicare Coverage of Innovative Technology (CMS-3372-F)* (Jan. 12, 2021), https://www.cms.gov/newsroom/fact-sheets/medicare-coverage-innovative-technology-cms-3372-f; *See also* the final rule, Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary," 86 Fed. Reg. 2987 (Jan. 14, 2021).

medical devices often go years between FDA authorization before Medicare covers the technology. One study analyzed 64 novel devices and diagnostics authorized by FDA between 2016 and 2019, finding that only 44 percent of those technologies achieved nominal Medicare coverage with a median time to coverage of 5.7 years.[24]

This rule also codified a definition of "reasonable and necessary," similar to the definition described in the Medicare PIM and discussed above.[25] Codifying this definition aimed to "bring clarity and consistency to the existing coverage determination processes for items and services under Part A and Part B."[26]

CMS ultimately repealed this rule in November 2021 after delaying its implementation in March of that year, citing concerns that "the provisions in the final rule may not have been sufficient to protect Medicare beneficiaries."[27] In the announcement, CMS also stated that agency would consider alternative approaches to reforming the coverage process.

Transitional Coverage for Emerging Technologies

In June 2023, CMS issued a notice with comment on a proposed Transitional Coverage for Emerging Technologies (TCET) pathway.[28] TCET is intended to build on the agency's Parallel Review program—in which FDA and CMS concurrently review a medical device's clinical data—and the CED pathway. CMS issued the final notice for TCET in August 2024.[29]

Under the TCET pathway, CMS will accept up to five TCET candidates per year and utilize the agency's NCD with CED process. To be eligible, the device must be an FDA-designated Breakthrough Device, fit within a Medicare benefit category, not already be subject to an existing NCD, and not otherwise excluded from coverage by statute or regulation.[30]

The TCET pathway process for an accepted device begins with a pre-market evidence review with CMS. Upon FDA market authorization, CMS and the Agency for Healthcare Research and Quality (AHRQ) jointly review and approve an Evidence Development Plan (EDP), and then an NCD with CED is formulated. After a third-party contractor reviews the

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[24] Zachary A. Sexton et al., *Time From Authorization by the US Food and Drug Administration to Medicare Coverage for Novel Technologies*, JAMA (Aug. 4, 2023), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2807906.
[25] CMS, *supra* note 23.
[26] *Id.*
[27] Press Release, CMS, *CMS Repeals MCIT/R&N Rule; Will Consider Other Coverage Pathways to Enhance Access to Innovative Medical Devices* (Nov. 12, 2021), https://www.cms.gov/newsroom/press-releases/cms-repeals-mcitrn-rule-will-consider-other-coverage-pathways-enhance-access-innovative-medical; *See also* final rule, 86 Fed. Reg. 62944 (Nov. 15, 2021) (repealing the "Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" final rule, which was published on January 14, 2021, and was to be effective on December 15, 2021).
[28] CMS, *Notice with Comment - Transitional Coverage for Emerging Technologies (CMS-3421-NC)* (Jun. 22, 2023), https://www.cms.gov/newsroom/fact-sheets/notice-comment-transitional-coverage-emerging-technologies-cms-3421-nc; *see also* Meeting Notice, 88 Fed. Reg. 41633 (Jun. 27, 2023).
[29] CMS, *Final Notice — Transitional Coverage for Emerging Technologies (CMS-3421-FN)* (Aug. 7, 2024), https://www.cms.gov/newsroom/fact-sheets/final-notice-transitional-coverage-emerging-technologies-cms-3421-fn; *See also* Meeting Notice, 89 Fed. Reg. 65724 (Aug. 12, 2024).
[30] CMS, *Final Notice — Transitional Coverage for Emerging Technologies (CMS-3421-FN)* (Aug. 7, 2024), https://www.cms.gov/newsroom/fact-sheets/final-notice-transitional-coverage-emerging-technologies-cms-3421-fn.

additional evidence generated by the manufacturer, CMS will reconsider the device's NCD as appropriate. The agency anticipates coverage under a TCET NCD will last five or more years.[31]

Some stakeholders raised concerns that the TCET pathway will not go far enough to improve Medicare coverage of innovative medical devices and about CMS's limitation of the pathway to only five Breakthrough Devices per year, among other issues.[32]

IV. LEGISLATION

H.R. 842, Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act (Rep. Arrington)

This legislation would allow for Medicare coverage of, and payment for, FDA cleared or approved multi-cancer early detection (MCED) screening tests.

H.R. ____, [Ensuring Patient Access to Critical Breakthrough Products Act of 2025]

This legislation would provide for temporary or transitional Medicare coverage of FDA cleared or approved Breakthrough Devices for four years while CMS works to make a permanent nationwide coverage determination.

H.R. ____, [To amend title XVIII of the Social Security Act to ensure transparency in the national coverage determination process under the Medicare program and to make certain adjustments to Medicare local coverage determinations.]

This legislation would require the HHS Secretary to determine whether a request for an NCD is complete within 90 days of receiving the request, as well as allow the Secretary to work directly with the entity who submitted the request to update and resubmit the request if the Secretary finds that the application is incomplete. Additionally, the Secretary would be required to make a summary of all complete NCD requests publicly available on CMS's website. Regarding LCDs, the bill would direct the Secretary to require that MACs not develop any LCDs that conflict with any law, regulation, NCD, payment policy, or coding policy.

H.R. 3826, Expanding Access to Diabetes Self-Management Training Act of 2025 (Rep. Schrier)

This legislation would expand coverage for diabetes outpatient self-management training services and remove patient cost-sharing and deductible requirements under Medicare Part B. The legislation would also require the Center for Medicare and Medicaid Innovation (CMMI) to test a model covering virtual diabetes outpatient self-management training services.

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[31] *Id.*
[32] Final Notice, Medicare Program; Transitional Coverage for Emerging Technologies, 89 Fed. Reg. 65724 (Aug. 12, 2024).

VI. STAFF CONTACTS

If you have questions regarding this hearing, please contact Annabelle Huffman of the Committee staff at (202) 225-3641.