



Façade of Evidence:

How Medicare's Coverage with Evidence Development Paradigm Rations Care and Exacerbates Inequity

February 13, 2023

Executive Summary

The Medicare program is the predominant insurer for the over 65 and disabled populations and provides medical coverage for 64 million Americans. By statute, the Centers for Medicare & Medicaid Services (“CMS” or “the Agency”) provides coverage for items and services that are deemed “reasonable and necessary” under the Social Security Act (the “Act”). By comparison, the U.S. Food & Drug Administration (“FDA”) generally approves a drug or biological product based on a finding that it is “safe

and effective” based on the Federal Food, Drug, and Cosmetic Act. Separately, medical devices are approved based on a “reasonable assurance” of safety and efficacy to receive FDA approval.

Given the FDA’s rigorous, evidence-based approval process, CMS has largely considered FDA-approved drugs and biologics as “reasonable and necessary.” Medicare can formally establish national coverage policy for Medicare Part B

physician-administered services or therapeutics through a National Coverage Determination (“NCD”) or allow a Medicare contractor to establish regional coverage guidelines. More commonly, the need for therapeutics and services are considered on a claim-by-claim basis.

CMS has the option to issue a NCD to set a single coverage standard on how an FDA-approved product or service is covered nationally in the Medicare Part B program. Between 2012 and 2022, CMS issued 336 NCDs, primarily for medical devices and services. CMS utilizes a range of potential coverage outcomes for NCDs, from full coverage to a prohibition on coverage. Given the size of the Medicare population, NCDs represent a high-stakes decision by the Agency that can either procure coverage for a new therapeutic or result in nearly 20% of the U.S. population being unable to potentially access a treatment for a given condition. Unfortunately, it is not uncommon for the CMS coverage decision process to become highly politicized due to its economic impacts on public and private payers, industry, specialty providers, and national and regional medical systems and hospitals.

In recent years, CMS has escalated its focus on the prices of drugs, biological products, and medical devices at a time when growth in U.S. healthcare cost increases have outpaced

economic growth, notwithstanding the fact that such considerations fall outside of Medicare’s legal mandate. Drug pricing and payment policies are statutorily distinct from coverage considerations. CMS has repeatedly insisted that it does not consider the price of medical products and services when determining coverage policy; however, former HHS assistant secretary Dr. Richard Frank has characterized NCDs as “the most powerful coverage tool that Medicare has and have generally been reserved for Medicare services that are costly ...”ⁱ

Since 2005, CMS has turned to using an extralegal paradigm known as coverage with evidence development (“CED” or an “NCD requiring CED”). Initially, CED was utilized to accelerate access to medical devices, which have fewer clinical trial requirements in comparison to drugs and biologics. As time passed, CMS expanded its use of CED to other therapeutic types and diagnostics. Under CED, the Agency denies Medicare coverage for an FDA-approved item or service *except* when it is provided to beneficiaries within a population-limited clinical study, such as a CMS-approved clinical trial or data registry. Beneficiaries who are ineligible under the strict CED requirements, cannot access the clinical study sites, or are reluctant to be required to

enroll in a clinical study to receive access are left without coverage.

Once CMS places a treatment in CED, it is extraordinarily difficult for the coverage restriction to be lifted.

An August 2022 systematic review of CED program history, published in *The American Journal of Managed Care* identified that, between 2005–2022, CMS issued a total of 27 NCDs requiring CED. Only four have been retiredⁱⁱ by the

Agency, which has taken an average of 8 years to do so.ⁱⁱⁱ Under its current paradigm, CMS has enabled 22 CEDs to continue in perpetuity, including several that have been ongoing for more than 15 years.^{iv}

Additionally, CMS sets “conditions of coverage” (e.g., the treatment is only provided for beneficiaries in certain settings of care and overseen by designated specialists) for health facilities participating in CED studies that often prohibit access for beneficiaries in rural communities and in communities of color. In some cases, the lack of enrollment from these populations has

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provided the Agency justification to continue a CED determination. In practice, NCDs requiring CED have been operationalized and evolved to restrict access to potentially life-

saving therapies for millions of Medicare beneficiaries.

CMS’s unchecked use of CED has led to harmful consequences including:

- The continuation of restrictive coverage requirements for an indefinite period of time;
- Barriers to beneficiary access for potentially clinically meaningful items and services and the deterioration of health outcomes;
- Perpetuation and exacerbation of access to care barriers for beneficiaries of color and those from rural communities;
- The regulatory repudiation of the FDA’s statutorily-authorized accelerated approval program;
- The imposition of unnecessary costs and burdens on sponsors and healthcare providers; and

- The failure to advance the Congressional intent of Medicare.

As a result of these harmful outcomes, it is imperative that CMS cease its use of CED. However, CMS has indicated its intent to instead deploy additional NCDs requiring CED by commissioning a November 2022 report from the Agency for Healthcare Research and Quality (AHRQ) on recommendations to refine CED study design requirements.^v On February 13-14, 2023, the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) will use the final AHRQ report

ⁱⁱ Sean Dickson et al., *Limiting Coverage Based On Efficacy And Safety: A Path Forward For Medicare Regarding The Alzheimer's Treatment Aducanumab*, Health Affairs (June 7, 2021), <https://www.healthaffairs.org/doi/10.1377/forefront.20210604.489197>.

ⁱⁱ There were two CEDs, artificial hearts and home oxygen for cluster headaches, that resulted in revocation of the NCD and deferral of coverage decisions to local contractors.

ⁱⁱⁱ See Emily P. Zeitler et al., Coverage with Evidence Development: Where Are We Now? 28 AM. J. MANAGED CARE 382, 382 (Aug. 2022), <https://www.ajmc.com/view/coverage-with-evidence-development-where-are-we-now>. Dr. Zeitler's et al conclusions are not new. Other studies have similarly concluded that "CED schemes . . . are often costly, complex, and challenging." Carlo Federici et al., Coverage with evidence development schemes for medical devices in Europe: characteristics and challenges, 22 EUR. J. HEALTH ECON. 1253, 1253–73 (Nov. 2021).

^{iv} See Zeitler, *supra* note **Error! Bookmark not defined.**,

as a basis for its discussion and provide its recommendations to CMS.^{vi} Other potential expansions of CED by CMS include a proposed rule that conditions coverage of technologies (and potentially including drugs) on the collection of additional evidence in CMS-approved studies^{vii}; and recommendations from the Medicaid and CHIP Access Commission (MACPAC) for Congress to grant states outright authority to limit Medicaid formularies based upon Medicare NCD determinations.^{viii}

To read the full report, visit:

www.agingresearch.org/facadeofevidence

at 385–87.

^v Agency for Healthcare Res. & Quality, *Analysis of Requirements for Coverage With Evidence Development (CED) – Topic Refinement* (Nov. 2022), <https://effectivehealthcare.ahrq.gov/products/coverage-evidence-development/research-report>.

^{vi} MEDCAC Meeting: Analysis of Coverage with Evidence Development (CED) Criteria: <https://www.cms.gov/medicare-coverage-database/view/medcac-meeting.aspx?medcacid=79>.

^{vii} Fleisher LA, Blum JD. A Vision of Medicare Coverage for New and Emerging Technologies—A Consistent Process to Foster Innovation and Promote Value. JAMA Intern Med. 2022;182(12):1241–1242.

^{viii} Medicaid Coverage based on Medicare National Coverage Determination: Review of Draft Chapter and Recommendations for March Report, MACPAC, January 26, 2023, https://www.macpac.gov/wp-content/uploads/2023/01/04_Medicaid-coverage-based-on-Medicare-national-coverage-determination-NCD_-_Review-of-recommendations-and-draft-chapter-for-March-report.pdf.