Society for Women's Health Research

June 7, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave SW
Washington, D.C. 20201

Carolyn M. Mazure, PhD
Chair, White House Initiative on Women's Health Research
White House Gender Policy Council
1600 Pennsylvania Ave NW
Washington, D.C. 20036

Dear Administrator Brooks-LaSure and Dr. Mazure:

The following 29 undersigned organizations are enthusiastic about the White House Initiative on Women's Health Research and the myriad opportunities it holds to make truly meaningful investments in women's health research and ultimately, transform women's health in this country.

We look forward to seeing the White House Initiative operationalized and federal departments and agencies' commitments come to fruition. While we were happy to see the participation and commitment from the Centers for Medicare and Medicaid Services (CMS), we are writing to express concern about the agency's commitment, as outlined in the Fact Sheet for the March 18 Executive Order on Advancing Women's Health Research and Innovation.[1] Under the header, "Reflect Women's Health Needs in National Coverage Determinations," the Fact Sheet states that CMS "will strengthen its review process, including through Coverage with Evidence Development guidance, to ensure that new medical services and technologies work well in women, as applicable, before being covered nationally through the Medicare program." According to CMS, this is to "help ensure that Medicare funds are used for treatments with a sufficient evidence base to show that they actually work in women, who make up more than half of the Medicare population."

While we recognize and appreciate CMS' intent to reflect women's health needs, we are concerned that the shortcomings of the coverage with evidence development (CED) policy could have unintended consequences, leading to situations in which Medicare beneficiaries who need treatment are being denied care.

Under a CED policy, CMS 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, and those who are reluctant to enroll in a clinical study in order to receive access are left without coverage.

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

[1] https://www.whitehouse.gov/briefing-room/statements-releases/2024/03/18/fact-sheet-president-biden-issues-executive-order-and-announces-new-actions-to-advance-womens-health-research-and-innovation/

of CED to other therapeutic types and diagnostics. The appeal of the CED policy, as suitably described in a 2013 *Health Affairs* blog article, is "that it promises to provide access to promising technology while it collects additional evidence on the technology's effectiveness."[2] However, the CED policy is flawed; in practice, it is limiting access to medical therapies and services, potentially exacerbating disparities for already underserved older adults and hindering innovation. It is also worth noting that the agency's CED policy was not authorized by Congress—it was created and implemented by CMS agency guidance[3] as a National Coverage Determination (NCD) requiring provider and beneficiary study participation.

Once CMS places a treatment in CED, it is extraordinarily difficult for the coverage restriction to be lifted. Between 2005 and 2024, CMS issued a total of 27 CEDs[4] for a number of treatments, from cochlear implants to less-invasive heart valve replacement procedures, and more recently, for monoclonal antibody therapies (mAbs) in early Alzheimer's disease. In nearly 20 years, the agency has only retired five of the CED policies.

We are concerned that CMS' "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 often prohibit access for beneficiaries in rural communities and in communities of color. For women – particularly those of color and those living in rural areas – this may be an even greater challenge due to the intersectionality of health equity for women. In some cases, the lack of enrollment from these populations has provided the agency justification to continue a CED determination. For example, an analysis of registry data from 2012-2018 published in the November 2021 *JAMA Cardiology* found that zip codes with higher proportions of socioeconomically disadvantaged, Black, and Hispanic populations had significantly lower rates of transcatheter aortic valve replacement (TAVR) compared with zip codes with more affluent and White populations.[5] This has occurred despite CMS' stated need for why the coverage restrictions must continue when the CED was reconsidered—hinging upon the need for additional data on outcomes for individuals of color.[6]

Beyond the uncertainty and variability around the process itself, the utilization of CED results does not seem to be operating as intended. As noted by Kathryn Phillips, PhD, in a 2022 *JAMA Viewpoint* piece, "Despite the long history of CEDs, almost no published evidence exists from CMS or independent evaluations on whether CEDs are successfully implemented and whether the results change coverage policies."[7]

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[2] "Medicare's Reset On 'Coverage with Evidence Development'", Health Affairs Blog, April 1, 2013. DOI: 10.1377/hblog20130401.029345

[3] https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?MCDId=27

[4] Zeitler, E, Gilstrap, L. Coverage With Evidence Development: Where Are We Now?, The American Journal of Managed Care, August 2022, Volume 28, Issue 8, Am J Manag Care. 2022;28(8):382-389.

[5] https://jamanetwork.com/journals/jamacardiology/fullarticle/2786194

[6] In the 2019 reconsideration of the TAVR CED, CMS acknowledged: "Evidence [that] is insufficient for minority populations. We also await reports on longer-term outcomes for benefits and harms, including quality of life, for our beneficiaries. We continue to believe that the current coverage under CED offers the appropriate balance of quality and access, while simultaneously stimulating innovation of devices, procedural techniques, and indications for use (for subpopulations and patients with various comorbidities), and so we are continuing coverage with evidence development." Transcatheter Aortic Valve Replacement (TAVR) (CAG00430R) Decision Memo, supra note 104.

[7] Phillips KA. CMS Coverage With Evidence Development—Challenges and Opportunities for Improvement. *JAMA Health Forum.* 2022;3(9):e223061. doi:10.1001/jamahealthforum.2022.3061

Examining the CED process through the lens of mild cognitive impairment and Alzheimer's disease, for whom two-thirds of the patients diagnosed are women, we can see the implications for patients. For reference, in 2022 CMS finalized an NCD that required CED for mAbs targeting amyloid for the treatment of Alzheimer's disease.[8] The policy was applied to the entire class of mAbs, impacting therapies that were already approved by FDA as well as future therapies.[9] For individuals living with progressive neurodegenerative diseases, such as Alzheimer's disease, the hindrance in access means that these patients may become ineligible for FDA-approved use of the disease-modifying treatment before they are able to access it.

Given these concerns, our organizations urge the Administration to exercise caution in increasing the use of CED for Medicare coverage decisions, and to thoughtfully consider how unique women's needs may be best incorporated into the Medicare program broadly for greater health equity. We welcome the opportunity to meet with appropriate members of CMS and the Gender Policy Council to learn more about the agency's plans to implement this commitment to the Executive Order as well as to share our insights and recommendations on how best to incorporate the women's perspective into the process for meaningful change. This is a critical and cross-cutting issue, and we look forward to working with you and our colleagues in the Administration to ensure that federal policies benefit—and do not unintentionally harm—our nation's patients.

Thank you for your time and consideration of our meeting request. If you have questions, or if you would like additional information, please contact Society for Women's Health Research (SWHR) President Kathryn Schubert at kathryn@swhr.org or SWHR Chief Advocacy Officer Lindsey Miltenberger at lindsey@swhr.org.

Sincerely,

Alliance for Aging Research
Alliance for Patient Access
Alliance for Women's Health and Prevention
Alzheimer's Association
Alzheimer's Impact Movement
American Academy of Neurology
Arthritis Foundation
Bone Health and Osteoporosis Foundation
BrightFocus Foundation
Caregiver Action Network

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[8] https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=305. Accessed 14 May 2024.

[9] At time of writing, the FDA has granted traditional approval to lecanemab and the agency is expected to determine whether a traditional approval for a second product (donanemab) in the near future. CMS's initial decision on mAbs for the treatment of Alzheimer's disease was made based on data for aducanumab, which previously had been granted accelerated approval by the FDA. Aducanumab is no longer marketed (as of January 2024) by the manufacturer.

Global Alzheimer's Platform Foundation
Global Coalition on Aging Alliance for Health Innovation
HealthyWomen
Heart Valve Voice-US
LEAD Coalition (Leaders Engaged on Alzheimer's Disease)
Looms For Lupus
Lupus and Allied Diseases Association, Inc.
National Consumers League
National Menopause Foundation
National Minority Quality Forum
Nevada Chronic Care Collaborative
RetireSafe
Society for Women's Health Research
The Headache and Migraine Policy Forum
The Mended Hearts, Inc.
Toronto Memory Program
UsAgainstAlzheimer’s
Voices of Alzheimer’s
WomenHeart

CC: Jennifer Klein, White House Gender Policy Council