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Responses to QFR From House E&C Hearing "Examining Policies to Enhance Seniors' Access to Breakthrough Medical Technologies"

Questions for the Record from the Honorable Mariannette Miller-Meeks

1. **Is H.R. 842, the Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act, a coverage mandate?**

a.) What process would the Centers for Medicare & Medicaid Services (CMS) use to evaluate coverage of MCED tests?

The "Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act" is not a Medicare coverage mandate. The legislation would create the authority for the Centers for Medicare & Medicaid Services (CMS) to use an evidence-based process to cover blood-based MCED tests and future test methods once approved by the U.S. Food and Drug Administration (FDA), while maintaining CMS's authority to use an evidence-based process to determine coverage parameters for these new types of tests. The legislation affirms that multi-cancer detection tests are designed to complement, not replace, existing screening methods, noting that beneficiaries receiving a multi-cancer detection test would still have full access to other recommended screening exams.[1]

As the CMS notes, "Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category)."[2] CMS makes its national coverage determinations (NCDs) through an evidence-based process, with opportunities for public participation. The CMS describes its procedures for making NCD determinations on its webpage here: "Medicare Coverage Determination Process."[3]

2. There were some questions about MCEDs and false positive rates. How do the false positive rates of MCED technologies compare to current cancer screenings?

Current standard of care (SoC) cancer screening tools save lives and tremendously valuable. A 2023 study conducted by University of Michigan and University of Chicago experts concluded that the prior 25 years of cervical, breast, colorectal, and lung cancer screening had saved a total of 12 million years of life and contributed $6.5 trillion of economic impact.[4]

One of the tradeoffs to achieving these valuable outcomes is that cancer screening tests are imperfect, and can result in false positives. For example, mammography has a roughly 10 percent false positive rate.[5] Low-dose CT for detecting lung cancer among those with a history of smoking has a roughly 13 percent false positive rate.[6] Stool-based colorectal screening has a roughly 10 percent false positive rate.[7] Cytology for cervical cancer detection has a roughly 14 percent false positive rate.[8]

Given their intent for concurrent detection across cancer types and organ sites, which represents a different and complementary strategy to single cancer screening, MCEDs are intentionally designed

to limit false positives and associated population scale harms. For example, one of the leading MCED screening test innovators has demonstrated a false positive rate less than 1 percent.[9] With the exception of colonoscopy (which visually identifies and removes cancer and precancer), MCED tests have lower false positives than any of today's recommended cancer screenings.

3. Even when a breakthrough medical technology is FDA-cleared or approved, patients in rural communities often wait years for coverage and access — especially when those technologies are not traditional drugs or devices, but software-driven innovations like autonomous artificial intelligence systems that bring specialist-level diagnostic care directly into primary care and other frontline settings.

a. What do you believe are the most effective steps Congress and CMS can take to ensure that these kinds of diagnostic and preventive innovations reach rural and aging populations more quickly — particularly when they improve chronic disease management, close care gaps, support earlier detection of disease, and reduce pressure on limited specialist capacity?

The logistical ease of MCED testing (from a blood draw) could benefit those living in rural communities who may experience more difficulty in seeing doctors for physical screening exams or more difficulty in accessing specialized screening services. This could have a particularly important impact in ameliorating racial and socioeconomic disparities in cancer screening availability. This matters, especially when cancer deaths in America's rural areas are 14 percent higher than in urban areas (with that disparity increasing over time). Moreover, the five-year cancer survival rate (for all cancers) in America's rural areas is 8 percent lower than in urban areas.[10]

In part due to America's urban/rural divide, the extent of cancer screening also varies considerably by state. For instance, the percentage of adults ages 50 to 75 who reported being up to date with colorectal cancer screening in 2016 ranged from 75.3 percent in Massachusetts to 59.9 percent in Mississippi.[11] Likewise, the percentage of female Medicare enrollees ages 65 to 74 that received an annual mammography screening in 2017 was 39 percent in Mississippi, compared with 54 percent in Massachusetts.[12]

Education of physicians and citizens living in America's rural communities regarding the availability of different cancer screening modalities—including MCED screening options—is vitally important. It's also critical that clinical trials for such MCED tests be designed to include underrepresented populations. For instance, the United Kingdom's National Health Service (NHS) is conducting a clinical trial of GRAIL's Galleri MCED test. In the trial, NHS ensured that, "regions were selected to include areas of high cancer mortality, socioeconomic deprivation, and ethnic diversity; eligible participants will be identified from these regions."[13] As the NHS noted, "A variety of methods are employed to enroll a representative study population. … These methods include the use of mobile phlebotomy clinics that facilitate access in economically deprived areas, monitoring of participant representativeness by postcode with dynamic adjustment of enrollment, providing interpreters and wheelchair accessibility, and targeted local campaigns. Blood will be collected at 3 annual visits (baseline, year 1, year 2) unless cancer is diagnosed."[14]

By their nature, (and while noting they should be used complementary to other approved cancer screening tests) MCED tests can provide cancer screening options where there are not readily available diagnostic test machines available, such as low-dose CT or MRI machines. This can extend access to cancer screening options for citizens living in rural areas physically far away from their physicians, clinics, or their medical equipment.

Questions for the Record from the Honorable Robin L. Kelly

1. I was pleased to see almost all of the physicians on the Subcommittee express support for this bill at the hearing. Can you please provide information on the depth and breadth of clinician support for H.R. 842?

The "Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act" has support from hundreds of clinician societies across the country, including leading advocates such as the American Cancer Society, American Association for Cancer Research, Friends of Cancer Research, Research!America, and many others. In fact, the Prevent Cancer Foundation has generated support from over 500 organizations for the MCED Screening Coverage Act.[15]

ENDNOTES

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2. Centers for Medicaid and Medicare Services, "Medicare Coverage Determination Process," https://www.cms.gov/medicare/coverage/determination-process.
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5. Susan G. Komen Foundation, "Accuracy of Mammograms," https://www.komen.org/breast-cancer/screening/mammography/accuracy/.
6. Lanwei Guo et al., "Accuracy of baseline low-dose computed tomography lung cancer screening: a systematic review and meta-analysis" *China Medical Journal* Vol. 36, No. 9 (April 27, 2023): 1047–1056, https://pmc.ncbi.nlm.nih.gov/articles/PMC10228483/.
7. Exact Sciences, "Cologuard: Frequently Asked Questions," https://www.cologuardhcp.com/resources/faq.
8. Jane J. Kim, "Screening for Cervical Cancer in Primary Care: A Decision Analysis for the US Preventive Services Task Force" *Journal of the American Medical Association* Vol. 320, No. 7 (2018): 706–714, https://jamanetwork.com/journals/jama/fullarticle/2697702.
9. Nima Nabavizadeh, "Safety and performance of a multi-cancer early detection (MCED) test in an intended-use population: Initial results from the registrational PATHFINDER II study," https://oncologypro.esmo.org/video-series/pathfinder-2-multi-cancer-early-detection-test-in-an-intended-use-population.
10. The National Grange, "New research finds disproportionate impact of cancer on rural communities," February 2, 2023, https://www.morningagclips.com/new-research-finds-disproportionate-impact-of-cancer-on-rural-communities/.
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12. County Health Rankings and Roadmaps, "Mammography screening" (accessed December 1, 2020), https://www.countyhealthrankings.org/explore-health-rankings/measures-data-sources/county-health-rankings-model/health-factors/clinical-care/quality-of-care/mammography-screening.
13. Charles Swanton et al., "NHS-Galleri Trial Design: Equitable study recruitment tactics for targeted population-level screening with a multi-cancer early detection (MCED) test" *Journal of Clinical Oncology* Vol. 40, No. 16 (June 2022), https://ascopubs.org/doi/10.1200/JCO.2022.40.16_suppl.TPS6606.
14. Ibid.
15. Prevent Cancer Foundation, "Prevent Cancer Foundation leads more than 500 organizations in support of Medicare Multi-Cancer Early Detection Screening Coverage Act in the Senate" June 2, 2023, https://preventcancer.org/news/prevent-cancer-foundation-leads-more-than-500-organizations-in-support-of-medicare-multi-cancer-early-detection-screening-coverage-act-in-the-senate/.