Congress of the United States
Washington, DC 20515

April 14, 2021

Ms. Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20510

Dear Acting Administrator Richter:

As Co-Chairs of the Senate Diabetes Caucus and the Congressional Diabetes Caucus, we write to express our support for recently proposed changes to the Medicare local coverage determination (LCD) for continuous glucose monitors (CGMs). Specifically, we support the proposal to remove the requirement for the use of four finger stick tests prior to initiating CGM therapy and the additional proposal to use the word "administration" rather than "injection" in the coverage document, so that users of inhaled insulin can qualify for CGM coverage. However, we also write to draw your attention to additional technical changes to the LCD that are needed.

Recent estimates suggest that more than 32 percent of Medicare Fee-for-Service beneficiaries have diabetes,[1] as well as more than 28 percent of Medicare Advantage (MA) enrollees,[2] making diabetes one of the most prevalent chronic conditions for Medicare patients. Diabetes is also one of the most costly chronic conditions for the health care system, as projections from the American Diabetes Association indicate that direct medical care costs for diabetes exceeded $237 billion in 2017.[3] Eliminating current barriers to access to CGMs will help Medicare beneficiaries improve their control of blood glucose levels, which holds the potential for improved outcomes, enhanced quality of life, and even a reduction in acute care costs.

The proposed changes to the LCD will make it simpler for Medicare beneficiaries with diabetes to access this critical technology. We applaud the thorough review of evidence used as the basis of these proposals. We encourage the Centers for Medicare and Medicaid Services (CMS) to work closely with appropriate stakeholders to apply the same rigor to all criteria in this policy, ensuring that any coverage criteria included in the final version of the LCD are firmly grounded in current clinical evidence.

We are particularly concerned that while the proposed changes would eliminate the explicit requirement that Medicare beneficiaries use four or more finger stick tests per day prior to initiating CGM therapy, a very similar requirement is retained in the proposed criterion that

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[1] Andes LJ, Li Y, Srinivasan M, Benoit SR, Gregg E, Rolka DB. Diabetes Prevalence and Incidence Among Medicare Beneficiaries — United States, 2001–2015. *CDC Morbidity and Mortality Weekly Report* 2019;68:961–966. Available at: http://dx.doi.org/10.15585/mmwr.mm6843a2

[2] Medicare Payment Advisory Commission, "July 2020 Data Book: Health Care Spending and the Medicare Program," July 2020. Available at: http://medpac.gov/docs/default-source/data-book/july2020_databook_entirereport_sec.pdf?sfvrsn=0

[3] American Diabetes Association, "Economic Costs of Diabetes in the U.S. in 2017,"*Diabetes Care*, 2018; 41:917–92. Available at: https://care.diabetesjournals.org/content/diacare/41/5/917.full.pdf

requires that insulin dosing be adjusted frequently each day based on blood glucose monitor (BGM)/CGM readings. If, as the proposed LCD indicates, there is no clinical justification for requiring the use of finger stick testing prior to initiating CGM therapy, then this same requirement should be removed wherever it appears in the LCD, not just in the one criterion that has been proposed for elimination. We note that recent studies have demonstrated that black and Hispanic Medicare beneficiaries with diabetes are significantly less likely than white beneficiaries to meet the current requirement for four finger stick tests per day, which could exacerbate racial disparities in health outcomes for people with diabetes.

Existing clinical evidence justifies the use of CGM by people with diabetes who use insulin less frequently than three times per day, and in some cases, not at all. We encourage you to re-examine CGM coverage standards for these populations. In addition, we urge you to examine ways to ensure that Medicare's CGM coverage rules eliminate recertification burdens for new Medicare beneficiaries who have recently transitioned to Medicare coverage after previously having a CGM covered through commercial or employer-based health insurance. Far too often, these new Medicare beneficiaries must navigate a complex recertification system to obtain Medicare coverage of a CGM product that they had already been using for years prior to enrolling in Medicare.

Together we can work to ensure that Medicare beneficiaries are able to access the CGM devices that they need to control their blood glucose levels and improve their overall health. We appreciate your review of the coverage issues outlined in this letter.

Sincerely,

Jeanne Shaheen
United States Senator
Co-Chair, Senate Diabetes Caucus

Susan M. Collins
United States Senator
Co-Chair, Senate Diabetes Caucus

Diana DeGette
Member of Congress
Co-Chair, Congressional Diabetes Caucus

Tom Reed
Member of Congress
Co-Chair, Congressional Diabetes Caucus