May 21, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U. S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Brooks-LaSure:

We are non-diabetes organizations, locking arms together to oppose any efforts by the Centers for Medicare and Medicaid Services (CMS) to restrict beneficiary access to FDA-approved devices for self-management of Type 1 and insulin-dependent Type 2 diabetes.

We are increasingly disturbed by the CMS Coverage and Analysis Group's leveraging of research debates to justify utilization management of Part B items and services. This process of positioning the agency's **Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) to re-evaluate clinical outcomes for an entire class of medical products**—that the FDA already legitimately determined to be safe and efficacious—takes valuable time and resources away from diabetes researchers, clinicians, and patient advocates to serve people living with diabetes.

No external organizations requested this evidence review of end points for trials of diabetes devices. Nor was the federal health agency charged with CMS evidence reviews—the Agency for Healthcare Research and Quality—consulted. CMS convened a MEDCAC subgroup in February 2024 that was not publicly announced until about a month after it occurred. This subgroup reviewed a 48-page Clinical Endpoints Review (CER) report, written by an outside contractor, on diabetes devices, continuous glucose monitors (CGMs), insulin pumps, and automated insulin delivery (AID) systems, and enlisted one guest endocrinologist to provide responses to CMS's questions. It also raises questions about the agency's judgment or motives when it pursues this topic without reasonable justification in light of its struggles to manage resources.

To be clear—no one in the diabetes community asked for this.

According to the **American Diabetes Association**, more than 37 million people have diabetes in the United States, with many unaware that they're living with the condition. Today, diabetes causes more deaths than breast cancer and AIDS combined.

Diabetes is a chronic condition that requires proactive daily management of glucose levels. High blood glucose levels can lead to serious and life-threatening acute complications, such as ketoacidosis or death. Over time, high blood glucose can lead to severe chronic complications like diabetic retinopathy, kidney and nerve nephropathy, and cardiovascular disease. On the opposite end of the spectrum is hypoglycemia, or low blood glucose levels, which in severe cases can lead to disorientation, seizures, difficulty speaking, loss of consciousness, coma or death.

Here's where CMS' interests lie—diabetes is also the most expensive chronic disease in the United States. That makes medical devices for diabetes self-management a rich target for Medicare Part B coverage restrictions. This should not be done. The standards of care established by the American Diabetes Association and American Association of Clinical Endocrinology unequivocally endorse the use of continuous glucose monitors and insulin pumps by people who are insulin dependent. These endorsements rest on a foundation of voluminous clinical data, with scores of studies affirming the medical necessity of these technologies. The use of these devices is established science and there is no basis whatsoever for calling that into question.

This exercise is similar to one CMS staged in 2021, when mundane academic debate on targeting amyloid was leveraged to squash coverage for the entire class of FDA-approved disease-modifying therapies for the treatment of early Alzheimer's in April 2022.

The effectiveness of CMS' cost-cutting strategy in Alzheimer's lies in the small number of Medicare-related claims paid for Leqembi, the second FDA-approved therapy in the class and the first to receive traditional approval. Since July 2023, based on claims data, only a scant 4,000-5,000 patients have started on Leqembi, with approximately 2,000-2,500 patients currently on treatment. Of patients treated to date, an estimated 85-90% are on Medicare (only 25-30% of those have MA) and 10-15% are on commercial insurance.

Of course, there are ongoing Leqembi research questions and other questions in the field. And while there's still a good amount we don't know, this isn't unique to Alzheimer's treatments. In fact, it's common not to know how new FDA-approved therapies will impact every potential Medicare beneficiary. It makes sense, then, that the **federal statute authorizing Medicare** starts with a non-interference clause that prohibits CMS from "supervision or control over the practice of medicine or the manner in which medical services are provided." Clinicians should be able to help Medicare patients decide which interventions are best for them, without complicated coverage barriers dictating care.

It comes down to this: people with diabetes need access to devices that provide real-time information and effectively manage their disease, prevent life-threatening complications, and live to see another day. The FDA-approved medical devices for self-management allow them to do that. Such devices also assist primary care doctors, endocrinologists, and diabetes nurse practitioners with overall care management insights and timelier treatment adjustment. Chronic diseases like diabetes rob people of time, and time is of the essence.

CMS is a payer; it is not a biomedical expert agency like the FDA or anyone's family doctor. The actions being taken by CMS on diabetes self-care devices are an overreach of agency authority and undermining of public trust in the FDA and more broadly in biomedical science itself. Ultimately, the agency and this advisory committee should not be staging research debates to vindicate itself from what's really happening here—a set-up to the rationing of patient care.

Sincerely,

Alliance for Aging Research
Alliance for Women's Health and Prevention
American Cochlear Implant Alliance
American Kidney Fund
American Society of Consultant Pharmacists
Association of Black Cardiologists
Caregiver Action Network
Global Alzheimer's Platform Foundation
Global Coalition on Aging Alliance for Health Innovation
Healthy Men Inc.
HealthyWomen
Let My Doctors Decide
Lupus and Allied Diseases Association, Inc.
Melanoma Research Alliance
National Association of Nutrition and Aging Services Programs
National Caucus and Center on Black Aging
National Consumers League
National Grange
National Hispanic Council on Aging
National Medical Association
National Minority Quality Forum
Nevada Chronic Care Collaborative
Partnership to Fight Chronic Disease
Prevent Blindness
RetireSafe
The Balm In Gilead, Inc
Voices of Alzheimer's

cc: U.S. House and Senate Health Committee Chairs and Ranking Members; and Congressional Diabetes Caucus Co-Chairs