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I am writing on behalf of the American Diabetes Association (ADA), the nation's largest voluntary health organization concerned with the health of people with diabetes. An estimated 34 million Americans and nearly 750,000 Arizonans have diabetes, a chronic illness that requires continuing medical care and ongoing patient self-management to prevent acute complications and reduce the risk of long-term complications, such as blindness, amputation, kidney failure, heart attack, and stroke.

Advances in treatments, including continuous glucose monitoring (CGM), have been shown to be effective tools in diabetes management and the prevention of complications associated with the disease. Unfortunately, there continue to be gaps in access to CGM and other technologies among under-served populations, including – and perhaps most acutely – in the Medicaid population. ADA recommends you implement measures to broaden access for people with diabetes to these technologies that will enable them to better manage their diabetes, and which may result in fewer adverse health outcomes or even premature deaths.

ADA respectfully submits the below recommendations for your consideration. These recommendations broadly reflect our support for measures that will expand access to CGM technology for Arizona Health Care Cost Containment System (AHCCCS) Medicaid beneficiaries with diabetes.

Ensure coverage for adults and children with Type 1 diabetes and adults and children with Type 2 diabetes who use insulin

ADA's 2021 *Standards of Medical Care in Diabetes (Standards)*, which is updated annually by a committee of U.S. experts in diabetes care, provides that the use of professional CGM and/or intermittent real-time or intermittently scanned CGM can be helpful in identifying and correcting patterns of hyper- and hypoglycemia and improving A1C levels in people with diabetes on noninsulin as well as basal insulin regimens.¹

¹ American Diabetes Association: Standards of Medical Care in Diabetes 2021, Diabetes Care 44: Supp. 1, p.S88 (January 2021).

Eliminating burdensome requirements that expand access to diabetes management technologies is vital to reducing disparities in utilization particularly among under-served people with diabetes. The ADA supports the removal of the following requirements.

- ***Eliminate the requirement that beneficiaries use a blood glucose monitor to test four times per day to be eligible for CGM***

As you may be aware, the Centers for Medicare and Medicaid Services (CMS) recently updated its coverage guidelines to permanently remove the BGM testing requirement for a CGM under Medicare, effective July 18, 2021². We urge you to reconcile current AHCCCS coverage guidelines for CGM with that of CMS, as this criterion is not supported by current clinical evidence or consensus.

Specifically, current standards of clinical practice do not support a restriction on CGM coverage that limits access to patients with a demonstrated history of BGM self-testing at least four times per day.³ Eliminating this requirement will better align with current Medicare coverage criteria for therapeutic CGMs with peer-reviewed clinical evidence and standards of practice recommended by ADA. This revision acknowledges what the ADA has long supported: coverage criteria, and the regulatory landscape more broadly, should reflect the diversity of diabetes management practices of individuals living with this condition. The technology available to improve the lives of people living with diabetes is rapidly changing, and the ADA strongly encourages the elimination of a minimum daily testing requirement to access CGM for the greatest number of individuals.

- ***Eliminate the requirement establishing a minimum number of daily insulin injections and replace “injections” with “administrations”***

Approaches to diabetes management and technology access should accommodate a variety of clinically appropriate strategies, as noted above. The ADA believes that requirements specifying a minimum number, i.e., “three or more” daily administrations of insulin, limits access to CGM for low-income and other patients who need it and recommend removal of this requirement. Furthermore, ADA supports the use of the word “administration” instead of “injection” in requirements related to insulin usage, as it permits users of inhaled insulin to benefit from CGM therapy. This adjustment would also align AHCCCS guidance with that of CMS, as this change was also included in the most recent CMS local coverage determination (LCD), effective July 18, 2021.⁴

- ***Eliminate prior authorization barriers and make devices available through multiple channels to increase accessibility***

Prior authorization requirements can present barriers that delay timely access to devices, medications, or therapies. These prior authorization barriers, which include step therapy protocols, frequently override what a provider believes to be in his or her patient’s best clinical interest. ADA recommends that AHCCCS ensure that coverage and formulary decisions be based on clinical evidence and the direction of health care providers. Additionally, patients must be equipped with tools including a clear and timely appeals process for denials of coverage.

² <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=33822&ver=31>

³ 4. American Diabetes Association: Standards of Medical Care in Diabetes 2021, Diabetes Care 44: Supp. 1, p.S85 (January 2021).

⁴ <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=33822&ver=31>

Broaden Channels of Access to CGM-ADA also recommends that CGM be made available through as many channels as possible including both mail-order and local pharmacies in order to increase access for the diverse population that can benefit from the devices.

Ensure patient- and provider-centered choices for CGM devices

We respectfully urge that AHCCCS take extra care to avoid making choices that would limit access for people with diabetes to CGM or any technology that those individuals and their doctors believe is most appropriate to manage their diabetes. ADA's 2021 *Standards* provide that the choice of technology should be individualized based on patient's needs, desires, skill level, and availability of devices. These are determinations that should be made by a patient in conjunction with their health care provider. Additionally, individuals who have been successfully using CGM should be able to continue to have access to that device across health care payers in order to avoid interruption in access that may result from the need for new training and education or lack of supplies and equipment. If coverage changes must occur, ADA recommends steps be taken to ensure a smooth transition process. At minimum, AHCCCS should adopt a transition period coupled with an exceptions process, enabling beneficiaries currently successfully using a CGM to continue to use that item and its associated supplies regardless of new limitations or exclusions.

The American Diabetes Association appreciates the opportunity to submit recommendations for your consideration and looks forward to working with you to implement measures aimed at increasing access to CGMs to AHCCCS Medicaid beneficiaries in Arizona.

Should you have any questions regarding these comments, please contact me at lkeller@diabetes.org.

Sincerely,



Laura Keller
Director State Government Affairs