American Association of Diabetes Educators
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September 21, 2018

Lisa Trumbell, DMEPOS Policy Specialist
Bureau of Medicaid Policy and Health System Innovation
Medical Services Administration
P.O. Box 30479
Lansing, MI 48909

RE: Project Number: 1833-DME, Continuous Glucose Monitors

Dear Ms. Trumbell:

The American Association of Diabetes Educators (AADE) appreciates the opportunity to offer comments in response to the Michigan Department of Health and Human Services (MDHHS) proposed policy draft addressing coverage of personal use continuous glucose monitors (CGM).

AADE is a multi-disciplinary association of healthcare professionals dedicated to integrated self-management as a key outcome in the care of people with diabetes and related chronic conditions. Representing over 14,000 professional members including nurses, dietitians, pharmacists, exercise specialists, and others, AADE has a vast network of practitioners working with people who have, are affected by, or are at risk for diabetes. This includes over 400 members in the state of Michigan. Given our unique membership and perspective, we have included the comments below for consideration as the MDHHS finalizes this proposed policy draft.

Standards of Coverage

1. **Recommend expanding the proposed policy draft to include Individuals with type 2 diabetes.**

   AADE requests that the MDHHS include coverage for CGM for individuals with type 1 diabetes, as well as those with type 2 diabetes. In 2015, AADE convened a thought leader summit and published a white paper with the goal of improving patient outcomes through more effective use of CGM systems. The findings of the summit, and in the subsequent white paper, concluded that individuals newly-diagnosed with type 2 diabetes may use CGM to learn how their glucose responds to various forms of food and physical activity.[1]The American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) published *Clinical Practice Guidelines for Developing a Diabetes Mellitus Comprehensive Care Plan* discussing that CGM should be considered for patients with type 1 diabetes and type 2 diabetes on basal-bolus therapy to improve A1C levels and reduce hypoglycemia (Grade B; BEL 2). The guidelines go on to describe early reports suggesting that even patients not taking insulin

[1]American Association of Diabetes Educators. (2015). CGM Summit White Paper. Retrieved from: https://www.diabeteseducator.org/docs/default-source/default-document-library/aade-2015-cgm-summit-white-paper-final.pdf?sfvrsn=0

may benefit from CGM (Grade D; BEL 4).[2] The American Diabetes Association's (ADA) *Standards of Medical Care in Diabetes- 2018: Assessment of Glycemic Control* outline how CGM plays an important role in assessing the effectiveness and safety of treatment in subgroups of patients with type 1 diabetes and selected patients with type 2 diabetes. CGM may also be a helpful tool in those with hypoglycemia unawareness and/or frequent hypoglycemic events.[3] Based on these guidelines and standards of care, AADE supports coverage of CGM for individuals with type 1 and type 2 diabetes.

2. **Propose broadening current language requiring that beneficiaries be under the care of an endocrinologist.**

AADE recognizes the high quality of diabetes care provided by endocrinologists, but individuals with diabetes may not always be under the care of an endocrinologist. People with diabetes are often treated by a range of clinical specialties included MDs, DOs, PAs, and NPs. AADE believes that the proposed policy draft should be inclusive of the healthcare providers currently providing diabetes care. The requirement for beneficiaries to be under the care of an endocrinologist may create barriers to care for the Medicaid population in the state. Studies show that geographical access to an endocrinologist may pose a challenge to individuals in both rural and urban settings. One study published in *BMC Health Services Research* examined population-based access to endocrinologists in the US. The study specifically identified the percentage of the population with access to at least one endocrinologist within a 20-mile distance radius. In rural areas they found that of individuals ages 0-17, 26 percent had access, of individuals 18-64, 55.5 percent had access, and of those 65 and older, 51.5 percent had access to at least one endocrinologist. In urban areas, coverage improved, but it was still not complete coverage. Only 82.4 percent of individuals 0-17 (Medicaid age) had access to at least one endocrinologist.[4]

AADE suggests that the MDHHS consider broader language to describe who may be providing care to the beneficiary. An example could include the following: "The beneficiary is under the care of a healthcare professional, preferably an endocrinologist." By revising the language under the standards of coverage section and throughout the proposed policy draft, AADE hopes that MDHHS will minimize disparities and ensure beneficiaries can access the CGM benefit.

3. **Propose reconsideration of requirement for the beneficiary to test blood glucose a minimum of four times per day to be eligible for CGM use.**

Payers limit the number of diabetes test strips covered per day. For example, Medicare only covers three diabetes test strips per day, though they will cover more if there is documentation provided to the supplier. This proposed requirement for beneficiaries to test blood glucose a minimum of four times per day to meet the standards of coverage will create an undue documentation burden for providers and

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[2] The American Association of Clinical Endocrinologists and the American College of Endocrinology. (2015). *Clinical Practice Guidelines for Developing a Diabetes Mellitus Comprehensive Care Plan.* Retrieved from https://www.aace.com/files/dm-guidelines-ccp.pdf

[3] American Diabetes Association. (2018). *Standards of Medical Care in Diabetes- 2018: Assessment of Glycemic Control*

[4] Lu, H. Holt, J.B., Cheng, Y.J, Zhang, X., Onufrak, S., Croft, J.B. (2015). Population-based geographic access to endocrinologists in the United States, 2012.*BMC Health Services Research* 15:541. *Retrieved from:* https://doi.org/10.1186/s12913-015-1185-5

suppliers. This will impede access to CGM for the beneficiary and may cause issues with eligibility under MDHHS's new CGM policy.

Documentation

4. **Propose removing requirement for a professional CGM trial prior to prescribing personal use CGM**

   AADE is concerned that this requirement may be too burdensome for beneficiaries, physicians, and other treating providers. A professional CGM trial requires individuals to come in for an initial office visit, where the device is inserted. In one to two weeks, the individual must then drop off the device for download or return for a follow-up visit and review the results. Only after this occurs does the documentation for the prior authorization begin. Requiring beneficiaries to go through a professional CGM trial before being prescribed a personal use CGM translates to more office visits and can delay the time it takes for beneficiaries to begin the therapy. This could be especially cumbersome for those who face transportation challenges and other access issues. Current CGM systems are specifically designed and FDA-approved for personal use and self-administration. An order for a personal use CGM should be able to be filled easily at a local pharmacy. AADE believes this professional CGM trial requirement may create barriers to care for the beneficiary related to access, delaying therapy, and additional costs. This policy may also increase costs for the state of Michigan.

Payment Rules

AADE wishes to comment generally on the payment rules as this is a critically important aspect to coverage and can result in beneficiaries being denied access to care if policies are not thoroughly considered. We encourage the state to maintain appropriate coding and reimbursement levels to prevent disruptions in care and barriers to access. AADE also urges the MDHHS to ensure that they have enough suppliers that will participate in filling orders for CGM.

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AADE appreciates the opportunity to comment on the MDHHS proposed policy draft on CGM. Please contact Kate Thomas, Director of Advocacy, by phone at 312-601-4821 or via email at kthomas@aadenet.org should you have any questions regarding AADE's comment letter.

Sincerely,

Charles Macfarlane, FACHE, CAE, Chief Executive Officer