Whereas, Type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM) pose large and steadily increasing health threats for both adults and youth in the United States, with approximately 26.8 million adults and 210,000 youth under the age of 20 currently diagnosed with either disease1–8; and

Whereas, There is increasing evidence for the role of glycemic variability in the development of diabetic complications and mortality, particularly cardiovascular disease, stroke, and kidney disease, which alongside diabetes are four of the top 10 leading causes of death in the U.S.7–12; and

Whereas, Glycemic variability for both T1DM and T2DM patients overall has been shown to reduce quality of life and increase the burden of diabetes to healthcare systems, which currently stands at over $1 billion annually12–15; and

Whereas, National trends in U.S. hospitalizations show an increasing number of admissions for hypoglycemia among those with T2DM in recent years, with highest rates among Black Medicare beneficiaries and those older than 75 years old16; and

Whereas, Investigators found that frequency of hypoglycemic events can be markedly reduced in individuals with impaired hypoglycemia awareness through use of continuous glucose monitors (CGM) for patients with T1DM, T2DM and gestational diabetes mellitus17,18; and

Whereas, CGM use has been demonstrated to improve patients’ quality of life, reduce fear of hypoglycemia, and provide a sense of empowerment to patients and their caregivers19–27; and

Whereas, Data show that restrictive access to CGMs in the Medicare and Medicaid populations may have deleterious health, economic, and quality of life consequences17,26; and

Whereas, Many Medicare beneficiaries are subject to restrictive criteria for eligibility of CGMs, such as documenting four fingerstick glucose tests per day for coverage of CGMs, despite only 100 test strips per 3 months being covered for non-insulin dependent diabetics17,28,29; and

Whereas, As of February 2020, 11 of 36 state Medicaid programs have required similar stringent criteria of individuals needing to document four fingerstick glucose tests per day for coverage of CGMs, and only four states have openly committed to Medicaid covering CGMs in patients with T2DM regardless of durable medical equipment (DME) classification17; and

Whereas, CGMs offer a cost-effective alternative to traditional self-monitoring via finger prick at an additional $653 over a patient’s lifetime, translating to $8898 per quality-adjusted life year
(QALY) gained that is well below the $100,000 per QALY cost-effectiveness threshold often cited in healthcare economics studies\textsuperscript{30,31}; and

Whereas, Approximately 14\% of adults under 65 covered by Medicaid have a form of diabetes\textsuperscript{32}; and

Whereas, Retrospective analysis of patients prescribed to a professional CGM for T2DM showed no statistically significant increase in total annual costs compared to those who were not prescribed a professional CGM, but did see an improvement in hemoglobin A1c (HbA1c) without intensification of the current treatment regimen\textsuperscript{19,33}; and

Whereas, While long-term cost effectiveness studies have demonstrated CGMs’ potential to decrease overall costs for patients with T2DM through elimination of test strips and lancets, a majority of financial benefit is due to lower HbA1c readings and mitigation of direct diabetes related complications such as hospitalizations, emergency room visits, non-diabetes prescription medications, and indirect costs such as hampered productivity, which collectively account for 73.1\% of total diabetes care cost\textsuperscript{17,33}; and

Whereas, The lowest-cost option among CGMs, with an out-of-pocket price of less than $100 for uninsured individuals, are an alternative non-invasive glucose monitor called flash glucose monitoring which provides glucose readings on demand and allows for downloadable glucose data, and use has been found to decrease acute diabetes-related events and all-cause inpatient hospitalizations in patients with T2DM treated with short or rapid acting insulin\textsuperscript{34-36}; and

Whereas, Patients with T2DM treated with oral agents are often placed on a basal-bolus regimen of insulin while admitted to the hospital for glucose control, and use of flash glucose monitoring in these patients during admission demonstrated lower average daily glucose and increased detection of hypoglycemia\textsuperscript{37,38}; and

Whereas, CGMs have been able to provide increased insight into nocturnal glucose levels, glucose metabolism during exercise and feeding, and relative impact of medications on ambient glucose than any form of episodic elf-monitoring of blood glucose for all patients with diabetes, and CGM users spent significantly less time in hypoglycemic ranges compared to their self-monitoring of blood glucose counterparts\textsuperscript{17,39}; and

Whereas, AMA Directive D-185.983 asks our AMA Board of Trustees to consider a legal challenge, if appropriate, to the authority of the Centers for Medicare & Medicaid Services (CMS) and other health care insurers placing onerous barriers on diabetic patients to procure medically necessary “durable medical equipment and supplies”; and

Whereas, Certain CGMs which require adjunctive therapy are deemed “non-therapeutic” and thus are ineligible to be classified as durable medical equipment (DME) and supplies, despite their ability to influence medical decision making\textsuperscript{40}; and

Whereas, CMS Proposal CMS-1739-P includes a section on reclassifying “therapeutic” and “non-therapeutic” CGMs as DME, as access to DME has been associated with better outcomes and significantly lower healthcare spending due to patients’ ability to receive care at home, and variations in Medicaid definitions of DME have been linked to variations in geographic healthcare expenditure\textsuperscript{40,41}; and
Whereas, Increased eligibility and access to all glucose monitors, including CGM and flash glucose monitoring, would provide improved, cost-effective health care outcomes for low-income patients with diabetes on Medicaid and Medicare\(^{19,33-35,37,38}\), and

Whereas, Medicaid and public state medical insurance expansions that include CGM devices have been demonstrated to improve glycemic control and reduce disparities in pediatric patients with type 1 diabetes\(^{42,43}\), and

Whereas, Current AMA policy H-330.885 supports coverage of CGM for Medicare patients with insulin-dependent diabetes but does not address Medicaid or CHIP; therefore be it

RESOLVED, That our American Medical Association advocate for broadening the classification criteria of Durable Medical Equipment to include all clinically effective and cost-saving diabetic glucose monitors (Directive to Take Action); and be it further

RESOLVED, That our AMA amend AMA Policy H-330.885, “Medicare Coverage of Continuous Glucose Monitoring Devices for Patients with Insulin-Dependent Diabetes,” by addition and deletion to read as follows:

Medicare Public Insurance Coverage of Continuous Glucose Monitoring Devices for Patients with Insulin-Dependent Diabetes H-330.885

Our AMA supports efforts to achieve Medicare coverage of continuous and flash glucose monitoring systems for all patients with insulin-dependent diabetes by all public insurance programs. (Modify Current HOD Policy)

Fiscal Note: Not yet determined

Received: 10/12/22

References:
42. Ravi SJ, Coakley A, Vigers T, Pyle L, Forlenza GP, Alonso T. Pediatric Medicaid Patients With Type 1 Diabetes Benefit
32. Ng BP, Shrestha SS, Lanza A, Smith B, Zhang P. Medical Expenditures Associated With Diabetes Among Adult Medicaid
18. Anderson JE, Gavin JR, Kruger DF. Current Eligibility Requirements for CGM Coverage Are Harmful, Costly, and
17. Lipska KJ, Ross JS, Wang Y, Fonseca V, Shi L. Economic burden of hypoglycemia: Utilization of emergency department and
8. Ng BP, Shrestha SS, Lanza A, Smith B, Zhang P. Medical Expenditures Associated With Diabetes Among Adult Medicaid

Resolution: 816 (I-22)
RELEVANT AMA POLICY

Diabetic Documentation Requirements D-185.983
1. Our AMA Board of Trustees will consider a legal challenge, if appropriate, to the authority of the Centers for Medicare & Medicaid Services (CMS) and other health care insurers placing onerous barriers on diabetic patients to procure medically necessary durable medical equipment and supplies. 2. Our AMA Board of Trustees will consider a legal challenge, if appropriate, to the authority and policy of CMS and other insurers to practice medicine through their diabetes guidelines, and place excessive time and financial burdens without reimbursement on a physician assisting patients seeking reimbursement for supplies needed to treat their diabetes. Res. 730, A-13

Medicare Coverage of Continuous Glucose Monitoring Devices for Patients with Insulin-Dependent Diabetes H-330.885
Our AMA supports efforts to achieve Medicare coverage of continuous glucose monitoring systems for patients with insulin-dependent diabetes. Res. 126, A-14

CMS Required Diabetic Supply Forms H-330.908
Our AMA requests that CMS change its requirement so that physicians need only re-write prescriptions for glucose monitors every twelve months, instead of a six month requirement, for Medicare covered diabetic patients and make the appropriate diagnosis code sufficient for the determination of medical necessity. Sub Res. 102, A-00; Reaffirmation and Amended: Res. 520, A-02; Modified: CMS Rep. 4, A-12; Reaffirmed: CMS Rep. 1, A-22

Physician Ordering of Durable Medical Equipment and Home Health Services H-330.936
The AMA urges CMS and other payers to require that durable medical equipment and home health and other outpatient medical services be ordered by the physician responsible for the patient's care, with appropriate documentation of medical necessity, before such services are offered to the patient or family; and that suppliers provide to the physician the charge for all durable medical equipment and home health and other outpatient services prior to the time the physician signs the order. Res. 112, I-96; Reaffirmed by Res. 122, A-97; Amended: CMS Rep. 4, I-97; Reaffirmation: A-99; Reaffirmation: A-04; Reaffirmation: A-08; Reaffirmed: CMS Rep. 01, A-18

Access to Medical Care D-480.991
Our AMA shall work with the Centers for Medicare and Medicaid Services to maximize access to the devices and procedures available to Medicare patients by ensuring reimbursement at least covers the cost of said device or procedure. Res. 130, A-02; Reaffirmation: A-04; Reaffirmed: CMS Rep. 1, A-14